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ISMP

Community/Ambulatory Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

QuarterWatch™ (Quarter 3 2017)

Emerging Risks with Inhaled Medications Using the Ellipta Device, the Controversy with Antidepressants, and Loperamide Abuse

The latest issue of ISMP's *QuarterWatch*™ (see box on **page 4**) examines drug safety issues identified by monitoring new adverse drug event reports submitted to the US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS). New data received during the third quarter (Q3) of 2017 include 291,999 adverse drug event reports from the US and abroad. In this issue, we examine:

- Confusion among GlaxoSmithKline's (GSK) line of inhalers using the Ellipta device
- The controversy with antidepressants, with perspectives from a large new meta-analysis published in *The Lancet* and a case study of the newest antidepressant to reach the market, vortioxetine (**TRINTELLIX**)
- Abuse of over-the-counter (OTC) loperamide (**IMODIUM A-D**, others); how it was identified reveals new insights into detecting emerging risks with older drugs

Errors with Breo, Anora, and other "Ellipta" Inhalers

New Ellipta devices. In 2013, GSK introduced **ELLIPTA**, an inhaler device capable of combining several active ingredients. The Ellipta brand name for this device was imbedded in the drug names of five products that use the device:

- **BREO ELLIPTA** (fluticasone and vilanterol), for asthma and COPD
- **ARNUITY ELLIPTA** (fluticasone), for asthma
- **ANORO ELLIPTA** (umeclidinium and vilanterol), for COPD
- **INCRUSE ELLIPTA** (umeclidinium), for COPD
- **TRELEGY ELLIPTA** (fluticasone, umeclidinium, and vilanterol), for COPD

Adverse events with inhalers. For the 12 months ending with Q3 2017, we investigated 557 adverse event reports indicating that patients, pharmacists, and physicians were confusing inhalers with the same Ellipta device but different active ingredients. Compared to all other drugs examined during this period, 557 reports is a large number. Most of the reported errors involved Breo Ellipta (48%) and Anoro Ellipta (43%). The reports indicated problems in one or more of these categories: name confusion (61.2%), dispensing errors (54.9%), and prescribing errors (15.6%). The product confusion reports indicated issues with both packaging and labeling. Although we saw few error reports for Arnuity Ellipta versus Anoro Ellipta, the similar brand names suggest a potential for confusion.

Causes of confusion. While the ingredient brand names (e.g., Breo, Anoro) are sufficiently unique to identify the products without the inhaler device information, some practitioners and patients appear to believe the products are named Ellipta or are mixing them up because of the common Ellipta name. A *Safety Brief* in the December 2016 *ISMP Medication Safety Alert!* Community/Ambulatory newsletter noted this prob-

Figure 1. Image from website for Breo Ellipta (left) compared to the actual product (right).

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SAFETY briefs

Mix-up between polyethylene glycol and propylene glycol. Our sister organization, ISMP Canada, published a report of a pharmacy mix-up that caused propylene glycol to be dispensed to a patient instead of polyethylene glycol (PEG 3350; **MIRALAX**), resulting in patient harm (www.ismp.org/ext/1). The patient had called the pharmacy to request "polyethylene glycol" in preparation for a colonoscopy. Although not specified in the report, this is often prepared by dissolving the contents of a 238 gram bottle (8.3 ounce) of MiraLAX or generic equivalent PEG 3350 in 2 liters of liquid. Unfortunately, the pharmacist ordered and dispensed propylene glycol. Within hours after ingesting 500 mL of the propylene glycol mixture, the patient developed nausea and vomiting requiring a hospital visit. Propylene glycol is metabolized into pyruvic and lactic acids. At the hospital, the patient was diagnosed with severe metabolic acidosis requiring hemodialysis.

ISMP Canada mentioned that there was no pharmacist intervention when the product was ordered, packaged, or dispensed (e.g., confirmation of the indication with the patient). Although not stated in the report, this event may be a case of mistaken identity in which the pharmacist ordered the wrong product and failed to detect the error prior to dispensing it. Look-alike, sound-alike product names clearly played a role in this event. Many clinics and physician offices provide patients with colonoscopy instruction sheets that list the brand name MiraLAX along with the generic name, polyethylene glycol 3350. Patients should be encouraged to bring the instruction sheet to the pharmacy to compare it to the product dispensed.

