FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING

USER Facility Reporting

Issue No. 6 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 1993

FLOWCHARTS PROMOTE INTERNAL REPORTING PROCEDURES

by Emanuel Furst, Ph.D.

Because device-related deaths and injuries occur infrequently, it is often difficult to maintain staff awareness of the internal incident reporting procedure for such events. Personnel may forget that they are reported differently from routine repair requests. They may also be unaware of the extensive information required to satisfactorily investigate a device-related incident. Flowcharts can be useful for training staff, for refreshing their knowledge, and for providing on-the-spot guidance when an incident occurs.

Incident (unusual event) reporting is ordinarily accomplished through completion and routing of an "incident form." Immediate notification of the risk manager or other designated person should be required for serious incidents. Internal programs are usually designed to handle the more common incidents — but these are not device-related. Investigation of medication errors, falls, and other incidents generally does not require much physical evidence or extensive information. In contrast, a successful device investigation is generally based on physical evidence (such as control settings), and it is necessary to have access to the specific device. To implement the reporting provisions of the Safe Medical Devices Act (SMDA), it is necessary to raise the level of staff awareness in order to conduct more effective investigations.

Successful investigation of a device-related incident often depends on rapidly responding to the scene, interviewing staff while events are fresh, retaining the packages and disposable accessories, and capturing the equipment. The investigation may require knowledge of the physical arrangement of medical equipment, room furnishings, and staff. Interconnections between devices and connections to utilities may be important. Some microprocessor-based devices will retain the device history for a limited time if they are not turned off or unplugged. Follow-up may require the lot number of a disposable product. For these reasons, it is essential for the staff to recognize (continued on page 2)

IMPLEMENTING A MEDICAL DEVICE TRACKING SYSTEM AT THOMAS JEFFERSON UNIVERSITY HOSPITAL

by Dan Benson and Dave Bell

Introduction

The Safe Medical Devices Act of 1990 (SMDA) amended section 519(e) of the Food, Drug, and Cosmetic Act to require tracking for certain medical devices as of August 29, 1993 (see page 4). Anticipating this change, in the fall of 1992 Thomas Jefferson University Hospital began planning a system to comply with the new requirements. The Department of Biomedical Instrumentation (DBI) was given this responsibility because we coordinate all recall and alert activities related to manufacturers, the Food and Drug Administration (FDA), and other government agencies. Our system is designed to maintain records of device receipt, distribution, and implantation and to quickly and efficiently supply this information to the manufacturers.

Initial Planning

The Equipment Safety Committee—with representatives from the operating room and the departments of Risk Management, Supply Processing and Distribution, and Biomedical Instrumentation—meets every two weeks to (continued on page 4)

In This Issue:

Flowcharts Promote Reporting ... (from page 1)

when a device-related event has occurred and immediately notify those responsible for investigating it. If an incident is not serious and the physical situation is not complex, it may be acceptable to save all devices for later investigation. The author prefers procedures that require **immediate reporting** of all device-related incidents, so the investigator can determine whether the incident requires immediate investigation.

Initial training and periodic reminders should develop the ability to: (1) recognize a device-related incident; (2) take any necessary actions to protect patient and staff, and (3) follow the facility's reporting procedures. A flowchart can help to maintain this awareness and remind the staff of the procedure. If readily available, it will also be useful when an incident takes place. If the flowchart includes procedures for reporting incidents related to drugs, utilities and other causes, it will facilitate the overall risk management program.

The flowchart on page 3 illustrates one possibility for use in a nursing unit. Other flowcharts might be part of the procedure for performing an incident investigation and for reviewing the results of each investigation to determine if it is reportable. When developing flowcharts, you may find that the facility's actual practice differs from the written or desired procedures. This presents an opportunity to develop realistic and efficient procedures.❖

Emanuel Furst, Ph.D., is a consultant in medical instrumentation. Previously, he was Director of Biomedical Engineering at the University Medical Center in Tucson, Arizona. He is a member of FDA's General Hospital and Personal Use Devices Panel and the Committee on Healthcare Safety of the Joint Commission on Accreditation of Healthcare Organizations.

Dr. Furst is the recipient of several awards, including the Clinical Engineering Achievement Award of the Association for the Advancement of Medical Instrumentation. Questions and comments on this article may be directed to Dr. Furst at P.O. Box 42102, Tucson, AZ 85733; telephone 602-745-5906.

MEDWATCH

by Gale G. White, M.S., R.N. and Dianne L. Kennedy, M.P.H., R.Ph.

