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ISMP

Community/Ambulatory Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

QuarterWatch (2 years of data ending June 2017)

Safety signals for pharmaceutical contraceptives

The latest issue of ISMP's *QuarterWatch* compares the markedly different safety profiles of the five leading pharmaceutical approaches to contraception:

- **Combination oral contraceptive pills**, which combine ethinyl estradiol, a chemical variant of progesterone, and sometimes a third component (e.g., ferrous fumarate)
- **Emergency contraception pills**, intended for single use after failure of another contraceptive method or unprotected sex, which contain a substantial dose of synthetic progesterone
- **Long-acting etonogestrel implants**, which provide reversible, long-acting contraception using a thin plastic rod containing etonogestrel (a form of progesterone) implanted in the upper arm
- **Levonorgestrel intrauterine devices (IUDs)**, which provide long-acting contraception with a device emitting a synthetic form of progesterone
- **Copper-releasing IUDs**, which provide emergency and long-term contraception with a device emitting copper

These methods of contraception are used by an estimated 15 million women ages 15-44 years, making them one of the most widely used drug interventions in medicine.

Methods

To conduct the analysis, we used data from 43,342 adverse event reports submitted to the US Food and Drug Administration (FDA) over 2 years ending in June 2017, including 14,759 serious and 28,583 non-serious events. The number of events reported for each of the five contraceptive methods appears in **Table 1** on page 2. Our analysis did not distinguish between different brand products in the same group, and excluded patches, rings, and injectable forms of contraception. For combination oral contraceptive pills, we also excluded progesterone-only oral products and combinations without ethinyl estradiol.

General Key Findings

Safety record. The overall safety record for these five contraceptive methods was very good. Despite a very large population of women using these products, we identified 72 reported deaths over 2 years, 316 reports of life-threatening events, 1,491 events that resulted in hospitalization, and 217 events requiring intervention to prevent harm. This strong safety record is of interest given the known adverse events associated with these products, particularly blood clots with combination oral products, complications such as uterine perforation with IUDs, and ectopic pregnancies with IUDs and implant products.

Unintended pregnancies. Systematic surveys report a probability of contraception failure over 12 months of 7.2% for combination oral products, 6% for all IUDs, and 1.4% for implants. In our study, unintended pregnancies were reported for all five contraceptive methods. The proportion of reports was highest for combination oral products, mostly due to missed doses, and lowest for levonorgestrel IUDs (**Table 1**, page 2). Reports of unintended pregnancies associated with implants were higher than expected, due in part to being left in place beyond the recommended efficacy period. Real-world efficacy of these

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SAFETY briefs

Wrong-patient errors at drive-thru. Like wrong-patient errors that occur at the pharmacy counter, we continue, on a regular basis, to receive reports of wrong-patient errors at the pharmacy drive-thru. In the most recent case, a patient was given the medications intended for another patient with the same name and birth year. One factor that contributed to the event was the pharmacy staff member could not hear the patient clearly due to the noise from the rain falling at the time. In another event, the reporter indicated that the inability to clearly hear the patient in the drive-thru contributed to the wrong patient event. In a third report, a patient in the drive-thru was erroneously given another patient's prescription of oxyCODONE 20 mg tablets. The patient took two oxyCODONE tablets and was sick most of the night.

These errors happen for a number of different reasons. If there are medications in the will call area for patients with similar or the same names, pharmacy staff may select the wrong patient's bag. The process of identifying the patient can also be flawed if a full name and date of birth are not requested and provided. Only using an address to identify patients is not ideal, as people with the same last name often live together and addresses may not be up-to-date in computer systems. Another factor unique to the drive-thru, is the sound quality of the intercom or phone system. When staff cannot clearly hear or understand patients, the risk of error increases.

While drive-thru access to drop off and obtain prescriptions is seen as a customer convenience service, it can and does distance the patient from pharmacy staff, particularly the pharmacist. We can't help

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products may be weaker than women expect due to both the properties of the contraceptive itself as well as the actions or omissions of the patient or healthcare professional.

