



**National
Association of
Neonatal
Nurses**

Medication Safety in the NICU

Position Statement #3073

NANN Board of Directors
June 2021

As the professional voice of neonatal nurses, the National Association of Neonatal Nurses (NANN) recommends a comprehensive approach to medication safety in the NICU that integrates available technology, focused healthcare provider medication safety education, standardized medication processes, and robust medication error reporting and prevention efforts. NICU patients are uniquely vulnerable to medication errors and require additional safeguards embedded within the medication-use process to reduce medication errors and mitigate harm. NICU healthcare providers should be proactive in evaluation and implementation of safe medication practices.

Association Position

Procedures, safeguards, and strategies that ensure accurate dosing and administration of medications to the smallest and most fragile patient populations are a primary concern for bedside practitioners in the neonatal intensive care unit (NICU). Healthcare providers must ensure that drug therapy achieves maximum benefits and avoids unintended consequences. As NICU medication administration policies and procedures are developed, organizational, environmental, and human factors should be taken into consideration. NICU medication safety practices should be reviewed on a regular basis for compliance, usability, and technology enhancements.

Background and Significance

Despite efforts in the United States to standardize a definition of *medication error*, various definitions are used in the literature, in national organizations, within hospitals, and among healthcare professionals. For simplicity in this position statement, a medication error is any “preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer” (National Coordinating Council for Medication Error Reporting and Prevention, n.d.).

Varying definitions of *medication error* and multiple methods of data collection used in published studies make it difficult to determine an accurate medication-error prevalence. In addition, voluntary reporting and retrospective reviews identify only a fraction of all medication error events. For example, one observational study observed more than 300 medication errors during an 8-month period but only two of these observed errors were reported by healthcare providers (Palmero et al., 2019).

Published studies indicate medication errors in the NICU are common, ranging from 13 to more than 200 medication errors per 100 NICU admissions (Esqué Ruiz et al., 2016; Simpson et al., 2004; Stavroudis et al., 2010) or approximately 5% of all medication orders (Dabliz & Levine, 2012). In older studies, multiple investigators demonstrated that NICU patients are more likely to experience a medication error than other hospitalized patients and to experience more harm when a medication error does occur (Gray & Goldmann, 2004; Kugelman et al., 2008; Sharek & Classen, 2006; Simpson et al., 2004). Very preterm infants (24 to 27 weeks gestational age) are an at-risk population for medication errors with a reported incidence as high as 57%, compared with 3% of full-term infants (Eslami et al., 2019; Kugelman et al., 2008). Medication errors occur eight times more often in NICU patients than adult patients. Infants less than 32 weeks gestational age and those with more drugs prescribed are more likely to experience an error (Palmero et al., 2019). In a multinational study, a median of 3-11 medications were prescribed per NICU patient and an inverse relationship was seen between gestational age and number of prescribed medications (Krzyzaniak & Bajorek, 2016; Truter et al., 2017). Many of the medication errors in the NICU are preventable (Alghamdi et al., 2019).

There isn't one most common medication error reported in the NICU. This is likely due to the multiple definitions of medication errors and near misses, varying methodologies

of published studies, and categorization of harm (Stavroudis et al., 2010). Medication errors occur at any phase of the medication-use process, from ordering to administration. Prescribers are more likely to make a dosing error; a review of 58 studies found the highest incidence of errors occurred during the prescribing phase, most of which (82.6%) were dosing errors (Kaushal et al., 2001; Krzyzaniak & Bajorek, 2016; Simpson et al., 2004). Medication errors made by nurses most often occur during administration and include administering at the wrong time and misprogramming the syringe pump (Chuo et al., 2007; Esqué Ruiz et al., 2016; Hicks et al., 2007; Ligi et al., 2008). Pharmacists' most common medication errors involve errors during the review of medication orders and inaccurate dilution of medications (Antonucci & Porcella, 2014).

