Medical News

EDITED BY GINA PUGLIESE, RN, MS; MARTIN S. FAVERO, PHD

A Highly Resistant Strain of VRE Takes Over

Dr. David Pegues and coinvestigators at the Harvard School of Medicine and the Massachusetts General Hospital initiated prospective, laboratory-based surveillance for vancomycin-resistant *Enterococcus* (VRE) among patients at the Massachusetts General Hospital. They report the epidemiological and microbiological findings of the first 169 patients identified with clinical VRE infection. Analysis of surveillance data and pulsed-field gel electrophoresis of DNA from VRE strains facilitated the identification and characterization of a highly resistant clone of *Enterococcus faecium (van*A) that rapidly disseminated throughout the hospital in 1995. The observation that a single strain type was able to emerge among multiple other resistant strains to become the dominant VRE strain in the hospital suggests that this strain may have characteristics that differ from other equally resistant strains of VRE that allow it to persist and spread in the hospital environment. Although the strain proved to be resistant to all antibiotics tested except chloramphenicol, which could explain persistent fecal VRE colonization, the investigators are still in the process of trying to determine other factors, including environmental factors, that might explain how this strain became the dominant VRE strain in the hospital.

FROM: Pegues DA, Pegues CF, Hibberd PL, et al. Emergence and dissemination of a highly vancomycin-resistant *van*A strain of *Enterococcus faecium* at a large teaching hospital. *J Clin Microbiol* 1997;35:1565-1570.

FDA Warns of Improperly Cleaned Devices—Rented or Leased

Dr. Bruce Burlington, director of the FDA's Center for Devices and Radiologic Health, wrote a letter on April 17, 1997, to a number of professional societies and organizations alerting them of the risk of contamination of medical devices that are rented or leased by healthcare facilities. Excerpts from Dr. Burlington's letter are summarized below.

Reusable (nondisposable) medical devices that are rented, leased from third parties, or exchanged with other institutions may not be cleaned properly, disinfected, or sterilized prior to delivery to the healthcare facility. Dr. Burlington's letter pointed out that improper handling of devices between uses can contaminate facilities and expose individuals, including healthcare providers and couriers who come into contact with this equipment, to biohazardous material. Also, the presence of residual organic material on such equipment may compromise the effectiveness of sterilization procedures.

The FDA recommended that healthcare facilities renting or leasing reusable medical devices from a third party should review all rental or leasing contracts, agreements, and other written documents to ensure that the parties responsible for cleaning, disinfecting, or sterilizing the equipment are identified clearly. If the healthcare facility is responsible for cleaning, disinfecting, or sterilizing equipment for reuse, it should ensure that all appropriate personnel are aware of this responsibility and are trained properly and equipped to perform these tasks. If a third party is responsible for cleaning, disinfecting, or sterilizing equipment for reuse, the healthcare facility should review the third party's operating procedures to determine that its facilities, equipment, processes, and personnel are adequate to perform these operations. The healthcare facility should be sure that the third party is familiar with the manufacturer's instructions for cleaning, disinfecting, and sterilizing the device. (The FDA is now recommending that such instructions be provided for newly marketed devices.) If a third party is responsible for cleaning, disinfecting, or sterilizing equipment for reuse, the healthcare facility must ensure that its own personnel are trained properly and equipped to handle, package, and label contaminated equipment for shipment back to the supplier.

In some cases, third-party suppliers also may reprocess or refurbish medical devices between uses. When the contract calls for these services, the healthcare facility should ensure that the supplier is familiar with the device manufacturer's specifications for the product. Healthcare facilities may wish to establish quality-assurance procedures to be sure that reprocessed or refurbished devices fulfill these specifications.

The Center for Devices and Radiological Health is interested in collecting data on adverse events that may have resulted from improperly cleaned, disinfected, or sterilized medical devices and asks that such incidents be reported. Practitioners employed by healthcare facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Practitioners not employed by facilities required to submit such reports can report the incident directly to MedWatch, the FDA's voluntary reporting program. Reports can be submitted by telephone, (800) FDA-1088; fax,(800) FDA-0178; or mail to the FDA (HF-2), 5600 Fishers Ln, Rockville, MD 20857. Direct questions to Nancy Pressly, FDA Office of Surveillance and Biometrics, Center for Devices and Radiological Health, HFZ-510, 1350 Piccard Dr, Rockville, MD 20850; fax, (301) 594-2968; e-mail nap@cdrh.fda.gov.

FROM: Food and Drug Administration. Risk of contamination of reusable medical devices; Washington, DC: FDA; 1997. Letter.