Unless absolutely needed for routine compounding, eliminate propylene glycol as

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lem after ISMP received reports of confusion between the various inhalers, particularly when practitioners refer to these products only by the device name Ellipta. In that *Safety Brief*, we described a dispensing error in which a prescription for Incruse Ellipta was misread, and the more familiar Breo Ellipta inhaler was dispensed. The five products also come in similar packaging, differing only in color, brand name, and ingredient specifications. Once the package is opened, the inhalers are of similar design, shape, and size.

Online instructional videos and other materials for these products further increase the risk of confusion because they do not accurately distinguish between products. If consumers or practitioners visit the product websites to learn how to use this inhaler device, they are exposed to erroneous and misleading images of the product. For example, at www.mybreo.com, the image of the Breo Ellipta inhaler is different than the actual product. The web version prominently features only the "Breo" brand name, and the label contains no other information; "Ellipta" is missing, as are the generic drug names, strengths, and other important label information (**Figure 1**, page 1).

Worse yet, at www.ismp.org/ext/11, a GSK video about how to use the Breo Ellipta inhaler portrays the device with a label that only reads "Ellipta" (**Figure 2**). This perpetuates confusion between the products using the same Ellipta device but with different active ingredients. Or, it could make patients believe they have been dispensed the wrong drug.

Figure 2. Image from Breo Ellipta video instructions only includes the device name on the product label.

Conclusion. GSK and the FDA should re-evaluate the packaging and labeling of the Ellipta inhaler products as a group given the repots to submitted to FAERS. GSK should also correct the inaccurate product portrayals on its websites.

The Controversy with Antidepressants and a Case Study of Vortioxetine (Trintellix)

Widespread antidepressant use despite limited efficacy. When modern antidepressants were first introduced more than 30 years ago, they were believed to be so effective that they rapidly replaced the standard treatment, psychotherapy. Years later, it was revealed that nearly half of antidepressant clinical trials had failed to demonstrate a benefit, with many trial failures never published by pharmaceutical companies. This helped to trigger new legal requirements for full disclosure of all clinical trial results. Other meta-analyses showed only small differences with placebo, mostly confined to the severely depressed. However, this did not prevent antidepressants from becoming the most widely used psychiatric drugs. While many patients will experience substantial improvement in depression a few weeks after starting an antidepressant, careful measurement of the drug effect itself is revealing. Add this to a history of reports linking antidepressants to suicidal behaviors in young adults, and the debate about the effectiveness and safety profile of antidepressants continues today.

Reappraisal: "All antidepressants are effective." In February 2018, *The Lancet* published the largest antidepressant meta-analysis to date which included published and unpublished studies encompassing 116,477 patients enrolled in 522 clinical trials of 21 antidepressant drugs (Cipriani A, Furukawa TA, Salanti G, et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis. *Lancet*. 2018;

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a stock item, and assess how it may be listed in wholesaler systems to be sure it cannot be easily mixed up with polyethylene glycol. If the product is necessary, store it with other compounding chemicals, keep it far away from PEG 3350, inform staff about its proper use, and add auxiliary warning labels on the container to prevent confusion with PEG 3350. ISMP Canada also recommended computer alerts if adding products to a patient's profile that are intended for compounding use only, and suggested questioning patients if they request such products.

Standardization of expiration dates needed. Does "19 MAR 18" on a product label mean that it expires on March 18, 2019, or March 19, 2018? It is difficult to understand how something so important as a product's expiration date is not communicated clearly, in a standard way. While the US Code of Federal Regulations (CFR) (Part 211) sets forth the conditions under which an expiration date must be listed on labels, it does not specify how expiration dates must be expressed. In the absence of standard regulations, inconsistent expressions of expiration dates have led to confusion and misinterpretation of the date beyond which manufacturers cannot guarantee full potency and safety of the drug.

