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ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

ISMP Call to Action: Resist the land of *Not Yet* and distribute FREE NurseAdvise*ERR*® to all nurses

In addition to the *ISMP Medication Safety Alert!*, ISMP publishes **NurseAdvise*ERR***, a free monthly newsletter specifically for frontline nurses (**Figure 1**). This 4- to 5-page, peer-reviewed newsletter is an abbreviated version of the *ISMP Medication Safety Alert!* covering some of the high-priority medication safety issues discussed in this newsletter, but tailored for nurses. **NurseAdvise*ERR*** is designed to meet the unique medication safety and educational needs of nurses who receive medication orders, administer medications, and monitor the effects of medications on patients. The publication was launched with educational grants in 2003 due to our deep concern that frontline nurses were not being made aware of significant medication errors reported to the ISMP National Medication Errors Reporting Program (ISMP MERP), along with the recommended strategies to prevent errors. ISMP continues to receive educational grants from various companies and foundations to offer the newsletter free to all nurses, as well as medication and patient safety officers, quality and risk management staff, faculty who provide nursing education, and nursing students.


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NurseAdvise*ERR*

Educating the Healthcare Community About Safe Medication Practices

Newborn naming conventions and wrong-patient errors

According to the Centers for Disease Control and Prevention (CDC), nearly 4 million infants are born in the US each year, including approximately 132,000 multiple births.[1] Unique characteristics of this newborn population pose significant challenges regarding accurate patient identification, which has led to wrong-patient errors.[2,3] Unlike most older children and adults, newborns cannot speak and thus cannot participate in the patient identification process.[3,4] Also, it is often difficult to distinguish one infant from another based on physical appearance or sex.[3,5] Furthermore, hospitalized newborns may not have a given first name immediately after birth and often have similar last names, medical record numbers, and birthdates that can lead to errors caused by patient misidentification.

Newborns at Risk of Wrong-Patient Errors

During childbirth, one patient, the mother, becomes two or more patients, the mother and her newborn infant(s).[6] Because newborn identification is a priority immediately after birth, hospitals and birthing centers typically utilize a newborn naming convention that assigns a temporary, nondistinct first name, such as Babyboy/Babygirl, BoyGirl, or BBiBG, plus the mother's surname to identify newborns, as parents may not have decided on the newborn's first name for various reasons.[4,7] These temporary, nondistinct names do not convey the added discrimination typically provided by unique first names. This results in many patients with similar identifiers, including mothers and their infants with the same last names, and many infants with the same nondistinct first names. In communities where there are a lot of commonalities among surnames, unrelated newborns could also have the same last name and nondistinct first name if they are the same sex (e.g., two unrelated babies identified as Smith, Babygirl).

Newborns in neonatal intensive care units (NICUs) and multiple birth siblings are particularly at risk for misidentification. In a NICU, newborns tend to receive more medications and treatments than healthy newborns,[3,8] and 1 in every 4 serious medication error in this setting is caused by misidentification.[1,9] Twins and other multiples are at risk because they could have the same birthdate, sex, and last name.[3] In addition to having the same nondistinct first and last name, multiples are often assigned a letter or number distinguisher (e.g., BabygirlA/BabygirlB) that may easily be overlooked. Furthermore, multiples often have a sequential medical record number differentiated by only one digit from a sibling since most are created in numerical order based on time of admission/birth.[3] In one study, more than half of the average daily census of a NICU was at risk for wrong-patient errors as a result of similar names or medical record numbers.[10] Multiple birth siblings accounted for more than half of this risk (although more than a quarter of singletons were at risk too). Given the increased possibility of premature birth and low birth weight, multiples make up more than 10% of the population in a NICU.[3]

Two other unique conditions with the newborn patient population increase the risk of errors caused by misidentification. First, the newborn's electronic health record (EHR) must be changed from a temporary name to a permanent given name prior to or upon discharge when preparing official documentation for a birth certificate.[4,7] This transfer process is unique to newborns and fraught with the risk of errors. Lastly, long temporary newborn names can become truncated in the EHR,[3] on name bracelets, and on medica-

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Your *Reports* at *Work*

FDA tells pen injector needle manufacturers to improve patient instructions

Thanks to your reporting about patients who failed to remove the inner pen needle cover prior to administering insulin, the US Food and Drug Administration (FDA) has asked needle manufacturers to update labeling and improve patient instructions for use.