Psychiatric symptoms. While some studies have shown that hormonal contraceptives are associated with an increase in depression and other psychiatric side effects, others have reported no association or a positive effect on mental health. Nevertheless, in our data set, psychiatric symptoms were 4 to 7 times more likely to be reported with contraceptives providing sustained doses of hormones compared to the non-hormonal copper IUD (**Table 1**). The most common symptoms included depression, anxiety, mood swings, loss of libido, and irritability. The strongest signals were seen for oral combination products and levonorgestrel IUDs. We also found that psychiatric symptoms are reported substantially less frequently than many other adverse effects reported for contraceptive products.

Key Findings for Specific Methods

Levonorgestrel IUDs. Levonorgestrel IUDs had the weakest safety profile of the five methods of contraception by several measures. It accounted for the largest number of serious injury reports, the largest number of direct reports to FDA, and the most cases of reported psychiatric symptoms, notably depression (**Table 1**). The large number of reports has persisted over many calendar quarters, which may be related to the serious warnings in the product labeling, the most prominent of which notes up to half of the pregnancies that occur may be ectopic. Another reason for the weakest safety profile is that the product category combines all the risks associated with insertion, dislocation, and expulsion of the device, along with the risks associated with hormonal contraceptives. However, levonorgestrel IUDs had the fewest reports associated with unintended pregnancies.

Table 1. Adverse Event Reports for 5 Forms of Pharmaceutical Contraception (2 Years Ending June 2017)

Type of Contraception/ Number of Cases	Levonorgestrel Intrauterine Devices (IUDs)	Copper IUDs	Emergency Contraception Pills	Etonogestrel Implants	Oral Combination Pills
	Number of cases (percent of all reports received for the type of contraception)				
Total Adverse Event Reports	15,897	6,179	7,568	9,933	3,765
Serious Adverse Events	8,166 (51.4)	2,481 (40.2)	595 (7.9)	1,747 (17.6)	1,770 (47.0)
Unintended Pregnancies	836 (5.3)	339 (5.5)	411 (5.4)	578 (5.8)	313 (8.3)
Psychiatric Side Effects	1,924 (12.1)	103 (1.7)	206 (2.7)	731 (7.4)	476 (12.6)

Copper IUDs. This method, along with the levonorgestrel IUDs, shared a large number of device-related complaints, including expulsion and dislocation. There were also a large number of complaints that the device broke, became embedded in the uterus, or caused vaginal hemorrhage or muscle spasms necessitating removal. They do not appear to cause the psychiatric symptoms observed with the sustained hormonal methods (**Table 1**). Health professionals need to be aware of the need for expertise in safely inserting and removing the copper IUD, and women need to be aware of the risk of device expulsion.

Emergency contraception pills. Emergency contraception pills had the best safety profile of the five groups, given the one-time rather than ongoing exposure to the products. The safety profile for this method was dominated by a large number of nonserious reports directly from consumers about abnormal menses, and a few reports of other adverse effects such as nausea and vomiting.

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but be concerned that pharmacy drive-thrus make it more difficult to identify patients and deliver quality and safe services, including patient education. To help prevent wrong-patient errors at the drive-thru, always ask the patient to provide at least two patient identifiers—their full name and full date of birth—when picking up prescriptions. Consider asking the patient for a physical form of identification to minimize the risk of mishearing the patient. If the sound quality is not sufficient to clearly hear and understand the patient, ask the patient to come into the store. At the point-of-sale, one of the most effective ways to prevent this error is to open the bag of filled prescriptions with the patient to verify that the medications are for the correct patient. Unfortunately, this is not always possible depending on the design of the pharmacy drive-thru. Before completing the transaction (i.e., before returning the patient's form of payment or change), have the patient open the bag in the car and conduct their own verification. While talking with the patient is more difficult and potentially less private when the patient is in the drive-thru, it is nonetheless critical to design systems to ensure confidential communication before a prescription is dispensed.

