

Advocating for patients in an era of drug-delivery problems

Learn what steps you can take to help patients avoid drug contamination and cope with drug shortages.

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RECENT HEADLINES have exposed serious drug-safety issues. No longer can patients feel confident that the drugs they need will be safe—or even available. As a nurse, you need to stay current on these problems so you can provide guidance to patients and act as patient advocate. This article addresses three critical drug-delivery issues—contamination of drugs prepared by compounding facilities, critical drug shortages, and infections caused by improper use of injectable drugs.

Since the mid-1960s, drug development and safety in the United States has been regulated closely by the Food and Drug Administration (FDA). Many laws currently in place were enacted many decades ago, after the morning-sickness drug thalidomide was found to cause serious birth defects. Some infants whose mothers had taken the drug were born without limbs or with severely malformed limbs. The resulting shock and outrage led Congress to enact laws to protect patients and ensure drug safety and efficacy. These laws established guidelines for drug development and evaluation, requiring proof of safety and efficacy before a drug is approved. Approved drugs may

lose their approval if serious adverse effects emerge after sales begin. Drug-manufacturing facilities are inspected and held to strict standards.

For the most part, approved drugs used in this country are safe and effective when used as directed. But that doesn't necessarily mean all precautions have been taken to ensure patient safety. Recent problems have shaken patient confidence. Understanding the cause of these problems is crucial to determining what the FDA, healthcare workers, and patients can do to prevent drug-related illnesses and deaths.

Problems involving compounding pharmacies

In September 2012, a cluster of serious and some fatal meningitis cases occurred across the country. They were traced back to spinal injection of steroids for pain relief. In all reported cases, the victims had received drugs prepared by the same compounding pharmacy in Massachusetts. More than 50 deaths and 680 illnesses have been linked to that facility; inspections there found meningococcal contamination and resultant contamination of sealed drugs. Further studies also



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LEARNING OBJECTIVES

1. Identify potential problems with drug compounding.
2. Discuss drug shortages.
3. Describe unsafe injection practices.
4. Explain the nurse's role as patient advocate related to drug-delivery issues.

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What is a compounding pharmacy?

A compounding pharmacy alters an approved drug in some way to tailor it for a particular patient. Examples include changing a tablet to liquid form, making a more concentrated drug form for pediatric use, and removing allergens that might be in binders. This important service helps many patients safely receive drugs.

Compounding pharmacies may exist within hospitals, clinics, or the corner pharmacy—or they can be large freestanding facilities. Over the years, some compounding facilities have changed their focus and are now producing drugs in larger quantities than some pharmaceutical manufacturing plants.

turned up various bacterial contaminants. The pharmacy was shut down. (See *What is a compounding pharmacy?*)

In recent years, efforts to limit healthcare costs and save provider time in preparing drugs have led compounding pharmacies to produce large amounts of some of the highest-risk drugs, often without a specific prescription for a particular patient. In many cases, these drugs are shipped across the country to various hospitals and clinics. In late March 2013, the FDA reported problems with a compounding pharmacy that was repackaging the powerful antineoplastic Avastin (bevacizumab) as an ophthalmic agent. Serious eye infections were reported, leading to a recall of all sterile products shipped from that facility. Of special concern to the FDA, the drug isn't approved as an ophthalmic agent and warnings had been sent to providers about side effects of such use. The lesson learned from this incident was that despite publicity and efforts to curtail problems with compounding pharmacies, these problems are still occurring.

With our aging and increasingly mobile population, along with changes in the healthcare-delivery system and hospital outsourcing of certain time-consuming activities, many compounding pharmacies have become quite large. Typically, hospitals outsource drug compounding to save time and money, as outsourcing costs can be significantly lower than an individualized in-hospital approach. Over the past few years, the FDA has warned many large compounding facilities about going beyond the scope of their purpose.

Under current law, state health departments or pharmacy boards are responsible for monitoring compounding pharmacies—but most states aren't equipped for this task. The Massachusetts compounding pharmacy at the center of the meningitis outbreak hadn't been totally open with the state in describing the scope of its activities, and state agencies weren't aware of potential problems until the FDA learned of reports of illness and death.

Who should be responsible for monitoring production and cleanliness standards in these facilities and for ensuring that products leaving them meet safety standards? That remains unclear. While the FDA has been reluctant to overstep the states' authority, many states believe large compounding facilities (which prepare drugs in large quantities) should be under FDA control. With the current system, some things obviously have fallen through the cracks.