These data demonstrate that NICU patients are a high-risk population and require additional systemwide safeguards against medication errors (American Society of Health-System Pharmacists [ASHP], 2018). Additional systemwide safeguards identified in the safety science literature include building redundant safety checks, such as NICU-specific order sets and independent double-checking/dose verification of medications prior to administration (Maaskant et al., 2015; Reason, 2000; The Joint Commission, 2015); integrating pharmacists on rounds in the intensive care unit (Kaushal et al., 2008); and standardizing and hardwiring medication administration processes (Zhang et al., 2017). Healthcare providers must be especially vigilant when working with medications in the NICU.

The NICU and Medication Errors

Three important variables make the medication administration process in the NICU uniquely and inherently risky: the vulnerable nature of NICU patients, the complexity of the medication dosing and the preparation and administration process, and the challenges of the NICU environment. These variables are summarized in the table below:

Vulnerable and Unique NICU Patient	Complexity of Medications Used and Medication Administration in the NICU	NICU Environment
<ul style="list-style-type: none"> • Maturation changes • Variable responses to drugs • Long hospital stays • Nonverbal • Higher-order multiples and hospitals' nondistinct naming conventions • Drug dosing based on gestational age and weight 	<ul style="list-style-type: none"> • Off-label use of medications • Medications are small volume and often adult strength, requiring additional manipulation • Limited information regarding side effects and compatibilities 	<ul style="list-style-type: none"> • Complex work environment • Unpredictable workflow • Poor lighting, loud noise • Increased distractions and interruptions

The Vulnerable and Unique NICU Patient

Patients in the NICU are undergoing maturational changes in drug-sensitive systems including renal, gastrointestinal, and hepatic systems, resulting in variable responses to drugs. Medications are universally weight based, requiring calculations for each dose. Many drugs are dosed by gestational age, making prescribing additionally complex. In premature infants, the immaturity of developing body systems affects the absorption, distribution, metabolism, and excretion of drugs, and therefore, an exponential risk for medication errors is present (Antonucci & Porcella, 2012; Stavroudis et al., 2008).

NICU patients often have long hospital stays, increasing exposure to medications and medication errors. They are nonverbal and unable to actively participate in the patient identification process, which can increase the likelihood of wrong-patient errors. The opportunity for wrong-patient error is further increased by naming conventions commonly used in hospitals, which are nondistinct and may be temporary (eg, “Babyboy” or “Babygirl”), and the likelihood of patients that are twins and higher-order multiples. Wrong-patient errors are common, with an incidence rate of 25% of reported medication errors (Adelman et al., 2019; Adelman, Aschner, Schechter, Angert, Weiss, Rai, Berger, et al., 2017; Adelman, Aschner, Schechter, Angert, Weiss, Rai, Parakkattu, et al., 2017; Dabliz & Levine, 2012; Gray et al., 2006).

Complexity of Medications Used and Medication Administration in the NICU

Medications commonly used in the NICU are an independent risk factor for medication errors (Conroy, 2011). These medications often are either unlicensed (i.e., not registered) or have off-label uses (Hsieh et al., 2014). In 2018, the Institute for Safe Medication Practices (ISMP) published a list of high-alert medications that can cause significant patient harm when used in error. Identifying high-alert medications for the NICU is an important safety step; a NICU-specific high-risk medication list should also incorporate data from each individual NICU medication error prevention program, helping all providers to be cautious when interacting with drugs on the list. In a recent study, administration of the high-alert medications described by ISMP has been shown to be a risk factor for harm in neonatal patients (Stavroudis et al., 2010). High-risk medications used in the NICU, modified from the ISMP high-alert medication list are in a Table 1.

Very few studies have been conducted involving medications commonly used in neonates, and information about dosing and anticipated side effects is limited and variable. The medications dispensed are often adult strength, requiring complex, multistep dilutions prior to dispensing or administering, which increases the opportunity for errors. Multiple neonatal and pediatric medications require less than 0.1 mL of stock solution to prepare the dose, leading to a higher incidence of error (Uppal et al., 2011). Anti-infective agents, opioids, and total parenteral nutrition, including intralipids, are commonly involved in medication errors and preventable adverse drug events (Alghamdi et al., 2019; Chuo et al., 2007; Garner et al., 2015; Hicks et al., 2007; Stavroudis et al., 2010). Of note, 80% of drugs used in the NICU have no safety or prescribing information for use in this population (Antonucci & Porcella, 2012).

