Patient Safety

Cardiac complications linked to solution

If your OR uses injectables mixed by an outside company, make sure the contract includes specific requirements for quality assurance monitoring and reporting. That’s the advice of a surgical services director after her hospital discovered that bags of its cardioplegia solution prepared by an outside pharmacy were contaminated. The contaminated solution apparently was the source of respiratory complications in cardiac surgery patients at Mary Washington Hospital in Fredericksburg, Va. One of the patients died, and 2 required long hospital stays. The hospital suspended its cardiac surgery program for 2 weeks in September while it investigated the problem.

The cardioplegia solution and 11 other injectable products were voluntarily recalled Sept 16 by the manufacturer, Central Admixture Pharmacy Services Inc (CAPS), Lanham, Md (www.capspharmacy.com). The products were distributed in Maryland; Delaware; Washington, DC; and Virginia.

The company said gram-negative bacteria were identified in 3 different types of cardioplegia solutions made at its Lanham, Md, plant on 2 separate days. CAPS advised customers immediately to examine their inventory and quarantine products subject to the recall.

The recall applies only to products manufactured at the Lanham, Md, plant. CAPS said none of its other pharmacies in the US are affected.

The hospital investigates
Mary Washington suspended cardiac surgery Sept 9 when 3 patients developed systemic inflammatory response syndrome (SIRS) after coronary artery bypass surgery. The cases occurred within an 8-day period in late August and early September, according to press reports.

Though all patients on cardiopulmonary bypass have some degree of systemic response, most cases are mild, noted Donald Stern, MD, director of the Rappahannock Area Health District, who participated in the investigation. In 1% to 10% of patients, the reaction is severe. “What causes this to manifest in certain patients is not clear,” he says. In this situation, he said it is likely that the cardioplegia exacerbated the inflammatory response.

Cardioplegia solution cultured
The unusual cluster of illnesses prompted an investigation, during which the hospital’s perfusionists began looking at their process. As part of the investigation, they cultured the cardioplegia solution, which yielded the bacteria and endotoxins. The hospital had contracted with CAPS to mix the solution according to the hospital’s specifications.

Initially concerned the solutions might have been contaminated in-house, the hospital called in the Virginia Depart-ment of Health, which in turn called in the Centers for Disease Control and Pre-vention (CDC) and the Food and Drug Administration (FDA). The agencies took unopened bags of the solution from the hospital and performed their own testing, which also found contamination.

The health department and the CDC concluded the cardioplegia solution was the most likely source of the illnesses in that cluster of patients in early September, Dr Stern said. He said the cardioplegia solution was contaminated by 3 types of gram-negative rods and endotoxins. The hospital decided to resume mixing its own cardioplegia solution, as it had before the contract with CAPS. Dr Stern said the health department recommended that the hospital could resume cardiac surgery.

Hospital officials said it was the hospital’s cardiac team, led by surgeon John Armitage, MD, that recognized the problem, identified the possible cause, halted
surgery, and summoned outside help, according to the Sept 23 Free-Lance Star, a local newspaper.

The hospital’s vice president of medical affairs, Thomas Ryan, MD, said: “The FDA and the CDC cultured gram-negative bacteria out of bags that were never opened here. It was impossible for us to get anything into those bags. They took the bags away from us whole.”

**A director’s advice**

Based on the experience, Mary Washington’s director of surgical services, Heather Carelock, RN, MPA, CNOR, advises OR directors to make sure specific requirements for quality monitoring and reporting are included in every contract for admixtures that a facility signs with an outside firm. Specifically, says Carelock, “I would want to see a certain number of cultures on a regular basis, such as every 6 months. I would also have the hospital perform its own quality studies, such as taking cultures on these products quarterly.”

She adds: “I’m proud that we have an environment that supports and encourages staff to ask difficult questions. The investigation started with the perfusionists looking at their practice and the staff nurses looking to their leadership to follow up.” Though the decision to shut down the program and invite in the Department of Health was difficult, she says, “we did what was best for our patients and our community.”