Standard pen needles have outer and inner needle covers, both of which must be removed prior to injection. However, hospitals often use safety needles, which have an outer cover that must be removed, but there is no inner cover to remove. An inner shield over the needle automatically retracts during injection and covers the needle after injection to prevent needlestick injuries. After discharge, patients may receive standard pen needles from their pharmacy and not know that the inner needle cover must be removed, especially if they have not been taught this step while hospitalized. If the inner cover of a standard pen needle is not removed, patients may not receive the medication. ISMP and the American Society of Health-System Pharmacists (ASHP) published a National Alert Network (NAN) Alert about this issue (www.ismp.org/node/xx) in October 2017.

In response to these concerns, FDA has asked needle manufacturers to review their labeling and educational materials and to update and clarify the need to remove the inner needle cover/cap before injection. The agency also requested manufacturers to add a warning in the labeling, such as: "Remove both the outer cover and the inner needle cover before an injection. If both the outer cover and the inner needle cover are not removed before use, the medication or dose may not be injected, which may result in serious injury or death."

Supported by educational grants from Novartis and Fresenius Kabi | NOVARTIS | FRESENIUS KABI

Figure 1. ISMP publishes a free monthly nursing newsletter, **NurseAdvise*ERR***, which is currently supported by educational grants from Novartis and Fresenius Kabi (NeoMed also donates to the effort). To subscribe, please visit: www.ismp.org/node/138.

Although we are in our seventeenth year of publication of **NurseAdvise*ERR***, we are worried that many US hospitals are not distributing this free resource to nurses, thus missing a key opportunity to involve nurses as an integral safety partner to solve the most formidable medication safety challenges. The predominant goals of **NurseAdvise*ERR*** are to arm nurses with critical medication safety information and to bring the nursing voice to an interdisciplinary team to assist hospitals in understanding the underlying causes of medication errors and redesign their systems to prevent patient harm. And, the nursing voice can be quite powerful, both within the organization and nationally!

For example, in 2010, ISMP conducted a survey via **NurseAdvise*ERR*** during which more than 17,500 nurses made it abundantly clear that the Centers for Medicare & Medicaid Services (CMS) rule requiring administration of all medications within 30 minutes of their scheduled time was often impossible to follow, leading to serious, unintended consequences. Nurses spoke up about feeling compelled to take unsafe shortcuts to comply with the rule, including removing medications from an automated dispensing cabinet (ADC) via override, documenting administration at the scheduled time but actually giving the medication early or late, failing to use barcode scanning to avoid documentation of late administration, borrowing medications from other patients, skipping independent double checks, and many other risky shortcuts. The nurses' input on this important

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SAFETY briefs

HIGH-ALERT

FDA label guidance needed for sterile compounders. We are still receiving complaints and error reports related to the lack of standardized labeling of prefilled syringes and premixed intravenous (IV) infusion products prepared by compounding pharmacies and outsourcers. As we pointed out in our March 22, 2018 newsletter (www.ismp.org/node/998), the US Food and Drug Administration (FDA) does not hold outsourcing facilities to the same labeling standards as commercial manufacturers. For example, if certain conditions are met, federal law exempts compounded drugs from the requirement for labeling with adequate directions for use. ISMP has also published several **Safety Briefs** showing that some compounders deviate from USP <7> container labeling standards.

We recently received an error report involving ketamine syringes compounded by QuVa Pharma. Though they are properly

Figure 1. Unnecessary volume statement, "5 mL in 5 mL Syringe," on ketamine syringe compounded by QuVa Pharma.

labeled with the concentration per total volume (50 mg/5 mL [10 mg/mL]), the unnecessary statement, "5 mL in 5 mL Syringe," located below the concentration (**Figure 1**) led to confusion and an error. A nurse removed a ketamine syringe from an automated dispensing cabinet (ADC). She misunderstood the volume statement to mean the concentration was 5 mg/5 mL and withdrew 5.7 mL (instead of 0.57 mL) for a 5.7 mg dose, a 10-fold overdose. The error was not caught until after administration. The patient was observed for hypotension, and his vital signs remained stable.

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medication safety topic unquestionably served as a catalyst to national changes. In 2011, CMS eliminated the longstanding 30-minute rule for all scheduled medications, highlighting our effort (www.ismp.org/node/361). Now, hospitals are expected to classify scheduled medications into categories that reflect appropriate timing for administration that balances patient safety with the need for flexibility in work processes.

