Vapotherm Devices Contaminated With *Ralstonia*

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Vapotherm respiratory gas administration devices are being voluntarily recalled, following federal government reports that 29 hospitals in 16 states found *Ralstonia* organisms colonizing the devices, and cultures from approximately 40 pediatric patients also yielded the bacteria.

The Centers for Disease Control and Prevention and the Food and Drug Administration late last year had advised clinicians to use alternative devices to provide humidified oxygen therapy until the source of contamination has been identified and removed. They also recommended that any patients who have been exposed to the Vapotherm system be monitored for signs and symptoms suggesting infection, including fever, poor feeding, irritability, and changes in hematologic indices.

In addition, "clinicians may want to consider *Ralstonia* species infection in the differential diagnosis of symptomatic patients even if the organism has not been isolated," the FDA said in a public health notification (www.fda.gov/cdrh/safety/122005-vapotherm.html).

In response, the device manufacturer, Vapotherm, announced last month that it would recall and disinfect Vapotherm 2000i and 2000h devices. Units will then be returned to the owners with updated disinfection and usage recommendations.

Contamination of the Vapotherm system was first reported by the CDC and the FDA in October 2005, after a Pennsylvania hospital isolated *Ralstonia* in several patients who had used the device. The Vapotherm system is used "to add moisture to and to warm breathing gases for administration to patients," according to its manufacturer, Vapotherm Inc. (Stevensville, Md.).

Since the October reports, the CDC and FDA have found additional cases of *Ralstonia* contamination. Cultures of unused Vapotherm cartridges at two hospitals yielded *Ralstonia*, but cultures of other unused cartridges from the same lot did not grow the organism.

After the procedures for disinfecting the device that were listed in its original instructions were found to be inadequate, the manufacturer issued new instructions for chloride dioxide disinfection.

However, this method also "may not achieve sustained bacterial control," according to the FDA.

Several alternative devices are listed on the FDA Web site cited above.

Ralstonia, gram-negative bacteria usually found in water and soil and on plants, formerly were included in *Pseudomonas* or *Burkholderia* species and still can be misidentified as such. "Infections caused by *Ralstonia* should be treated on the basis of results of susceptibility testing of the patient's isolate," according to the CDC (MMWR 2005;54:1-2).

"Clinicians who elect to use Vapotherm are encouraged to weigh the risk of potential bacterial contamination of the device against the benefits Vapotherm might provide patients who require humidified oxygen therapy," the CDC said.

For more information about the recall, visit www.vtherm.com/recall. Cases of colonization or infection with *Ralstonia* or related bacteria (gram-negative rods) in patients exposed to Vapotherm should be reported to the manufacturer, to local or state health departments, and to the CDC at 800-893-0485. Adverse events associated with medical devices should be reported to the FDA's MedWatch program at www.fda.gov/Medwatch or by calling 800-332-1088 or faxing 800-332-0178. ■