Medical News

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Additional news items in this issue: S aureus *With Reduced Susceptibility to Vancomycin,* page 199; *FDA Holds Open Meeting on Reuse of Single-Use Devices,* page 217; *Epidemic of Pneumonia Associated With Mechanical Ventilation,* page 221; *Person-to-Person Spread of* Aspergillus, page 228.

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

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