When nurses are consistently provided with information about risks that are causing potentially harmful errors and are given a chance to speak up, they are a powerful group. If nurses in your organization are NOT receiving and reading **NurseAdviseERR**, they may have MISSED out on learning about these key risks and more since January 2019.

- Concern about wrong patient errors between the *mother* and her newborn due to recent changes in the newborn naming convention that embed the mother's first name into the newborn's temporary name (prior wrong patient errors were more often between newborns with similar/same names)
- Failed insulin administration via pen devices in the home because patients have not been taught to remove the inner needle cover on a standard pen needle prior to injection (safety needles with retractable needle covers are not used in the home)
- **RITUXAN HYCELA** (ri**TUX**imab/hyaluronidase) and **HERCEPTIN HYLECTA** (trastuzumab/hyaluronidase-oysk) must be administered *subcutaneously* despite unusually large dose volumes well over the usual limit of 2 mL; these large volume subcutaneous doses risk being administered intravenously (IV)
- Optional adhesive cover (without medication) that can be applied over a clo**NID**ine patch has been mistaken as the actual clo**NID**ine patch and applied alone
- Simulation products used for training purposes that have made their way into patient care areas and were mistaken as the real medications or solutions
- A neuromuscular blocking agent administered to an unventilated patient, which was associated with the unsafe retrieval of a medication from an ADC (by override) after typing just two letters of a drug name into the search field, selecting the wrong medication from the screen, and several other systematic safety failures
- Ongoing fatal cases of intrathecal administration of IV vinca alkaloids, which led ISMP to call upon the US Food and Drug Administration (FDA) to remove instructions for preparation and administration of vinca alkaloids by syringe from product labeling, in favor of safer dilution in a minibag
- Mix-ups between epidural analgesia and IV antibiotics in labor and delivery areas
- Errors due to incorrect interpretation of glucometer results due to codes used to present the results
- Announcement of updated ISMP guidelines for the safe use of ADCs and electronic communication of medication-related information, along with an invitation to comment on updated draft guidelines for smart infusion pumps

Where else can frontline nurses get information like this?

Healthcare is an industry that professes to be racing towards high reliability; but rather than nurturing a healthy preoccupation with failure, we have a natural tendency to be too optimistic and overconfident in our abilities and systems. We tend to view errors that happen elsewhere as irrelevant in our own work, so the stories of risk and errors

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QuVa also provides fenta**NYL** in a premixed IV bag (**Figure 2**) with a similar unnecessary volume statement, "100 mL in 150 mL Bag," which appears in a slightly larger font than the statement about the total amount per bag, "1000 mcg/100 mL (10 mcg/mL)." The bag size is irrelevant but has the potential to be misinterpreted as the product strength, similar to the previously cited error.

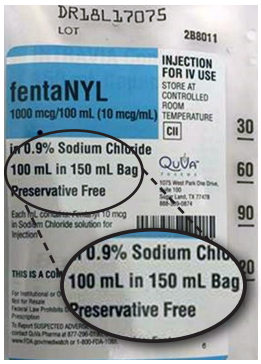

Figure 2. Similar unnecessary volume statement, "100 mL in 150 mL Bag," on compounded fenta**NYL** IV bag.

Standardized labeling, like the labeling requirements for manufacturers, should exist for 503B compounders to avoid medication errors. We encourage FDA to publish guidance for 503B outsourcers, to establish specific standards for this industry. This could also help with the consistency of labeling from 503A pharmacies. Meanwhile, the hospital where the ketamine error occurred has decided to cover the "5 mL in 5 mL Syringe" statement with a "Note Dosage Strength" auxiliary label to prevent confusion (**Figure 3**).

Figure 3. Hospital covers unnecessary volume statement with "Note Dosage Strength" auxiliary label. If adopted, the diluent information (concealed in this photo) should also remain visible.

