MEDICAL DEVICE REPORTING

User Facility Reporting

Issue No. 30 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Spring 2000

Workshop Held on Hospital Beds and Vulnerable Patients

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

On February 24-25, representatives from the Federal government, medical bed industry, national health care associations, and consumer advocacy groups met in Stuart, Florida, for a second meeting of the Hospital Beds and the Vulnerable Patient Workgroup. The National Patient Safety Foundation hosted the Florida meeting that addressed concerns related to patient entrapment in medical bed rails.

The key objectives of the workshop were to identify reasons for entrapment, identify those persons at high risk of entrapment, and discuss methods for reducing hazards. As the workshop progressed, the topic areas were reconfigured to reflect the most important issues. They are:

- reconciliation of regulatory definitions and requirements related to hospital beds;
- development of a new universal standard of care for the use of bed rails;
- assessment of "legacy" (older) equipment now in use and creation of suitable options for continued use of this equipment;
- development of new design guidance to improve safety in the bed environment and an evaluation of this guidance;
- enhancement of scientific knowledge on the bed environment; and
- outreach efforts designed to focus on improvement in patients safety concerning beds and bed rails.

The workshop consisted of presentations and discussion of the six issue areas. Each issue group had made substantial progress in the 10 months since the first meeting in Washington, D.C.

Partners in this effort are the Food and Drug Administration, Health Care Finance Administration, manufacturers of medical beds, Joint Commission on the Accreditation of Healthcare Organizations, American Health Care Association, American Hospital Association, American Nurses Association, American Medical Directors; National Association for Home Care; American Society for Healthcare Risk Management; American Association of Homes and Services for the Aging, National Citizens' Coalition for Nursing Home Reform, Untie the Elderly, U.S. Veterans Affairs Hospitals, and ECRI.

Meeting Highlights

Latest Research

The workshop began with a report on the latest medical research of Dr. Richard Neufeld and Joan Dunbar from New York's Jewish Home and Hospital. Dr. Neufeld presented results of his current research topic, "Bed-related Incidents and Injuries Among Nursing Home Residents and Staff." He found that residents using the study bed had significantly more bed-related incidents, but only one-third as many serious injuries requiring medical attention. Also, staff had significantly fewer and less serious injuries when working with the study bed compared to the control bed. The study bed was designed with smaller rails specifically developed for use in nursing homes.

Continued on page 2

In This Issues:

Conference Held on Hospital Beds and Vulnerable Patients.....1
Pacing Your Patients 3
MEDSUN - Using Facility Reporting for the New Millennium.....3
Full Field Digital Mammography Approved for use in MQSA-Certified Facilities 4
Meeting Calendar - Reuse Discussions 4
Serious Complications Associated with Pulmonary Artery Catheters 5

HOSPITAL BEDS - *From page 1*

Ms. Dunbar presented the findings of her research topic, "Side rails and the Attitudes of Nursing Home Residents, their Families and Staff." The following conclusions were reached from the study.

- Bed rails did not prevent residents from getting out of bed.
- Staff was divided as to whether or not bed rails posed an increased risk to safety and injuries.
- Family members misunderstood the safety of bed rails.

Federal Government Initiatives

In response to requests from providers and survey agencies, the Health Care Finance Administration (HCFA) and the Food and Drug Administration (FDA) are writing a joint memorandum to clarify each agency's position regarding physical restraints and the use of bed rails as a restraint. Within the next few months, the memorandum will be sent to the State Survey and Certification Agencies and health care providers to clarify information related to this topic.

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) joined the workshop by telephone to discuss its position on bed rails as physical restraints. Their definition of physical restraints is consistent with HCFA's definition. The HCFA representatives discussed surveyor inconsistency in the long-term care facilities and HCFA's effort to reduce this variation through enhanced surveyor training. HCFA's reporting requirement for restraint-related deaths and injuries in hospitals and long term care facilities was reviewed.

Veterans Administration Hospitals

The Veterans Affairs (VA) Hospitals discussed its research to increase patient safety. This included:

- assessment of the biomechanics of horizontal and vertical patient transfers with a variety of equipment (wheelchairs, stretchers, beds, lifts, etc.).

Side rail and bed configurations are very important factors in the success of a transfer for both the patient and caregiver.