HIGH-ALERT

Label immediate containers. We recently heard from a mother of a toddler that her daughter was inadvertently administered daily overdoses of cefdinir 250 mg/5 mL oral suspension. The child was supposed to receive 3 mL of the antibiotic by mouth each day. However, her parents were administering 14 mL a day in 2 doses. The pharmacy did not affix the pharmacy label, which presumably contained the correct administration directions, to the actual bottle of medication. When the medication was initially brought home, the outer carton, to which the pharmacy label was likely affixed, was thrown away. The only dosage information that remained was on the manufacturer's label on the bottle. This information indicated

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Etonogestrel implants. The safety profile for etonogestrel implants raised three safety concerns. First, this method differed from the others in the large number of complaints regarding implantation, including reports that it was difficult to use, that it broke, or concerns about product quality. Problems were even reported with the newer **NEXPLANON** product, which replaced **IMPLANON**, despite a redesigned tool. This suggests the need for improved education and training of medical providers and the need to reevaluate the design of the insertion tool. Second, hundreds of reports indicated that the device had migrated, was dislocated, or caused a complication at removal. The third safety signal was apparent use beyond the 3-year recommended treatment period. Except for patient device identification cards provided in the implant packages, we were not able to identify any system to ensure that women were notified after 3 years of the need to remove or replace the implant. Studies are needed to more accurately assess the extent of the problem and identify cost-effective solutions.

Oral combination pills. The safety data for oral combination products highlight two prominent risks: unintended pregnancy through missed doses and serious injuries from pulmonary embolism and deep vein thrombosis. The adverse event data confirm these well-documented risks but do not identify new safety issues. By a wide margin, oral combination pills are the most commonly used method of pharmaceutical contraception while accounting for the smallest number of adverse event reports (**Table 1**, page 2).

The full QuarterWatch report with references can be found at: www.ismp.org/sc?id=1702.

Mix-ups between lamotrigine and labetalol

PROBLEM: Between October and November 2017, ISMP received 4 reports of mix-ups between oral labetalol, an antihypertensive, and lamotrigine*, an anticonvulsant that is also used to treat bipolar disorder. Further investigation identified a total of 13 cases involving this name pair, either reported to ISMP or the US Food and Drug Administration (FDA). Of the 13 cases, 6 were reported during 2017. All were dispensing errors.

Mix-ups between lamotrigine and labetalol can result in adverse events, including breakthrough seizures or hypotension if a patient receives labetalol in error, or life-threatening skin rash, hypersensitivity, or untreated hypertension if a patient receives lamotrigine in error. Untreated hypertension during pregnancy can also result in adverse events for the fetus (decreased placental blood flow) and the mother (renal failure, seizures, stroke).

Skin rashes were reported in 2 cases when lamotrigine was given instead of the prescribed labetalol. Lamotrigine has a Boxed Warning for serious skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis. This risk may be increased when the recommended initial dose (usually 25-50 mg or less) is exceeded. Of the 6 cases where lamotrigine was dispensed in error, all involved 100 mg or 200 mg, which is greater than the recommended initial dose of lamotrigine, but is a usual therapeutic dose for labetalol.

Three of the cases involved exposure to lamotrigine during pregnancy instead of the intended labetalol, used to manage hypertension during pregnancy. The risk of lamotrigine in pregnancy in humans is not known, as there are no adequate and well-controlled studies in pregnant women. Product labeling notes that, in animals, lamotrigine was developmentally toxic at doses lower than those administered clinically. Lamotrigine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Errors have also happened with patients being treated for psychiatric indications who took labetalol instead of lamotrigine.

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that a child's dose was "14 mg/kg/day in a single dose or in two divided doses, depending on age, weight and type of infection." The child's parents misunderstood this statement and gave her 14 mL a day in 2 doses. When the medication ran out early, the patient's mother realized the manufacturer's dosing information required a calculation using the child's weight in kilograms and discovered the dosing error. At the time of the report, the child was suffering with diarrhea.

It is critical that the pharmacy label be affixed to the immediate container from which doses will be retrieved. If this is not possible for some reason, remind patients to retain the label which includes the directions for use and the patient's name. When labels are only applied to outer cartons, there is a risk that it will be disposed of before the medication is used. Of course, opening the bag at the point-of-sale to review the medication and directions for use with the patient's parent may have helped them intercept the dosing error.

