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Community/Ambulatory Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Open the bag to catch errors at the point-of-sale

Giving a correctly dispensed prescription to the wrong patient is a common error in community pharmacies. In fact, it's the most common complaint the Institute for Safe Medication Practices (ISMP) receives through the National Consumer Medication Errors Reporting Program. Roughly a quarter of the events ISMP has received involve patients ingesting the wrong medication. These reports are only the tip of the iceberg as a study conducted by ISMP found that this error happens about once for every 1,000 prescriptions dispensed.[1] With close to 4 billion prescriptions dispensed each year, an average of 7 errors happen each month at every pharmacy across the US.

Most people trust and expect that the pharmacist will dispense their prescriptions accurately. However, pharmacists are human and can make mistakes, as could the person who rings up the sale. It is time for pharmacies to implement key, simple strategies to reduce the risk of these errors from reaching patients.

How errors happen

Giving a correctly filled prescription to the wrong patient can happen for several reasons. First, a mistake can be made when placing the prescription in a bag for pick-up. These errors often stem from working on more than one patient's prescription at a time, and then placing the patient's medication in a bag intended for another patient. Most people pick up their medication and leave the pharmacy without ever opening the bag. Furthermore, many pharmacies do not require staff to open the bag prior to ringing up the sale, so they do not view each prescription in the bag with the patient to be sure it is for the correct person. People may notice the error once they get home, but a government study shows that only about half of patients confirm their name on the prescription label, and only about three-quarters confirm the medication's name prior to use.[2] As a result, many people have taken the wrong patient's medication.

Another way a correctly filled prescription can be given to the wrong patient is when pharmacy staff selects the wrong patient's bag from the will call area. The process of identifying the patient can be flawed if a full name and date of birth are not asked and provided at the point-of-sale. Some pharmacy staff believe they know their patients by sight and have not developed the safe habit of always asking patients to state their full name and date of birth. Or, caregivers, friends, and family members who pick up prescriptions for the patient may not know the patient's date of birth. Thus, the wrong patient's bag may be chosen if there are medications in the will call area for patients with a similar or the same last name. 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.

Consequences of errors

Taking a contraindicated medication. If your patient does not notice the error and takes another patient's medication, it could be a medication to which the patient has a contraindication. For example, a pregnant woman who intended to fill a prescription for

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Unexpected painful breath. When teaching patients about proper use of an inhaler, be sure to emphasize the importance of recapping the device after use. The importance of replacing caps was recently illustrated in an April 9, 2015 *BMJ* case report. A woman who had asthma accidentally inhaled a small earring while using her asthma medication (www.ismp.org/sc?id=564). She got her uncapped inhaler from her purse. As she inhaled the medication, she felt a painful scratch in her throat and started coughing blood. She was taken to the emergency department, where the earring was removed from her lung. If the inhaler's cap had been in place, the loose earring in her purse would not have gotten into the inhaler. Another event was reported in April 2015, in England (www.ismp.org/sc?id=543). A woman used her inhaler and suddenly felt something shoot to the back of her throat. She

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18TH 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 11**. Join us for a gala at **The Chicory** in New Orleans on **December 8** as we celebrate this year's winners! Please visit www.ismp.org/Cheers/ to submit a nomination, register for the gala (click on Support), or make a donation to support ISMP medication safety efforts.

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an antibiotic to treat an infection was accidentally given another woman's prescription for methotrexate. Both women had the same last name and very similar first names. The pregnant woman took one tablet of methotrexate before noticing the error. Methotrexate prevents cell growth and should never be taken by a pregnant woman as it can cause birth defects or miscarriage. The pregnant woman was seen in the emergency department, but it was too early to determine if the unborn child had been harmed.

Omission of the correct medication. Another problem with receiving and taking the wrong patient's medicine is that the patient may not be taking their prescribed medication. This can lead to untreated health conditions that worsen over time or cause other adverse effects. For example, a patient who had been prescribed an antibiotic for a serious bacterial infection accidentally received another patient's antidepressant, sertraline (**ZOLOFT**), instead. After 10 days, the patient became very ill as the infection went untreated. In another event, a patient had been prescribed a pain reliever but instead received another patient's prescription for allopurinol, a gout medication. After days of pain without relief, she noticed the error and called the pharmacy to correct the mistake.