- a three-year study identifying 12 high-risk tasks which predispose caregivers to injuries. Several of these tasks were related to hospital beds. The VA has redesigned these tasks and is in the process of evaluating the redesigned tasks to improve safety. Bed height and side rail locations are factors.
- development of a National Veterans Administration resource guide on safe patient equipment for VA clinicians and purchasers.
- development of a prototype of a safe patient room of the future that can be adapted to all patient settings.
- method design to evaluate the change in bed rail use. The process of change is compared between units that are supportive and units that are resistive. Interventions that are effective in making those changes are identified.
- creation of an adverse event system for reporting errors in the VA that is more comprehensive and less blame related.

Bed Research

ECRI, a technology assessment firm, designed and sent surveys to about 3200 hospitals, 10,000 long-term care facilities, and 200 manufacturers to identify the types of medical beds, bed rails, and mattresses (bed systems) currently in use in the United States. The survey will provide valuable information that can be applied to new bed designs. Representatives of the Canadian government shared the results of their work with dimensional standards for bed rails.

Universal Standards of Care and Education

The workgroup is developing a standard of care for use of bed rails in hospitals, long term care facilities, and home health settings. This standard of care is based on a clinical assessment of the individual patient's needs. The guidelines include guiding principles, assumptions made, policy considerations, and risk intervention. In addition, an educational strategy is beginning to take shape. This collaborative effort of government, industry, and the health care community has been vital to understanding and creating a safer patient environment. The authors will continue to participate in the Hospital Beds and the Vulnerable Patient Workgroup and to summarize for *Bulletin* readers the results of the issue groups. The next conference is planned for October 2000.

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

Coming in the Summer Issue

- Report on AAMI Reuse Workshop
- Device Tracking of Cardioverter Defibrillators
- Protecting Your Patient's Eyes

Pacing Your Patients*

By Diane Dwyer, R.N., B.S.N.

A patient with third-degree heart block and a heart rate of 32 beats/minute was treated with a transcutaneous pacemaker. When the pacemaker was started, the device sent a continuous pacing "leads off" message. The patient was given atropine and recovered.

What went wrong?

Ineffective pacing can result from a patient's medical condition, improper device handling, or failure of the device or its components. In this case, the device was removed from service and returned to the pacemaker manufacturer for evaluation. Testing revealed that the pacing "leads off" prompt was linked to a failure of the attached pacing cable.

What precautions can you take?

- Know your facility's policy for using transcutaneous pacemakers.
- When monitoring patients with transcutaneous pacemakers, check their condition first and then the equipment including adhesive electrodes, connections, and the unit itself.
- Learn and use standard transcutaneous pad placement sites and alternative sites.
- Prevent ineffective pacing therapy and skin burns by recording when electrodes and pacing pads are replaced and repositioned. Follow the manufacturer's guidelines. The correct placement of electrodes and pads is critical for optimum functioning of the equipment.
- Keep the manufacturer's manual on safety information, routine daily maintenance, training, and trouble shooting in a convenient location. Check for proper functioning of pacers and defibrillators (including cables) during every shift.
- Have a replacement battery and backup device available in case of sudden failure.
- When removing a faulty device, keep the electrodes and cables with the unit for the manufacturer to evaluate.

*Adapted from the March issue of *Nursing 2000*.

Diane Dwyer, R.N., B.S.N., is a nurse consultant in the Center's Office of Surveillance and Biometrics.

MEDSUN - User Facility Reporting for the New Millennium

Suzanne Rich, R.N., B.A.

The Safe Medical Devices Act (SMDA) of 1990 requires that user facilities report incidents that reasonably suggest that a medical device has, or may have, caused or contributed to an adverse event involving a patient death or serious injury. User facilities include hospitals, nursing homes, ambulatory surgical facilities, and outpatient diagnostic and treatment facilities.

SMDA affects over 40,000 user facilities and requires health care professionals to recognize that an adverse event may be device-related and initiate a report through their organization to the manufacturer and/or FDA. The agency has provided training to the user community through the establishment of a network of trainers, but this has proven difficult to sustain over time and has resulted in a current lack of awareness among practicing clinicians.

In an effort to promote awareness and improve the quality of information received from user facility reports, FDA's Center for Devices and Radiological Health (CDRH) began exploring barriers to user facility reporting and developed a pilot study. This occurred just prior to the passage of the Food and Drug Administration Modernization Act (FDAMA) that requires FDA to replace the universal user facility reporting system with one that limits user reporting to a subset of representative user facilities.

