

(HCV). September 21, 2001. <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01103.html>.

Reuse of Single-Use Devices: FDA Delays Enforcement

Hospitals that reprocess single-use devices (SUDs) have been given an extension on the date when the FDA will begin enforcing its new reprocessing requirements covering medical-device reporting, tracking, corrections and removals, quality system, and labeling. The extended deadline is August 14, 2002.

Hospitals still are required to register with the FDA and to list the SUDs they plan to reprocess. The FDA shortly will begin inspecting hospitals to assess their compliance with the requirements, but it intends to use those inspections as an opportunity to educate hospitals in the new requirements rather than to enforce actions. The education policy will be in effect until August 14, 2002, "provided that the hospitals are taking steps to correct the violations noted in the inspection and that the violations do not pose a serious public health threat."

FROM: AHA news online; October 11, 2001. <http://www.AHA.org>.

FDA, Center for Devices and Radiological Health. Changes in enforcement of FDA's requirements on reprocessing of single-use devices. <http://www.fda.gov/cdrh/reuse/reuse-letter-092501.html>.

Reuse of Single-Use Devices Not Widespread

Two recent surveys of hospitals found that reuse of single-use devices is not widespread and that the majority of hospitals use third-party reprocessors. Nearly one half (47.8%) of all respondents to an ECRI e-mail survey on single-use device (SUD) reuse reported that they will not allow any reuse in light of last year's FDA regulations. Most respondents did not change their decisions on reuse as the August 14, 2001, enforcement deadline approached; those who did change generally were less willing to reuse devices than they had been previously. Most facilities (86.4%) that plan to continue reuse will do so exclusively through third-party reprocessors.

In a recent study completed by JCAHO for the FDA, hospitals reported reusing medical devices intended for single use at a relatively low rate. Of the 800 hospitals polled, 11% reuse SUDs and only 2% reuse class III devices posing the highest risk to patient safety. The most commonly used class III devices are electrodes used during angioplasty for coronary artery disease. Other reused class III devices include endotracheal tubes and angioplasty catheters. The report shows that 80% of hospitals reusing SUDs rely on commercial vendors registered and listed with the FDA to reprocess these devices. The study was conducted between September 2000 and March 2001 at hospitals of all sizes.

FROM: JCAHOnline. August 2001. <http://www.jcaho.org/tip/jonline0801.html>.

Infection Rates in Low-Birth-Weight Neonates

Zafar and coinvestigators from St Louis conducted a study to determine factors associated with an increasing rate of nosocomial infections (NIs) in infants with very low birth weights. They performed a retrospective review of clinical and NI databases for all infants with birth weights of $\leq 1,500$ g admitted to an academic neonatal intensive care unit between January 1, 1991, and December 31, 1997 ($n=1,184$). Two study periods were compared: 1991 to 1995 and 1996 to 1997. Among the 1,085 infants who survived beyond 48 hours, the proportion who developed NIs increased from 22% to 31% ($P=.001$), and the infection rate increased from 0.5 to 0.8 per 100 patient-days ($P<.001$) during the period from 1996 to 1997. During that same period, the median duration of indwelling vascular access increased from 10 to 16 days ($P<.001$), and the median duration of mechanical ventilation increased from 7 to 12 days ($P<.001$). Although the device-specific rate of bloodstream or respiratory infections did not change, the increase in infections was directly attributable to the increasing proportion of infants who required these devices. In both study periods, the peak incidence of initial infection occurred between 10 and 20 days of age. For the entire sample, proportional hazard models identified birth weight, duration of vascular access, and postnatal corticosteroid exposure as significant contributors to the risk of infection.

The authors concluded that the increasing number of technology-dependent infants was the primary determinant in the increase of NIs. Because these infections occur in a small proportion of infants, understanding the host factors that contribute to this vulnerability is necessary to control NIs in neonatal intensive care units.

FROM: Zafar N, Wallace CM, Kieffer P, Schroeder P, Schootman M, Hamvas A. Improving survival of vulnerable infants increases neonatal intensive care unit nosocomial infection rate. *Arch Pediatr Adolesc Med* 2001;155:1098-1104.

Efficacy of Surveillance for Infection Control in a Surgical Service

Delgado-Rodriguez and colleagues, from the University of Jaen in Spain, conducted a study to assess the efficacy of surveillance of nosocomial infection (NI) in infection control at a service of general surgery. A surveillance study that included 1,483 patients with a prospective identification of NI was carried out. Its results were discussed with the staff, and a program on NI control was implemented. One year after the pre-intervention study, a similar study that included 1,506 patients was done. The main outcome measure was NI. Incidence rates, incidence rate ratios, crude and multiple-risk factor adjusted for by

Poisson regression analysis, and their 95% confidence interval rates were estimated.