Misuse of the incorrect medication. Patients who are accidentally given the wrong person's medicines have occasionally misused these medications for recreational purposes or to harm themselves. In one case, a patient went to the pharmacy to pick up prescriptions for an allergy medication and oxy**CODONE**, an opioid pain reliever. The pharmacy found that the prescription containers had been accidentally given to another patient. When this patient was called, he denied receiving the wrong prescriptions, presumably because of the oxy**CODONE**—a common drug of abuse. In another case, a woman who had picked up a prescription for **PREMARIN** (estrogen) found another patient's medication also in the bag when she arrived home. The medication was amitriptyline (**ELAVIL**), an antidepressant. Later, a pharmacist received a call from a local hospital to tell her the woman was in the emergency department after taking 30 amitriptyline tablets dispensed by the pharmacy for another patient, in what appeared to be a suicide attempt.

Breach of protected health information. Another consequence of this type of error is that confidential information is accidentally disclosed to the person who receives another person's medication. The full name and address of the patient, along with the drug name, are on the pharmacy label. For sensitive medications, such as psychiatric drugs or medications that treat human immunodeficiency virus (HIV), patients may be deeply troubled that another person is aware of this information.

Recommendations to prevent harm

While there are several strategies community pharmacies can implement to detect wrong patient errors, there are 3 relatively simple steps that can practically eliminate the risk of a patient taking home another patient's medication by mistake.[1]

At the point-of-sale, have the patient review the pharmacy labels and contents of each prescription container to check that the medication is correct—even if this requires opening the bag. This simple step alone can cut the risk in half of patients taking home a correctly filled prescription intended for another patient. To facilitate this process, consider employing a will call system that uses clear plastic hanging bags to hold the prescription containers and receipts awaiting pick up or do not staple the paper bag shut. However, this may not be appropriate when a friend or caregiver picks up the prescription. In these cases, patient's should be notified to open the package at home, check the contents before taking any of the medication, and call the pharmacist with any concerns or questions.

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began gasping for air and spitting up blood. She ran outside, and a neighbor came to her rescue and called emergency medical services. The woman eventually coughed out a fake nail that had been part of a set she had worn weeks ago. In this case, the inhaler's cover had been in place before use, so the nail had probably lodged in the inhaler while using it when wearing the nails.

Figure 1. Teach patients to always replace the cap (left) on the inhaler (right) after use.

Tell patients to always inspect the inhaler thoroughly before use to ensure that there are no unwanted objects within the inhaler. Also advise them to replace the inhaler cap after every use. If a foreign object enters the inhaler, it places the person at risk of breathing in the object and causing choking or respiratory difficulties.

Blue dye allergy. ISMP received a report from a family member of a resident in a long-term care (LTC) facility who had a severe allergy to blue dye. Despite documentation of this allergy in the electronic health record (EHR) at the facility and in the pharmacy computer system, a pharmacist dispensed a medication that contained blue dye for this resident several times. While nurses at the LTC facility didn't notice the blue dye allergy in the EHR, fortunately, the resident was alert and reminded nurses about the allergy. Although not common, an anaphylactic reaction can be triggered by the color dye used in drugs in a patient with an allergy to the dye.

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The second strategy is to always ask the patient to provide two patient identifiers—their full name and date of birth—when picking up prescriptions. This is important even if you "know" your patients. Compare their answer to the information in the computer system or on the prescription receipt. Never ask a "Yes" or "No" question by reading aloud the patient's date of birth. This step reduces the risk of the wrong medication going home with the patient by one-third.

Talking to the patient about their medications reduces the risk of taking home the wrong medication by another 25%. Again, pharmacists should engage the patient in dialog by asking questions that do not have "Yes" or "No" answers. Patient education sessions should include a discussion of the medication's purpose to help ensure the correct medication is being dispensed to the correct patient. As mentioned before, patient counseling at the point-of-sale may not be possible if someone other than the patient is obtaining the medication(s), so important information must be conveyed to the patient via telephone.