The pilot study resulted in the development of a pilot reporting program, the Medical Device Surveillance Network (MEDSUN). The goal is to improve the protection of the health and safety of patients, users, and others by reducing the occurrence of medical device-related adverse events, and, if they do occur, reducing the likelihood that they will be repeated. To accomplish this goal the following objectives serve as cornerstones for pilot development:

- collection of high quality data about adverse medical device events;
- analysis of data to identify newly emerging device problems and changes in device use; and
- timely dissemination of data to healthcare practitioners, industry, and CDRH pre- and post-market programs on emerging device problems that have been identified.

By targeting a cross-section of user facilities that are anticipated to be representative of the total universe of institutions, more complete information will be obtained on reportable adverse events. This will help FDA to rapidly identify hazards associated with medical devices and will enhance FDA's ability to provide timely feedback to the user community on solutions to problems identified through the MEDSUN reporting program.

Suzanne Rich, R.N., B.A., is a supervisory nurse consultant in the Center's Office of Surveillance and Biometrics, Division of Postmarket Surveillance.

Full Field Digital Mammography Approved for Use in MQSA-Certified Facilities*

On January 28, 2000, the Food and Drug Administration (FDA) approved the Senographe 2000D Full Field Digital Mammography (FFDM) system for marketing and immediate use in facilities that are MQSA screen-film certified. Developed by General Electric, this is the first approved full field mammography system that produces digital images using a solid-state receptor, in contrast to analog images currently produced on radiographic film.

"Digital technology may enhance a woman's mammography experience by reducing the need for additional exposures and allowing for easy transfer of images - a real benefit to highly mobile patients," noted John McCrohan, Director of the Division of Mammography Quality and Radiation Programs (DMQRP).

As of January 28, 2000, the Senographe 2000D falls under the jurisdiction of the MQSA final regulations. At the present time, accreditation bodies are developing a process for accrediting FFDM units. Until further FDA notice, FFDM units are exempt from MQSA accreditation requirements.

To use an FFDM system lawfully, a facility must maintain its accreditation status for at least one screen-film system. The facility is subject to an annual on-site MQSA inspection of its FFDM system at the same time its screen-film system(s) is/are inspected. Further, as a prerequisite for the extension of its MQSA certification to include continued use of the FFDM system, the facility must provide FDA with documentation indicating that it:

- follows the quality assurance program and quality control tests, actions limits, and frequencies outlined in the manufacturer's quality control manual;
- employs personnel who meet all applicable requirements, including eight hours of digital-related initial training for all personnel who begin using the digital system after April 28, 1999, the effective date of the MQSA final regulations; and
- provides an FFDM equipment evaluation, performed by a qualified medical physicist. This evaluation must be performed six months before submitting materials to FDA.

After reviewing these materials for assurance of mammography quality, FDA will issue a letter to the facility extending its certificate to include the FFDM unit.

*From *Mammography Matters, 2000;* 7(1):1. Food and Drug Administration, Center for Devices and Radiological Health.

Meeting Calendar - Reuse Discussions

Association for the Advancement of Medical Instrumentation (AAMI)	San Jose, CA	June 3-7
Health Industry Group Purchasing Association (HIGPA)	Las Vegas, NV	June 14-16
Associations of Food and Drug Officials (AFDO)	Burlington, VT	June 20
Association of Professionals in Infection Control (APIC)	Minneapolis, MN	June 22
American Society for Healthcare Risk Management (ASHRM)	New Orleans, LA	November 2-5

Serious Complications Associated with Pulmonary Artery Catheters*

*By: Chih-hsin Liu, R.N., M.S.N., and Caroline C. Webb, R.N., M.S.N., C.C.R.N.**

The purpose of this article is to present the case report review and analysis as well as the adverse event data associated with catheter-related pulmonary artery (PA) rupture as reported to the Food and Drug Administration's (FDA) medical device reporting (MDR) system.

An elderly (82 years old) female was admitted for cardiac surgery and had a pulmonary artery catheter (PAC) placed while in the operating room. After surgery, she was transferred to the surgical intensive care unit for observation. On postoperative day 1, it was noted that the PAC showed a consistent wedge tracing (i.e., the wave-form tracing of pulmonary artery wedge pressure). The catheter was flushed, and the patient was encouraged to cough. There was no change noted in the hemodynamic waveform. The balloon was checked and found to be deflated. The catheter was withdrawn from 55 cm to 50 cm without significant changes in the graphic waveform. The balloon was checked again to be sure that it was deflated and then withdrawn from 50 cm to 45 cm. Immediately after the second repositioning, the patient started coughing and expressing blood-tinged sputum, followed by frank hemoptysis. The patient went into cardiac arrest and died despite aggressive resuscitative measures.(1)

