

# Hospitals hunt substitutes as drug shortages rise

May 30 2011, By LAURAN NEERGAARD , AP Medical Writer

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(AP) -- A growing shortage of medications for a host of illnesses - from cancer to cystic fibrosis to cardiac arrest - has hospitals scrambling for substitutes to avoid patient harm, and sometimes even delaying treatment.

"It's just a matter of time now before we call for a drug that we need to save a patient's life and we find out there isn't any," says Dr. Eric Lavonas of the American College of Emergency Physicians.

The problem of scarce supplies or even completely unavailable medications isn't a new one but it's getting markedly worse. The number listed in short supply has tripled over the past five years, to a record 211 medications last year. While some of those have been resolved, another 89 drug shortages have occurred in the first three months of this year, according to the University of Utah's Drug Information Service. It tracks shortages for the American Society of Health-System Pharmacists.

The vast majority involve injectable medications used mostly by medical centers - in emergency rooms, ICUs and cancer wards. Particular shortages can last for weeks or for many months, and there aren't always good alternatives. Nor is it just a U.S. problem, as other countries report some of the same supply [disruptions](#).

It's frightening for families.

At Miami Children's Hospital, doctors had to postpone for a month the

last round of chemotherapy for 14-year-old Caroline Pallidine, because of a months-long nationwide shortage of cytarabine, a drug considered key to curing a type of leukemia.

"There's always a fear, if she's going so long without chemo, is there a chance this cancer's going to come back?" says her mother, Marta Pallidine, who says she'll be nervous until Caroline finishes her final treatments scheduled for this week.

"In this day and age, we really shouldn't be having this kind of problem and putting our children's lives at risk," she adds.

There are lots of causes, from recalls of contaminated vials, to trouble importing raw ingredients, to spikes in demand, to factories that temporarily shut down for quality upgrades.

Some experts pointedly note that pricier brand-name drugs seldom are in short supply. The Food and Drug Administration agrees that the overarching problem is that fewer and fewer manufacturers produce these older, cheaper generic drugs, especially the harder-to-make injectable ones. So if one company has trouble - or decides to quit making a particular drug - there are few others able to ramp up their own production to fill the gap, says Valerie Jensen, who heads FDA's shortage office.

The shortage that's made the most headlines is a sedative used on death row. But on the health-care front, shortages are wide-ranging, including:

- Thiotepa, used with bone marrow transplants.

- A whole list of electrolytes, injectable nutrients crucial for certain premature infants and tube-feeding of the critically ill.

- Norepinephrine injections for septic shock.
- A [cystic fibrosis](#) drug named acetylcysteine.
- Injections used in the ER for certain types of [cardiac arrest](#).
- Certain versions of pills for ADHD, attention deficit hyperactivity disorder.
- Some leuprolide hormone injections used in fertility treatment.

No one is tracking patient harm. But last fall, the nonprofit Institute for Safe Medication Practices said it had two reports of people who died from the wrong dose of a substitute painkiller during a morphine shortage.

"Every pharmacist in every hospital across the country is working to make sure those things don't happen, but shortages create the perfect storm for a medication error to happen," says University of Utah pharmacist Erin Fox, who oversees the shortage-tracking program.

What can be done?

The FDA has taken an unusual step, asking some foreign companies to temporarily ship to the U.S. their own versions of some scarce drugs that aren't normally sold here. That eased shortages of propofol, a key anesthesia drug, and the transplant drug thiotepa.

Affected companies say they're working hard to eliminate backlogs. For instance, Hospira Inc., the largest maker of those injectable drugs, says it is increasing production capacity and working with FDA "to address shortage situations as quickly as possible and to help prevent recurrence."

But the Generic Pharmaceutical Association says some shortages are beyond industry control, such as FDA inspections or stockpiling that can exacerbate a shortage.

"Drug shortages of any kind are a complex problem that require broad-based solutions from all stakeholders," adds the Pharmaceutical Research and Manufacturers of America, a fellow trade group.

Lawmakers are getting involved. Sen. Herb Kohl, D-Wis., is urging the Federal Trade Commission to consider if any pending drug-company mergers would create or exacerbate shortages.

Also, pending legislation would require manufacturers to give FDA advance notice of problems such as manufacturing delays that might trigger a shortage. The FDA cannot force a company to make a drug, but was able to prevent 38 close calls from turning into shortages last year by speeding approval of manufacturing changes or urging competing companies to get ready to meet a shortfall.

"No patient's life should have to be at risk when there is a [drug](#) somewhere" that could be used, says Sen. Amy Klobuchar, D-Minn., who introduced the bill.

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