The other opioid crisis: Hospital shortages lead to patient pain, medical errors

March 20 2018, by Pauline Bartolone, Kaiser Health News

Credit: CC0 Public Domain

Even as opioids flood American communities and fuel widespread addiction, hospitals are facing a dangerous shortage of the powerful painkillers needed by patients in acute pain, according to doctors,

pharmacists and a coalition of health groups.

The shortage, though more significant in some places than others, has left many hospitals and surgical centers scrambling to find enough injectable morphine, Dilaudid and fentanyl—drugs given to patients undergoing surgery, fighting cancer or suffering traumatic injuries. The shortfall, which has intensified since last summer, was triggered by manufacturing setbacks and a government effort to reduce addiction by restricting drug production.

As a result, hospital pharmacists are working long hours to find alternatives, forcing nurses to administer second-choice drugs or deliver standard drugs differently. That raises the risk of mistakes—and already has led to at least a few instances in which patients received potentially harmful doses, according to the nonprofit Institute for Safe Medication Practices, which works with health care providers to promote patient safety.

In the institute's survey of hospital pharmacists last year, one provider reported that a patient received five times the appropriate amount of morphine when a smaller-dose vial was out of stock. In another case, a patient was mistakenly given too much sufentanil, which can be up to 10 times more powerful than fentanyl, the ideal medication for that situation.

In response to the shortages, doctors in states as far-flung as California, Illinois and Alabama are improvising the best they can. Some patients are receiving less potent medications like acetaminophen or muscle relaxants as hospitals direct their scant supplies to higher-priority cases. Other patients are languishing in pain because preferred, more powerful medications aren't available, or because they have to wait for substitute oral drugs to kick in.

The American Society of Anesthesiologists confirmed that some elective surgeries, which can include gall bladder removal and hernia repair, have been postponed.

In a Feb. 27 letter to the U.S. Drug Enforcement Administration, a coalition of professional medical groups—including the American Hospital Association, the American Society of Clinical Oncology and the American Society of Health-System Pharmacists—said the shortages "increase the risk of medical errors" and are "potentially life-threatening."

In addition, "having diminished supply of these critical drugs, or no supply at all, can cause suboptimal pain control or sedation for patients," the group wrote.

The shortages involve prefilled syringes of these drugs, as well as small ampules and vials of liquid medication that can be added to bags of intravenous fluids.

Drug shortages are common, especially of certain injectable drugs, because few companies make them. But experts say opioid shortages carry a higher risk than other medications.

Giving the wrong dose of morphine, for example, "can lead to severe harm or fatalities," explained Mike Ganio, a medication safety expert at the American Society of Health-System Pharmacists.

Calculating dosages can be difficult and seemingly small mistakes by pharmacists, doctors or nurses can make a big difference, experts said.

Marchelle Bernell, a nurse at St. Louis University Hospital in Missouri, said it would be easy for medical mistakes to occur during a shortage. For instance, in a fast-paced environment, a nurse could forget to

program an electronic pump for the appropriate dose when given a mix of intravenous fluids and medication to which she was unaccustomed.

"The system has been set up safely for the drugs and the care processes that we ordinarily use," said Dr. Beverly Philip, a Harvard University professor of anesthesiology who practices at Brigham and Women's Hospital in Boston. "You change those drugs, and you change those care processes, and the safety that we had built in is just not there anymore."

Chicago-based Marti Smith, a nurse and spokeswoman for the National Nurses United union, offered an example.

"If your drug comes in a prefilled syringe and at 1 milligram, and you need to give 1 milligram, it's easy," she said. "But if you have to pull it out of a 25-milligram vial, you know, it's not that we're not smart enough to figure it out, it just adds another layer of possible error."

During the last major opioid shortage in 2010, two patients died from overdoses when a more powerful opioid was mistakenly prescribed, according to the institute. Other patients had to be revived after receiving inaccurate doses.