We just received a report of an unusual expiration date that is difficult to interpret on Hospira's PACLitaxel injection. On the outer carton "200131" is stamped, which is intended to convey an expiration date of January 31, 2020. However, nurses and pharmacists might easily be confused by these numbers. If all four digits were used for the year, with dashes in between the numbers, the date would be clear (2020-01-31).

Another confusing example can be seen on Teva products, which display the month the product will expire as a 2-letter abbre-

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391[10128]:1357–66). The authors concluded that all 21 antidepressants "were more efficacious than placebo in adults with major depressive disorder." While it was one of the most optimistic and comprehensive assessments of antidepressants published in several years, the clinical trials studied were limited to patients with more severe forms of depression and lasted only 6-8 weeks, even though many people who take antidepressants do not suffer from severe depression and 68% report long-term use. In addition, the only measures of safety were the overall dropout rate and dropouts for adverse drug effects, even though most antidepressants warn about suicidal behaviors in young adults, serotonin syndrome, precipitation of manic episodes, sexual dysfunction, and other serious adverse effects.

Examination of vortioxetine. QuarterWatch examined the safety and efficacy of one of the 21 antidepressants in *The Lancet* meta-analysis, vortioxetine, as it had a median ranking for efficacy in the meta-analysis, and it is the newest major antidepressant to reach the market (2014). This meant up-to-date FDA requirements and public disclosure of all clinical trial results. The 10 clinical trials conducted to demonstrate efficacy at various doses illustrate the marginal benefits typical of antidepressants. Over 8 weeks, patients receiving both placebo and active drug improved substantially, with depression scores dropping by 34-44% in one large North American pivotal trial. But differences between placebo and treatment groups were small—only 2-3 points on a depression scale of 0-60. Three of 5 trials conducted in the US failed to document a statistically significant benefit, and in 1 unsuccessful trial, the efficacy of an approved antidepressant (**DUL**oxetine [**CYMBALTA**]) used for comparison to vortioxetine also could not be distinguished from placebo. The trials were limited to patients with more severe forms of depression, where the chances of demonstrating benefit were highest.

To evaluate the safety profile of vortioxetine, QuarterWatch also examined the most recent adverse event data for the 12 months ending in Q3 2017. Vortioxetine had substantial numbers of reported cases of aggression/hostility (n=339), suicidal/self-injurious thoughts and behaviors (n=155), and sexual desire disorders (n=160). These adverse effects have also been reported with other antidepressant drugs. A new signal indicated that vortioxetine might also cause eating disorders (n=69) and weight gain (n=201), mainly from excessive hunger or abnormally large food intake (n=163). The manufacturer, Takeda Pharmaceuticals U.S.A., told us that many of the reports came from an online consumer survey and might reflect symptoms of major depression rather than a drug effect.

Conclusion. The QuarterWatch review illustrates that *The Lancet* meta-analysis failed to communicate the marginal efficacy and substantial side effect profiles of antidepressant drugs. Patients' depression indeed improved on vortioxetine treatment, but differences from an inactive placebo were small. Only more severe depression was studied. We also saw a signal for a new side effect not previously prominent: eating disorders leading to weight gain. However, this signal requires further study to establish its validity, patient characteristics, and incidence. Despite decades of use, questions about efficacy and the incidence of severe adverse effects of antidepressants still linger.

Discovering a Dangerous New Use for OTC Loperamide

New risk with an older drug. The emergence of a new risk with loperamide (e.g., **IMODIUM A-D**, others), a 40-year-old antidiarrheal drug long available over-the-counter (OTC), begins with a story about a fortunate 39-year-old woman who presented to an emergency department (ED) after experiencing episodes of seizure-like activity and a life-threatening dysrhythmia. A loperamide overdose was the cause. In this case, the woman had substance abuse issues and had been taking 50 to 100 loperamide (2 mg) caplets a day, instead of the recommended maximum of 4 caplets. Loperamide is an

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viation. In **Figure 1**, does "EXP. MA-2019" indicate that the product expires in March or May? If "JU" is used, does it stand for June or July? If the month is abbreviated at all, at least 3 letters should be used.