Overview of PAC Use

PACs, also known as Swan-Ganz catheters, were introduced by Drs. Swan and Ganz in the 1970s. PACs provide diagnostic and monitoring hemodynamic information not available from other clinical sources. They are widely used for hemodynamic monitoring in critically ill patients, despite recent controversial risk-benefit issues surrounding their use. About 1.5 million catheters are sold in the United States annually with 30% of PACs used in cardiac surgery, 30% in cardiac catheterization laboratories and coronary care units, 25% in high-risk noncardiac surgery and trauma, and 15% in medical ICUs. Although PACs have been used for more than 25 years, concerns regarding the safety of their use have been raised in several publications.(1, 2, 3, 4) Some large observational studies have associated excessive morbidity and mortality with PAC use.(7)

Complications associated with PACs include PA rupture, cardiac perforation or tamponade, thrombus, and sepsis or infection. PA rupture is the most acute and often fatal complication with a reported incidence between 0.016% and 1.0% (8, 9, 10, 11, 12), and a mortality above 50%.(10, 13) A 1987 autopsy study reported the incidence of catheter-induced PA rupture may be greater than reported, since only 1 in 3 PA ruptures was diagnosed before autopsy.(14) In 90% of reported cases, hemoptysis is the major presentation of PA rupture.(15) Hemoptysis need not be dramatic, but it can be as insidious as blood-tinged or blood-streaked sputum with coughing or suctioning.

Adverse Event Reporting on PACs

When reviewed, FDA's MDR database revealed a total of 714 adverse event reports (death, injury, and malfunction) associated with PAC use received between June 1993 and June 1999. The reported problems associated with death are categorized in Figure 1. Of the 48 deaths, 42 are related to PA rupture (88%). There are also 19 injuries associated with PA rupture. The 61 PA rupture adverse events were analyzed to evaluate risk factors and patient characteristics. Some data such as sex and age in some of the reports are not available for analysis because of incomplete submissions by reporters.

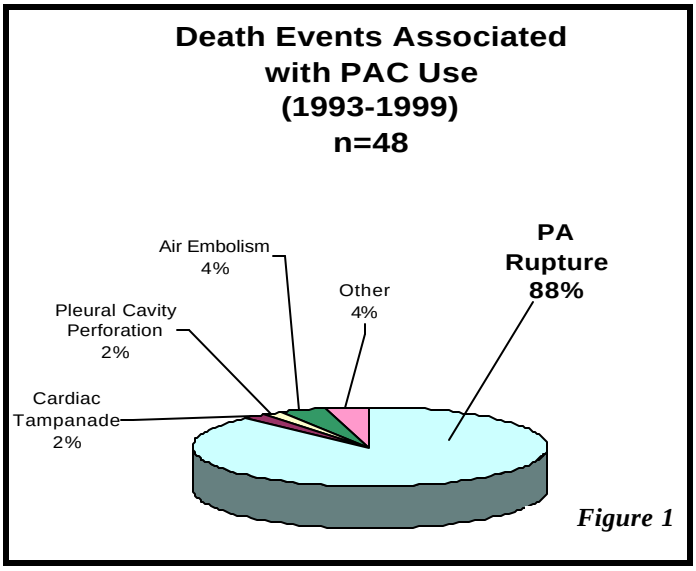

Figure 1

Sex

Of the 61 reported cases of PA rupture, 44 of the patients were women, 10 were men, and 7 were unknown (Figure 2). Women constituted 85% of the deaths (35 of the 41 deaths of known sex), whereas men were only 15% (6 of 41 deaths). In one study, female gender was proposed as a risk factor.(16)

