

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

ISMP National Vaccine Errors Reporting Program

One in three vaccine errors associated with age-related factors



Advances in immunization technology and knowledge of diseases have spurred an ongoing stream of new vaccines and periodic changes to vaccination schedules to optimize disease protection. Today, according to the World Health Organization (WHO), immunizations prevent between 2 and 3 million deaths per year. Despite this success, many children and adults in the US remain vulnerable to the 24 vaccine-preventable diseases that are targeted by 45 different single and combination vaccines available today. Some people are vulnerable because they have not been offered vaccinations; others opt-out of recommended immunizations due to misunderstanding. However, errors with vaccines can also leave patients unknowingly unprotected against serious diseases such as hepatitis A and B, pertussis, diphtheria, cervical cancer, and many others.

Since September 2012, ISMP has been operating the ISMP National Vaccine Errors Re-

Table 1. Vaccines most frequently cited in reports

Vaccine	% of All Reports
Influenza Virus	
■ Trivalent, Types A and B	
■ Quadrivalent, Types A and B	
■ Live, Intranasal (Quadrivalent, Types A and B)	20
■ Live, Intranasal (Trivalent, Types A and B)	
DTaP-IPV	
Diphtheria and Tetanus Toxoids, Acellular Pertussis Adsorbed, and Inactivated Poliovirus	12
HepA	
Hepatitis A, Inactivated	10
Tdap	
Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Adsorbed	9
DTaP	
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed	8
HepB	
Hepatitis B (Recombinant)	7
MMRV	
Measles, Mumps, Rubella, Varicella Virus Live	7
DTaP-IPV/Hib	
Diphtheria and Tetanus Toxoids, Acellular Pertussis Adsorbed, Inactivated Poliovirus, and Haemophilus Influenzae b Conjugate	5

porting Program (ISMP VERP) to collect data about the types of vaccine errors and their underlying causes. While it is not possible to determine the frequency of vaccine errors from the ISMP VERP or any other current vaccine error reporting program, given their dependence on spontaneous reporting, estimates from systematic review of vaccination records suggest that errors occur in about 27-35% of all vaccinations.¹³ In this newsletter, we provide a summary of nearly 4 years of vaccine errors reported to the ISMP VERP through June 30, 2016.

Volume and types of error reports

Between September 2012 and June 2016, a total of 1,754 reports have been submitted to the ISMP VERP. Most of these vaccine errors came from practitioners who work in outpatient settings, where most children and adults receive vaccines. Given its voluminous use, influenza virus vaccines were most frequently involved in the reported errors, accounting for 20% of all reports. However, errors involving other vaccines were more common in specific settings based on the typical patient populations served. For example, errors with hepatitis A vaccine were most

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19th Annual ISMP Cheers Awards

Each year, ISMP celebrates individuals and organizations that have set a standard of excellence in the prevention of medication errors during the previous 12 months. Nominations for this year's **Cheers Awards** will be accepted through **September 9**. ISMP accepts outside nominations, including self-nominations. The prestigious awards spotlight efforts from all healthcare disciplines, including nursing, medicine, and pharmacy, and winners have represented all practice areas, including acute care, long-term care, home care, and community pharmacy settings. To submit a nomination, please visit: www.ismp.org/sc?id=1777.

SAFETY briefs



Temporary bleomycin importation. Due to the shortage of bleomycin injection in the US, the US Food and Drug Administration (FDA) is allowing temporary importation by Amneal Biosciences of a product manufactured by Cipla Ltd. at an FDA-inspected facility in Verna, Goa, India (www.ismp.org/sc?id=1776). The product is sold elsewhere under the Willow Pharmaceuticals label. Several features of the container label will not be familiar to US practitioners.

First, the imported product container label indicates that the vial contains bleomycin 15,000 international units (**Figure 1**, on page 2). Although the difference is unexplained, this is actually the same active ingredient, bleomycin sulfate, in the same strength as the US FDA-approved Bleomycin Sulfate for Injection, USP, 15 units per vial (1,000 international units of Bleomycin Sulfate Powder for Injection equals 1 unit of Bleomycin Sulfate USP) (**Figure 2**, on page 2). The term "international units" is not allowed on US drug

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commonly reported by staff in public health immunization clinics. Errors with zoster and pneumococcal vaccines were frequently reported by staff at community pharmacies. Errors with the anthrax, typhoid, and yellow fever vaccines were most commonly reported by staff at military locations.