To combat these complex medication error issues, ISMP and the Vermont Oxford Network (VON) collaboratively developed a list of standard concentrations of neonatal drug infusions, with the goal of decreasing medication errors and stimulating the development of standardized infusion-device drug libraries (ISMP & Vermont Oxford Network, 2011). In 2019, the World Health Organization (WHO) published its latest Model List of Essential Medicines for Children, which built on its 2007 and 2010 publications. This effort was undertaken to provide the best information to healthcare providers administering medications to children (WHO, 2019).

Medication administration in the NICU relies heavily on the use of syringe pumps due to the need for low flow rates (0.1-0.5 mL/hour) and small medication volumes. Delivery of medications via syringe pumps requires special caution as the flow can be variable, resulting in clinically relevant and potentially dangerous side effects to the NICU patient (Sherwin et al., 2014; van der Eijk et al., 2013). The U.S. Food and Drug Administration issued a safety communication denoting syringe pump flow problems (delayed drug delivery, over-infusion, and under-infusion) resulting in serious clinical consequences including unstable blood pressure (2016). All healthcare providers in the NICU should be aware of the methods to reduce variability of flow infusion when using a syringe pump for medication administration.

Additional unique variables that negatively affect drug delivery and safety in the NICU include drug preservatives, highly variable intravenous infusion tubing set-ups and filters, slow intravenous flow rates, significant dead space volumes (potential overdose), small drug dose volumes and limited flush volumes, and limited drug incompatibility information (De Giorgi, 2010; Sherwin et al., 2014).

The NICU Environment

The complex, high-stress NICU environment increases risk to patients. These environmental factors include a demanding workload, unpredictable workflow, quickly changing patient acuity, poor lighting and loud noise, and frequent distractions and interruptions. Multiple studies demonstrate that distractions and interruptions during the medication administration process are a major contributing factor in medication errors (Beyea, 2007; Hayes et al., 2015). The NICU meets the criteria as a high-risk environment, which requires specialized attention to reduce the risk of medical error (Dabliz & Levine, 2012). In addition, human factors such as fatigue, burnout and complacency, having a false sense of security with technology, poor team communication, and intimidation also may contribute to medication errors (Handyside & Suresh, 2010; Melnyk, 2021; Montgomery et al., 2021; Rogers et al., 2017; Samra et al., 2011).

The NICU structure and workflow process is an important variable, including human factors and workplace hazards (Handyside & Suresh, 2010; Samra et al., 2011). Medication administration can be compromised on multiple levels, including delivery of medications to the wrong patient, dispensing errors, and the design and malfunction of medical devices. At the organizational level, staffing levels, look-alike and sound-alike

drug names, inadequate staff education, cost-cutting measures, poor communication, and the environmental design of the unit can contribute to medical errors (Handyside & Suresh, 2010; Rack et al., 2012; Strudwick et al., 2018).

Prevention of Medication Errors in the NICU

Multiple factors place the NICU patient at increased risk for a serious medication error. These factors create an urgency for all NICU healthcare professionals to embrace medication-error prevention strategies at every stage of the medication-use process.

Though few trials exist in the literature comparing the effectiveness of preventive strategies, most medication errors occurring in the NICU are preventable (Frey et al., 2000; Sharek et al., 2006). Research studies focused on the effectiveness of prevention of medication errors are largely descriptive in nature and often are single-hospital experiences or quality improvement reports, limiting the applicability of results across NICUs. Recent systematic reviews have demonstrated that no single medication-error prevention intervention has been identified as more effective than another (Maaskant et al., 2015; Nguyen et al., 2018; Rinke et al., 2014; Santesteban, 2015).

