FOOD AND DRUG ADMINISTRATION

USER Facility Reporting

Issue No. 12 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Summer 1995

HUMAN FACTORS AND MEDICAL DEVICES

By Jay A. Rachlin

In the Spring issue of the *User Facility Reporting Bulletin*, we announced that a new column dedicated to human factors issues and medical devices would begin in the Summer issue. This article introduces the subject and explains why human factors are important to the Food and Drug Administration (FDA) and should be important to you.

The discipline of human factors is dedicated to reducing human error and improving user performance by designing equipment with an understanding of the characteristics of the **user** and the work **environment.** Human factors practitioners include psychologists, engineers, computer scientists, architects, medical doctors, and others concerned with the safe operation of medical devices. Design of devices, training of users, and development of user instructions are some of the primary human factors concerns.

Human factors problems are often encountered in the healthcare community. Not infrequently, serious errors are made by highly competent professionals, and poor device design is often found to be a significant cause. Such errors usually cannot be eliminated simply by adding labels or offering further

(Continued on page 3)

WHEN TO FILE AN MDR REPORT

By Chester T. Reynolds

One of the difficult aspects of user facility reporting is deciding when to report an adverse event to the Food and Drug Administration (FDA) and/or the manufacturer. The threshold for reporting starts with the identification of a device-related event that has, or may have, caused or contributed to a death or serious injury. The automatic submission of an MDR report is not warranted just because a device was being used when an adverse event occurred. The user facility is responsible for making a judgment based on the facts and circumstances observed by its medical personnel. A device-related death or serious injury should be reported if **any** of the following assessments applies:

- the medical device actually caused or contributed to the outcome; or
- the medical device cannot be ruled out as a possible cause of the event; or
- the healthcare professional suspects that the medical device was involved, since there is no other plausible explanation for the patient's condition. *(Continued on page 2)*

WHEN TO FILE AN MDR REPORT -*(from page 1)*

If a healthcare professional does not observe or suspect that a medical device contributed to a death or serious injury, the event should not be reported. But, what should be done if the situation is unclear, e.g., the device **might** be associated with a death or serious injury? In this instance the event should be reported and the circumstances should be described in detail in the narrative.

> "FDA does not want user facilities to report events that are clearly not device-related or in which the only association is proximity."

Why does FDA want user facilities to submit MDR reports if the association with a medical device is unclear? The answer lies in the variety of problems that can be associated with medical devices and the difficulty of establishing cause and effect. For example, during treatment a patient might experience a severe reaction that is perceived as drug-related but may actually be caused by latex sensitivity from any one of several medical devices being used.

One benefit of user facility reporting is that each report is entered into a centralized database that includes information from other sources. The collected information is reviewed by FDA's clinicians, and emerging problems and trends can be identified. Healthcare professionals are often the first to become aware of problems in the device/patient interaction. Early observations by healthcare professionals have led to the identification of problems resulting from such factors as design, materials, and manufacturing processes. The earlier a problem with a medical device is identified, the faster it can be resolved.

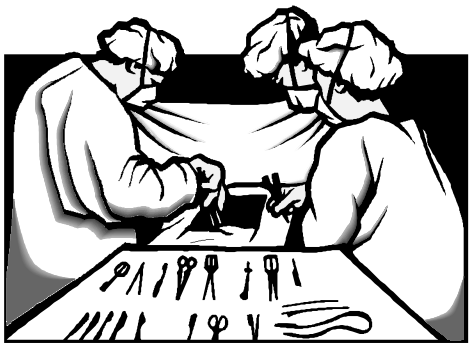
The following examples are representative of situations in which reports from healthcare professionals have resulted in corrective actions:

- A dialysis nurse submitted an MDR report about an incident involving eight patients who had exhibited various symptoms during dialysis, including severe hypotension. FDA then ordered an inspection of the dialysis facility during which the investigators discovered high serum aluminum levels in patients treated at the facility. Further investigation revealed that aluminum from components in the dialysate storage and delivery system was leaching into the dialysate solution. This led to an FDA Safety Alert, *Aluminum and Other Trace Element Contamination in Dialysis Facilities* (May 20, 1992), directed to physicians and users.
- An Army medical clinic reported a problem during attempts to resuscitate an infant. FDA's investigation discovered that the expiratory channel had become occluded after a lubricant was used in reconnecting the endotracheal tube and the connector. FDA subsequently issued a Public Health Advisory, *Occluded Endotracheal Tube* (February 28, 1994), to manufacturers, foreign governments, and users.
- MedWatch received a call from a dental office reporting that an employee had been momentarily unable to release her hand from an ultrasonic cleaning device. FDA's investigation revealed that there was electrical leakage from the lid even though the unit was turned off. In another incident, an electrical fire started in an ultrasonic device that had been turned off prior to cleaning. The manufacturer identified the cause of the problem and initiated a device recall.