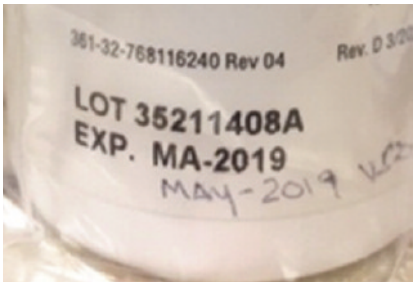

Figure 1. Is the product's expiration date the end of March or May 2019?

We also received a report about the format used to express lot numbers, expiration dates, and other identifiers on bottles of doxycycline 50 mg capsules from Zydus Pharmaceuticals (**Figure 2**). The top number is the NDC. The second number is another product identifier. The third line is the expiration date with 17 representing the year the product was manufactured and 191031 denoting an expiration date of October 31, 2019. The last line is the lot number.

Figure 2. The products expiration date and lot number are not clearly denoted or formatted.

Clearly, standards are needed for expressing dates in a uniform way that does not cause confusion. We have increased our efforts to alert USP and the US Food and Drug Administration (FDA) about the need for standardization.

<800> HazRx Mobile App. USP has launched the <800> HazRx Mobile App, a tool that combines information from three data resources: the National Institute for Occupational Safety and Health (NIOSH), RxNorm, and USP General Chapter <800>.

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opioid that is 40-50 times more potent than morphine in the gut. But absorption from the gut is poor, and little drug passes the blood-brain barrier at normal doses; thus, it takes a large amount of loperamide to induce a euphoric high or cope with withdrawal symptoms. The primary medical problem with a loperamide overdose is that it can cause potentially fatal cardiac events including QT interval prolongation, torsades de pointes or other ventricular arrhythmias, and cardiac arrest.

FDA warnings. Loperamide was approved in 1976, and because of what was seen as low abuse potential, FDA approved it for OTC use in 1988. But if one takes 10 to 20 times the recommended dose, the effects can be similar to using opioids such as oxy**CODONE**. In June 2016, FDA released a Drug Safety Communication that loperamide abuse was causing serious and fatal cardiac events. The warning was apparently based on 48 case reports to FAERS received over 39 years. In January 2018, FDA issued an updated Drug Safety Communication, reporting that it was working with the manufacturers to develop abuse-resistant packaging with fewer doses. However, these communications did not report how many overdoses might be occurring or how FDA first learned of the issue.

Literature-based post-market surveillance. The primary source of abuse-related harm from loperamide turned out to be published reports in the medical literature. Because literature-based reports are prepared by practitioners for scientific publication, case reports are typically of higher quality than ordinary adverse event reports. Beginning around 2014, the medical literature began to feature case reports of near-fatal cardiac disorders linked to intentional loperamide overdoses, similar to the case described above. An event in which a 19-year-old was found dead at home after hosting a party revealed another problem: standard toxicology screens detected loperamide, but not loperamide overdoses. When the medical examiner reviewed 21 deaths where loperamide had been detected, mass spectrometry established that loperamide overdoses contributed to 19 of the 21 deaths. Poison control centers also reported that loperamide overdoses had doubled between 2009 and 2015. As required, loperamide manufacturers were monitoring the literature and communicating relevant studies to the FDA via the FAERS. An alert FDA staff investigated and followed up with warnings and proposed abuse-resistant packaging.

Conclusion. The way loperamide abuse was identified illustrates insights into post-market surveillance and detecting emerging risks with older drugs. While FDA acted promptly, it took years to identify the problem of abuse. Even today, the true incidence of overdoses remains unknown. While voluntary reporting and contributed safety case studies clearly deserve praise, the lack of more effective systematic assessment of emerging drug harm remains a glaring defect not only for older drugs but for all OTC and prescription drugs. Better and more comprehensive systems are needed to assess emerging drug risks, estimate incidence, and support methods to reduce them.

The full QuarterWatch report with references can be found at: www.ismp.org/node/482.

What is QuarterWatch™?