Interventions to prevent medication errors include systemwide changes, such as computer prescriber order entry, standardized formularies, standardized preparation and administration guidelines (Kaushal et al., 2001; Lucas, 2004; Taylor et al., 2008; York et al., 2019), smart infusion pump (intravenous pumps with integrated drug library) use, and a barcode system for medication administration, which has been found to decrease preventable adverse drug events by 47% (Morriss et al., 2009, 2011). Including pharmacists on rounds, built-in redundant safety checks, and standardization at all phases of the medication-use process are associated with medication-error reduction (Lepee et al., 2012).

Computer Prescriber Order Entry

Implementation of computer prescriber order entry (CPOE) in pediatric inpatient settings, including the NICU, demonstrated reduction in all types of medication errors, and the reduction was significantly enhanced when clinical decision support (CDS) was also implemented (Rinke et al., 2014; York et al., 2019). Additional research is needed to understand the potential limitations of CPOE systems in neonatal intensive care as technical difficulties affect usability, including weight-based dosing, changing gestational ages, and inconsistent modifications of adult-oriented CPOE systems (York et al., 2019). Implementation of CPOE systems in the NICU has not resulted in significant improvement in mortality (Chuo & Hicks, 2008; York et al., 2019).

Barcode Medication Administration

Barcode medication administration (BCMA) is a system designed to reduce medication errors during the administration phase. BCMA utilizes scanning of the patient, scanning the medication prior to administration, and matching and integrating both actions with an electronic medication order and into an administration record to ensure a portion of the “rights.” The “rights” BCMA can ensure include right patient, right medication, and right time. BCMA is not able to ensure other important rights at point of administration, such

as right route, right dose, and right reason, all of which require the healthcare professional (most commonly the registered nurse) to ensure all “rights” and safety checks are complete.

When implemented as intended, BCMA is effective in reducing medication errors; however, very few published studies included NICUs (Strudwick et al., 2018). This is important as the barriers to BCMA in the NICU may be unique and significant when compared to other inpatient units. One single-center study demonstrated a significant reduction in both medication errors and adverse drug events when BCMA was introduced in the NICU (Morriss et al., 2009).

Evidence is building demonstrating that workarounds are common with BMCA, including scanning the patient and/or the drug after medication administration or placing the patient identifier and/or drug label elsewhere (Rack et al., 2012). In the NICU, BMCA barriers may include technical issues when scanning the patient identifier (patient identification band) or medication syringe (bar code unreadable) and false alerts. More studies are needed to understand the effectiveness and common workarounds of BCMA in the NICU.

Smart Pump Technology

Smart infusion pumps are intravenous infusion pumps with dose error-reduction systems (DERS) integrated software and drug libraries that have reduced medication errors associated with medication administration. Smart infusion pumps are in use in more than 80% of US hospitals and are common in the NICU (ISMP, 2020b). Smart pumps may reduce medication errors in the NICU if the drug library is tailored to commonly used NICU medications and medication concentrations (Lemoine & Hurst, 2012; Melton et al., 2019). Workarounds that bypass integrated safety technology may be common with smart pumps. NICU leaders need to track data related to common workarounds and the use of basic infusion and overrides. Without tracking this data, these types of alerts can increase alert fatigue at the bedside (ISMP, 2020a; Lemoine & Hurst, 2012).

Pharmacists in the NICU

The involvement of pharmacists in medication order review and on patient care rounds is associated with reduced medication errors (Cunningham, 2012). Errors occur at each stage of the medication-use process, and pediatric pharmacists’ interventions often occur prior to or during the prescribing phase. Integrating the pharmacist during patient care rounds provides an effective error reduction strategy along with opportunities for healthcare provider education (Hermanspann et al., 2017; Krzyzaniak & Bajorek, 2016).

Building Redundancy of Safety Checks

Redundant systems within a process reduce errors (Gosbee, 2006; Reason, 2000; The Joint Commission, 2015; White et al., 2010). Examples of redundant systems within the medication-use process includes provider order entry using a NICU-specific order set with integrated drug dosing and weight-based calculations, pharmacist verification of order and double check at drug dispensing, BCMA, independent double-check/dose

verification prior to administration, and use of smart infusion pumps. Each safety check provides opportunities to catch different types of errors prior to reaching the patient.

