FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING — FDA MEDICINE MANUFACTURERS

# USER Facility Reporting

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## PRESERVING THE EVIDENCE! THE FIRST STEP IN AN INCIDENT INVESTIGATION

*By Marvin Shepherd*

Many healthcare professionals believe that the investigation of an incident begins after the risk manager is notified of an adverse event. However, the results of the investigation may rest on actions taken by the heathcare professional immediately following the incident.

Investigations are intended to ultimately identify the cause(s) of an incident. The determination of cause rests on knowing about a device and its accessories and how they were handled following an event. Some investigations have resulted in an indeterminate cause for reasons such as: (1) the devices were not properly identified and were later placed back in service; (2) the accessories for the device were disposed of; or (3) the rough handling of a device accessory introduced mechanical damage. These and other actions following an adverse event can result in a poor quality investigation. *(Continued on page 2)*

## THE IMPORTANCE OF INFORMATION ABOUT USE ERROR AND HUMAN FACTORS IN ADVERSE EVENT REPORTING

*by Thomas Gross, M. D.*

Human factors is the science of human-machine interaction. In the medical device world, it encompasses (1) the interactions between a device and its users, (2) the characteristics of the user and of the device that influence that interaction, and (3) problems that sometimes occur during device use. In this context, the Food and Drug Administration (FDA) is interested in several aspects of the medical devices that users operate, including the basic design of the device, controls and displays, alarms, operating logic, labels, training materials, instructions, and manuals necessary to install, operate, and maintain the device.

FDA defines use error as those errors induced by design, labeling, or instructions that could cause the user to be misled, tricked, confused, or overburdened physically, sensually, or cognitively. The real question is whether the device is sufficiently "user-safe," i.e., the manufacturer has taken the user's capabilities into account when designing the device.

**FDA is not interested in reports of negligence cases or malpractice suits.** We look at an incident to determine if the device, its labeling, or its instructions could have induced or contributed to the error. A key concept of reporting adverse events is that of device-relatedness, i.e., did the device cause or contribute to the adverse event?

*(continued on page 6)*

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## Preserving The Evidence - *(from page 1)*

The following are some suggestions for preserving potential evidence until the formal investigation begins. They do not represent official Food and Drug Administration (FDA) policy but offer only general guidance.

- Record the manufacturer, model, and serial number of all devices involved in the adverse event. Record this information on the patient's record and/or on the unusual occurrence form. If the device is disposable or has disposable accessories, also record the catalogue number and lot number of all disposables. It is important to have the actual device and any accessories that were involved in the adverse event.

- Do not clean, process, or repair the device.

Cleaning, processing, or repairing a device can affect its performance and its safe use. Some cleaning may be required before testing, but the investigator will determine which methods are acceptable. When the device is contaminated with biohazards waste, it must be retained according to the facility's safety policies and procedures. Label as **Biohazardous Waste.**

- Record the names of all healthcare professionals present at the incident.

The investigator may wish to interview them at a later date.

- Tag or label the device and prepare for storage.

When tagging or labeling the device, indicate that it was involved in an adverse event, the date of the event, and the name of the person who labeled the device. Indicate on the label that the device is not to be used, cleaned, repaired, or destroyed without approval of the individual in authority such as a risk manager. If the adverse event involves more than one device, all devices involved should be labeled and secured.

- Save the packaging of all disposable accessories involved in the event and secure with the device.

The packaging of disposables typically includes not only the catalogue number of the device but the lot number as well. This information is important not only to uniquely identify the disposables but to identify all items of the same lot number (in case they need to be removed from use). Also, some specifications included in the packaging may be useful to the investigator.

Occasionally, the packaging may be contaminated with biohazardous waste. Carefully follow your facility's policies and procedures for the safe handling of biohazardous waste while securing the packaging.

- Before unplugging a device from its electrical power source or

removing the batteries, check to see if memory in the device will be lost.

Many devices have computerized memories that may be lost if the batteries are removed or if the device is unplugged from its electrical source. Investigators may use this memory to determine specifically when certain device-related conditions occurred. To determine which devices have computerized memories and how they should be handled after an event, contact your clinical engineer.

- Tape knobs and dials.

It is helpful during an investigation to know what the dial and knob settings were during an incident. If there are knobs and dials on the device, place tape over them to hold the positions used during the event.

- If persons having access to the secured area primarily speak a language other than English, consider labeling the device in the second language.

Proper labeling can help to prevent mistakes about the status of the device. *(continued on page 3)*

## Preserving The Evidence - *(from page 2)*

- Place the device and its accessories in a container to prevent subsequent damage.

Laser fibers, pressure transducers, bronchoscopes, and other sensitive devices could be damaged by rough handling. Return the device to its case or place it in a container to prevent such damage. It is important to protect the storage case from any contaminant.

**Do not send devices to FDA without prior approval.**

- Secure the device(s) in a locked room or cabinet.