The most frequent types of reported vaccine errors included:

- Wrong vaccine (23% of all reports)
- Wrong age for vaccination (20%)
- Wrong vaccine dose (12%)
- Extra vaccine dose (9%)
- Wrong vaccine interval (7%)

The vaccines most often involved in the errors reported to the ISMP VERP can be found in **Table 1** (page 1). The Table also lists the full generic names of the vaccines abbreviated in this report according to the system used by the Advisory Committee on Immunization Practices (ACIP) (www.ismp.org/sc?id=1773).

Age-related contributing factors in aggregate vaccine reports

Among all vaccine errors submitted to the ISMP VERP, age-related contributing factors were reported most often and were linked to more than 1 in every 3 error reports (38%) (**Table 2**). Thirteen percent of all reported vaccine errors were due to confusion that arose between numerous age-dependent vaccines that target the same diseases, particularly with influenza virus vaccines, hepatitis A and B vaccines, and various combination vaccines that target diphtheria, tetanus, and pertussis. Another 13% of the errors involved lack of familiarity with the recommended ages for various vaccines or a failure to take a step as simple as verifying the patient's age prior to administration. The measles, mumps, rubella, varicella vaccines joined those previously mentioned as one of the most frequently involved in these types of errors. Similar vaccine abbreviations and labeling or packaging, and dense storage conditions, played a role in the remaining 12% of age-related vaccine errors. Along with previously mentioned vaccines, the *Haemophilus influenzae* type b-containing vaccines were also involved in er-

Table 2. Leading Age-Related Contributing Factors and Vaccines

Contributing Factor	% of All Reports	Vaccines Most Often Involved
Age-dependent formulations of same vaccine	13	Influenza
		DTaP, Tdap, DTaP-HepB-IPV, DTaP-IPV/Hib, DTaP-IPV
		HepA
		HepB
Not familiar with indicated patient ages for vaccines	8	DTaP, Tdap, DTaP-IPV/Hib, DTaP-HepB-IPV, DTaP-IPV
		Influenza
		MMRV
Patient age not verified before administration	5	Influenza
		DTaP, Tdap, DTaP-IPV
		HepA
		MMRV
Similar vaccine abbreviations	5	Tdap, DTaP, DTaP-IPV
		MMR and MMRV
		HepB, Hib, HepB-Hib
Products stored near one another	4	Varicella virus vaccine and MMRV
		Tdap and DTaP
		DTaP-IPV and DTaP-IPV/Hib
Similar vaccine container labels/packaging	3	MMRV and MMR
		HepA and HepB
		Tdap, DTaP, DTaP-IPV, DTaP-HepB-IPV

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product labels. One issue is that “international units” is abbreviated “IU,” which has occasionally been misread or misunderstood as “IV” (intravenous) when the intended route was different. Another fea-



Figure 1. Imported product label.



Figure 2. US product label.

ture which is not seen on US labels is the abbreviation “K” for “thousand” because it is also the chemical symbol for potassium, which this product is not. We’re not sure if “Bleo” is a brand name or a shortened form of bleomycin, but neither would be allowed on US labels. Also note the absence of a barcode on the imported drug label. In order to facilitate scanning, addition of a printed barcode label will be necessary. The Amneal label does not include an indication for malignant pleural effusions, which is in US labeling. Finally, US labels state “Rx only,” but the imported label states, “prescription only medicine.”

⚡ Healthcare consumers are watching!

A consumer (also a nurse) reported that an unlabeled syringe was observed at a dermatologist’s office during her son’s appointment for a wart removal. The unlabeled syringe was on a table with a piece of paper under it. Her son asked if the injection was for him, and the nurse replied, “No, that’s for a different type of procedure.” On another occasion, the consumer noticed an unlabeled syringe of what looked like propofol in an oral surgeon’s treatment room, but it clearly was not needed for her procedure, which did not require sedation.

