AN OUTBREAK OF *ENTEROBACTER CLOACAE* BLOODSTREAM INFECTIONS DUE TO INTRINSICALLY CONTAMINATED SALINE SOLUTION

BACKGROUND

Intrinsic contamination of parenteral solutions is an uncommon cause of nosocomial bloodstream infections. Between November 2 and November 5, 1998, 11 children developed clinical sepsis within 24 hours after receiving care at a hematology-oncology outpatient clinic/day hospital at a local hospital (Hospital A).

METHODS

A case-patient was defined as any child who developed fever and/or chills within 24 hours after receiving care at the Hospital A hematology-oncology clinic/day hospital between November 2 and November 5, 1998. Medical records of all patients seen in the clinic/day hospital during that time were reviewed to look for common exposures; parents of all children receiving hematology/oncology care at Hospital A were contacted to look for additional cases. We observed procedures in the clinic and collected samples of opened and unopened parenteral solutions and medications and swabs of environmental surfaces in the clinic and day hospital treatment rooms. *E. cloacae* isolates were genotyped in the Public Health Laboratory (PHL), using pulsed-field gel electrophoresis (PFGE).

RESULTS

Of the 57 patients reviewed, 11 (19.3%) met the case definition. The median age was 5 years (range 1-15 years). All had underlying hematologic or solid tumor malignancies. Seven (64%) were female. All affected children recovered without sequelae related to the infection. All case-patients had central intravascular catheter access lines that were used during their clinic visit for blood draws (n=11), receipt of chemotherapy or other medications (n=6), or transfusion of blood products (n=3). After access, intravascular catheters were flushed per protocol with 10 ml of sterile 0.9% sodium chloride packaged in pre-filled flush syringes distributed by CAPS (Braun-McGaw, Detroit, Michigan). The entire supply of heparin and normal saline products was removed from the clinic/day hospital on the morning of November 5, pending results of the investigation. *E. cloacae* was isolated from the blood of 10 of 11 case patients and from two unopened 10 ml. pre-filled saline flush syringes. *E. cloacae* isolates from case-patients were indistinguishable by PFGE from *E. cloacae* isolated from the unopened saline syringes. No additional cases were identified at Hospital A after the implicated product was removed from circulation.

The manufacturer, in collaboration with State and Federal Public Health and Food and Drug authorities, issued a nationwide recall of its saline products on November 9, 1998. On November 13, 1998, the Centers for Disease Control and Prevention announced the recall of the contaminated product based on the results of this investigation in the *Morbidity and Mortality Weekly Report (MMWR*;47[44]:959-60). To our knowledge, no cases in other jurisdictions were identified.

CONCLUSIONS

Intrinsic contamination of a "sterile" saline product with *E. cloacae* at some point in the manufacturing or distribution process resulted in this nosocomial outbreak. Prompt recognition by Hospital A clinical and infection control staff, collaboration between local, state and federal Public Health and Food and Drug authorities, along with the manufacturer's cooperation in implementing a timely product recall, were factors that likely limited the scope of this outbreak. This outbreak is a reminder that intrinsic contamination of parenteral products, while uncommon, continues to occur and highlights the need for continued attention to quality control, particularly as emphasis on cost containment intensifies.