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Update: Public Health Notification Regarding *Ralstonia* Associated with Vapotherm® Respiratory Gas Administration Devices — United States, 2005

This report updates information previously published regarding contamination of Vapotherm® respiratory gas administration devices (Vapotherm, Inc., Stevensville, Maryland) with *Ralstonia* spp. (*1,2*). The Food and Drug Administration (FDA) has issued an updated Preliminary Public Health Notification, advising health-care providers to use alternative devices until the source of the contamination has been identified.*

CDC continues to receive information regarding *Ralstonia* spp. associated with Vapotherm use. Twenty-nine institutions in 16 states have reported recovery of *Ralstonia* spp. from Vapotherm devices and from approximately 40 pediatric patients. The majority of these cases appear to represent colonization, although one infection has been reported to CDC and other cases remain under investigation. In addition, the recommended disinfecting protocol has reportedly failed to eradicate *Ralstonia* spp. in three separate tests. Based on pulsed field gel electrophoresis analysis, isolates from facilities in six states were determined closely related genetically, a finding that suggests intrinsic contamination of some part of the device. Cultures of unused Vapotherm cartridges performed by two hospitals have yielded *Ralstonia* spp. However, cultures of other unused cartridges from some of the same lots did not grow organisms in testing performed by CDC and the cartridge manufacturer.

The source of contamination and the extent to which biofilm growth might be a contributing factor remain unknown. Although the majority of organisms found in Vapotherm devices by CDC and reporting institutions have been *Ralstonia* spp., other bacteria (e.g., *Burkholderia cepacia, Alcaligenes xylosoxidans, Klebsiella pneumoniae, Proteus mirabilis, and Sphingomonas paucimobilis*) have been recovered from used cartridges or machines. CDC continues to work with the manufacturer and FDA to determine the source of contamination of Vapotherm devices.

Ralstonia spp. are gram-negative bacteria found in the environment, primarily in water, soil, and on plants; occasionally *Ralstonia* spp. are isolated from clinical samples (e.g., respiratory secretions of cystic fibrosis patients). These organisms formerly were included in the genus *Pseudomonas* or *Burkholderia*; however, DNA characterization has revealed *Ralstonia* to be a distinct genus. The organism grows readily on media routinely used by clinical microbiology laboratories (i.e., trypticase soy agar with 5% sheep blood or MacConkey agar) (*3*). When both biochemical tests and automated identification systems are used, *Ralstonia* spp. can be misidentified as *Burkholderia* spp. or, less often, as non-aeruginosa *Pseudomonas* spp. Signs and symptoms of an infection with *Ralstonia* are similar to those observed in other bacterial infections. Infections caused by *Ralstonia* spp. should be treated on the basis of results of susceptibility testing of the patient's isolate.

The current labeling for the Vapotherm device was cleared for marketing on August 18, 2004, with the indication, "to add moisture to and to warm breathing gases for administration to patients." Other devices are marketed for this general indication. FDA and CDC currently recommend use of alternative devices until the source of contamination can be identified. A list of humidifiers can be found in the FDA 510(k) database, by entering "BTT" in the "Product Code" field.† Several heated humidifiers on the list have specifications similar to the Vapotherm device. Humidifiers will require a gas source, connectors, and a patient interface (mask or nasal cannula) to make a complete system for administration of breathing gas.

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. Patients who

* Available at http://www.fda.gov/cdrh/safety/122005-vapotherm.html.

† Food and Drug Administration. 510(k) database. Rockville, MD: Food and Drug Administration. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

have been exposed to Vapotherm should be monitored for signs and symptoms of infection, and clinicians should consider *Ralstonia* spp. infection in the differential diagnosis of exposed, symptomatic patients.

Hospitals should report cases of colonization or infection with *Ralstonia* or related bacteria (gram-negative rods) in patients exposed to Vapotherm directly to the device manufacturer and local or state public health departments and CDC by telephone 800-893-0485. Adverse events associated with medical devices should be reported to MedWatch, FDA's voluntary reporting program at http://www.fda.gov/Medwatch/report.htm; by telephone, 800-FDA-1088; by fax, 800-FDA-0178; or by mail, MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

References

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2. CDC. Update: *Ralstonia* associated with Vapotherm oxygen delivery device—United States, 2005. MMWR 2005;54:1104–5.
3. Gilligan PH, Whittier S. *Burkholderia, Stenotrophomonas, Ralstonia, Brevundimonas, Comamonas and Acidovorax*. In: Murray PR, Baron EJ, Pfaller MA, Tenover FC, Yolker RH, eds. Manual of clinical microbiology. 7th ed. Washington, DC: American Society of Microbiology; 1999:526–38.