Then, more recently, another consumer took her mother to a neurologist for a continued on page 3—**SAFETY briefs** >

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errors due to labeling or nomenclature problems. We focus this year's analysis upon these vaccines which were most frequently associated with age-related contributing factors.

Age-related influenza virus vaccine errors

Influenza virus vaccine is available in many formulations that differ based on the patient's age. The vaccine does not have distinct adult and pediatric formulations. Some formulations are indicated for both children and adults within certain age ranges. Given this and the high frequency of administration in all age groups, it is not surprising that influenza virus vaccine was the most common type of vaccine implicated in age-related errors among vaccines with age-dependent formulations. Many errors involved knowledge deficits regarding the recommended age ranges for each type of influenza virus vaccine and included giving an adult dose/volume of the vaccine to a child or vice versa, administering the high-dose formulation to an adult younger than 65 years, and administering the live nasal formulation to a child younger than 2 years or an adult older than 49 years. Manufacturer labeling and packaging issues that make it difficult to distinguish various age-dependent formulations and US Food and Drug Administration (FDA) requirements to list the generic name before the brand name were also causative factors with many of these errors (**Figure 1**).



Figure 1. A 38-year-old patient received Sanofi Pasteur's Fluzone High-Dose after the practitioner failed to notice "High-Dose" after "Fluzone," which was partly obscured by the gray plunger visible in the background.

Age-related hepatitis A (HepA) vaccine (HAVRIX, VAQTA) and hepatitis B (HepB) vaccine (ENGERIX-B, RECOMBIVAX HB) errors

Two brands of the hepatitis A vaccine—Havrix (GlaxoSmithKline) and Vaxta (Merck & Co.)—are both available in pediatric/adolescent and adult formulations in 0.5 mL (pediatric/adolescent) and 1 mL (adult) single dose containers. Errors have occurred in which the pediatric/adolescent formulation (0.5 mL) was administered to an adult, and vice versa. These errors were often due to vaccine labeling similarities. While the adult and pediatric/adolescent Vaxta syringes have different color plungers and the vials have different color caps, the text and the primary color on the cartons is similar, and the text on the syringes and vials is small. Color differentiation is also used for the adult and pediatric/adolescent forms of Havrix. However, the syringes must be turned away from the drug name to further view whether it contains an adult or pediatric/adolescent dose. The age notation on vial labels is at the very bottom and is easy to miss.

Similar labeling issues have led to errors with the hepatitis B vaccine. The two vaccines—Engerix-B (GlaxoSmithKline) and Recombivax HB (Merck & Co.)—are available in pediatric/adolescent and adult dose vials and syringes in a consistent concentration but in different volumes. Label differentiation using color has not prevented errors, as the label notations about the different age-based formulations are not prominent. Engerix-B syringe labels must be turned away from the drug name to view the age-specific indication (**Figure 2**). With Recombivax HB vials, differentiation between the adult and pediatric/adolescent formulations is not prominent (**Figure 3**, page 4) and has led to errors. In fact, one of the most frequently reported events with hepatitis B vaccines involved dosing errors in which a child received an adult's dose or an adult received a child's dose.



Figure 2. The Engerix-B syringe must be turned away from the drug name to view "For Pediatric/Adolescent Use Only."

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nerve block to treat head and neck pain. A nurse holding two unlabeled syringes and a sheet of paper in her hand ushered them into a treatment area. They remained in the room for about 30 minutes, along with the 2 unlabeled syringes, until a physician assistant (PA) arrived in the treatment room. The consumer reported her concern about the unsecured and unlabeled syringes, suggesting several adverse scenarios that could happen as a result. First, a patient might try to divert or tamper with the unknown medications in the syringes, or even self-administer the contents of one or both syringes; furthermore, a nurse could put the syringes of unknown medications into the wrong treatment room, where a PA or physician could assume the syringes contained the anticipated medications and inject the unknown medications without confirmation. While the consumer spoke up and did everything possible to address the risk she observed, she probably ruffled some feathers in the office for bringing this to the PA's attention. However, soon after, the neurologist came into the room, proceeded to freshly prepare the needed medications, and assured the consumer that he would address the risk. Kudos to the consumer for speaking up! The proper labeling of prepared syringes of medications is absolutely critical to safety.