MEDWATCH

What Is MedWatch?

MedWatch is the new Food and Drug Administration medical products reporting program. It includes voluntary and mandatory reporting of adverse events and product problems for **all** medical products on the market (drugs, medical devices, biologics, and special nutritional products). MedWatch is a postmarketing surveillance program based on a partnership among health professionals, user facilities, industry, and FDA. It is designed to ensure the safety of all products used in medical practice.

The goals of the MedWatch program are to: (1) increase awareness of drug- and device-related deaths, injuries, and diseases and the need to report to FDA; (2) clarify what events should be reported; (3) make reporting as easy as possible; and (4) provide feedback to health professionals on safety problems.

FDA hopes that reporting adverse events and product problems through MedWatch will become a fundamental part of the medical culture. Over 70 health professional and industry organizations have joined FDA as MedWatch partners and are educating their members about the importance of reporting.

What is the relationship between MedWatch and SMDA?

The voluntary MedWatch form (**FDA Form 3500**) and information on reporting to FDA are being widely disseminated by the MedWatch partners. This may cause some confusion for health professionals at user facilities with respect to their institution's mandatory reporting under the Safe Medical Devices Act (SMDA). Therefore, user facilities need to take a proactive approach to the reporting of adverse events and product problems and educate all professional staff about the relationship between MedWatch and SMDA reporting.

User facilities are required by SMDA to report:

- device-related **deaths** to both FDA and the manufacturer, and
- device-related **serious injuries** and **serious illnesses** to the manufacturer or to FDA if the manufacturer is not known.

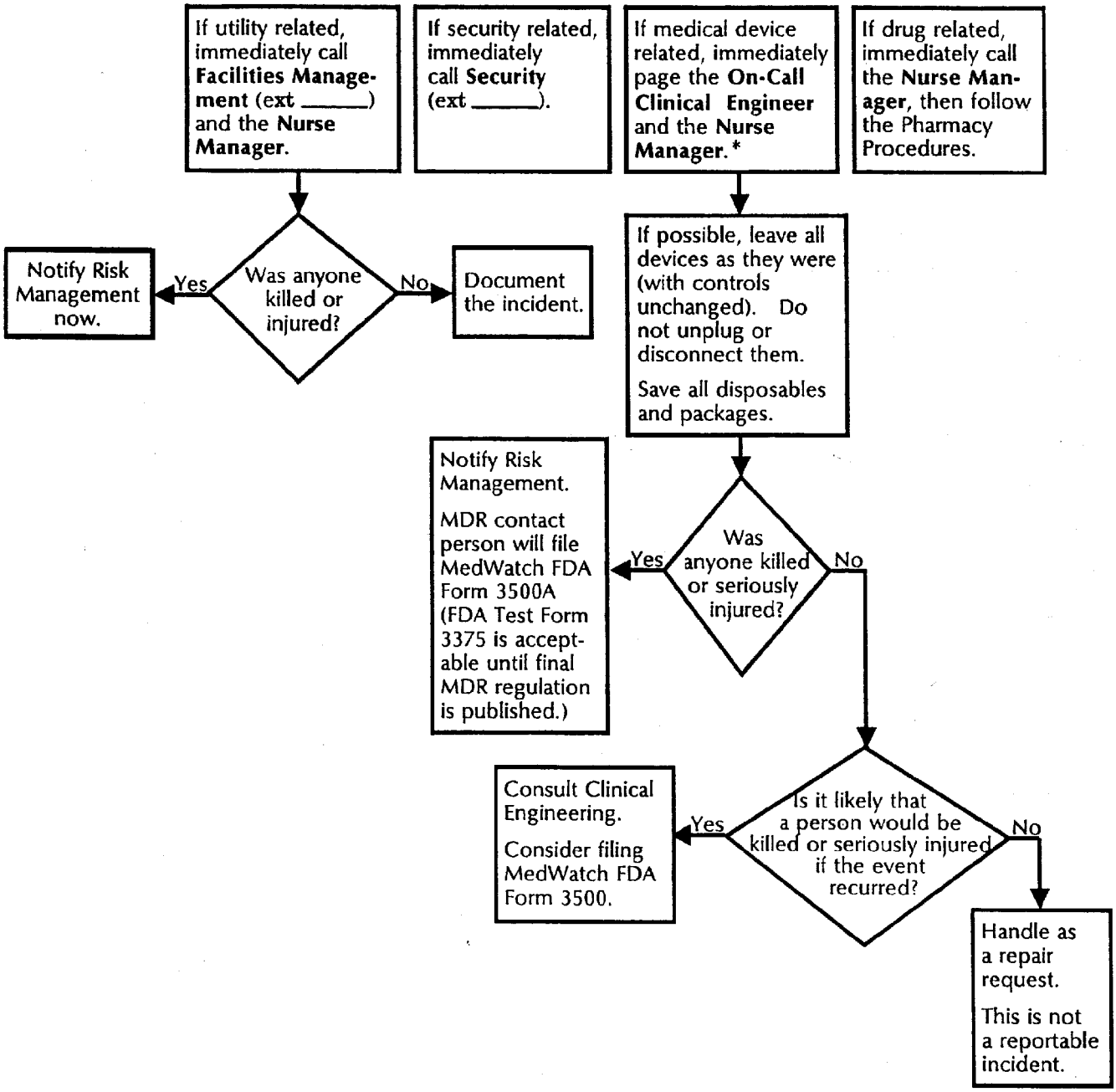
These reports are **mandatory** and should be submitted to FDA on the mandatory version of the MedWatch form (**FDA Form 3500A**). **FDA Test Form 3375** may be used for these reports until the final regulation is published, but facilities are encouraged to begin using the mandatory MedWatch form now.