Since identifying the problem at the Massachusetts facility, the FDA and Massachusetts authorities have made surprise inspections at other large compounding facilities and have shut down four for failing to meet safety standards. Some believe this is a "too little, too late" approach. Nonetheless, this tragic ex-

ample has brought an unaddressed issue to the forefront and should impel authorities to make needed changes to prevent similar incidents. As this article is published, the debate continues and no clear answer has been found. Congress, the FDA, and the compounding pharmacies continue to debate the roles each should play in ensuring patient safety. In early May 2013, Congress published a statement declaring that the FDA should be involved in oversight of large compounding pharmacies that prepare drugs for institutions or clinics, not just individual patients. The Institute for Safe Medication Practices (ISMP) has published guidelines on sterile-compound preparation, available at www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf.

Your role as patient advocate

Compounding-pharmacy problems are largely beyond the nurse's control. Nonetheless, make sure you're informed and up-to-date on this issue so you can answer patients'



Why are drug shortages occurring?

Failure of drug-manufacturing facilities to pass FDA inspection is the main cause of recent drug shortages. This failure has led to manufacturing delays until improvements are made. The FDA has been under pressure to lower inspection standards—but we need only look at recent problems at compounding pharmacies to realize this isn't the answer.

Other causes of drug shortages include difficulty obtaining needed drug ingredients and FDA limitations on how much of a controlled substance a manufacturer can produce in a single year. With prescriptions for some limited-production drugs increasing (such as those used to treat attention deficit-hyperactivity disorder), the limit is reached earlier in the year than anticipated, and shortages result.

Yet another cause of shortages is that a particular drug may have poor sales and profitability. Drug manufacturing is a business, and when a business isn't making a profit, changes have to be made. Sometimes, the change is to discontinue a poor-selling or unprofitable drug.

questions and help allay their fears. Question policies and procedures you believe could harm patients. Collaborate with the pharmacist as well; pharmacists can best explain the process of drug compounding and preparation, helping other healthcare team members understand the issues. Also, the latest information is available through pharmacy newsletters and alerts.

Drug shortages

Another serious drug-delivery issue is shortages of important drugs, most of them injectables. In 2010, 178 drugs were reported to be in short supply and no longer available for patient care. In 2011, when the shortages peaked, 215 drugs were in short supply—most of them liquid injectable drugs commonly used in critical care. Patients who needed these drugs were unable to get them. Emergency personnel reportedly were withholding morphine because they'd heard of a morphine shortage. In December 2012, an alarming report in *The New England Journal of Medicine* revealed a higher relapse rate in pediatric, adolescent, and young adult cancer patients when an acceptable substitute for a drug they were receiving wasn't available due to shortages.

This potentially life-threatening situation led President Obama to sign an executive order in 2011. As a result, letters were sent to drug

manufacturers reminding them of their responsibility to report shortages or drug discontinuations. FDA staffing resources were increased to address the shortage and related public safety concerns and to ensure early notification of shortages. (See *Why are drug shortages occurring?*)

Since the executive order, many of the issues underlying shortages are being addressed. Experts are encouraged by the decline in shortages between 2011 and 2012. The FDA and drug manufacturers have been working together closely to:

- provide early warning of potential problems to alert prescribers they need to seek an acceptable alternative to drugs in short supply
- encourage adoption of discontinued drugs by other manufacturers
- find ways to make manufacturing plant inspections and penalties less costly.

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Bottom line: We still have drug shortages, but the situation is improving.

Your role as patient advocate

You can take a proactive approach to help protect patients when a drug becomes unavailable. The FDA website at www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm has a section devoted to current and anticipated drug shortages and explains what's being done to address them. On the website of the American Society of Health System Pharmacists (www.ashp.org/shortages), you can search for shortages by drug name or current status of a shortage. Also, you can consult a pharmacist to learn of potential problems and seek solutions. Being well informed is the best way to learn the facts and avoid confusion about drug-shortage rumors and to prevent errors caused by misunderstandings or misinformation. The pharmacist also can help manage patients' drug regimens and answer their questions.

Unsafe injection practices

According to a 2012 report by the Centers for Disease Control and Prevention (CDC), unsafe injection practices in clinics and private physician offices have led to more than 150,000 cases of illness since 2001—from hepatitis C to life-threatening methicillin-resistant *Staphylococcus aureus* (MRSA). In 2012, the CDC reported on investigations of local outbreaks of infections caused by improper injection practices. The agency concluded that the vast majority of injections in this country are given properly and under closely followed protocol—but about 5% don't follow protocol and cause patient illness. In many cases, investigators found that small clinics or private offices were reusing single-dose vials and even single-dose syringes for more than one patient. Seeking to save money when fluid remains in the

vial, some providers had instructed staff to swab the top of the vial and use the remaining drug for another patient; some clinics surveyed didn't even reswab the vial. Potentially, this can cause drug contamination. Reuse of single-use syringes usually involved changing the needle, but in that case, the syringe might not be sterile.

