MEDICAL DEVICE REPORTING

User Facility Reporting

Issue No. 29 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Winter 1999

REUSE OF SUDs SINGLE-USE DEVICES*

The practice of reusing medical devices that are labeled or intended for one time use began in hospitals in the late 1970s. Before then, most medical devices were considered to be "reusable." They were usually made from glass, rubber, or metal and reprocessing usually involved wiping, dipping, and soaking in disinfectants. Original equipment manufacturers (OEMs) began to sell "single-use" devices (SUDs) as a result of market demand for disposable equipment, the development of new plastics, and the use of ethylene oxide sterilization. Hospitals began to see products labeled as "single-use only" that were similar to devices that had previously been or were being sold as "reusable."

The practice of reprocessing SUDs increased when hospitals found that reuse was not only a cost-saving measure but reduced medical waste. Hospitals then started reprocessing more complex products such as cardiac catheters and anesthesia breathing circuits. Since reprocessing these types of devices requires more complex decontamination and sterilization procedures, an industry of third party reprocessors evolved to meet the needs of the hospitals. The increase in the types of SUDs being reprocessed and the expanded use of third party reprocessors have heightened concerns for patient safety and equitable regulation of OEMs and reprocessing firms.

FDA has developed a list of frequently reprocessed SUDs that range from technologically simple to complex devices. Examples include:

- Surgical saw blades
- Surgical drills
- Laparoscopy scissors
- Orthodontic (metal) braces
- Electrophysiology catheters
- Electrosurgical electrodes and pencils
- Respiratory therapy and anesthesia breathing circuits
- Endotracheal tubes
- Balloon angioplasty (PTCA) catheters
- Biopsy forceps

Continued on page 2

CROSS-CONTAMINATION OF HEMODIALYSIS MACHINES: AN UNEXPECTED RISK

By Marie H. Reid, R.N., B.S.N.

Staff noticed fluctuations of the fluid levels in the arterial drip chambers of the dialyzers, indicating rapid and frequent changes in the bloodline pressures and/or wetted external transducer protectors (TP). The dialysis center notified ECRI which then contacted the Food and Drug Administration (FDA). Because of patient safety concerns, FDA issued a safety alert titled "Potential Cross-Contamination Linked to Hemodialysis Treatment" (May 1999; http://www.fda.gov/cdrh/safety/althin.html) to notify the hemodialysis community of the potential for blood contamination.

What went wrong?

Investigators found that when blood fluid levels fluctuate within the arterial/venous chambers of a blood tubing set, blood crosses the TP causing "strike-through" (wetted barrier) of the TP device. This crossover can lead to blood contamination of the internal pressure tubing set and pressure sensing port, as evidenced upon device inspection by dried blood in the tubing. When wetted, TPs lose their ability to correctly transmit pressure changes through to the sophisticated monitors/alarms within the hemodialysis system.

TPs can prevent the transmission of certain blood-borne pathogens between patients. If an internal TP becomes contaminated, it may not be readily apparent to

Continued on page 3

In This Issues:

REUSE - *From page 1*

The list varies in type of device, material, risk of use, and severity of clinical conditions of use. Some devices have features such as long narrow lumens, fragile plastic components, and unsealed electronic controls that make cleaning difficult. Other devices on the list, such as drill bits, are less complex and are relatively easy to clean.

Reports of Patient Injuries

FDA reviewed its Medical Device Reporting (MDR) database and found that between August 19, 1996 and December 7, 1999, manufacturers had submitted 245 adverse-event reports that were associated with the reuse of SUDs (7 deaths, 72 injuries, 147 malfunctions, and 19 reports classified as "other"). The reports listed 70 different types of products, but FDA could discern no pattern of failures with reused SUDs that differs from those observed with the initial use of SUDs. The MDR reports, however, do not allow an accurate assessment of the failure rates, since device failures in general are under reported. Also, infections that may have resulted from improperly reprocessed SUDs would be hard to trace back to the reused devices.