⚡ Mislabeled oral syringe package. Notice something wrong with the oral syringe in **Figure 1**?



Figure 1. Ezy Dose oral syringe holds 10 mL capacity, not 5 mL as stated on package label.

The syringe capacity is actually 10 mL, not 5 mL as stated. Oral syringe manufacturers should also be working to eliminate household measures, such as teaspoons, as mentioned on the label. We also believe that dosage "corks"

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An additional source of error involves differences in the recommended dosing units of each brand product. For hepatitis A vaccine, the dose is 720 units (0.5 mL) for pediatric/adolescents and 1,440 units (1 mL) for adults when using Havrix. When using Vaqta, the dose is 25 units (0.5 mL) for pediatric/adolescents and 50 units (1 mL) for adults. Similarly, the recommended doses of the two brands of hepatitis B vaccine are different. Enderix-B dosing is 10 mcg (0.5 mL) for pediatric/adolescents and 20 mcg (1 mL) for adults. Recombivax HB dosing is 5 mcg (0.5 mL) for pediatric/adolescents and 10 mcg (1 mL) for adults. Dosing errors have occurred in which patients received the wrong age-specific volume. In some cases, adults have received half the intended dose when Enderix-B was dosed according to Recombivax HB dosing. One reason the latter errors occurred is that healthcare providers changed from one brand of hepatitis B vaccine to the other without updating the doses or volumes listed in electronic or paper order sets.



Figure 3. While cap colors are different, notations about adult (L) and pediatric (R) formulations of Recombivax HB are easy to miss.

Age-related DTaP (DAPTACEL, INFANRIX), Tdap (ADACEL, BOOSTRIX), DTaP-IPV (KINRIX, QUADACEL), DTaP-HepB-IPV (PEDIARIX), or DTaP-IPV/Hib (PENTACEL) errors

The dominant issues reported with these vaccines are the same issues that have long been reported to ISMP and FDA—confusion between the different age-dependent formulations and combination products. This group of vaccines is particularly vulnerable to errors due to:

- The large number of different vaccines and various combinations of vaccines in this category, many with different targeted ages
- Differences between the recommended ages for the individual components of combination vaccines and the combination vaccine itself
- Similar or confusing manufacturer labeling and/or packaging
- Similarities in standard vaccine abbreviations, the inability to recall the correct abbreviations, and misinterpretation of abbreviations
- The large number of words related to product names to be squeezed into the small space available on single-dose vials or syringes, necessitating a small font size
- Similar generic and brand names

For example, 60 errors have been reported in which DTaP (diphtheria and tetanus toxoids, acellular pertussis) was administered instead of Tdap (tetanus toxoid, reduced diphtheria toxoid, acellular pertussis), or vice versa. Similar vaccine abbreviations and confusion among brand names (Adacel, Boostrix [Tdap]; Daptacel, Infanrix [DTaP]) appear to be contributing factors in these errors, along with not understanding the differences between the two vaccines and the recommended age ranges for administration.

Second only to errors with the influenza virus vaccine, errors with Kinrix (DTaP-IPV) were the most frequent among all vaccine errors. With many of the errors, Kinrix (indicated for children 4 to 6 years old) was given to children younger than 4 years old, when separate components should have been administered to these younger patients. Another common error occurred when Kinrix had been administered instead of the intended vaccine Pediarix (DTaP-HepB-IPV), indicated for children 6 weeks to less than 7 years, or Pentacel (DTaP-IPV/Hib), indicated for children 6 weeks to less than 5 years. Several reports suggest that packaging similarities have led to the mix-ups between Kinrix and Pediarix. More than 50 of the errors with Kinrix also listed staff unfamiliarity with the age-related indications as a contributing factor. Complex vaccination schedules have also contributed to mistakes with the timing of these vaccines, particularly when children are following an alternate or delayed schedule of immunizations.

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(or “Dosage-Korc,” as the company calls the stopper that’s also in the package) are unsafe. Children have removed the Christmas tree-type “cork” to drink medicines. The removed adapter is also a choking hazard for children. A warning appears in small font to recap the medication to prevent product instability, but no warning regarding accidental poisoning or choking hazard can be seen on the package. The safety cap should always be put back on the bottle between uses, but this type of adapter makes it very easy for parents to miss that step.

