Neonatal and pediatric patient safety: Focus on medication

Clinical decision support for neonatal and pediatric drug therapy
Children are an especially vulnerable patient population, particularly with regard to medication safety.\textsuperscript{1,11} It is estimated that neonatal and pediatric patients are at least three times more vulnerable to harm due to adverse drug events and medication errors than the adult population.\textsuperscript{2,3,11,1}

Limited published literature and clinical trials are available to support safe and effective drug therapy.\textsuperscript{22} There are a limited number of drugs that are approved by the US Food and Drug Administration (FDA) for use in children.\textsuperscript{22} Most of the drugs prescribed to children are used off-label, and this presents a set of unique problems.\textsuperscript{17,18,19,20,21,22}

Clinicians require population-specific, evidence-based clinical tools to help them provide safe and effective drug therapy support for neonatal and pediatric patients. These clinical tools must provide up-to-date, evidence-based drug dosing information, as well as functionality that provides warnings for inappropriately entered dosage values.

With population-specific drug-dosing content and calculators, we believe clinicians have the best evidence and information they need to help them treat even the most complex patients.

**Drug therapy**

Many published studies and policies focus on patient safety with regard to neonatal and pediatric drug therapy, the risks for patient harm due to adverse drug events and medication errors, and the potential for decreasing these errors.\textsuperscript{1,2,3,4,5,6,7,8,9,10,11}

Organizations such as the American Academy of Pediatrics (AAP), the Institute for Safe Medication Practices (ISMP), The Joint Commission and the Pediatric Pharmacy Advocacy Group (PPAG) have provided policy statements, position papers and safety bulletins to advise and promote a culture of pediatric patient safety.\textsuperscript{1,3,12,13} These organizations encourage all individuals and institutions caring for these vulnerable populations to be aware of the challenges of providing safe and effective drug therapy. They provide guidance and recommendations for implementing a comprehensive approach for improving processes and making system enhancements essential for improving quality of care and reducing medication errors.
The pediatric population (including neonates) is three times more likely to experience a potential adverse drug event than the adult population.\textsuperscript{13, 24} An adverse drug event can be defined as either nonpreventable or preventable. A preventable adverse drug event, or medication error, is generally attributable to human error or system flaws and may or may not result in patient harm. Those that do result in patient harm can lead to increased healthcare costs, extended hospital stays, substantial patient morbidity and death.\textsuperscript{1, 14, 15} Neonates, particularly those in the neonatal intensive-care setting, are at highest risk for potential adverse drug events.

Other challenges regarding these populations include the limited availability of published literature and clinical trials to support safe and effective drug therapy, and the limited number of drugs that are FDA-approved for use in children. Approximately 60 percent of FDA-approved medications are not approved for use in the pediatric population.\textsuperscript{16} Additionally, neonates and pediatric patients require medication dosing based on body weight, body surface area and patient age. Dosing differences based on patient age and organ system maturity, particularly in neonates, infants and young children, are important considerations.\textsuperscript{8}

Using neonatal- and pediatric-specific information technology for drug therapy

The use of an FDA-approved drug in a specific population or for a specific condition that is not included in the product labeling is considered an off-label use. Estimates find 45 to 65 percent of drugs used in the neonatal intensive care setting are used off-label.\textsuperscript{17, 18, 19, 20, 21} In a cohort of hospitalized children, 78 percent received at least one drug used in an off-label manner during their hospital stay.\textsuperscript{22} In another study, only 11 percent of the most commonly used drugs in the pediatric intensive care setting were FDA-approved for children.\textsuperscript{23} The AAP states, “The off-label use of a drug should be based on sound scientific evidence, expert medical judgment or published literature.”\textsuperscript{24} Clinicians require current drug information focusing on the neonatal and pediatric populations. The IBM® Micromedex® NeoFax® and IBM® Micromedex® Pediatric Drug solutions provide the population-specific, evidence-based information required for clinicians to treat these complex populations.

Neonatal and pediatric patients require patient-specific dosing based on age, weight and indication. Dosage differences exist for many drugs based on gestational age, postnatal age or postmenstrual age in neonates. Younger infants may require a different drug dosage than older infants or children.\textsuperscript{1} The drug information and drug dosing calculators provided by Micromedex NeoFax and Micromedex Pediatric Drug account for all of these factors based on available evidence.
The most common medication error that occurs when treating the neonatal and pediatric patient populations is prescribing an inappropriate drug dosage, including incorrect dose or dosing interval. The use of pediatric-specific clinical tools that provide calculated doses of medications and include the dose in both milligrams and in milliliters is advocated. These clinical tools should also provide warnings with regard to inappropriately entered values for dose, dose interval, administration time and available concentration.

The Micromedex NeoFax and Micromedex Pediatric Drug dosing calculators provide an age-specific and an indication-specific dosage recommendation that includes all of the necessary route-specific information.

Figure 1. Dosing calculator example

The dosing calculators also provide warnings for entered values, including dose, interval, administration and concentration, which are considered outside the range of clinical appropriateness. The clinician can reconsider the value entered and revise as appropriate. The clinician can also choose to override the warning when clinically warranted.

Figure 2. Dosing calculator warning example
Organizations such as the AAP and the PPAG have provided guidance regarding maximum doses in pediatric patients. In general, weight-based doses should not exceed the recommended adult dose when providing drug therapy for overweight and obese children or adolescents. IBM® Micromedex® dosing calculators have applied maximum doses for all drugs and indications when appropriate.

Figure 3. Maximum dose warning example

The use of standard concentrations, smart-pump technology and appropriate medication labeling for continuous infusion medications has been shown to substantially reduce medication errors in neonatal and pediatric patients. The ISMP and Vermont Oxford Network (VON) have collaborated to standardize the concentrations of neonatal infusions for medications most commonly used in the neonatal intensive care setting and are encouraging national participation for incorporating these standard concentrations. All neonatal infusion medications in the Micromedex NeoFax system are defaulted to these recommended concentrations. The Joint Commission and PPAG support standardizing and limiting the number of drug concentrations for high-risk infusion medications in the pediatric setting. Pediatric infusion medications in the Micromedex Pediatric Drug system have incorporated appropriate default concentrations for this age group as well.

Conclusion

Safe and effective drug therapy for neonatal and pediatric patients is an important challenge for clinicians. These vulnerable patient populations require specific and helpful clinical tools to help meet their needs. These tools are designed to help clinicians improve medication safety and increase their comfort level in the provision of care. Evidence-based systems are designed to help clinicians improve clinical accuracy, drive efficiency and decrease the potential risk for adverse events. Drug-dosing calculators based on patient-specific information, including indication, weight and age also can help decrease the potential risk for adverse events. With population-specific drug-dosing content and calculators, we believe clinicians can use the best evidence to treat even the most complex patients.

Note: This paper was updated April 2018; the original release was December 2012.
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