QuarterWatch is an independent ISMP surveillance program that monitors adverse drug events reported to the FDA Adverse Event Reporting System (FAERS). The goal is to identify signals that may represent important drug safety issues. The sheer number of case reports have scientific weight, but because of variation in reporting rates, they reveal little about how frequently events occur and do not prove that the suspect drug caused the event described—only that an observer suspected a relationship. Thus, identified safety issues often require further investigation to determine their frequency and establish a causal relationship to the suspect drug.

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The tool helps to identify hazardous drugs at the point of practice and inform healthcare workers regarding the measures to take to help reduce their risk in accordance with established standards. To access the USP <800> HazRx Mobile App and a free download of USP <800>, visit: www.ismp.org/sc?id=3093.

Special Announcement

Nominate Safety Advocates for ISMP Cheers Awards

Each year, ISMP celebrates individuals, institutions, and groups who have demonstrated an exemplary commitment to medication safety and medication error prevention through innovative projects, programs, educational efforts, standard setting, and/or research. Nominations for this year's awards will be accepted through **September 7, 2018**. Medication safety advocates from all healthcare disciplines and practice areas, including community, acute, long-term, and home care settings, are encouraged to submit. Please visit www.ismp.org/cheers-awards to obtain more information, submit a nomination, or make a donation to support ISMP's medication safety efforts.

To subscribe: www.ismp.org/node/126

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ISMP Medication Safety Alert! 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 January 2018 and April 2018. 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/node/1080.

Key: ⚠ — ISMP high-alert medication

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Confusing requirements for SHINGRIX (zoster vaccine recombinant, adjuvanted) with those for ZOSTAVAX (zoster vaccine live)					
02/18	Different storage requirements, components/diluents, and routes of administration for the newly approved Shingrix and the more familiar Zostavax have led to errors. Shingrix lyophilized antigen and adjuvant suspension must both be refrigerated, while Zostavax lyophilized vaccine must be kept frozen, and the included sterile water diluent kept refrigerated or at room temperature. Shingrix is given intramuscularly while Zostavax is given subcutaneously.	Educate staff about the differences between Shingrix and Zostavax. Label the storage bins/shelves using the updated Centers for Disease Control and Prevention (CDC) vaccine labels, which draw attention to the differences in storage, component/diluent, and routes of administration (www.ismp.org/sc?id=3101). Store the Shingrix lyophilized component and adjuvant suspension together to reduce the risk of using the wrong diluent.			
Nurse order entry error					
04/18	A hospice patient was ordered morphine sulfate concentrated oral solution 100 mg per 5 mL, 5 mg (0.25 mL) every 4 hours sublingually. The patient's nurse called the pharmacy to request morphine 100 mg per 5 mL, promising to send an electronic order soon afterwards. When entering the order, the nurse could not find the correct concentration. Feeling rushed, she selected morphine solution 10 mg/5 mL and entered instructions for "2.5 mL (5 mg)" subcutaneously. This information was transmitted to the pharmacy, without prescriber review, and appeared on the electronic medication administration record. The facility's electronic health record automatically placed the name of the physician in the field, "doctor signed electronically." The potential 10-fold overdose was caught before reaching the patient.	Prescribers should enter orders directly into the electronic prescribing system. Do not use "auto verification" in which the prescriber's signature appears on nurse-entered orders before they are verified. Avoid using the comment field to clarify electronic orders since the pharmacist may miss the information or the interface may not properly transmit the information. Staff and prescribers should seek assistance if they cannot enter the correct drug, dose, or frequency into the electronic prescribing application. Report close calls and actual errors involving electronic prescribing to the ISMP National Medication Errors Reporting Program (www.ismp.org/merp).			