Research Findings

FDA continues to explore safety and effectiveness issues with the reprocessing of SUDs. Its researchers are studying the difficulty of cleaning SUDs, the effect of sterilization on materials, the efficacy of resterilization, and alteration in performance criteria. FDA scientists have examined SUDs after one time use, compared them to devices that had not been used, and simulated reuse in laboratory studies. Some of the factors examined are loss of elasticity in inflatable balloons, persistence of blood and biofilms, loss of original lubricants, the effect on catheter threading, and crystallization of liquid x-ray contrast materials. The research shows that the performance of some products is degraded by biofilms and repeated use. More research by industry, academia, and FDA is needed to address the issues of reuse and to develop consensus standards for reprocessing practices.

FDA's Current Policy

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that a medical device be safe, effective, and manufactured in accordance with Good Manufacturing Practices (GMPs). If a SUD is prepared for reuse by cleaning, repairing or refurbishing, it is being remanufactured. Although the Act provides controls for reprocessed devices, FDA has not regulated OEMs, third party reprocessors, and hospitals that reprocess devices in the same manner.

Original Equipment Manufacturers (OEMs). OEMs are subject to all the requirements of the FD&C Act including registration and listing, premarket notification [510(k)], premarket approval (PMA), submission of adverse event reports under MDR, labeling, corrections and removals, and tracking. FDA has enforced all of these requirements with respect to OEMs.

Third Party Reprocessors. Third party reprocessors are subject to the same regulatory requirements as OEMs with the exception of requiring premarket submissions. FDA has issued Warning Letters to third party reprocessors for various violations.

Hospitals. According to FDA's Compliance Policy Guide (Section 300.500 Reuse of Medical Disposable Devices, CPG 7124.16) hospitals that reprocess SUDs assume full responsibility and liability for their actions. They should ensure that the reprocessed SUDs are adequately cleaned and sterilized and that the device's safety, effectiveness, and quality are maintained. Currently, FDA provides no direct oversight or routine enforcement for in-hospital reprocessing. However, if a serious adverse event involving a reprocessed device were to occur, FDA would conduct an investigation and take appropriate action as needed.

FDA's Proposed Strategy on Reuse of SUDs

On February 8, 2000, FDA released for public comment the following two documents on the reuse of SUDs:

- Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (http://www.fda.gov/cdrh/reuse/1156.pdf)

- Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (http://www.fda.gov/cdrh/reuse/1029.pdf)

The first document describes a proposed risk categorization scheme for reprocessed SUDs; the second document describes the agency's priorities for enforcing various regulatory requirements. The public has until April 11, 2000, to submit comments to FDA (Dockets Management Branch, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 208520. The proposed reuse policies do not apply to SUDs that have been opened but not used in patients.

FDA believes the regulatory controls over reprocessed SUDs should be commensurate with the risk they pose to patients. The agency is seeking input on the development of a device categorization system based on the public health risk of reprocessing and reusing SUDs. FDA is proposing a three-tiered categorization of "low risk", "moderate risk", and "high risk." The risk category would depend on such factors as the complexity of the procedures needed to reprocess the device, the risk of infection from reusing the reprocessed device, any risk of performance

Continued on page 3

REUSE - *From page 2*

failure because of reprocessing, and the scientific information available on reprocessing the specific device.

For a SUD in the "high risk" category (i.e., devices that may pose a significant public health risk to patients and users after reprocessing), FDA is considering enforcing, within 6 months of issuance of the final agency guidance, all of the agency's regulatory requirements, including premarket applications. Under this approach, reprocessed devices in the "high risk" category would be removed from the market within a relatively short time if reprocessors and hospitals did not comply with the applicable premarket requirements.

For "moderate risk" SUDs, FDA is considering actively enforcing the premarket approval and notification requirements to ensure that the reprocessed device remains as safe and effective as the original product. The agency is considering allowing reprocessors to make declarations of conformity to recognized consensus standards as a means of complying with premarket requirements for these products. FDA believes that the premarket requirements for "moderate risk" SUDs will be actively enforced within 12 months of issuance of the final guidance. This would allow time to develop the necessary standards and for reprocessors to collect data needed to document the safety, effectiveness, and performance of the reprocessed SUD. The agency is seeking opinions on the kind of data necessary to determine safety and effectiveness of SUDs in the "moderate risk" category.