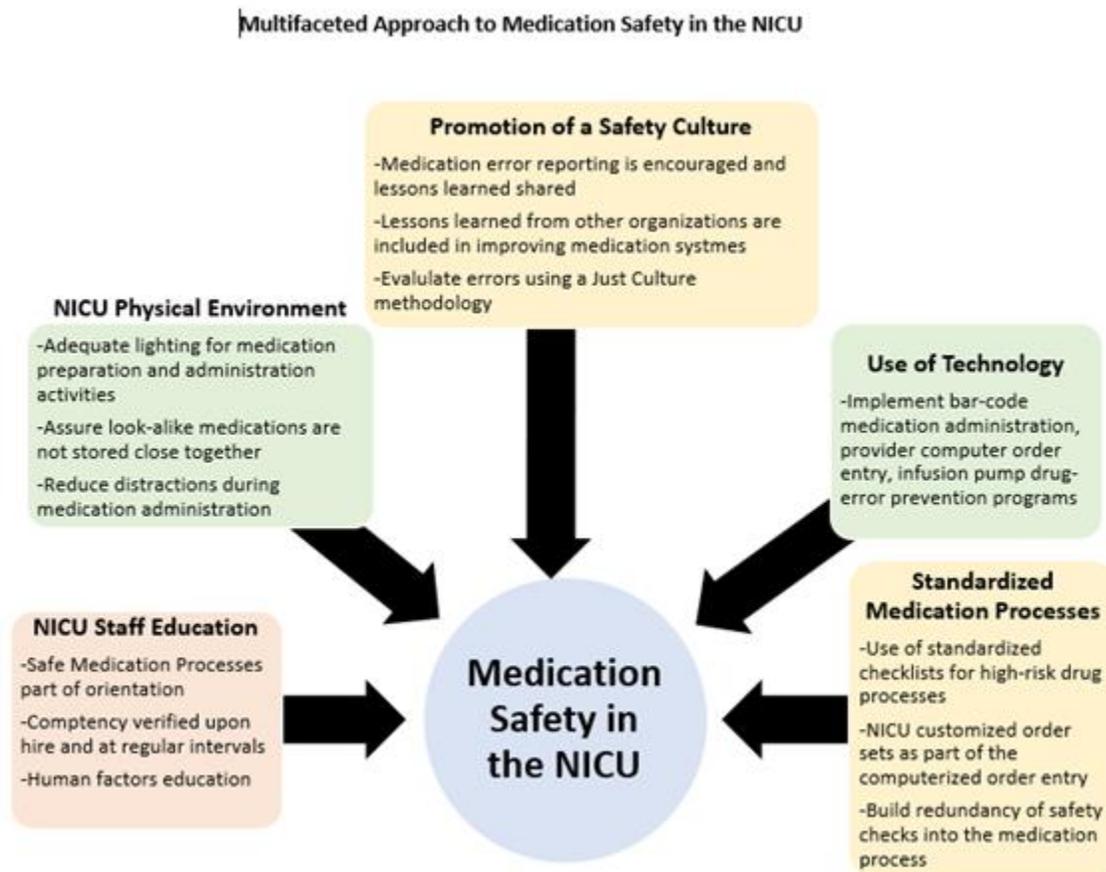
Independent double-checking of high-risk medications prior to administration is a recommendation from the Institute of Safe Medication Practices (ISMP) and other agencies (ASHP, 2018; ISMP, 2020a). Research is limited and results mixed on the effectiveness of double checks in preventing medication errors (Alsulami et al., 2012; Douglass et al., 2018; Schwappach et al., 2016; White et al., 2010). The method in which the double check is performed is critical to its effectiveness in preventing medication errors; independently performed double checks (in which the two providers separately confirm all components including drug, dose, time, patient, and route) can reduce 95% of medication errors (ISMP, 2003, 2019). If not performed independently, the double check's effectiveness is reduced significantly.