Premixed vancomycin IV bag not recommended in pregnancy. A ready-to-use, premixed vancomycin intravenous (IV) bag manufactured by Xellia Pharmaceuticals in various strengths was recently approved by the US Food and Drug Administration (FDA). One of the major challenges to providing vancomycin in a ready-to-use formulation was the ability to stabilize the drug in solution at room temperature for an extended length of time. This new premixed bag is stable for 16 months if maintained in the overwrap and

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illustrated in NurseAdviseERR may not seem worthy of attention. We were reminded of our natural tendency to be overconfident in our abilities and systems when an ISMP staff member recently shared the following message she had seen flash across the television screen between shows (source: Chuck Lorre Productions, #545):

> **I don't know about you, but I've been spending most of my time in the land of *Not Yet*. If you are unfamiliar with it, *Not Yet* is a happy place where all the bad things that seem likely to occur have not happened… yet. I like to think of it as a shimmering, shivering soap bubble whose fragile beauty is only made greater by the knowledge that it will soon burst, making way for the darker realm of *You Got To Be Kidding Me*.**
>
> **But not now.**
>
> ***Not Yet*.**
>
> **And yes, I would love to say *Not Ever*, but that place doesn't exist.**

ISMP Call to Action

ISMP is calling on all medication safety leaders to resist living in the land of *Not Yet* and to provide nurses with a practical tool like NurseAdviseERR to learn about emerging and ongoing risks that are clearly relevant to all hospitals. Please don't assume that nurses in your organization are receiving this publication or getting a copy of this newsletter. In late 2018, all current subscribers to NurseAdviseERR were asked to re-subscribe to accommodate a new customer management system. Many previous subscribers have done so, but others may have overlooked this step and may not realize that they are no longer receiving the newsletter.

Please talk to your nursing staff to find out if they are currently receiving NurseAdviseERR. Keep in mind—even if nurses currently receive the *ISMP Medication Safety Alert!,* it is crucial to also provide them with NurseAdviseERR, which presents medication safety issues from a unique nursing perspective. NurseAdviseERR also includes articles unique to nurses that do not appear in the *ISMP Medication Safety Alert!*

If nurses are not currently receiving NurseAdviseERR, forward this link to them to subscribe: www.ismp.org/node/138. The recommended subscription process is as follows:

- ISMP encourages one or two coordinators from each facility to subscribe to the newsletter. Each month, coordinators will receive an email directing them to log in to their account to access the latest newsletter. Coordinators will need to download a PDF version of NurseAdviseERR (look for a link to "Download PDF" in the right corner of the webpage) and **redistribute the PDF version** of the newsletter to all other nurses within their organization. Coordinators should NOT redistribute the original email, as only subscribers will be able to access the newsletter online.

- Individual nurses can also subscribe on their own but do not have permission to redistribute the newsletter. Having an individual subscription will allow nurses to view NurseAdviseERR at any time, in any location, on any device.

- Any healthcare professional, educator, or student having difficulty subscribing to the newsletter without a subscription fee may checkout with code **NURSE2019** to receive the newsletter for free.

History has shown that a medication error reported in one organization is likely to occur in another. It would be foolish to not utilize easily accessible information provided by others who have already experienced errors and are working towards improving their systems. NurseAdviseERR provides the lens for nurses to accomplish this. It costs nothing to use, but its value could be priceless.

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for 28 days outside of the overwrap. ISMP supports the use of commercially prepared, premixed parenteral products to the maximum extent possible. This new vancomycin product is a step forward in making more of these products available to end users. Baxter also manufactures a premixed frozen vancomycin product, although its storage at room temperature after thawing renders a shorter beyond-use date.

It is important to note that the Xellia vancomycin has a boxed warning about the risk of embryo-fetal toxicity due to excipients unique to its formulation (www.ismp.org/ext/276). The formulation is not recommended during pregnancy because the two excipients, polyethylene glycol (PEG 400) and N-acetyl D-alanine (NADA), caused fetal malformations in animal reproduction studies. Pregnancy tests for women of child-bearing age should be performed before prescribing this formulation. The frozen Baxter product does not have these excipients or carry this boxed warning.

If you stock the Xellia vancomycin premixed bag, implement strategies in the electronic health record (EHR) to prevent ordering this formulation for pregnant women, do not stock this product in automated dispensing cabinets, and require pharmacy to verify a negative pregnancy test on women of child-bearing age prior to dispensing it. Also, be sure to have an available alternative formulation suitable for use in pregnant patients.

Conversion between oral and IV levothyroxine. In the January 12, 2006 newsletter, ISMP discussed errors with drugs that have significant dosing differences between oral and intravenous (IV) administration, including levothyroxine. The conversion rate that has often been used when switching from oral to IV levothyroxine dosing has been based on information about the bioavailability of oral products, which has been believed to be about 50%, while it's 100% for IV doses. Thus, many locations convert the IV dose to 50% of the oral dose. However, we recently heard from a hospital that used the 50% oral to IV levothyroxine conversion rate to alert us that this no longer aligns with the literature.