Continued on page 6

PULMONARY ARTERY CATHETERS - *From page 5*

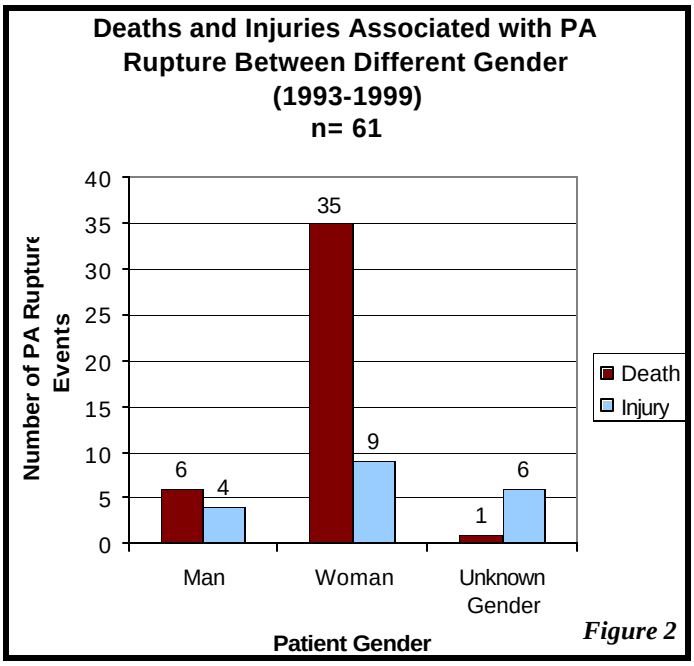

Figure 2

Age

Of the 61 reported PA rupture patients, 50 were 35 to 89 years old with a mean age of 73 ± 10.8 years SD. A disproportionate number of reports occur in women older than 55 years old, and there appears to be especially high incidence of PA rupture in women older than 55 years old (Figure 3).

Event Condition

The majority of reported catheter-related PA ruptures occurred with either difficulties of PAC insertion, migration of the catheter, or catheter manipulation. The most crucial period for the presentation of signs and symptoms of PA rupture is between 30 seconds and 10 minutes after pulmonary artery occlusion pressures (PAOP) have been obtained. It has also been reported that the migration of the catheter, presented graphically as an "overwedge" waveform, followed by catheter manipulation and balloon inflation can also lead to PA rupture.

One study analysis illustrates three mechanisms that can be responsible for PA perforation.

1. The balloon can disrupt the pulmonary artery.
2. The balloon inflation eccentrically can cause the tip to be propelled through the wall.
3. The catheter tip can be advanced too far distally and perforate the PA.(17)

Summary of Analysis

The current analysis of catheter-related PA rupture indicates this complication is likely related to a combination of the following factors:

- sex (female);
- age (postmenopausal);
- presence of cardiovascular disease, pulmonary hypertension, sepsis, or hypothermia;
- surgical history of cardiopulmonary bypass;
- treatment with anticoagulation therapy; and
- multiple insertions of PACs, frequent manipulation, or migration of the catheter

Among these risk factors, the most significant finding was the occurrence of catheter-related PA rupture in postmenopausal female patients. Further study to establish the causal relationship between catheter-related PA rupture and postmenopausal female patients is strongly recommended.

Nursing Care in Preventing Catheter-Induced PA Rupture

- Be aware of the potential for catheter-related PA rupture as a complication.
- Follow the instructions in the labeling of the device.
- Examine the PAC for component defects prior to insertion.(18) Do not use any faulty catheter and report any defects to the manufacturer.
- Conduct a baseline correlation between pulmonary artery diastolic pressure and PAOP for later reference. For the high-risk patient without mitral valve problems, consider using pulmonary artery diastolic pressure instead of PAOP, because PA rupture appears to be associated with balloon inflation.

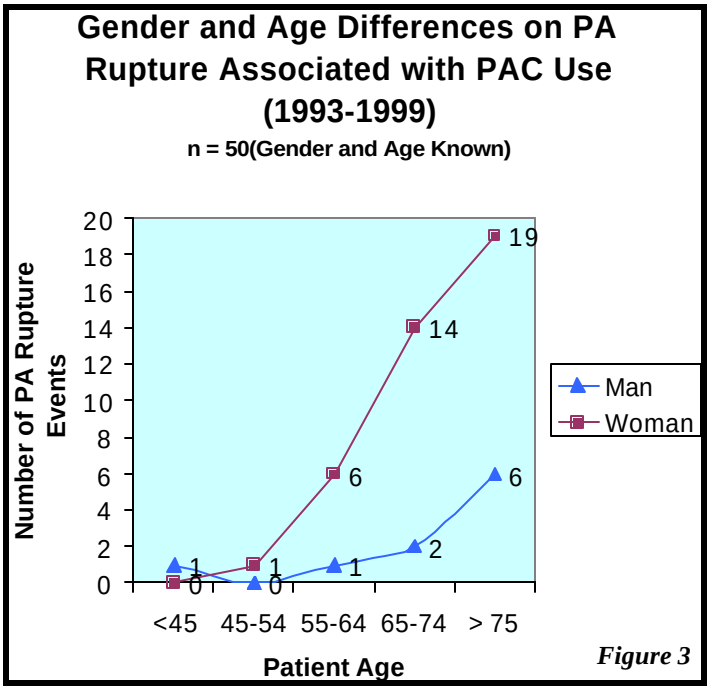

Figure 3

Continued on page 7

PULMONARY ARTERY CATHETERS - *From page 6*

- Keep manipulation of the PAC to a minimum after catheter insertion.
- Be aware of the location of the PAC during insertion, as evidenced by placement landmarks located on the device.
- Document the length of the placement and secure the catheter to prevent migration of the PAC.
- For the patient with high risk factors, PA insertion under fluoroscopic guidance might be needed.