Other recommendations to reduce the risk of wrong-patient errors include:

- Explore technological enhancements at the point-of-sale that require pharmacy staff to verify the patient's identity. For example, consider building a blind prompt that requires the pharmacy staff member to ask for the patient's date of birth and then key punch it into the register. If the date of birth does not match the patient's profile or is not entered, the transaction cannot be completed.
- Flag patients with similar names in computer systems. Alerts should appear when these patients are selected during data entry. These flags should also be visible at the point-of-sale.
- Separate areas designated for prescription pick-up and drop-off. This will help prevent confusion, overcrowding, and lack of confidentiality during patient counseling.
- Pharmacy managers and/or regional personnel for chain pharmacies should periodically perform quality control checks by observing the processes at the point-of-sale to ensure adherence to the standardized work practices.
- See **page 5** for tips you can share with patients on how to read a pharmacy label to verify that they have received the correct medication and know how to take it.

References

1) Cohen MR, Smetzer JL, Westphal JE, et al. Risk models to improve safety of dispensing high-alert medications in community pharmacies. *J Am Pharm Assoc.* 2012;52(5):584-602.
2) Trettin KW, Narus E. Implementation of a VA patient-centered prescription label. Chapter 47. In: Advances in Human Aspects of Healthcare, ed. Duffy VG, 2012. Boca Raton, FL: CRC Press; p. 429-38.

FDA Advise-ERR

Mefloquine—Not the same as Malarone!

PROBLEM: The US Food and Drug Administration (FDA) and ISMP have received reports that describe errors associated with the wrong frequency of administration with mefloquine as well as wrong drug errors in which mefloquine was dispensed instead of the intended **MALARONE** (atovaquone/proguanil). Both mefloquine (previously marketed as **LARIAM***) and Malarone are FDA approved for use in the treatment and prophylaxis of malaria, but they each have different dosing regimens (**Table 1** on page 4).

One report described two patients for whom mefloquine 250 mg was prescribed to be taken daily instead of weekly for malaria prophylaxis. After taking mefloquine daily for 11 days, both patients experienced a "cloudy head," dizziness, nausea, and vomiting that persisted for more than 10 days after mefloquine was stopped.

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"Do not substitute" orders for specific brands of medications without the offending dye can help prevent these types of errors. In addition to documentation in the pharmacy computer system, be sure the medication administration record includes a prominent display of any allergies that might be related to medications or their inactive ingredients, including dyes. Including specific product descriptions on the prescription label (e.g., blue, oblong tablet) may help people, particularly those who are color blind, identify the presence of dyes in products.

FDA's Sentinel Initiative falls short, study says. The US Food and Drug Administration (FDA) is hoping that a better, faster postmarket surveillance system, using electronic health data from millions of patients, will lead to more rapid identification of drug safety issues so that information can be better communicated to the field. However, so far, this is a vision not yet realized, according to a newly-published analysis in the journal *Drug Safety*. The analysis was conducted and published by Thomas J. Moore and Curt D. Furberg, two members of the project team that produce QuarterWatch, the ISMP drug safety publication that exam-

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ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

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Report medication and vaccine errors to ISMP: Call 1-800-FAIL-SAF(E), or visit 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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Three reports described prescriptions written for Malarone, but the pharmacy mistakenly dispensed mefloquine. The first patient, an 18-year-old man, took 4 tablets (1 g) of mefloquine daily for 2 to 3 days instead of the prescribed Malarone and developed a headache, nausea, vomiting, and confusion. In the other two events, the dispensing error was caught by the patients prior to taking the incorrect medication.

Although most of the reports did not state a reason why these errors occurred, knowledge deficits may have contributed to the mix-ups. One report stated that the incorrect substitution was performed because the pharmacist thought mefloquine was the generic of Malarone. Healthcare providers may be unfamiliar with antimalarial products due to infrequent use. Further, mefloquine and Malarone have overlapping tablet strengths and similar approved uses as antimalarial products, making confusion more likely.

Mistakenly believing that mefloquine and Malarone are the same or that they have the same dosing regimen for antimalarial prophylaxis and treatment may lead to serious adverse events including vomiting, syncope, QT prolongation, paranoia, anxiety, depression, or inadequate prophylaxis.

SAFE PRACTICE RECOMMENDATIONS: Healthcare providers should consider the following recommendations to reduce the risk of errors.