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Worth repeating...

Disposable standard pen needles and patient education

Some patients who use insulin pens have not been educated about proper use of disposable standard pen needles, as we have pointed out more than once, including in a 2017 National Alert Network (NAN) communication (www.ismp.org/node/44). It is such a problem that the US Food and Drug Administration (FDA) asked pen needle manufacturers to update the labeling and improve patient instructions for use (www.ismp.org/ext/155). The request was issued to help inform patients that it is necessary to remove the inner needle cover on standard pen needles to successfully administer the intended dose. Unlike *safety* needles used most often in inpatient settings, s*tandard* pen needles used in the home have outer and inner needle covers, both of which must be removed prior to injection.

Despite these labeling changes, we have learned of yet another patient who was not aware of the need to remove the inner needle cover for more than a year! The patient was admitted to a hospital with gait change, slurred speech, blood glucose of 57 mg/dL, and a hemoglobin A1c of 13.9%. During medication reconciliation it was discovered that, until the day before admission, the patient had not been removing the inner needle cover of his **LANTUS SOLOSTAR** (insulin glargine) and **NOVOLOG FLEXPEN** (insulin aspart). He described administering an entire Lantus SoloStar pen per day and using a napkin to soak up the excess insulin that leaked onto his skin when injecting himself.

The day before presenting to the hospital, the patient had attended a diabetes self-management educational course and learned that he had not been removing the inner cover of the pen needle. After this realization, he removed the inner cover and injected the prescribed amount of insulin, which his physician had continually increased over the course of the year (Lantus 150 units in the morning and 156 units at bedtime; Novo**LOG** 80 units before each meal) to control the patient's blood sugar. The patient developed hypoglycemia after injecting the prescribed amount, which was much higher than required had he been administering each dose correctly from the start of treatment. During admission, the patient required significantly less insulin (Lantus 15 units at bedtime and Novo**LOG** 4 to 6 units before each meal) than prescribed before his admission.

Although it may seem improbable that this misadministration happened for more than a year, it did! And, it ultimately resulted in patient harm, illustrating the significance of patient education and correct device demonstration. When dispensing an insulin pen and standard pen needles, educate the patient about proper use and employ the teach-back method to ensure patient understanding. Contact pen needle manufacturers for demonstration devices to physically show patients which covers to remove prior to administration. If a patient's blood glucose level remains elevated after insulin administration, prescribers should suspect misuse of the device as a possible cause before increasing the dose. If suspecting improper use, ask the patient to demonstrate the administration process or to explain, step-by-step, how they are using the device.

If you would like to subscribe to this newsletter, visit: www.ismp.org/node/10

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit our website at: www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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More recent information mentions that bioavailability of oral levothyroxine products is approximately 60–80% in euthyroid patients (www.ismp.org/ext/277) and may be slightly higher in hypothyroid and hyperthyroid patients. The American Thyroid Association (ATA) published updated Guidelines for the Treatment of Hypothyroidism in 2014 (www.ismp.org/ext/278). In the update, ATA states that, if there are concerns about significant malabsorption or there are other clinical reasons why a patient cannot be given enteral levothyroxine, IV levothyroxine may be administered until enteral absorption improves. If using IV levothyroxine, the recommended equivalent IV dose is approximately 75% of the oral dose (not 50%), assuming the enteral levothyroxine dose had achieved euthyroidism.

If not already done, be sure to update any applicable references/policies/protocols to reflect the updated conversion factor between oral and IV levothyroxine of 75%. It's also important to periodically review drug references, including commercially available charts and guidelines in your organization, to identify and correct outdated information. If changes are made to incorporate updated recommendations/best practices, all outdated reference materials should be removed from use and replaced as necessary. Ensure staff are aware of the updates through educational inservices and notices.

Special *Announcement*

Attend ISMP program at FSHP meeting

Will you be at the Florida Society of Health-System Pharmacists (FSHP) Annual Meeting in **Orlando** in August? If so, register now for a **FREE** ISMP breakfast seminar, supported by Fresenius Kabi, on ***Improving Intravenous Drug Delivery Safety***, which will be held Saturday, **August 3**. Program speakers will discuss the primary safety issues, at-risk behaviors, and ISMP guidelines and best practices associated with intravenous drug therapy. They will also discuss findings from the *Consensus Development Conference on the Safety of IV Drug Delivery Systems*. Seats go fast! For more information or to register, visit: www.ismp.org/node/1472.