If your hospital has an outpatient pharmacy, consider purchasing only syringe



Figure 2. A flow restrictor plugs into the neck of the prescription bottle and is difficult for children to pry out. The flow restrictor also allows the child-resistant bottle cap to be replaced without removing the flow restrictor.



Barcode—a must on immediate container label. Pack Pharmaceuticals brand of ciprofloxacin 0.3% ophthalmic solution does not contain a barcode on the bottle label itself. There is a barcode on the outer carton, but the bottle itself cannot be scanned (**Figure 1**, page 5). Once opened, the bottle should not be returned to the carton because it could be placed in the wrong carton.

Without a barcode on the bottle’s label, an incorrect medication could be selected and administered. The bottle does have some widely-spaced lines on the upper edge of the label that may be mistaken as a barcode; however, it was meant to

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Age-related errors with measles, mumps, rubella, varicella (MMRV) vaccine (PROQUAD)

Most of the age-related errors involving ProQuad were related to administration to children older than 12 years. All but one of the patients were teenagers, and almost half of the errors involved teens who were 13 and 14 years old. Although not mentioned specifically in all these reports, at least some of the errors were associated with teens who were following a catch-up immunization schedule. Once they exceeded the age of 12, the trivalent measles, mumps, rubella vaccine and a separate varicella vaccine should have been administered individually, as the quadrivalent vaccine ProQuad is recommended only for children 12 months to 12 years. Several reporters noted that their electronic health record failed to alert staff that the vaccines were not indicated based on the patient's age.

Age-related errors with *Haemophilus influenzae* type b (Hib) components of vaccines

While some errors with Hib or combination vaccines that included the Hib component were related to administration to a patient outside the recommended ages, most were caused by unfamiliarity with the components of combination vaccines or misunderstanding or misreading the HepB component as the Hib component. The latter events led to administration of the Hib vaccine to patients who were not within the recommended age range. For example, numerous reports involved administration of Kinrix (DTaP-IPV) by staff who mistakenly thought it contained Hib, and administration of Pediarix (DTaP-HepB-IPV) instead of Pentacel (DTaP-IPV/Hib), believing the HepB component of Pediarix was Hib.

Safe Practice Recommendations

FDA and vaccine manufacturers, and health professionals who prescribe, dispense, and administer vaccines, are urged to make changes that will reduce the risk of age-related vaccine errors. First, FDA and manufacturers should strongly consider seeking a federal regulatory change that allows the vaccine brand name to be listed first on vaccine labels, before the full generic names, which are often long and confusing. Next, vaccine manufacturers must continue to improve labeling and packaging to differentiate age-dependent formulations of the same vaccine. There are also many practice changes health professionals can make to prevent age-related vaccine errors:

Make safe purchasing decisions

- While not always possible, investigate purchasing different age-specific formulations of the same vaccine from different manufacturers to help distinguish them.
- If possible, stock only one manufacturer's adult and pediatric/adolescent formulations of the hepatitis A and the hepatitis B vaccines (both adult and pediatric/adolescent formulations from the same manufacturer have the same strength). If both brands must be available in stock, separate their storage, label the storage bins, and, when available, issue electronic reminders to staff to verify the dose.
- Whenever brands change, conduct specific training for all staff and ensure electronic and paper order sets are revised.

Affix warnings

- Affix auxiliary warning labels to vaccines when first received in the clinic, medical office, or pharmacy to draw attention to products with different formulations for neonatal, pediatric, adolescent, and/or adult patients.
- Affix auxiliary labels to select vaccines with problematic similar names to draw attention to key information that would help promote selection of the correct product.

Improve access to information

- Maintain up-to-date easy-to-read electronic immunization schedules for infants, children, teens, and adults, and post them in clinical areas where vaccinations may

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be used by the manufacturer as part of their internal quality control mechanism.

The US Food and Drug Administration (FDA) intends for barcodes to be on a drug's immediate container label as well as the outer container (or overwrap), unless the barcode is readily visible and machine-readable through the outer container (or overwrap) (www.ismp.org/sc?id=1687). This strategy will help to prevent medication errors when hospital personnel may need to scan the barcode during the dispensing process before the outer carton (or overwrap) is removed. ISMP has contacted the manufacturer to request that the label be revised. FDA has also been made aware of the problem. Until the product label is revised, you may want to use an alternative product.



