Medical News

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FDA Cites Medical-Device Reprocessor for Violations

A Phoenix, Arizona, medical-device reprocessor that contracts with hospitals has been warned by the FDA that it must correct serious problems in its decontamination operation at its Florida facility or face immediate regulatory action by the agency. In a warning letter, the FDA cited Alliance Medical Corporation for serious violations of the Federal Food, Drug and Cosmetic Act in its reprocessing of medical devices. The violations were found by the FDA during an inspection of the Apopka site in mid-November.

Alliance Medical has promised to correct the problems. The FDA will evaluate the adequacy of the firm's corrective action in a follow-up inspection. Alliance Medical contracts with hospitals to clean and reprocess medical devices and then returns the devices to the hospitals for use in surgery and other procedures. Alliance arranges for the used devices, stored in special containers, to be picked up from hospitals and shipped to their initial decontamination room at a waste-management facility in Apopka. After the devices are sorted and cleaned, they are sent to Alliance's Phoenix facility for further reprocessing before they are released for shipment to hospitals.

The FDA's recent inspection of the Apopka operation revealed serious violations involving good manufacturing practices and quality control and raised questions about the training of the workers, who were unfamiliar with quality control procedures. The violations included failure to implement a quality policy, maintain device history records, take corrective and preventive action, and adequately train personnel. The FDA has shared the findings from its inspection with OSHA.

FROM: FDA Press Release. FDA Cites Medical Device Reprocessor for Violations, December 27, 1999. http://www.fda.gov.

Supine Position Risk Factor for Ventilator-Associated Pneumonia

Pneumonia is the most frequent nosocomial infection among ICU patients. The incidence of nosocomial pneumonia in medical and surgical ICUs has been reported to range from 12.8 to 17.6 per 1,000 ventilator days. Although the semirecumbent position has been strongly recommended by the CDC, the benefit for prevention of nosocomial pneumonia has never been proven in a randomized clinical trial.

Dr. Krakulovic and colleagues from the University of Barcelona Hospital, Barcelona, Spain, recently investigated the frequency of nosocomial pneumonia in intubated and mechanically ventilated patients randomly assigned to either supine or semirecumbent body positions.

In this study, 86 intubated and mechanically ventilated patients of one medical and one respiratory ICU at a tertiary-care university hospital were randomly assigned to semirecumbent (n=39) or supine (n=47) body position. The frequency of clinically suspected and microbiologically confirmed nosocomial pneumonia (clinical plus quantitative bacteriological criteria) was assessed in both groups. Body position was analyzed together with known risk factors for nosocomial pneumonia.

The frequency of clinically suspected nosocomial pneumonia was lower in the semirecumbent group than in the supine group (3/39 [8%] vs 16/47 [34%]). This was also true for microbiologically confirmed pneumonia (semirecumbent 2/39 [5%] vs supine 11/47 [23%]). Supine body position and enteral nutrition were independent risk factors for nosocomial pneumonia, and the frequency was highest for patients receiving enteral nutrition in the supine body position (14/28, 50%). Mechanical ventilation for 7 days or more and a Glasgow Coma Scale score of less than 9 were additional risk factors.

The authors concluded that their findings confirm that the semirecumbent body position reduces frequency and risk of nosocomial pneumonia, especially in patients who receive enteral nutrition. The risk of nosocomial pneumonia is increased by long-duration mechanical ventilation and decreased consciousness.

FROM: Krakulovic MB, Torres A, Bauer TT, Nicolas J, Nogue S, Ferrer M. Supine body position as a risk factor for nosocomial pneumonia in mechanically ventilated patients: a randomised trial. *Lancet* 1999;354:1851-1858.

Clostridium difficile Epidemic

Since its etiologic role in pseudomembranous colitis was discovered 21 years ago, *Clostridium difficile* has been recognized as a major nosocomial pathogen throughout the world. A wide variety of strains are capable of causing disease, and outbreaks or epidemics of *C difficile*-associated diarrhea are often linked to a single strain; however, the relatedness of these strains among different institutions and geographic regions is not clear.

Dr. S. Johnson and colleagues at the Veterans' Affairs

Medical Center in Chicago, Illinois, reported on the findings of an investigation of the role of resistance genes and clindamycin use associated with an epidemic of *C difficile* in four hospitals in the United States between 1989 and 1992.