Regular use of multidose vials for multiple patients also carries a high risk for contamination and isn't recommended. Reasons for this practice include the desire to cut costs and poor understanding of contamination and injection protocol. Recently, ISMP urged hospitals to consider transitioning away from insulin pens due to numerous cases of contamination.

Most small clinics (such as pain, endoscopy, dental, and cardiology clinics) don't fall under the strict inspection regulations that apply to facilities that treat Medicare or Medicaid patients. Experts have suggested ways to correct this problem. For instance, drug companies could be asked to make drugs in vials containing a dose that's closer to the usual dose given and to produce syringes that can't be used twice.

However, educating all healthcare providers seems to be the most efficient solution. In the past 2 years, North Carolina, New York, and Nevada have added educational requirements for licensing of healthcare professionals that include proper

Crucial patient-teaching points

In your role as patient advocate, you can take the following steps to help patients avoid drug-related problems.

- Urge patients to compile a list of all drugs and other preparations they take—not just prescription drugs but over-the-counter drugs, vitamin and mineral supplements, street drugs, and herbal supplements. Instruct them to include drugs they've been prescribed but don't take. Encourage patients to feel free to share their drug information with healthcare providers; reluctance to share this information contributes to drug errors.
- Inform patients that herbal therapies are considered dietary supplements, which means they aren't subject to the same testing or quality-control measures that drugs are. Unfortunately, these products frequently are found to be contaminated.
- Teach patients to ask the following questions before receiving a drug: What safety and infection-control processes do you use? Where did this drug come from? Can I watch you draw up the drug into the syringe? Of course, many patients shy away from asking these questions, and some providers may feel insulted by them. But considering the incidence and consequences of drug problems, these questions need to be asked—and we need to teach patients it's appropriate to ask them. (Sometimes just asking a healthcare provider questions helps reinforce infection-control and safety procedures.) Also, educate colleagues on the importance of this information. Encourage them not to feel insulted by patients' questions but to see them as an opportunity to ensure safe patient care and provide more patient education.
- Advise patients receiving drugs that may be in short supply to do research to determine if a shortage is occurring or is likely to occur. Instruct them to visit www.fda.gov, click on "Drugs" and then click on "Drug Shortages." They'll find an index of current drug shortages, including drug availability and estimated shortage duration. Advise patients to discuss this information with their providers, who might lack the time to do such research themselves. Also encourage patients to speak with a pharmacist about a drug's availability. Knowing of a drug shortage in advance can guide important clinical decisions, which might include switching to a different drug, using approved substitutes, or accessing limited supplies in specific situations.
- Educate patients about drug safety and quality assurance. Direct them to www.fda.gov, where they can click on "For Consumers and Patients" and find a wealth of information about drugs. For instance, when you click on "Protect Yourself," you'll find articles on buying medications over the Internet, consumer safety alerts, and counterfeit drugs.
- Caution patients not to buy drugs over the Internet to try to bypass drug shortages or contamination. Many drugs sold on the Internet come from offshore manufacturers. They might be unsafe or contaminated—or might not even be the same drug the patient thinks he or she is ordering. Desperate or scared people may turn to any source that promises a quick solution; remind patients that the Internet "solution" might turn out to be deadly.



injection practices and safety. Still, even though review of protocols and safety practices by all healthcare providers who prepare or give injections may be the best way to end bad injection practices, employers concerned about immediate costs and waste from discarding partially full vials or buying more syringes may not want to take this step.

Your role as patient advocate

Because nurses typically administer

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injections, make sure you're aware of the potential for infections related to unsafe injection practices. Review proper injection procedures and infection-control measures on a regular basis. Know that in partnership with the Safe Injection Practices Coalition, the CDC has launched the One & Only Campaign (one needle, one syringe, one patient) to raise awareness. Visit www.oneandonlycampaign.org

to access training videos, reminder posters, and digital media kits.

Also, question practices used at your facility to save money that could put patients at risk. Urge drug companies to make single-use vials in the most common dosages to prevent waste and protect patients. Advocacy by nurses who provide frontline patient care may have a larger impact than bureaucrats in bringing about this much-needed change.

The most important part of your advocacy role is to adhere to three crucial safeguards:

- *Never* enter a single-use vial more than once.
- *Never* reuse a syringe or needle.
- *Always* follow recommended infection-control practices.

Education and advocacy: A potent duo

Solving drug-delivery problems may seem out of reach for nurses and patients, as these issues are largely system related. But through education and advocacy, you can take steps to keep patients safe from these problems—and other drug problems that could emerge in the future.

The best way to help patients stay safe is to teach them to advocate for themselves. Traditionally, the nurse has been the patient's advocate in the clinical setting. But today, a patient may be seen in many different settings; in some, he or she may not see a nurse at all. What's more, the patient and the healthcare professional who gives the drug typ-

ically are the only ones present during drug administration. This makes it all the more crucial for patients to act as their own advocates.