Improving NICU Medication Safety

To improve medication safety in the NICU, a multipronged approach is recommended (Nguyen et al., 2018). See Figure 1 below. Medication safety can be enhanced by implementation of technology (eg, BCMA, infusion pumps with dose-error reduction libraries, and CPOE); hardwired use of checklists (build redundancy in safety checks), standardized formularies, and drug concentrations; and inclusion of pharmacists on bedside rounds, not just in preparing and dispensing medications. The NICU environment must promote medication-error reporting with the culture of learning from errors and fostering prevention and improvement efforts (Aydon et al., 2016; Handyside & Suresh, 2010; Rogers et al., 2017).

Overreliance on technology limits overall medication error prevention; rather, a collective understanding and commitment to medication error prevention from all NICU healthcare providers involved in the medication-use process, along with a safety-conscious NICU environment, offers the most comprehensive strategy for preventing medication errors (Gray & Goldmann, 2004; Kanjia et al., 2019; Samra et al., 2011). NICU nurses must consider ALL rights of medication administration (right medication, right patient, right dose, right route, right time, right reason, expiration, and if drug levels are needed prior to administration) and are in an important position to identify potential adverse prescribing and dispensing errors (Pawluk et al., 2017; Simpson et al., 2004).

FIGURE 1



Recommendations

The Joint Commission (www.jointcommission.org) delineates specific hospitalwide medication safety standards applicable to the NICU. In addition to these standards and any applicable state standards, NANN recommends the following practices to those caring for the neonatal population.

Adoption of a Systems Approach to Medication Safety

1. Preventing medications errors requires a systemwide, multidisciplinary, patient-centered effort to create a culture of safety and identify and correct system and individual failures (Campino et al., 2016; Dabliz & Levine, 2012).
2. As part of creating a culture of safety in the NICU, all staff members should be encouraged to report medication errors or potential errors and engage in improving the medication-use process, and leaders should regularly share results of medication-safety efforts.
3. Medication errors, potential errors (near misses), adverse drug events, and systems issues should be reported in a confidential, nonpunitive environment. A system-based approach to error investigation must be a priority, with corrective action taken to reduce recurrences (Rogers et al., 2017; Thomas et al., 2011).

4. Medication errors should be evaluated in a multidisciplinary manner to enhance learning and application of new prevention efforts. Share this review with all staff and track action items to ensure implementation.
5. Medication safety should be part of the NICU quality improvement (QI) plan, including root-cause analysis (retrospective investigation of a sentinel event by a multidisciplinary team using observation, interviews, and chart reviews) and development of action plans that correct systems flaws.
6. Clear, specific policies and procedures that outline how medications are ordered, processed, dispensed, administered, and monitored must be established and be accessible to all healthcare professionals involved in the medication-use process in the NICU.
7. All technology implemented in the NICU to improve medication safety should be evaluated in a multidisciplinary fashion. The evaluation should include all aspects of the technology, including its efficacy in enhancing safety and whether it makes a positive impact on workflow issues.
8. The nursing staff should be involved in the development, implementation, and evaluation of medication delivery systems used in the NICU.
9. All staff members charged with ordering and administering medications must be familiar with and have access to error tracking and reporting systems. An open, just culture for the reporting and reviewing of medication errors is encouraged (Rogers et al., 2017).

Education

1. Provide staff with education and training, and medication-use technology to potentially reduce neonatal medication errors. Effective educational approaches, including simulation training, help to reduce medication errors when compared to self-learning modules (Keers et al., 2014). Research does not support a statistical or clinical difference between classroom learning or e-learning for medication errors (Simonsen et al., 2014).
2. Medication safety should be identified as a core competency for all staff in the NICU and be included in the orientation education given to all new hires in the NICU and in ongoing annual education. Medication safety education includes medication administration best practices and policy review and may be provided in a variety of modalities, including written, lecture, simulation, procedural review, and readily available medication reference material. Medication safety efforts should regularly be shared with all staff, with a focus on problem-prone processes and prevention efforts.
3. NICU staff members should remain current and proficient in the use of medication delivery devices (e.g., smart infusion pumps, syringe pumps) and be aware of the potential for errors with these devices (ASHP, 2018; ISMP, 2020b).
4. All healthcare providers who participate in the medication use process should participate in educational programs in calculating, prescribing, preparing, and administering medications for neonates (Stucky et al., 2003). A blended learning program (e-learning and classroom) has been found to be the most effective method of teaching to improve medication administration practices for registered

nurses, compared to classroom, e-learning, or virtual reality (Härkänen et al., 2016; Sherriff et al., 2012).