The shortage of the three medications, which is being tracked by the FDA, became critical last year as a result of manufacturing problems at Pfizer, which controls at least 60 percent of the market of injectable opioids, said Erin Fox, a drug shortage expert at the University of Utah.

A Pfizer spokesman, Steve Danehy, said its shortage started in June 2017 when the company cut back production while upgrading its plant in McPherson, Kan. The company is not currently distributing prefilled syringes "to ensure patient safety," it said, because of problems with a third-party supplier it declined to name.

That followed a February 2017 report by the U.S. Food and Drug Administration that found significant violations at the McPherson plant. The agency cited "visible particulates" floating in the liquid medications and a "significant loss of control in your manufacturing process (that) represents a severe risk of harm to patients." Pfizer said, however, that the FDA report wasn't the impetus for the factory upgrades.

Other liquid-opioid manufacturers, including West-Ward Pharmaceuticals and Fresenius Kabi, are deluged with back orders, Fox said. Importing these heavily regulated narcotics from other countries is unprecedented and unlikely, she added, in part because it would require federal approval.

At the same time, in an attempt to reduce the misuse of opioid painkillers, the Drug Enforcement Administration called for a 25 percent reduction of all opioid manufacturing last year, and an additional 20 percent this year.

"DEA must balance the production of what is needed for legitimate use against the production of an excessive amount of these potentially harmful substances," the agency said in August.

When the coalition of health groups penned its letter to the DEA last month, it asked the agency to loosen the restrictions for liquid opioids to ease the strain on hospitals.

The shortages are not being felt evenly across all hospitals. Dr. Melissa Dillmon, medical oncologist at the Harbin Clinic in Rome, Ga., said that by shopping around for other suppliers and using pill forms of the painkillers, her cancer patients are getting the pain relief they need.

Dr. Shalini Shah, the head of pain medicine at the University of California, Irvine health system, pulled together a team of 20 people in

January to figure out how to meet patients' needs. The group meets for an hour twice a week.

The group has established workarounds, such as giving tablet forms of the opioids to patients who can swallow, using local anesthetics like nerve blocks and substituting opiates with acetaminophen, ketamine and muscle relaxants.

"We essentially have to ration to patients that are most vulnerable," Shah said.

Two other California hospital systems, Kaiser Permanente and Dignity Health in Sacramento, confirmed they're experiencing shortages, and that staff are being judicious with their supplies and using alternative medications when necessary. (Kaiser Health News, which produces California Healthline, is not affiliated with Kaiser Permanente.)

At Helen Keller Hospital's emergency department in Sheffield, Ala., earlier this month, a 20-year-old showed up with second-degree burns. Dr. Hamad Husainy said he didn't have what he needed to keep her out of pain.

Sometime in January, the hospital ran out of Dilaudid, a drug seven times more potent than morphine, and has been low on other injectable opioids, he said.

Because Husainy's patient was a former opioid user, she had a higher tolerance to the drugs. She needed something strong like Dilaudid to keep her out of pain during a two-hour ride to a burn center, he said.

"It really posed a problem," said Husainy, who was certain she was in pain even after giving her several doses of the less potent morphine. "We did what we could, the best that we could," he said.

Bernell, the St. Louis nurse, said some trauma patients have had to wait 30 minutes before getting pain relief because of the shortages.

"That's too long," said Bernell, a former intensive care nurse who now works in radiology.

Dr. Howie Mell, an emergency physician in Chicago, said his large hospital system, which he declined to name, hasn't had Dilaudid since January. Morphine is being set aside for patients who need surgery, he said, and the facility has about a week's supply of fentanyl.

Mell, who is also a spokesman for the American College of Emergency Physicians, said some emergency departments are considering using nitrous oxide, or "laughing gas," to manage patient pain, he said.

When Mell first heard about the shortage six months ago, he thought a nationwide scarcity of the widely used drugs would force policymakers to "come up with a solution" before it became dire.

"But they didn't," he said.