As a nurse and a patient advocate, one of your key goals is to help patients feel comfortable sharing information with healthcare providers and asking them questions about their health care, especially drugs. Teaching patients to provide feedback and input to providers is critical to good nursing care. Help them feel empowered to ask questions of healthcare practitioners without fearing their inquisitiveness or self-advocacy could affect the care they receive. (See *Crucial patient-teaching points*.)

Keep in mind, too, that many patients are prescribed drugs by multiple providers, and some patients take over-the-counter drugs and nutritional or herbal supplements as well. What's more, even if providers obtain a thorough drug history, only the patient knows what he or she is actually taking. (Just because a drug is prescribed doesn't mean the patient's taking it.)

Given the changes in our healthcare system and the information overload of the 21st century, today's patient must be perceived as a key healthcare team member—and even take the lead. This will require a major shift in approach and attitude on the part of both healthcare providers and patients. Nurses can be pivotal in making this happen. ★

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PURPOSE/GOAL

To provide nurses with information related to drug delivery so they can serve as patient advocates

LEARNING OBJECTIVES

1. Identify potential problems with drug compounding.
2. Discuss drug shortages.
3. Describe unsafe injection practices.
4. Explain the nurse's role as patient advocate related to drug-delivery issues.

Please mark the correct answer online.**1. Which statement about compounding pharmacies is accurate?**

- a. They alter an approved drug in some way to tailor it to a patient.
- b. Their main purpose is to produce large quantities of approved drugs.
- c. They do not provide a useful service for patients and providers.
- d. They add substances to improve a drug's marketability.

2. Who is responsible for monitoring compounding pharmacies?

- a. Food and Drug Administration (FDA)
- b. State health departments or pharmacy boards
- c. Medical or pharmacy boards
- d. U.S. Department of Health and Human Services

3. Which of the following has published guidelines on sterile-compound preparation?

- a. Centers for Medicare & Medicaid Services
- b. FDA
- c. Institute for Safe Medication Practices
- d. U.S. Department of Health and Human Services

4. Which statement about drug manufacturing and compounding pharmacies is correct?

- a. An effort to limit healthcare costs and save drug preparation time have led compounding pharmacies to produce large amounts of drugs.
- b. In recent years, drug shortages have caused a decline in the use of compounding pharmacies.
- c. Since contamination cases arose in 2012, compounding pharmacies have not had additional problems.
- d. Contamination cases in 2012 resulted in several illnesses but no patient deaths.

5. The most common drugs in short supply have been:

- a. oral drugs used in ambulatory surgery.
- b. oral drugs used in the emergency department.
- c. liquid injectable drugs used in critical care.
- d. liquid injectable drugs used in pediatric care.

6. The most common reason for a drug shortage is:

- a. poor sales and profitability of a particular drug.
- b. more frequent inspections by FDA inspectors.
- c. insufficient supply of a needed ingredient for a particular drug.
- d. failure of drug-manufacturing facilities to pass FDA inspection.

7. Which statement about the reason for drug shortages is correct?

- a. Patients are being seen in fewer healthcare facilities and less often.
- b. The Department of Health and Human Services requires more inspections.
- c. Compounding pharmacies have been proliferating.
- d. Prescriptions for some limited-production drugs have increased.

8. Which statement about the use of multidose vials is accurate?

- a. Multidose vials containing anticoagulants can be used for multiple patients.
- b. Multidose vials do not need to be swabbed between uses.
- c. Regular use of multidose vials for multiple patients is an accepted practice.
- d. Regular use of multidose vials for multiple patients isn't recommended.

9. Which statement about using single-use vials is correct?

- a. Entering a single-use vial more than once is accepted practice.
- b. Never enter a single-use vial more than once.
- c. You can re-enter a single-use vial if you change the syringe.
- d. You can re-enter a single-use vial if you change the needle.

10. Which entity has launched the One & Only Campaign in partnership with the Safe Injection Practices Coalition?

- a. Commonwealth of Massachusetts
- b. American Association of Pharmacists
- c. Centers for Disease Control and Prevention
- d. FDA

11. Herbal supplements are:

- a. not to be included in the patient's list of preparations he or she is taking.
- b. subject to the same quality-control measures as drugs.
- c. subject to the same chemical testing as drugs.
- d. considered to be dietary supplements.

12. Which of the following actions related to drug delivery should you *not* instruct the patient to take?

- a. Order the drug over the Internet if there's a shortage.
- b. Watch the care provider draw up the drug into the syringe.
- c. Ask the care provider where the drug came from before administration.
- d. Ask the care provider what infection-control processes he or she uses.