FDA anticipates that "low risk" SUDs would include those devices that pose little or no potential public health risk to patients or users after reprocessing. The agency believes that devices in this category would be a low priority and would not be subject to all of the premarket submission requirements.

The agency is also considering whether OEMs should provide information in the labels of their SUDs to alert users and reprocessors of the risks or vulnerabilities associated with reprocessing their devices. Full details on the proposed strategy are available on the Internet at http://www.fda.gov/cdrh/reuse.

**This article is based on the testimony of David W. Feigal, Jr., M.D., M.P.H., Director of the Center for Devices and Radiological Health (CDRH), before the Subcommittee on Oversight and Investigations, Committee on Commerce, U.S. House of Representatives, February 10, 2000, and on other FDA documents on reuse of single-use devices.*

CROSS CONTAMINATION - *From page 1*

the staff member using the equipment. Using a new blood tubing set and external TP and routine maintenance are not adequate to detect internal machine contamination. FDA's principal concern is the possibility that equipment cross-contamination could permit the transfer of blood-borne pathogens from patient to patient. Using a wetted transducer could expose patients to unnecessary risk. Vigilant observation of the TP performance is crucial. If there is any question of contamination, inspect the machine to assure the integrity of the internal TP.

What precautions can you take?

To minimize the risk of breaching a TP with subsequent contamination of the hemodialysis machine:

- always use an external TP and pressure alarm according to the manufacturer's instructions.
- watch for fluctuations of the blood drip chamber level and be alert for blood line pressure alarms.
- immediately replace the external TP if it becomes wetted. After installation, inspect the TP. If fluid is visible on the side of the TP that faces the machine, have qualified personnel open the machine and check for contamination (blood) after the treatment is completed.
- have qualified personnel inspect all hemodialysis machines, including the internal pressure tubing set and pressure sensing port for evidence of any blood contamination.
- if contamination has occurred, take the machine out of service and disinfect before further use.

Careful attention to the safe use of TPs can prevent cross-contamination of blood-borne pathogens. Report problems to FDA's MedWatch program to help identify and address device-related public health issues:

- by telephone, to 1-800-FDA-1088.
- by FAX, send Form 3500 to 1-800-FDA-0178.
- by mail, send Form 3500 to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857-9787.
- electronically, to http://www.fda.gov/medwatch/index.html.

User facilities are required to report any device-related deaths to both FDA and the device manufacturer and any serious injuries to the manufacturer. Use the mandatory MedWatch Reporting Form 3500A.

Marie H. Reid, R.N., B.S.N., is a Senior Nurse Consultant in CDRH's Office of Surveillance and Biometrics.

To get a copy of the May 1999 FDA Safety Alert "Potential Cross-Contamination Linked to Hemodialysis Treatment" go to http://www.fda.gov/cdrh/safety/althin.html

WORKING GROUP FORMED TO ADDRESS THE PROBLEM OF PATIENT ENTRAPMENT IN HOSPITAL BEDS

By Mary L. Pijar, B.A., Jay Rachlin, M.S., and Joan F. Todd, B.S.N. , R.N., M.S.

In August 1995, the Food and Drug Administration (FDA) issued a safety alert titled, "Entrapment with Hospital Bed Side Rails" (http://www.fda.gov/cdrh/bedrails.html) in response to numerous adverse event reports of patient injuries and deaths due to entrapment in hospital beds. Often, it was reported that the patients were attempting to leave their beds and became trapped by the raised side rails. Other times, the patient simply turned over in the bed, became trapped between the mattress and bed frame, and strangled to death. In addition to the safety alert, FDA's Center for Devices and Radiological Health (CDRH) met with the industry and discussed alternative designs based on how the side rail would be used by the caregiver.

The problem continued, particularly entrapment of vulnerable patients who are often elderly, frail, of low body weight, and/or disoriented. Consequently, in May 1998, FDA met with the industry, and all agreed the problem was multi-factorial and needed to be addressed by the various interest groups involved. Possible solutions would involve not only design and safety issues but also regulatory and nursing practice issues. To this end, FDA organized a two-day workshop in April 1999, with representatives from the relevant groups. The goal of the workshop was to provide a forum to identify the reasons for entrapment and the persons at high risk for entrapment, as well as to discuss ways for reducing hazards.