Figure 1. The product barcode is only on the outer carton and not on the ciprofloxacin ophthalmic bottle itself. Lines at the top of the bottle label do not encode the NDC number.

Special Announcement

ISMP MSI

Join us at the **ISMP Medication Safety Intensive (MSI)** workshop in Las Vegas on **December 2 and 3** to learn unique ISMP principles and techniques that can maximize your organization's medication safety efforts. This workshop will help you learn to identify, analyze, and control medication safety risks using real-world case examples for practice. For more information or to register, visit: www.ismp.org/sc?id=351.

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be administered. Include the brand and generic names of all vaccines, the approved abbreviations, and the range of ages appropriate for administration. (We could not find a list of all brand and generic vaccines and their age-specific recommendations, but adding this information to the current list of vaccines and acronyms provided by the ACIP [www.ismp.org/sc?id=1773] would be very useful.)

- On order sets, medication administration records (MARs), and vaccination records, list the brand names and all components of combination vaccines. When space permits, list full generic names of all components. If abbreviations must be used, employ only the ACIP approved abbreviations (see link above). Make necessary revisions if brands change.

Store vaccines safely

- Store vaccines in refrigeration and freezer units large enough for organized and labeled stock.
- Separate pediatric and adult formulations of vaccines in storage areas.
- Label the specific locations where vaccines are stored to facilitate correct, age-specific selection (**Figure 4**).
- Do not store vaccines with similar labels, names, abbreviations, or overlapping components (e.g., DTaP, Tdap) immediately next to each other.

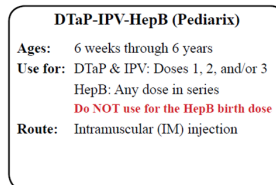


Figure 4. Example of label for storage locations of vaccines.

Educate patients and caregivers

- Provide all patients, parents, or legal guardians with a Vaccine Information Statement (VIS) in their preferred language prior to vaccination. If a combination vaccine contains the components DTaP, HepB, Hib, or IPV, provide the Pediatric Multiple Vaccine VIS. VISs are available on the Centers for Disease Control and Prevention (CDC) (www.ismp.org/sc?id=1774) and the Immunization Action Coalition (www.ismp.org/sc?id=1775) websites and have been translated into more than 40 languages. The VISs can be printed, viewed, and displayed on smart phones, tablets, or other mobile devices and imported into an electronic file. Time to read the VIS and ask questions *before* vaccination should be provided.

Verify the patient's age

- Prior to prescribing, dispensing, or administering a vaccine, verify the patient's age by asking the patient or caregiver for a birth date and referencing the patient's health record, immunization record, and/or MAR. Also check immunization registries before ordering and administering vaccines to verify the patient's current vaccination status and indicated ages for administration.
- Prior to vaccine administration, compare the patient's current age with information on an applicable immunization schedule and VIS.
- Ask patients or parents to help verify the vaccine prior to administration by reading the VIS and checking that the patient is within the specific ages for the vaccine.
- Employ point-of-care barcode scanning to verify that the correct vaccine and age-specific formulation has been selected and prepared for administration to a patient.
- Build alerts in order entry systems to warn health professionals if a specific vaccine is prescribed and selected for a patient who is older or younger than the recommended ages for vaccine administration.

Educate staff

- Discuss vaccine errors that can occur and how to prevent them with health professionals who prescribe, dispense, and administer vaccines.

References appear in the middle of the right column.

TEXTBOOK Errata

The American Society of Health-System Pharmacists (ASHP) has issued a recall and correction notice for the book, *NICU Primer for Pharmacists*. On page 29 in Chapter 3, Parenteral Nutrition, under the heading "Macronutrients: Carbohydrates," examples of typical glucose infusion rates appear as "mg/kg/hr." However, this should be "mg/kg/min." A full explanation appears here: www.ismp.org/sc?id=1768.

ASHP is asking print copy holders to return the copy to ASHP for replacement. Ebook owners should delete their current copy and go to the ASHP website ebook library for a replacement.

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