HIGH-ALERT

Look-alike bottles. We were recently alerted to a photo of look-alike manufacturer medication bottles (**Figure 1**) posted on Twitter. The photo shows a potentially dangerous look-alike situation between oxy**CODONE** 15 mg tablets and oxybutynin 15 mg extended-release tablets, both manufactured by Amneal. The container colors, drug names (both beginning with "Oxy"), strengths, bottle shape, cap shape, and bottle size are all similar. In our experience these elements of similarity often combine and contribute to medication dispensing errors. To prevent mix-ups between these products, explore ordering one of them

Figure 1. Look-alike oxy**CODONE** and oxybutynin extended-release bottles from Amneal.

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Overlapping 100 and 200 mg strengths of lamotrigine and labetalol tablets can increase product similarity and may have contributed to some reported errors. The various strengths may also be packaged with labels that use similar font colors (**Figure 1**). For example, Teva, Par, and NorthStar use the same lavender color to print the 200 mg strength on the labels, perhaps drawing one's attention more to the strength than to the product names. Additionally, both lamotrigine and labetalol may appear as a scored, round, white tablet, depending on the manufacturer, of which there are many. Thus, patients receiving refills may not recognize that a dispensing error has occurred. It's also possible that some errors may have involved the return of tablets to the wrong container, subsequently causing a dispensing error later. Storage near one another of the similarly sized, white-colored bottles of both products was another contributing factor reported.

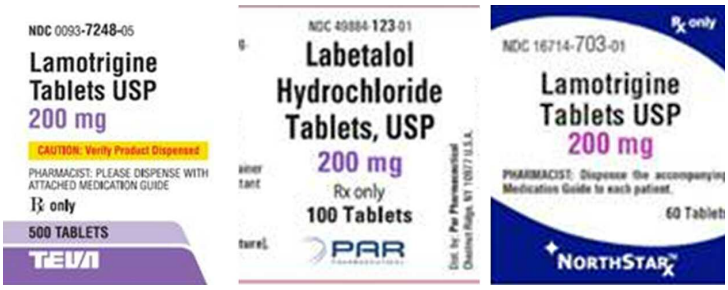

Figure 1. Teva lamotrigine and Par labetalol tablet strengths share a nearly identical lavender color where "200 mg" is listed, which may be a factor in mix-ups. The Par product has also been confused with NorthStar lamotrigine, which also shares a similar color.

A handwritten prescription also contributed to an error in which labetalol was mistaken as **LAMICTAL*** (lamotrigine). The letters b and e in labetalol looked like the m in Lamictal, resulting in misinterpretation. In addition, both drug names start with "LA," end with "L," and incorporate a similar "AL" or "OL" letter sequence at the end of the drug name.

Safe Practice Recommendations: To draw attention to the drug name on the product label, consider using a marker to circle the name. Another important measure in preventing name mix-ups is knowing each medication's purpose and the patient's condition. When prescribers include the purpose with the prescription, it helps the pharmacist identify why the patient is receiving the drug. Prescriptions from a psychiatrist that are interpreted as labetalol should raise a question. Contact prescribers for clarification when a patient is ordered lamotrigine for the first time and the starting dose is higher than 50 mg as this could indicate a prescribing error. Also, talking to patients about their use and knowledge of medications reduces the risk of taking home the wrong medication. At the point-of-sale in outpatient or community pharmacy settings, pharmacy staff should open the bag of medications and ask the patient to review the pharmacy labels and contents of each prescription container to check that the medication is correct. Electronic prescribing combined with barcode scanning in the pharmacy also helps to decrease error potential.

***Note:** Lamo**TRI**gine and La**MIC**tal appear on ISMP's list of drug names with tall man letters because lamo**TRI**gine has been confused with lami**VUD**ine, and La**MIC**tal has been confused with Lam**ISIL**. For this article only, we have not used the recommended tall man letters so we can better demonstrate the similarities between the drug names lamotrigine and labetalol; however, ISMP continues to recommend the use of tall man letters for lamo**TRI**gine, lami**VUD**ine, La**MIC**tal, and Lam**ISIL**.*

ISMP thanks LCDR Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS, and Ashleigh Lowery, PharmD, BCCCP, from the US Food and Drug Administration Division of Medication Error Prevention and Analysis, for their contribution to this article.