References

1. Medical Device Adverse Event Report, Manufacturer and User Facility Device Experience Database, 1993-1999. Available from URL: http://www.fda.gov/cdrh/maude.html
2. Pulmonary Artery Clinical Outcome (PACCO) Workshop. FDA and the National Heart, Lung and Blood Institute. August 25-26, 1997; Alexandria, VA.
3. Blumberg MS, Binns GS. Swan-Ganz catheter use and mortality in the assessment of medical technology. *Int J Epidemiol* 1980; 9:361-7.
4. Gore JM, Goldberg RJ, Spodnick DH. A community-wide assessment of the use of pulmonary artery catheters in patients with acute myocardial infarction. *Chest* 1987; 92:721-7.
5. Spodnick D. Physiologic and prognostic implication of invasive monitoring. *Am J Cardiol* 1980; 46:173-5.
6. Tuman KJ, McCarthy RJ, Spiess BD, DaValle M. Hompland SJ, Dabir R, et.al. Effect of pulmonary artery catheterization on outcome in patients undergoing coronary artery surgery. *Anesthesiology* 1989; 70:199-206.
7. Connors A, Speroff T, Dawson N, Thomas C, Harrell FE, Wagner D, et.al. The effectiveness of right heart catheterization in the initial care of critically ill patients. *JAMA* 1996; 276:889-97.
8. Boyd KD, Thomas SJ, Gold J, Boyd AD. A prospective study of complications of pulmonary artery catheterization in 500 consecutive patients. *Chest* 1983; 84:245-9.
9. Choh JH, Khazei AH, Ihm HJ, Thatcher WC, Batty PR. Catheter induced pulmonary arterial perforation during open-heart surgery. *J Cardiovasc Surg* 1994; 35:61-4.
10. McDanial DD, Stone JG, Faltas AN, Khambatta HJ, Thys DM, Antunes AM, et. al. Catheter-induced PA hemorrhage. *J Thorac Cardiovasc Surg* 1981; 82:1-4.
11. Stone JG, Khambatta HJ, McDaniel DD. Catheter-induced pulmonary arterial trauma: can it always be averted? *J Thorac Cardiovasc Surg* 1983; 86:146-50.
12. Urschel JF, Myerowitz PD. Catheter-induced pulmonary artery rupture in the setting of cardiopulmonary bypass. *Ann Thorac Surg* 1993; 56:585-9.
13. Kelly TF, Morris GC, Crawford ES, Espada R, Howell JF. Perforation of the pulmonary artery with Swan-Ganz catheters. Diagnosis and surgical management. *Ann Surg* 1981; 193:686-92.
14. Fraser RS. Catheter-induced pulmonary artery perforation. *Hum Pathol* 1987; 18:1246-51.
15. Hartman G, Steib A, Ludes B. Perforation of the pulmonary artery following Swan Ganz catheterization. *Ann Fr Anesth Reanim* 1988; 7:486-93.
16. Hannan AT, Brown M, Bigman O. Pulmonary artery catheter-induced hemorrhage. *Chest* 1984; 85:128-31.
17. Barash PG, Nardi D, Hammond G, Walker-Smith G, Capuano D, Laks H, et.al. Catheter-induced pulmonary artery perforation. Mechanisms, management and modifications. *J Thorac Cardiovasc Surg* 1981; 82:5-12.
18. Keckeisen M. Protocols for practice: pulmonary artery pressure monitoring. Aliso Viejo (CA); *American Association of Critical-Care Nurses*; 1998. p.8.

Chih-hsin Liu, R.N., M.S.N., is a nurse consultant in the Center's Office of Surveillance and Biometrics, Division of Postmarket Surveillance. Caroline C. Webb, R.N., M.S.N., C.C.R.N., is a clinical trials specialist and health science administrator with the National Heart, Lung, and Blood Institute, National Institutes of Health.

*Adapted from an article in the International *Journal of Trauma Nursing 2000*; 6 (1): 19-26 (January-March).

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