Infections from tainted steroids ranged in severity: update

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CDC study looked at meningitis, other conditions in 6 hardest-hit states.

(HealthDay)—The tainted steroid injections that caused a deadly meningitis outbreak last year seem to have triggered a broad range of symptoms in patients, according to a new study by the U.S. Centers for Disease Control and Prevention.

Since it began in September 2012, the outbreak of fungal meningitis has sickened 750 people in 20 states, resulting in 64 deaths, based on the latest CDC figures from last month.

The illnesses have all been traced to fungus-contaminated steroid medications that were given in injections to treat back and joint pain. A single company, the Massachusetts-based New England Compounding Center, distributed the drugs.

In the Oct. 24 issue of the *New England Journal of Medicine*, CDC researchers give a fuller account of the illnesses in six U.S. states that were hardest hit by the outbreak.

"This is the first detailed look at the early clinical course of patients involved in this outbreak," said study author Dr. John Jernigan, of the CDC's division of healthcare quality promotion.

Of 328 people who fell ill after having steroid injections near the spine, 81 percent had an infection affecting the central nervous system (CNS)—the brain or spinal cord. That usually meant meningitis, which is an inflammation of the membranes around the spinal cord and brain.

Some people had other types of infections of the central nervous system, either in combination with meningitis or not. Thirty-five people suffered a stroke—believed to be caused by the meningitis, Jernigan said—and strokes were to blame for most of the 26 deaths in these states.

The rest of the patients (19 percent) had infections that stayed localized to the injection site and did not get into the central nervous system—such as infections of the discs between the vertebrae.

Overall, the severity of patients' symptoms ranged from "very mild" to "life-threatening," the CDC team reported.

According to Jernigan, it's not clear why some people's infections did not invade the central nervous system. But nearly all of those non-CNS infections were seen in one state, Michigan. "We don't have an explanation for that," Jernigan said.

Whatever the details of the infections, the bottom line remains the same, according to Dr. Michael Carome of the Washington, D.C.-based watchdog group Public Citizen.

"This was a public health disaster," said Carome, who heads Public Citizen's health research group. "We think the great tragedy is, this was wholly preventable."

The tainted steroids behind the outbreak were made in a process called compounding, where a pharmacist mixes or alters drug ingredients to create a medication that meets particular patients' needs.

According to the U.S. Food and Drug Administration, compounding fills a vital role for people who have special medication needs. If they are allergic to a dye used in an FDA-approved drug, for instance, compounding pharmacies can remove that dye.

The problem, according to Public Citizen and other groups, is that some compounding pharmacies have moved into widespread drug distribution that goes beyond their traditional scope. Compounded drugs are not approved by the FDA, Carome pointed out, and the pharmacies themselves have escaped the FDA scrutiny that drug manufacturers face.

But that's not because the federal agency lacks the authority, Carome said. Oversight of the specialty pharmacies has traditionally fallen to states, but when the companies take on large-scale manufacturing, the FDA should, and needs to, step in, according to Public Citizen and other critics.

"We believe they already have the authority to intervene," Carome said. "Moving forward, we think the FDA needs to be more aggressive in its enforcement."

Since the outbreak, the agency has stepped up its inspections of compounding pharmacies, and there have been a number of injection-product recalls from various pharmacies due to concerns about contamination.

For its part, the New England Compounding Center ceased operations after the start of the fungal meningitis outbreak last fall.

The CDC and state officials estimate that around 14,000 Americans may have gotten steroid injections from the pharmacy. One particular steroid, methylprednisolone acetate, has been linked to the disease outbreak.

As for what the public can do, Carome advised asking questions. If your doctor recommends an injection medication, he said, ask whether it's a compounded product. "If it is," Carome said, "ask why you're getting it, and whether there's an FDA-approved alternative."

At this point, study author Jernigan said, it's "very unlikely" that anyone exposed to steroids from the New England Compounding Center will fall ill. "But we can't say there's no risk," he added.

Jernigan agreed that the outbreak highlights the dire consequences of medication contamination. "Very bad things can happen when people are exposed to contaminated drugs," he said. "We need to take steps to make sure the medication supply is safe."

More information: The U.S. Food and Drug Administration has more about the risks of pharmacy compounding.