

NOSOCOMIAL RALSTONIA PICKETTII COLONIZATION ASSOCIATED WITH INTRINSICALLY CONTAMINATED SALINE SOLUTION

BACKGROUND

Ralstonia pickettii (formerly *Pseudomonas pickettii* or *Burkholderia pickettii*) is a gram-negative, non-lactose-fermenting bacillus that is uncommonly isolated from clinical specimens. This microorganism survives well in aqueous environments and has been associated with numerous outbreaks of nosocomial infection due to contamination of patient care solutions and pseudooutbreaks due to contamination in the laboratory.

During February 1 through April 30, 1998, *Ralstonia pickettii* was cultured from respiratory tract secretions of 19 infants and children in a pediatric hospital in Los Angeles County (Hospital A). Acute Communicable Disease Control and hospital infection control staff collaborated to identify the cause of the outbreak as intrinsically contaminated "sterile" 0.9% sodium chloride solution used for respiratory therapy.

METHODS

A case was defined as any Hospital A patient from whom *R. pickettii* was isolated from any site from February 1 through April 30, 1998 (epidemic period). Cases were identified by a review of microbiology reports. Clinical information was collected by medical record review; respiratory therapy and microbiology specimen processing policies and procedures were reviewed. Opened and unopened samples of selected solutions used for respiratory therapy and laboratory specimen processing were collected for microbiologic analysis. Unopened vials of saline solution used for respiratory therapy also were collected by Food and Drug Administration (FDA) staff for microbiologic analysis in their laboratory. Available case-isolates were identified and typed by conventional methods and by pulsed-field gel electrophoresis (PFGE) in the Los Angeles County Public Health Laboratory (PHL). The plant where the implicated saline solution was manufactured was evaluated by the FDA.

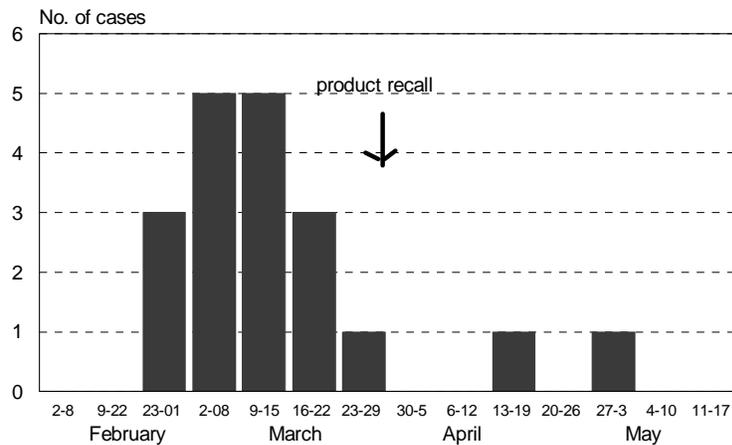
RESULTS

During February 1 through April 30, 1998 (the epidemic period), 46 respiratory specimens from 19 patients in Hospital A were culture positive for *R. pickettii* (Figure 1). During the previous year (pre-epidemic period), only three respiratory specimens from two patients with cystic fibrosis were culture positive for *R. pickettii*. Case-patients ranged in age from 4 days to 17 years (median, 2 months); 9 of 19 (47%) were male. All were hospitalized in an intensive care unit: neonatal ICU (n=9), cardiothoracic ICU (n=5), or pediatric ICU (n=5). All had serious underlying diseases and 18 were intubated and mechanically ventilated; the case-patient who was not mechanically ventilated had a tracheostomy. All

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patients, except one, had endotracheal suctioning using 0.9% sterile sodium chloride solution (Modudose: Kendall, Mansfield, MA) (Hospital A protocol recommends instillation of saline before tracheal suctioning). All case-patients were considered to be colonized since the isolation of *R. pickettii* was not associated with a change in clinical status. Only one case-patient received antimicrobial therapy specifically for *R. pickettii*. Three case-patients died as a result of their underlying diseases. Of 46 cultures positive for *R. pickettii* during the epidemic period, 20 (43%) were collected between March 1 and March 16, 1998. During these two weeks, 28% (20/71) of all respiratory cultures submitted from ICU patients in Hospital A were positive for *R. pickettii*.

**Figure 1. *Ralstonia pickettii* Respiratory Colonization
Hospital A, 1998**



R. pickettii was isolated from one of four lots of unopened 3-ml vials of 0.9% sterile sodium chloride solution (Modudose) in the Public Health and the FDA laboratories. Cultures from an opened bottle of sterile distilled water collected from the bedside of one of the case-patients grew *R. pickettii* as well as *Stenotrophomonas maltophilia*. Available case-isolates (n=9), isolates recovered from unopened vials of Modudose 0.9% sodium chloride, and the isolate from the opened bottle of sterile distilled water were indistinguishable by PFGE. The use of Modudose saline solution was discontinued at the hospital on March 30, 1998. Two additional cases occurred after that date.

DISCUSSION

On confirmation of Modudose contamination, the distributor voluntarily issued a nationwide product recall. Notification of the recall and a summary of the outbreak in Hospital A was published in the *Morbidity and Mortality Weekly Report (MMWR)* on August 17, 1999.¹ Subsequently, three additional hospitals, one each in California, Minnesota, and Louisiana reported clusters of *R. pickettii* associated with the implicated product to the Centers for Disease Control and Prevention (CDC); isolates from these clusters were indistinguishable from the Hospital A outbreak isolates by PFGE performed by CDC.²

The plant where the contaminated saline was manufactured was discovered to be the same plant associated with an outbreak of *R. pickettii* colonization traced to an intrinsically contaminated saline solution in 1983.³ Genomic comparison of isolates from the 1983 and 1998 outbreaks, performed by CDC, showed different banding patterns, suggesting that the outbreaks were not caused by the same strain.

In summary, when an outbreak of *R. pickettii* occurs, contamination of solutions should be suspected. Despite FDA regulations and manufacturers' quality control programs, intrinsic contamination of "sterile" solutions continues to occur. Timely detection by routine hospital-based surveillance, prompt reporting to local public health authorities, and the resulting timely product recall very likely contributed to the limited national scope of this outbreak.

The outbreak strain of *R. pickettii* was also recovered from an open bottle of distilled water at a patient's bedside in Hospital A, but not from an unopened bottle of the same lot from the same manufacturer, suggesting extrinsic contamination. Extrinsic contamination of other products, or failure to remove all of the contaminated product could explain the two additional cases that occurred in Hospital A after the product recall.

REFERENCES

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