The characteristics of the patients enrolled in both studies were compared. After the intervention, the trend was to attend patients with more severe conditions: higher frequency of liver failure, chronic obstructive lung disease, higher proportion of dirty surgical wounds, and higher scores on both Study on the Efficacy of Nosocomial Infection Control (SENIC) and National Nosocomial Infections Surveillance System indices. There were no significant differences in emergency surgery, duration of surgery, age, and gender. After the intervention, unnecessary chemoprophylaxis was reduced drastically, and a significant reduction in preoperative stay was observed. The nosocomial incidence rate fell from 18.4 to 14 per 1,000 patient-days. This reduction yielded an incidence rate ratio of 0.56 (95% confidence interval, 0.43-0.74%), adjusted for several variables (SENIC index, serum creatinine level, serum albumin level, antihistamine H₂ level, surgical wound, body mass index, chemoprophylaxis, and community-acquired infection). Significant reductions in surgical-site infection and urinary tract infection were observed, but the rate of respiratory tract infection remained unchanged.

The authors concluded that surveillance was effective in reducing NI.

FROM: Delgado-Rodriguez M, Gomez-Ortega A, Sillero-Arenas M, Martinez-Gallego G, Medina-Cuadros M, Llorca J. Efficacy of surveillance in nosocomial infection control in a surgical service. *Am J Infect Control* 2001;29:289-294.

Non-Touch Sink Taps Possible Source of Bacteria

Halabi and colleagues recently published a study that pointed out that non-touch fittings are associated with bacterial contamination. Hospitals and other health-care facilities have begun to install touchless water taps to lower water consumption as a cost-saving measure and to prevent healthcare workers from touching the tap, thus promoting hygiene. This study analyzed the bacteriological water quality of 38 non-touch water taps in different settings in a 450-bed secondary-care hospital in Upper Austria. Two different tap types were installed: 23 taps were without temperature selection, and 15 were with temperature selection (cold and warm). A membrane filtration method was used for bacteriologic assays, and the authors screened for both indicator organisms and *Pseudomonas aeruginosa* in 100-mL water samples. In 10 non-touch taps without temperature selection, the authors also screened for *Legionella* species in 500 mL water samples.

Seventy-four percent of the taps without temperature selection and 7% of the taps with temperature selection showed contamination with *P aeruginosa* ($P < .001$). None of the taps showed contamination with indicator organisms. Detailed analysis of the source of contamina-

tion revealed that the magnetic valve and the outlet itself were heavily contaminated, whereas the junction from the central pipe system was free of contamination. All 10 analyzed taps showed contamination with *Legionella* species. The authors concluded that the local contamination of non-touch fittings is a result of the low amount of water that flows through the outlet, the low water pressure, and the column of water, which is "still-standing" and has a temperature of approximately 35°C, thus providing nearly ideal growth conditions for *P aeruginosa*. Additionally, the presence of materials such as rubber and PVC in the fittings enhances the adhesion of *P aeruginosa* and thus the production of biofilms.

FROM: Halabi M, Wiesholzer-Pittl M, Schoberl J, Mittermayer H. Non-touch fittings in hospitals: a possible source of *Pseudomonas aeruginosa* and *Legionella* spp. *J Hosp Infect* 2001;49:117-121.

Epidemiology of VRE in Liver Transplant Patients

Vancomycin-resistant enterococci (VRE) are increasingly important as pathogens in liver transplant patients. To guide control efforts, Bakir and coinvestigators, from the University of Chicago Hospitals, conducted an epidemiological study of the frequency, source, and modes of transmission of VRE at their institution. During September 1998 through August 1999, weekly surveillance cultures were obtained from consenting liver transplant patients and from environmental surfaces in their rooms. Pooled handwash specimens from personnel also were obtained. Specimens were processed on selective media to detect VRE, and isolates were typed by pulsed-field gel electrophoresis. Information was collected from patient records concerning in-hospital treatment and clinical course.

Serial cultures were obtained during 33 admissions of 29 patients. VRE were detected in initial specimens from 6 admissions, and nosocomial acquisition of VRE occurred in 12 (44%) of the remaining 27 admissions. Seven different strain types of VRE were detected. The initial site of acquisition was stool in all cases; bile became culture-positive in only 2 patients. Overall, 16 (55%) of the 29 patients became colonized, usually after transplantation. VRE were detected in environmental cultures during 10 admissions and in 2 of 21 pooled hand washes. No statistically significant differences in clinical status or treatment were found when colonized patients were compared to non-colonized controls. The only VRE infection resulted from a choledochojunostomy anastomotic leak.

The authors concluded that alimentary tract colonization by VRE occurred commonly in liver transplant patients, probably by cross-transmission. The clinical consequences were modest in the patients studied, but colonized transplant patients provide a substantial reservoir for continued VRE transmission in hospitals.

FROM: Bakir M, Bova JL, Newell KA, Millis JM, Buell JF, Arnow PM. Epidemiology and clinical conse-