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Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Confusion between SANDIMMUNE (cycloSPORINE) and NEORAL or GENGRAF (cycloSPORINE [MODIFIED])					
03/18 ⚠	Sand**IMMUNE** is a nonmodified form of cyclo**SPORINE** that has decreased bioavailability compared to Neoral or Gengraf capsules and oral solution. These are not interchangeable, yet patients often receive Sand**IMMUNE** when a cyclo**SPORINE** modified oral formulation was intended. Four patients recently received Sand**IMMUNE** instead of the more appropriate form of the drug, Neoral or Gengraf.	Indicate the brand name in orders, medication histories, and medication reconciliation records. Clarify orders for cyclo**SPORINE** if the formulation is not specified. Clearly display the different drug forms in order entry systems and create a hard stop to force verification of the correct drug form during prescribing. Monitor blood levels if a transplant patient receives the wrong formulation.			
Order entry short codes may be too short					
02/18	Order entry errors can happen when just the first few letter characters and a strength are used to search and select a medication from computer listings. When entering a prescription for oxybutynin extended release 10 mg, a pharmacist used the first 3 letters of the generic name and the strength of the drug (i.e., "oxy10") to search for the product in the computer system. A number of products appeared on the screen, including oxybutynin extended release 10 mg and oxy**CODONE** extended release 10 mg. The pharmacist inadvertently chose "oxycodone SR 10 mg."	Typing at least 5 letter characters (unless the drug name contains 4 or fewer letters) along with the drug strength most often limits similar names from appearing together on the same screen. Work with your information technology staff and computer system vendor to implement this strategy in the order entry system. Use mixed case lettering (e.g., tall man letters) to help differentiate similar drug names in computer systems.			
Label immediate medication containers					
01/18	A patient received overdoses of cefdinir 250 mg/5 mL oral suspension. The child was supposed to receive 3 mL each day. However, the child's parents were administering 14 mL a day in 2 doses following the "directions" on the manufacturer's container label. The pharmacy had affixed the pharmacy label to the outer carton of the medication, which was disposed of when the prescription was brought into the home. Thus, the only dosage information that remained was on the manufacturer's label on the bottle.	It is critical that the pharmacy label be affixed to the immediate container from which medication doses will be retrieved. If this is not possible, remind patients to retain the label which includes the directions for use and the patient's name. Opening the bag at the point-of-sale to review the medication and directions for use with the patient's parents would have helped them reduce the risk of the dosing error.			

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Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Warning! Dilute sertraline oral concentrate					
04/18	Sertraline liquid oral concentrate is produced in a 20 mg per mL concentration. The concentrated solution is astringent and direct administration of the undiluted solution may numb the tongue and mouth for at least a day, even if the mouth is rinsed extensively. Recently, a young child was given the undiluted concentrate. The instructions on the prescription and pharmacy label did not direct the caregiver to dilute the solution before administration. The child became distressed after receiving the solution undiluted.	Educate prescribers and pharmacy staff about the need to dilute this product before administration. Mandate patient counseling. Do not cover important warnings or instructions on manufacturer labels with pharmacy labels. Add directions for dilution to orders and medication administration records in long-term care facilities. Apply auxiliary labels warning that the product must be diluted. Warn patients and caregivers to use only the manufacturer-supplied dropper to measure the solution and dilute only in one of the solutions listed in the package insert.			
Confusion between lamoTRIgine and labetalol					
01/18	More than a dozen mix-ups have been reported between oral labetalol and lamo**TRI**gine. The mix-ups have resulted in breakthrough seizures and hypotension in patients who received labetalol in error, and skin rashes or untreated hypertension in patients who received lamo**TRI**gine in error. Contributing factors include similar size bottles and label colors, overlapping strengths, side-by-side storage, and look-alike tablets.	When receiving orders for either drug, match the patient's condition to the proper indication. Use a marker to draw attention to the product's name on the bottle. In community pharmacies, ask the patient to review the labels and contents of each prescription container for accuracy. Use mixed case lettering (e.g., tall man letters) when expressing lamo**TRI**gine. Electronic prescribing and barcode scanning helps to decrease this error potential.			
Wrong-patient errors at drive-thru					
01/18	Wrong-patient errors occur at the pharmacy drive-thru. Factors contributing to these errors include sound quality of the intercom system and failure to use two patient identifiers (i.e., the patient's full name and full date of birth). 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. Mix-ups also can occur when prescriptions for patients with similar or same names are stored near each other in the will call area.	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 sound quality is not sufficient, ask the patient to come into the store. Ask patients to open the bag of filled prescriptions to verify that the medications are correct before completing the transaction (i.e., before returning the patient's form of payment or change).			

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