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from a different manufacturer. If these products are stored near one another, consider using shelf dividers to keep stock separated and neatly organized on shelves. Alternatively, storing the oxyCODONE product in a controlled substances safe or vault will separate these products from one another. Implementing barcode scanning during the production stage of the dispensing process can identify when the wrong product is selected from the shelf. We have notified the company about this situation and asked them to take steps to address the container labels of these products if they have not already done so.

Special Announcement

ISMP Fellowships: Learn from the Experts. Become an **ISMP Safe Medication Management Fellow** or an **FDA/ISMP Safe Medication Management Fellow**, and spend a year working with some of the nation's top leaders in risk identification, error prevention, and safe medication use methods. Applications for the 2018-2019 fellowships are due **March 31, 2018**. To apply, please visit: www.ismp.org/profdevelopment/.

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

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Editors: Michael J. Gaunt, PharmD; Michael Cohen, RPh, MS, ScD (hon), DPS (hon); Judy Smetzer, BSN, RN, FISMP; Ann Shastay, MSN, RN, AOCN. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.

ISMP AmbulatoryCare ActionAgenda

ISMP One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected agenda items have been prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. These agenda topics appeared in the *ISMP Medication Safety Alert!* Community/Ambulatory Care Edition between September 2017 and December 2017. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue to locate additional information. The Action Agenda is also available for download in a Word format at: www.ismp.org/Newsletters/ambulatory/actionagenda.asp. To learn how to use the ISMP Ambulatory Care Action Agenda at your practice site, visit www.ismp.org/newsletters/ambulatory/How_To_Use_AA.asp.

Key: ⚠ — ISMP high-alert medication

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Improper use of the insulin pen safety needles led to patient's death					
10/17 ⚠	While hospital staff often use insulin pens with a safety needle that does not require removal of the needle cover prior to injection, patients often use a standard insulin pen needle at home, which has a needle cover that must be removed before injection. Some hospitalized patients who have been taught to inject insulin using a pen with a safety needle have tried to inject insulin at home without removing the needle cover on a standard needle, thus failing to administer the insulin. One patient developed ketoacidosis and died.	Teach patients how to administer the insulin with the pen they will be using at home and require a return demonstration. Verify which pen needle the patient will be using and tailor the training to that needle. Remind patients that a standard pen needle is different from what may have been used in the hospital. Review injection technique with the patient if blood glucose levels are elevated. Establish a system to ensure that patients receive counseling when picking up new prescriptions and refills for insulin pen and pen needle products. A National Alert Network (NAN) communication offers further details (www.ismp.org/NAN/files/NAN-20171012.pdf).			
Liraglutide (VICTOZA, SAXENDA) dosage unit confusion					
11/17	The electronic prescribing network, Surescripts, recently identified inaccurate dosage information in some new prescriptions for liraglutide pen injectors. The issue is the inappropriate use of "mL," "milliliters," or "cc" as doing units rather than "mg" (e.g., "inject 1.2 mL sub-q EVERY DAY" instead of 1.2 mg). These pen injectors only display the dose in "mg." Since the concentration of liraglutide in both products is 6 mg/mL, prescribing in "mL" instead of "mg" results in a 6-fold overdose.	Prescribers should work with their electronic health record vendors to ensure that the dose creation tools provided to end users do not allow "mL" as a dose unit option for Victoza or Saxenda. Should a free-text prescription be necessary, type the patient directions with the dose unit in "mg" to ensure correct labeling, counseling, and administration of the intended dose. Pharmacists should clarify orders for Victoza or Saxenda with a "mL" dosage amount with the prescriber to verify the dose.			