- **Include brand and generic name**. Prescribe Malarone using both the brand and generic names, Malarone (atovaquone/proguanil), to provide redundancy and greater differentiation from mefloquine.
- **Include the indication on the prescription.** Prescribers should indicate whether the prescription or order is for prophylaxis or treatment of malaria.
- **Verify every order.** Verify prescriptions for antimalarial prophylaxis and treatment, which may not be commonly dispensed. This includes confirmation of the drug, frequency of administration, and dosing regimen of Malarone or mefloquine with each order or prescription.
- **Set frequency limits.** In order entry systems, establish an alert that will appear if mefloquine is prescribed daily and if Malarone is prescribed weekly.
- **Provide counseling.** Counsel all patients prescribed antimalarial products regarding its purpose (prophylaxis or treatment) and directions for use. Advise patients to read the Medication Guide when dispensing mefloquine, and to call their healthcare provider if they have any questions.

FDA Advise-ERR was provided by Jacqueline Sheppard, PharmD, and Vicky Borders-Hemphill, PharmD, from the FDA's Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis.

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ines drug risks reported through the FDA Adverse Event Reporting System (FAERS).

The concept of a better system using electronic health data—both insurance claims and electronic health records– originated nearly a decade ago. Congress mandated that FDA create the sentinel system with a goal of getting electronic health data from more than 100 million patients. Large research projects in the US and Europe were launched to test and validate the best methods for utilizing this mass of digital health data. The authors note that 6 years after FDA started the Sentinel Initiative, it has yet to be a primary source for new Boxed Warnings, Contraindications, or Warnings, as the system has had difficulties confirming known drug risks.

Still, the authors say that the Sentinel Initiative "has substantial growth potential" for improvements over time. But more investment in the Initiative is needed, and a realistic view of what can be achieved must be identified. The full study, "Electronic Health Data for Postmarket Surveillance: A Vision Not Realized," is available at: www.ismp.org/ sc?id=565.

Table 1. Adult dosing regimens for mefloquine (previously marketed as Lariam*) and Malarone (atovaquone/proguanil)†

Drug	Available Strengths	Adult Prophylactic Dosing	Adult Treatment Dosing
mefloquine	■ 250 mg tablets	■ One 250 mg tablet **once weekly** ■ Prophylactic drug administration should begin 1 week before arrival in an endemic area. Subsequent weekly doses should be taken regularly, always on the same day of the week, preferably after the main meal. To reduce the risk of malaria after leaving an endemic area, prophylaxis must be continued for 4 additional weeks.	■ Five 250 mg (1,250 mg) tablets to be given as a single oral dose.
Malarone (atovaquone/proguanil)	■ 250 mg/100 mg tablets ■ 62.5 mg/25 mg tablets	■ One 250 mg/100 mg tablet **per day** ■ Single dose, once daily ■ Start prophylaxis 1 or 2 days before entering a malaria-endemic area and continue daily during the stay and for 7 days after return.	■ 1,000 mg/400 mg (Four 250 mg/100 mg tablets) as a single daily dose for 3 days.