The standard for reporting is not difficult. FDA does not want user facilities to report events that are clearly not device-related or in which the only association is proximity. But, if a healthcare professional believes a device "may have caused or contributed" to the event, it should be reported to FDA in sufficient detail to enable an independent analysis.☑

Chester T. Reynolds is Associate Director for MDR Policy in the Office of Biometrics and Surveillance, CDRH.

HUMAN FACTORS AND MEDICAL DEVICES -*(from page 1)*



training. The likelihood of user error is significantly increased when equipment is designed without adequate consideration of users' perceptual, physical, and cognitive abilities. Noisy, poorly lit, and stressful operating environments often interact with bad equipment design to increase the burden on the user. Further problems include poorly written instructions, inadequate training, and limitations in the experience and capabilities of both lay and professional users. Device design and user instructions are especially relevant to the FDA mission.

The importance of good instructions in achieving correct device use is widely acknowledged; however, the ways in which the design of a device affect safe use are not as well understood. In human factors analysis, the term “user-interface design” is often employed to refer to the parts of the equip-ment with which the user interacts directly. User-interface design has a major influence on user performance, device safety, and ease of user training.

A problem reported to FDA illustrates this point:

A physician wanted to administer oxygen to an infant at a flow rate of 1.5 liters/minute and, therefore, adjusted the flow control knob to a setting midway between the 1 liter/minute and 2 liters/minute settings on the scale. The physician did not realize that no oxygen flow would occur when the knob was set to any position between labeled settings. The infant became hypoxic before the error was discovered. The device should have employed a rotary control with detents that snap into position and do not allow the user to leave the knob between indicated settings. This user-interface feature would have prevented the user from accidentally selecting a "no-flow" setting.

User-interface design problems that tend to "invite" user error include such things as:

- complicated or unconventional arrangements of controls, displays, and tubing;
- poor design that makes installation and maintenance unnecessarily complex;
- ambiguous or difficult-to-read displays;
- confusing or unnecessarily intrusive alarms;
- hard-to-remember, and/or confusing, device operating procedures;
- inadequate device feedback or status indication that causes user uncertainty; and
- poorly designed labeling.

You, as a medical device user, can have a significant impact on improving the design of medical equipment. Keep in mind the following characteristics of devices that help users avert problems. Well-designed devices:

- are consistent with the user's experience;
- are logical & not confusing;
- minimize the need for depending on memory and making mental calculations;
- do not overtax the user's strength, dexterity, visual ability, or auditory capacity;
- alert users to device-related problems;
- prevent users from making fatal errors that could otherwise occur easily; and
- are supported by readable and understandable labeling.

(Continued on page 4)

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 of 1990 and the Medical Device Amendments of 1992.

The publication’s contents may be freely reproduced. Comments should be sent to the Editor.

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HUMAN FACTORS AND MEDICAL DEVICES -*(from page 3)*

When reporting device-related deaths or serious injuries to FDA, please identify any human factors problems you believe may have been a contributing factor. Use the specific human factors codes found in the *MedWatch Mandatory Codes Reporting Manual*. FDA and/or the device manufacturers can then evaluate these problems and consider ways of preventing or reducing them.

As we mentioned in the previous issue, the Association for the Advancement of Medical Instrumentation (AAMI) and FDA will co-sponsor a two-day conference on human factors design and medical devices on September 12-13, 1995, at the Washington Hilton Hotel and Towers in Washington, D.C. The conference will provide a forum to encourage discussion of human factors issues among manufacturers, device users, and regulatory personnel. For additional information and to register for the conference, contact Laura Duffy at AAMI, 800-332-2264 or 703-525-4890, extension 260.☑

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Editor's Note: In future issues of the Bulletin, readers can look forward to more articles on human factors and medical devices. Topics will include:

- Recognizing problems in using medical devices
- Making wiser choices in device purchases
- How to report human factors device problems
- Human factors problems reported by device users

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