April 1999 Workshop

Representatives from manufacturers of hospital beds, healthcare organizations, medical research institutions, patient advocacy groups, and government agencies met to discuss the safety issues of hospital beds for vulnerable hospital patients, residents of long-term care facilities, and patients receiving home care. Formal presentations were given during the morning sessions. In the afternoon sessions, participants informally discussed the issues from the perspective of bed design, existing government regulations, and patient protocol and safety.

Formation of Issue Groups

So much information surfaced at the April workshop that it was obvious some structure was necessary before participants could tackle the problem. As a result, seven issue areas were formed. Issue leaders and volunteers from the various interest groups agreed to work on the following issues.

- Issue 1. Encourage consistency among the regulations and guidelines of the various regulatory bodies that affect manufacturers and the use of hospital bed rails in acute care facilities, long-term care facilities, and home healthcare settings.
- Issue 2. Establish universal standards of care for the use of hospital bed rails based on clinical assessment of individual patient and resident needs.
- Issue 3. Establish evidence-based design guidance. Determine the desired physical standards and specifications for bed systems (frame, mattress, and rail combinations) from a safety standpoint.
- Issue 4. Evaluate guidance for new designs of hospital bed-rail systems in the clinical environment.
- Issue 5. Legacy Equipment:
  a. Identify hazardous older (i.e., "legacy") equipment.
  b. Create suitable and affordable options for continued use of legacy equipment, where feasible.
- Issue 6. Enhance scientific knowledge to improve the clinical effectiveness and safety of bed systems.
- Issue 7. Create uniform educational outreach programs about the safety of bed systems for healthcare professionals, industry, and lay persons.

Future Activity

Since last April's meeting, the seven issue groups have been gathering data, holding telephone conferences, performing surveys, and looking into current nursing practice. A second two-day meeting was recently held in Florida on February 24th and 25th, and each issue group reported its progress and presented its recommendations. Watch for a report of the February 2000 meeting in the Spring issue of the Bulletin.

Mary L. Pijar is a public health advisor in the Center's Office of Health and Industry Programs/Division of Device User Program and Systems Analysis (DDUPSA) and Jay Rachlin is the Associate Director of DDUPSA. Joan Todd is a nurse consultant in the Office of Surveillance and Biometrics/Division of Post Market Surveillance.

AAMI 2000 CONFERENCE & EXPO TO FEATURE SESSIONS ON FDA REGULATION OF MEDICAL DEVICES

The annual conference of the Association for the Advancement of Medical Instrumentation (AAMI) will be held June 3-7, 2000, in San Jose, California. The program includes sessions on how FDA's regulation of medical devices affects their design, servicing, and reliability. Back by popular demand will be such topics as accident investigation, accident case studies, and FDA's new approach to servicers and reprocessors (see article on reuse of single-use devices (SUDs) on page 1 of the *Bulletin*).

On June 6, FDA staff members from the Offices of Complicance and Device Evaluation will hold a one day training session on reuse. The FDA staff will review the two draft guidance documents on categorizing the risks of reprocessed SUDs and enforcement priorities and will discuss final FDA reuse policy. The anticipated target audience will be risk managment, central services, hospital administration and infection control personnel.

For additional information about the conference and to register, contact AAMI at 3330 Washington Blvd., Suite 400, Arlington, VA 22201-4598 or call 1-800-332-2264, extension 260. You may also register online at http://www.aami.org.

Coming in the SPRING

- Pulmonary artery rupture associated with pulmonary artery catheters
- Ineffective pacing and the nurse's role in monitoring
- Report of the February 2000 meeting of working group on problems of patient entrapment in hospital beds
- Full field digital mammography approved for use in MQSA-certified facilities

User Facility Reporting Bulletin

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997. The *Bulletin's* contents may be freely reproduced. Comments should be sent to the Editor.

Editor: Nancy Lowe
Asst. Editor: Mary Ann Wollerton
Design: Edie Seligson

Department of Health and Human Services • Public Health Service • Food and Drug Administration
Center for Devices and Radiological Health, HFZ-230 • Rockville, MD 20857
FAX: (301) 594-0067 • e-mail: nsl@cdrh.fda.gov