The facility's risk manager or other person responsible for compliance with SMDA should inform the hospital staff that submission by an individual of a report to FDA on the voluntary version of the MedWatch form (**FDA Form 3500**) about a death or (continued on page 7)

Sample Flowchart

How To Report Incidents Involving Medical Devices, Drugs, Utilities, And Security

After caring for the patient, follow these procedures. If an incident involves two or more departments, notify each department.



* *Document the incident. Identify all personnel present and list their telephone extensions. If incident is medical device related, documentation should include the manufacturer's name and the device model, lot, or serial number as appropriate.*

DEVICES TO BE TRACKED AS OF AUGUST 29, 1993

- Vascular graft prosthesis of less than 6 mm diameter
- Vascular graft prosthesis of 6 mm and greater diameter
- Total temporomandibular joint prosthesis
- Glenoid fossa prosthesis
- Mandibular condyle prosthesis
- Interarticular disc prosthesis (interpositional implant)
- Ventricular bypass (assist) device
- Implantable pacemaker pulse generator
- Cardiovascular permanent pacemaker electrode
- Annuloplasty ring
- Replacement heart valve
- Automatic implantable cardioverter/defibrillator
- Tracheal prosthesis
- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion pump
- Breathing frequency monitor (apnea monitor) including ventilatory efforts monitor
- Continuous ventilator
- DC-defibrillator and paddles
- Penile inflatable implant
- Silicone inflatable breast prosthesis
- Silicone gel-filled breast prosthesis
- Silicone gel-filled testicular prosthesis
- Silicone gel-filled chin prosthesis
- Silicone gel-filled Angelchik reflux valve
- Infusion pump (electromedical only)

Implementing a Medical Device Tracking System ... (from page 1)

discuss device incident reporting and recall alerts. This committee reviews all SMDA activity and provided suggestions during the planning for the hospital's tracking system.

Initially, the committee's suggestion was to create a multi-user database system using the university mainframe computer. Each department involved with tracking would enter its data about the receipt and use of tracked devices. DBI would be the administrator of this database. We would print and mail activity reports to the manufacturers and handle retrieval of information related to recalls. We soon found that this plan could not be realized in time. Several key departments had no access to the mainframe; also, the backlog of existing Department of Information Services projects prevented immediate development of our system. The mainframe plan was shelved for future consideration, and we went back to the drawing board.

Next, we reviewed the proposed regulations, identified the requirements for providing information to manufacturers and FDA, and created a tracking information flowchart (see page 5). The committee decided to implement a manual system before August 29, 1993.