5. NICU nurses should know the diagnosis, patient, and intended pharmacologic recommended treatment, including both pharmacokinetics and pharmacodynamics (Dabliz & Levine, 2012).
6. Staff involved in ordering, preparing and administering medications should be aware that those at highest risk for medication errors are newborns less than 32 weeks, those with the highest number of prescribed medications (Palmero et al., 2019), and those at the youngest gestational ages (Krzyzaniak & Bajorek, 2016).
7. The most superior learning mechanisms are those that support a team approach, including nurses who administer medications and emphasize a systems approach to data analysis versus an individual case approach (Drach-Zahavy & Pud, 2010).

NICU Environment and Medication Safety

1. The specific environment in which medications are prescribed, prepared, and administered should be evaluated, with a focus on lighting, available workspace, control of distractions, availability of reference materials, and availability of frequently used supplies.
2. Adequate staffing levels must be followed, with acceptable workload and, schedule permitting, sufficient rest to prevent fatigue errors (Dabliz & Levine, 2012; Kenyon et al., 2007).
3. Staff members should attempt to reduce distractions during all phases of the medication process by avoiding interrupting medication ordering or medication administration.

Medication Ordering, Dispensing, and Administration Practices

1. System processes are recommended, including computerized order-entry with customized NICU order sets, limited interruptions during medication administration and patient handoff, barcode medication verification with limited workaround processes, and standard concentrations of medications when available (Brune et al., 2019; Jozefczyk et al., 2013; Morriss et al., 2009, 2011; Palmero et al., 2019).
2. Redundant safety checks should be built into the medication-use process, including dose-check verification prior to administration. Consider implementation of independent double checks of medications and calculations by another licensed professional prior to administration (ASHP, 2018; ISMP, 2003, 2019; Stucky et al., 2003).
3. Standard references should be identified for use in drug evaluation, selection, and use (ASHP, 2008; Eisenhut et al., 2011; Stucky et al., 2003).
4. NICUS should make available a reliable and standardized method to obtain pediatric and neonatal drug reference information, ideally electronically (De Giorgi, 2010).
5. All oral medications should be dispensed in an oral syringe (ASHP, 2018; ISMP, 2020a; Lucas, 2004).

Conclusions

NICU patients are uniquely vulnerable and require additional safeguards to ensure that medication errors are prevented and harm mitigated. Medication administration in the neonatal population is a high-volume, high-risk activity with a narrow margin of error between therapeutic benefits and lethal consequences. Working in a multidisciplinary and collegial fashion, NICU healthcare professionals should strive to develop standardized safety practices in the prescribing, dispensing, and administration of medications in the NICU. Along with these efforts, a robust plan for monitoring and reducing medication errors is critical.

TABLE 1

High-Risk Neonatal Medication Examples	
Class of Medication	Medications
Adrenergic agonists	Epinephrine Propranolol
Anesthetic agents	Inhaled agents Propofol Ketamine
Antiarrhythmics	Adenosine Propranolol
Antithrombotic agents	Low molecular weight heparin Heparin Lovenox®
Dextrose, hypertonic >20%	IV solutions 21-30% dextrose
Inotropes	Digoxin Dopamine Milrinone Vasopressin
Insulin	IV—regular insulin bolus and infusion
Liposomal forms of drugs	Liposomal amphotericin B
Moderate sedation agents (IV and oral)	Chloral hydrate (oral only) Dexmedetomidine Midazolam Ketamine Lorazepam
Opioids (IV and oral)	Morphine Fentanyl (IV only) Methadone
Neuromuscular blocking agents	Succinylcholine Rocuronium Vecuronium
Parenteral nutrition	TPN, HAL, clear fluids with amino acids
Sodium chloride, hypertonic >0.9%	3% sodium chloride

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