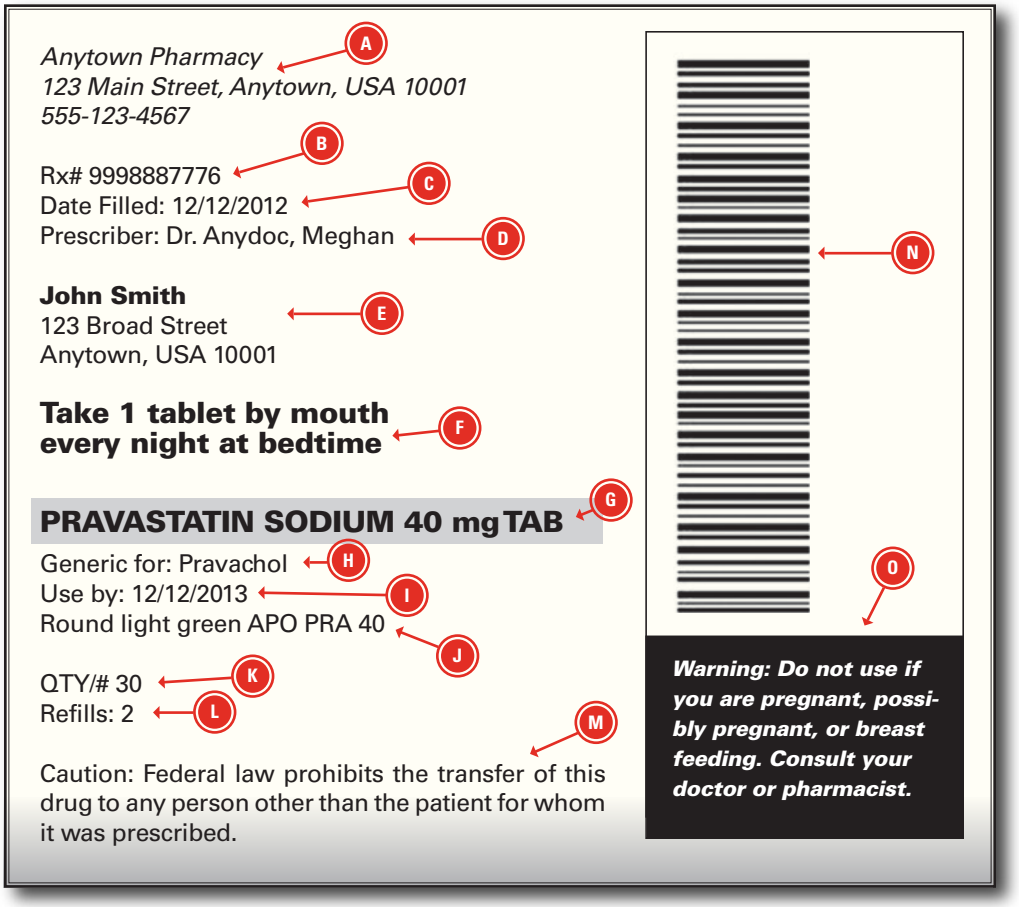
*Hoffman-La Roche voluntarily withdrew the Lariam new drug application in 2011 (76 FR 33310, June 8, 2011).
†The full Prescribing Information is available at: http://labels.fda.gov.

Reading the Pharmacy Label on Prescription Medicines

The purpose of the label on your prescription medicine is to provide you with crucial information about your medicine so you can take it properly. Most of the information on the label is required by state pharmacy laws. Each state may have slightly different label requirements. So labels may vary from state to state. Pharmacies may also decide to include certain information not required by state laws.

The sample pharmacy label provided below is representative of the information you will find on your prescription label. Where the information is located on your prescription label may be different than it is with the sample label. But you should be able to find all the information listed on the sample label on your prescription label. Additional information you may find on your prescription label is also listed below.

Information on Most Prescription Labels



A Pharmacy name, address, and telephone number

B Pharmacy-assigned number to document and identify this prescription

C The date the prescription was filled or refilled

D The healthcare provider who prescribed the medicine

E The legal name of the person taking the medicine *(The person's address or date of birth may be included.)*

F Directions regarding how to take or use the medicine, how often, and when to take it *(This should never say, "Take as directed," unless clear directions are provided on other packaging.)*

G Name and strength of the medicine *(For long medicine names or combinations of medicines, abbreviations may be used. Extended-release medicines may include abbreviations, such as CR, SR, XL, XR, and others. The medicine name, even if long, should not drop off the label or wrap around to the next line.)*

H Brand name of prescribed medicine *(If a brand name medicine was prescribed, but the prescriber allowed a generic medicine to be used instead, the brand name may be listed on the label.)*

I The date after which the medicine must be discarded

J A short description of what your medicine looks like *(This may include the smell of the liquid, or any letters or numbers on tablets or capsules.)*

K Number of tablets/capsules in the container when filled/refilled

L The number of remaining refills with the original prescription

M Federal caution statement that must be on container labels for controlled drugs *(This may be on all labels if it is part of the overall design of the pharmacy label.)*

N Prescription barcode

O Warning labels specific to the prescribed medicine about how it is used and its effects

P Additional information on some labels (not displayed above)

- ☐ Purpose of the medicine
- ☐ Pharmacy store number
- ☐ Patient's telephone number
- ☐ Initials of the pharmacist
- ☐ Original prescription date
- ☐ Prescription expiration date
- ☐ Prescriber's (doctor's) telephone number
- ☐ Manufacturer of the drug (and labeler if different)
- ☐ Insurance information