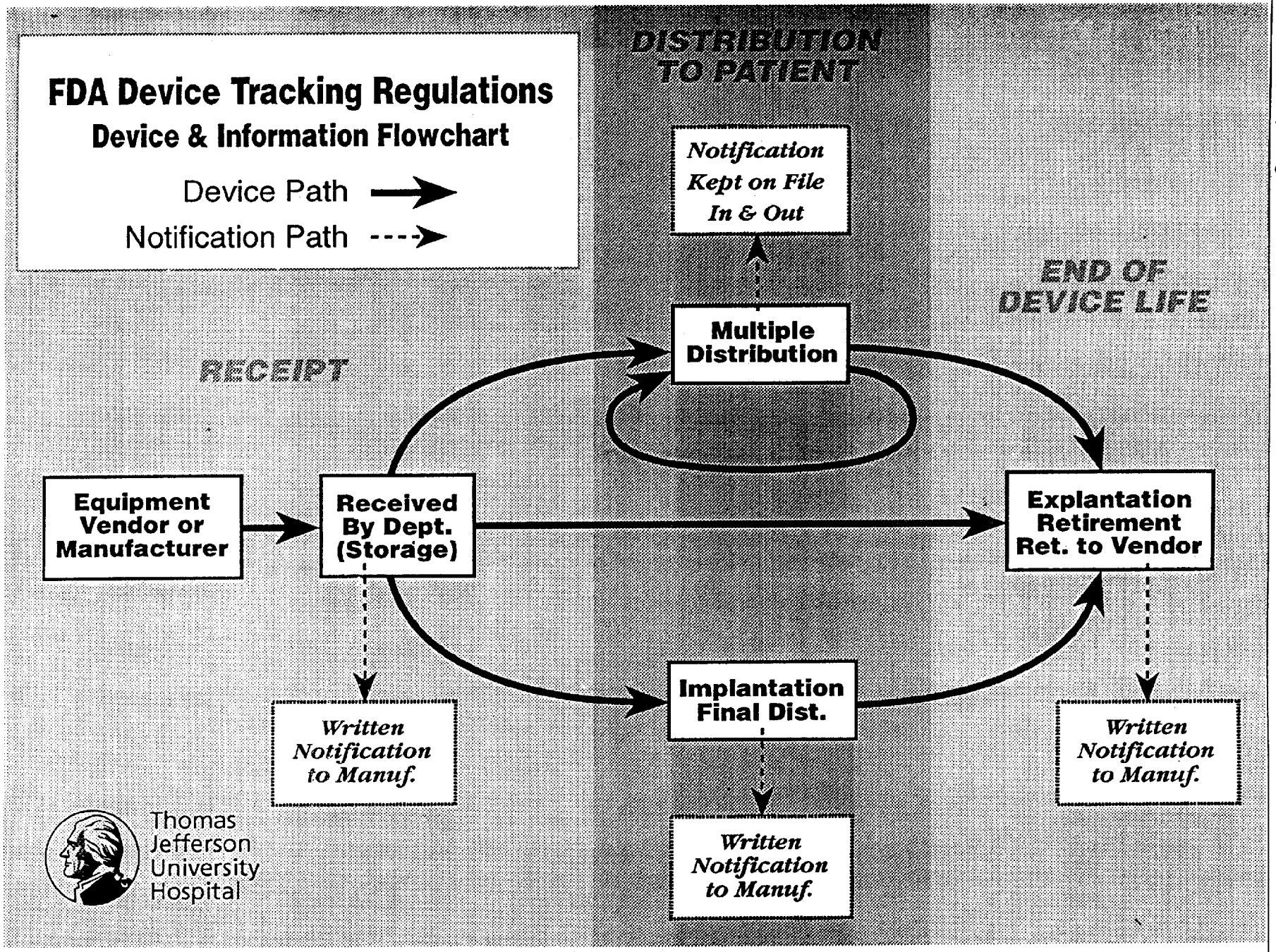
One key question remained concerning tracking of medical devices within the hospital. How could data from the time of receipt of a device within a department be correlated with information recorded later about the use of the device? It is not reasonable to expect a copy of the tracking form to remain with the device until it is used, for example during a procedure in the operating room. We decided to tag the device or its packaging with a unique identifier that would correlate with the form used for recording its receipt within the institution. Instead of a single form for recording all tracking information, a set of two distinct forms was designed.

The first form is used to record device information at the time of receipt. A key feature of this form is a preprinted adhesive sticker with a unique tracking number. This sticker is removed from the receipt form and placed on the device or its packaging. The second form is used to record all subsequent activity related to the trackable device: implantation, explantation, retiring from service, or returning to the manufacturer. When available, the unique tracking number is read from the device or packaging and recorded on the second form along with all necessary information related to the use of the device. (Devices received prior to August 29, 1993, do not have to be tracked and therefore are not given a tracking number.) Next, we solicited bids for printing our tracking forms. We soon learned that custom-designed forms (even with all design performed in-house) can take several months for delivery.

Developing a Tracking Database

DBI developed a tracking database for our computer network using commercially available software. We decided that the most efficient system would be for each department to complete a tracking form when a reportable activity occurs. A designated individual in the department thoroughly reviews the form for acccuracy and sends one copy to the manufacturer and one to DBI.

