Medical News

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

Additional news items in this issue: *Eradication of MRSA From a Health Center Ward and Nursing Home,* page 334; *Intra-abdominal VRE Infections: The New Threat,* page 346; Serratia *Outbreak From Contaminated Pressure-Monitoring Equipment,* page 356; *New Guidelines for Design and Construction of Hospitals,* page 362; *CDC Issues Infection Control Guidelines for Hemodialysis Centers,* page 369; *Transmission of TB to a Funeral Director During Routine Embalming, page 374; Nosocomial Urinary Tract Infection in Children,* page 397.

FDA: Reuse of Single-Use Devices

The FDA has announced the availability of the draft guidance entitled "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices." This draft guidance document provides premarket guidance to the medical device industry, including third-party and hospital reprocessors, and to the Center for Devices and Radiological Health staff, who are responsible for the premarket evaluation of submissions for reprocessed single-use devices or related enforcement activities. This draft guidance is neither final nor is it in effect at this time.

Submit written comments on the draft guidance by August 30, 2001, to Dockets Management Branch, 5630 Fishers Lane, Room 1061, HFA-305, Rockville, MD, 20852; telephone, 301-827-6860; fax, 301-827-6870. Specify Docket no. 01D-0232. Copies of the draft guidance can be downloaded from http://www.fda.gov/cdrh/ode/guidance/1331.pdf.

In a letter to hospital administrators and risk managers dated April 23, 2001, Dr. David W. Feigal, Jr, Director, of FDA's Center for Devices and Radiological Health indicated FDA will soon begin implementing its new policy of regulating in-hospital reprocessing of single-use medical devices (SUDs) the same way it regulates manufacturers of those devices. Under a plan that became official on August 14, 2000, hospital reprocessors are subject to "non-premarket" and "premarket submission" requirements.

Non-premarket requirements include registration and listing, reporting of device-associated adverse events, device tracking, device corrections and removals, quality system regulation, and proper labeling. Premarket requirements involve demonstrating that devices are safe and effective. The FDA rules do not apply to permanently implantable pacemakers, opened but unused SUDs, healthcare facilities other than hospitals, or hemodialyzers.

The FDA's enforcement deadlines differ for different classes of devices. The agency designates devices as class I, II, or III, for lowest, intermediate, and highest risk (the same classification system as it uses for new devices). One deadline has already passed: February 14, 2001, was the date for submission of premarket approval applications or premarket notifications (510[k]s) for class III SUDs. The next deadline is August 14, 2001, the date for hospital reprocessors to comply with (1) non-premarket requirements for class I, II, and III devices and (2) premarket requirements for a 510(k) submission for any class II device specifically exempted from the requirements. Finally, February 14, 2002, is the deadline for submission of a 510(k) for any class I SUD that is not specifically listed as exempt.

Dr. Feigal indicates that the FDA will begin enforcing the relevant requirements after each of the three deadlines and will take enforcement action if reprocessing continues and the hospital reprocessor has not obtained FDA marketing clearance by 6 months after the deadline. The letter also notes that all SUD hospital reprocessors are subject to inspections of their facilities by FDA investigators, whether or not these devices are subject to the premarket submission requirements under federal law.

FROM: FDA web site: http://www.fda.gov/cdrh/reuse/042301_reuse.html.

HCV Transmission in Dialysis: Role of Understaffing and Prevalence

To assess hepatitis C virus (HCV) incidence rates and identify determinants of infection among hemodialysis patients, a multicenter study was conducted in 58 units in Italy. An initial seroprevalence survey was conducted among 3,492 patients already on hemodialysis therapy as of January 1997 and among an additional 434 patients who began dialysis up to January 1998. HCV antibodies were assessed by third-generation enzyme immunoassays. Patients testing seronegative at baseline were enrolled in a 1-year incidence study with serological follow-up at 6 and 12 months. For patients who seroconverted, an HCV RNA assay was performed on stored baseline samples to confirm new infection. A nested case-control study was subsequently performed to investigate potential risk factors. For each incident case, three controls negative for both HCV antibodies and HCV RNA were randomly selected. At enrollment, HCV seroprevalence was 30.0%. During follow-up, 23 new HCV cases were documented, with a cumulative incidence of 9.5 cases/1,000 patient-years. By logistic-regression analysis, an increased risk for HCV infection emerged for patients attending the dialysis units with a high prevalence of HCV-infected patients at baseline (odds ratio [OR], 4.6) and for those attending units with a low personnel:patient ratio (OR, 5.4). Among extra-dialysis factors, a history of surgical intervention in the previous 6 months (OR, 16.7) significantly increased HCV risk.

These findings suggest that the combination of understaffing and a high level of infected patients in the dialysis setting increases the risk for HCV nosocomial transmission. This likely is related to an increased likelihood for breaks in infection control measures.

FROM: Petrosillo N, Gilli P, Serraino D, Dentico P, Mele A, Ragni P, et al. Prevalence of infected patients and understaffing have a role in hepatitis C virus transmission in dialysis. *Am J Kidney Dis* 2001;37:1004-1010.