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Confusion with measuring the correct dose with a U-500 insulin pen					
10/17 ⚠	A patient using a U-500 insulin pen showed a pharmacist how he turned the dose knob on the pen to "15" to deliver each prescribed dose of 75 units. He had previously used a U-100 syringe to measure each dose of U-500 insulin, stopping at the "15 units" marking on the syringe. But the U-500 pen delivers the actual dose dialed.	For U-500 insulin, only use a U-500 insulin pen or a U-500 insulin syringe. When patients are started on U-500, using either a vial or insulin pen, prescribers and pharmacists must engage patients, provide education, and verify that patients can accurately prepare and administer a dose. Tailor the education to the devices being used.			
Differentiating insulin types by touch and separate storage					
11/17 ⚠	A visually impaired woman who uses both rapid-acting and long-acting insulin pens stored them both in the refrigerator. She accidentally administered 50 units of the rapid-acting insulin at night. She woke up at 4 a.m. with a blood glucose value of 50 mg/dL.	Teach patients ways to differentiate insulin types by touch, such as applying adhesive tape or rubber bands to pens. Storing these products with prominent 'long-acting' or 'rapid-acting' stickers on the containers may help differentiate them. Avoid storing insulin pens together. Advise patients to keep long-acting insulins in the bedroom and rapid-acting insulins in the dining area, keeping in mind that sole reliance on medication location might be risky (if displaced by another person).			
Don't leave "Meds to Beds" prescriptions at bedside					
09/17	"Meds to Beds" programs bring prescription drugs to the patient's bedside prior to discharge and provide pharmacists with an opportunity to educate patients about their medications. We recently learned of an event in which a nurse gave a patient his medications, and then the patient opened the bag of discharge medications left at the bedside and nearly took the same medications.	Pharmacy and nursing staff should work collaboratively to provide patient education as part of a "Meds to Beds" program. Affix an auxiliary label to the bag of discharge prescriptions to remind patients that the medications are not for use while in the hospital. Do not leave the medications unsecured at the bedside. A plan should be established regarding where to secure these medications until discharge, after a pharmacist has reviewed them with the patient, and what to do if the patient is not in the room at the time of delivery.			

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Do not run test prescriptions to verify insurance coverage					
10/17 ⚠	To determine if a medication will be covered by the patient's insurance, a prescriber may send a prescription to the pharmacy to run a "test" claim. Doing so has resulted in a patient receiving an unintended medication. In the latest case, a patient was dispensed **GENVOYA** (cobicistat, elvitegravir, emtricitabine, and tenofovir alafenamide) after the insurance company approved the "test" claim.	Electronic health record and e-prescribing vendors along with their end users should ensure that no "test" prescriptions are sent. Only transmit electronic prescriptions that are intended to be dispensed to the patient. Prescribers that want to know if a medication is covered should call or have an assigned office-staff member call the insurance company or pharmacy benefit manager to inquire about coverage or check plan formularies.			
Mix-ups between mL and teaspoon dosing					
11/17 ⚠	Some community pharmacists change milliliters (mL) to teaspoon dosing or list both teaspoonful and mL (in parentheses), believing consumers are more familiar with household measures. In a recent case, an antibiotic suspension was prescribed for a child with otitis media. The pharmacy label directed the parent to "give 5 teaspoons" when the prescribed dose was actually 5 mL. Also, most oral dosing devices now display a mL scale, some exclusively.	Do not "translate" mL doses to teaspoons or list both teaspoons and mLs on labels. For oral liquids, adopt mL dosing as the standard for all pharmacy labels and computer systems. Always provide an appropriate metric dosing device and use teach back methods to educate patients and caregivers on how to measure the dose in milliliters.			
Dispense dose appropriate dosing devices					
12/17 ⚠	An infant was inadvertently administered a 10-fold overdose of digoxin by her parents. The patient was to receive 0.44 mL (22 mcg) with each dose. The pharmacy provided the patient's parents with a 5 mL oral syringe. When preparing a dose at home, the child's parent accidently measured and administered 4.4 mL (220 mcg). It is unclear how the patient's parents would have accurately measured 0.44 mL using a 5 mL device since the markings on many of these syringes only measure to the nearest 0.2 mL.	Review the dosing devices that come with manufacturer products and those purchased by the pharmacy. Stock appropriate metric measuring devices that correspond to potential label instructions and support accurate dose measurement. When dispensing an oral liquid, provide an appropriate dosing device that most closely matches the prescribed dose volume and limits the number of instrument fills needed to administer one dose. Use teach back methods to demonstrate how to measure and administer the dose and validate learning.			