DBI then enters the information into the database and makes a second check for accuracy of product information. If the information recorded at the time of device use does not match that (continued on page 6)


FDA Device Tracking Regulations
Device & Information Flowchart
Device Path
Notification Path
DISTRIBUTION TO PATIENT
Notification Kept on File In & Out
END OF DEVICE LIFE
Multiple Distribution
RECEIPT
Equipment Vendor or Manufacturer
Received By Dept. (Storage)
Explantation Retirement Ret. to Vendor
Written Notification to Manuf.
Implantation Final Dist.
Written Notification to Manuf.
Written Notification to Manuf.
Thomas Jefferson University Hospital

Implementing a Medical Device Tracking System ... (from page 4)

from the time of device receipt, the persons who completed the forms are contacted and every reasonable attempt is made to resolve the discrepancy.

Manufacturers' Responses

In the first month after the tracking regulation was effective, several manufacturers mailed us their own forms for recording tracking information. We informed them that we would supply them all information required under section 519(e), using our own forms, and that we would decline to use their individual forms. We adopted this policy for two reasons. Considerable inservicing time was necessary to instruct personnel on the proper utilization of our own tracking system and forms. We don't have the time or resources to expand this effort to include countless additional forms. Also, we had to consider the issue of compliance. It is obviously vital to the success of any device tracking system that all personnel involved complete the forms accurately and quickly. Adding a variety of manufacturers' forms would certainly decrease compliance on the part of hospital personnel.

Several manufacturers have requested additional information beyond what is federally mandated. This information includes the type of procedure, the site of implantation, and whether the implant is used in a critical or non-critical application. We decided not to release informationation beyond that required by FDA in order to avoid conflict with patient confidentiality and to lessen the burden on tracking personnel. (Unfortunately, device tracking is already perceived by hospital personnel as a necessary inconvenience.)

Future Plans

We are currently considering a multi-user networked system as an alternative to a mainframe system. The number of departments intimately involved in tracking is limited, so it appears that this will be adequate. Personal computers in the different departments will be tied via the university Ethernet backbone to a database server located in DBI. Designated personnel in each department will log information directly into the database. The burden of generating and mailing reports will then reside within our department, as originally planned. Beyond this system, a semi-automated paperless system is envisioned with fax-modems used to electronically send reports to the manufacturers.

Conclusion

After three months of device tracking, the Jefferson system appears to be functioning even better than originally anticipated. About 300 trackable items have been received and about 350 trackable devices have been implanted. Compliance with the documentation and notification procedures is quite high and only a few minor problems have been observed. These include occasional omission of the patient's telephone number and/or social security number and discrepancies in the device nomenclature. When these problems arise, hospital supervisors are notified and the appropriate individuals are trained in the correct way to complete the forms. Extensive inservicing in the hospital has resulted in a keen awareness of the types of devices that must be tracked and the need for proper documentation to effectively comply with the medical device tracking regulations. ❖

Dan Benson is a clinical engineer and Dave Bell is the Assistant Director, DBI, Thomas Jefferson University Hospital, 129 South Ninth Street, Philadelphia, PA 19107. Questions and comments about this article may be directed to Mr. Benson at the above address or by FAX at 215-955-5867.

FDA PUBLISHES RESULTS OF INFUSION PUMP INVESTIGATION

by Kathleen A. Franke

The Food and Drug Administration (FDA) recently published a report titled "Infusion Pump State Contract Investigation," based on a 4-year project. Under contract with FDA, the health departments of five states and the District of Columbia studied infusion pump use, as well as user training and practices, in both hospital and homecare settings. The 40-page report summarizes the information collected, analyzes the causes of problems, and makes recommendations for improvements. Copies are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; telephone 703-487-4650.

The study resulted from FDA concern about the increased use and variety of infusion pumps combined with the rise in AIDS/HIV patients and the expanded use of pumps in nonhospital settings. FDA designed the study to obtain data on large-volume and ambulatory infusion pump use; cleaning, testing, and preventive maintenance procedures; repair of infusion pumps; and training of users in a sample population of hospitals, home healthcare agencies, and durable medical equipment suppliers. (continued on page 7)

MedWatch ... (from page 2)

serious injury related to the use of a medical device **DOES NOT COMPLY** with SMDA reporting requirements and **DOES NOT RELIEVE** the facility of its responsibilities.

There are no federal regulations that require user facilities to report adverse events or product problems with drugs, biologics, or foods. The voluntary version of the MedWatch form **(FDA Form 3500)** can be used to report adverse events and product problems in regard to these items. If desired, the voluntary version may also be used to notify FDA of device events or problems that are not reportable under SMDA.