Case-control studies were performed at three of the four hospitals to assess the relation of the use of clindamycin to *C difficile*-associated diarrhea. All isolates of the epidemic strain and representative isolates of other strains identified during each outbreak were tested for susceptibility to clindamycin. Chromosomal DNA from these representative isolates was also analyzed by dot blot hybridization and amplification with the polymerase chain reaction (PCR) with the use of probes and primers from a previously described determinant of erythromycin resistance—the erythromycin ribosomal methylase B (ermB) gene—found in *Clostridium perfringens* and *C difficile.*

The use of clindamyin was found to be significantly increased among patients with diarrhea due to the epidemic strain of *C difficile,* as compared with patients whose diarrhea was due to nonepidemic strains. Exposure to other types of antibiotics or hospitalization in a surgical ward was not significantly associated with the risk of *C difficile*-associated diarrhea due to the epidemic strain. All epidemic-strain isolates were highly resistant to clindamycin (minimal inhibitory concentration, >256 μg/mL). DNA hybridization and PCR analysis showed that all these isolates had an ermB gene, which encodes a 23S ribosomal RNA methylase that mediates resistance to macrolide, lincosamide, and streptogramin antibiotics. Only 15% of the nonepidemic strains were resistant to clindamycin.

The investigators concluded that a strain of *C difficile* that is highly resistant to clindamycin was responsible for the outbreaks of diarrhea in four hospitals in different states. The use of clindamycin is a specific risk factor for diarrhea due to this strain. Resistance to clindamycin further increases the risk of *C difficile*-associated diarrhea, an established complication of antimicrobial use.

FROM: Johnson S, Samore MH, Farrow KA, Killgore GE, Tenover FC, Lyras D, et al. Epidemics of diarrea caused by a clindamycin-resistant strain of *Clostridium difficile* in four hospitals. *N Engl J Med* 1999;341:645-651.

TB Transmission to Embalmer

The risk of acquiring TB varies according to occupation and is high among funeral home workers. Embalmers are at particularly high risk for reactivity on tuberculin skin testing. The increased risk may be due to exposure to *Mycobacterium tuberculosis* during the embalming process, which involves the aspiration of blood and other body fluids from the cadaver, resulting in the generation of potentially infectious aerosols. However, the transmission of *M tuberculosis* from a cadaver to an embalmer, with the subsequent development of active TB, has not been described.

Sterling and colleagues recently reported transmission of TB from a cadaver (case 1) to an embalmer (case 2) confirmed by DNA fingerprinting by restriction fragment-length polymorphism (RFLP) analysis. The only known contact between the cases occurred at the time of embalming.

Case 1 was a 35-year-old man with AIDS who was hospitalized with fever and a cough. A chest radiograph showed infiltrates in the upper and middle portions of both lungs. A sputum sample was obtained for staining for acid-fast bacteria and culture, but the patient died on the day it was obtained. After the patient's death, the acid-fast smear was reported to be positive, and the culture grew *M tuberculosis.* Blood cultures for mycobacteria were not performed.

Case 2 was a 45-year-old man who worked as an embalmer. A test for antibodies to HIV, performed 2 years before presentation, had reportedly been negative. The patient did not have a history of TB and had not undergone tuberculin skin testing. He had been an embalmer for 15 years and could not remember ever embalming a cadaver that he knew had active TB. He performed at least 300 embalmings per year, always wearing gloves and usually wearing a mask. He had no history of percutaneous exposure to blood or of chronic skin lesions. He was diagnosed with pulmonary TB 31 months after exposure to case 1.

These cases were identified as part of an ongoing study of the epidemiology of TB. DNA fingerprinting was performed with *M tuberculosis* isolates from more than 90% of patients in Baltimore, Maryland, who had received a diagnosis of TB, confirmed by culture, between January 1994 and December 1998. Cases 1 and 2 were part of this study. RFLP analysis showed that the *M tuberculosis* isolates from patient 1 and patient 2 had an identical 10-band fingerprint pattern.

FROM: Sterling TR, Pope DS, Bishai WR, Harrington S, Gershon RR, Chaisson RE. Transmission of *Mycobacterium tuberculosis* from a cadaver to an embalmer. *N Engl J Med* 2000;342:246-251.

Epidemic Transmission of HIV in Egyptian Renal Dialysis Centers

In 1993 an epidemic of HIV infection occurred among 39 patients at two renal dialysis centers in Egypt. El Sayad and coinvestigators from the National AIDS Programme, Ministry of Health and Population, Cairo, Egypt, and the CDC's Hospital Infections Program investigated the outbreak. The hemodialysis centers, private center A (PCA) and university center A (UCA), were visited, HIV-infected patients were interviewed, seroconversion rates at UCA were calculated, and relatedness of HIV strains was determined by sequence analysis; 34 (62%) of 55 patients from UCA and 5 (42%) of 12 patients from PCA were HIV-infected. The HIV seroconversion risk at UCA varied significantly with day and shift of dialysis session.

Practices that resulted in sharing of syringes among patients were observed at both centers. Unmarked syringes were reused and stored on shared trays in between use at both centers. No documentation of prescreening HIV tests for patients at the PCA was available, and the dialysis staff at this center had no trained nurses. The analyzed V3 loop sequences of the HIV strain of 12 outbreak patients were >96% related to each other. V3 loop sequences from each of 8