How do I obtain MedWatch voluntary reporting forms and how do I submit voluntary reports?

Call 1-800-FDA-1088 to:

- request **FDA Form 3500** and/or the *FDA Desk Guide for Adverse Event and Product Problem Reporting;*
- report a quality problem with a drug; and
- report an adverse event or a quality problem with a device (anything NOT subject to SMDA).

To report by FAX, call 1-800-FDA-0178. To report by modem, call 1-800-FDA-7737.

Mail completed forms to:

MedWatch
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

NOTE: Do not send mandatory forms to this address.

How do I obtain MedWatch mandatory reporting forms and where do I send the completed forms?

To obtain up to 10 copies of the mandatory version of the MedWatch form **(FDA Form 3500A)**, instructions for completing the form, and the medical device coding manual, call 1-800-638-2041 or write to:

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Mail completed forms to:

FDA User Reporting, HFZ-351
Center for Devices and Radiological Health
Food and Drug Administration
P.O. Box 3002
Rockville, MD 20847-3002

Questions about MedWatch and its relationship to SMDA reporting can be FAXed to the Director of MedWatch at 1-800-FDA-0178. Other questions about mandatory reporting by user facilities may be FAXed to (301) 881-6670.❖

Gale G. White and Dianne L. Kennedy are both in the Office of the Commissioner, FDA. Gale is the Deputy Director of MedWatch and Dianne is the Director.

Infusion Pumps... (from page 6)

Problems

The study findings cannot be generalized to the entire United States, but they do provide useful insights. Over 18 percent of problems were attributed to user/caregiver error and 17 percent to design error. Some typical problems included:

- malfunctioning components (batteries, software, alarms, and displays);
- inadequate maintenance (lack of routine cleaning, inspection, and/or service);
- failure of users to follow instructions and inadequate length of training for pump users; and
- inadequate planning, and training, of patients prior to discharge.

Recommendations

Some of the major recommendations are:

Manufacturers should improve: (1) the design of pumps and accessories for safer, more effective and efficient use by health professionals, patients, and lay caregivers; (2) labeling; and (3) inservicing programs.

Physicians and **pharmacists** should propose improvements for infusion pump educational programs in medical and pharmacy schools and hospital inservices.

Nurses, the primary users of infusion pumps and accessories, should participate more actively in both the purchasing decisions and the development of educational programs at nursing schools and hospitals. They should concentrate on giving adequate training to the staff and implementing inservice procedures to provide proper cleaning and maintenance. Additionally, FDA encourages the active participation of nurses in (continued on page 8)

Infusion Pump Investigation... (from page 7)

professional societies to promote the proper use, care, and maintenance of all medical devices.

Home healthcare agencies should work more closely with medical facilities and durable medical equipment suppliers to improve their discharge planning methods to include more comprehensive and intensive training on the proper, safe, and effective use and maintenance of infusion pumps and accessories.

Durable Medical Equipment Suppliers should aggressively cultivate sound working relationships with manufacturers, the medical community, home healthcare agencies, and home users to develop good training programs and practices for their personnel and recipients of their services.

Regulatory agencies, at Federal, state, and local levels, must work together to continue surveillance of infusion pump manufacturing, pre- and post-marketing practices, and use in medical facilities and home settings.

~•~

In September 1993, the report was sent to over 50 professional and trade associations and individuals. FDA urged the recipients to collaboratively develop and implement solutions and expressed the Agency's interest in participating in such efforts.❖

Kathleen A. Franke is a public health advisor in the CDRH Office of Training and Assistance (OTA). She served on the Center's Infusion Pump Committee and OTA's Infusion Pump Task Force which resulted in the state contracts and several OTA studies.

User Facility Reporting

A Quarterly Bulletin

The *User Facility Reporting Bulletin* is an FDA publication to assist hospitals, nursing homes, and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act. The publication's contents may be freely reproduced. Comments should be sent to the Editor.

Editor: Nancy Lowe
Asst. Editor: Herb Spark
Graphics Specialist: Ron Jans

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-210)
Rockville, Maryland 20857

ATTN: Editor, User Facility Reporting Bulletin

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FIRST CLASS
POSTAGE AND FEES
PAID
PHS/FDA
PERMIT NO. G-285

Also Route to:

- ☐ Administration
- ☐ Risk Management
- ☐ Clinical Engineering
- ☐ Quality Assurance