This will prevent the device from being placed back in service. For larger systems such as X-ray or MRI, the doors should be closed and all entrances labeled "Do Not Enter." Practically, secured rooms and devices may need to be used despite a previous incident. Not allowing their use might prove medically unacceptable. Immediately contact responsible persons, such as the clinical engineer or the risk manager, regarding the safe use of these larger systems.

- Do not test the device or investigate the incident.

Testing the device or investigating the incident may result in the loss of pertinent evidence. A trained investigator knows how to perform an investigation and how to test the device without adversely effecting the integrity of the evidence.

- Contact the manufacturer about disposal of the device(s).

When the investigator has all the information needed, and you would like to dispose of the devices involved, contact the manufacturer to determine if the devices should be returned. If not, dispose of the devices in a safe manner. Do not send devices to FDA without prior approval.

The above guidelines should be a part of the in-service training for all healthcare professionals. The quality of any investigation begins with preserving the evidence. When properly performed, an investigation can provide information and clues that may prevent another incident from occurring.❀

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*Marvin Shepherd, a Professional Safety Engineer, specializes in medical device safety. For questions relating to this article, you may write to Mr. Shepherd at P.O. Box 3504, Walnut Creek, CA 94598; call (510) 945-0137; or send e-mail to marvins523@aol.com.*

## POTENTIAL HYPERSENSITIVITY REACTIONS TO CHLORHEXIDINE-IMPREGNATED MEDICAL DEVICES

*By Deborah Blum, R.N.*

On March 13, 1998, the Food and Drug Administration (FDA) issued a Public Health Notice about serious hypersensitivity reactions to chlorhexidine-impregnated medical devices. Because these types of reactions are not well known to device users and the full extent of the problems is not yet clear, FDA is giving you the information that it has available. We encourage you to report any hypersensitivity reactions to FDA. These reports will help us to evaluate the hazard that these products might pose and to decide what actions to take.

Since the mid 1970s, chlorhexidine-containing compounds have been used as an effective antimicrobial agent in antiseptic skin creams, mouth rinses, disinfectants, and some cosmetics. In the early 1990s, FDA cleared three types of medical devices that incorporate chlorhexidine: intravenous catheters, topical antimicrobial skin dressings, and implanted antimicrobial surgical mesh. *(Continued on page 4)*

## CHLORHEXIDINE-IMPREGNATED MEDICAL DEVICES - *(from page 3)*

Although the antimicrobial properties of chlorhexidine are well known, the hypersensitive reactions to it are not as well known. Anaphylactic and other types of reactions have been reported with topical and intra-urethral use and with chlorhexidine-impregnated catheters. These incidents have been reported in several countries. In one case in the Netherlands, a 61-year old man exhibited a severe allergic reaction to the chlorhexidine gel used for an intra-urethral (urological) procedure. In Australia, a man had an anaphylactic reaction and six other persons had severe reactions to chlorhexidine lubricant applied to urinary catheters.

The Japanese government informed FDA that 13 Japanese patients experienced anaphylactoid-type adverse events while being treated with central venous catheters (CVCs) impregnated with chlorhexidine. One patient subsequently died, although the exact cause of death is not known. Tachycardia, hypotension, and chest pain were some other symptoms experienced. It is unclear why some individuals had reactions and others undergoing the same treatment did not. One possible explanation is that increased exposure to chlorhexidine causes heightened sensitivity. Another explanation could be that some individuals have a genetic predisposition to react to this chemical.

Sale of chlorhexidine impregnated CVCs in Japan began in 1996. The 13 events occurred between June 1996 and July 1997; the manufacturer voluntarily withdrew its CVCs from the market in August 1997. To date, FDA has not received any reports of hypersensitivity reactions related to the 2.5 million CVCs sold in the U.S.

Other types of immediate systemic hypersensitivity reactions have been documented. In one study in the United States, six of 10 neonates weighing under 1000 grams showed local reactions to chlorhexidine gluconate-impregnated patches used to secure central venous catheters. Severe contact dermatitis in seven neonates with this type of dressing was also reported in another U.S. study. Two cases of occupational asthma in nurses were reported from exposure to chlorhexidine and alcohol aerosols. Bradycardia was reported in a neonate whose mother had used chlorhexidine topically on her breasts before nursing the infant.

FDA recommends that medical personnel who use chlorhexidine:

- Monitor their patients for possible hypersensitivity reactions;

- If a reaction occurs, monitor it carefully, provide immediate respiratory and/or cardiovascular support as needed, and discontinue use of chlorhexidine or devices containing this chemical as quickly as possible;

- Report any chlorhexidrine reaction that results in a death or serious injury following the **mandatory** adverse event reporting procedures established by your facility to comply with the Safe Medical Devices Act of 1990 (use Form 3500A); and

- Even if there is no mandatory reportable event, please report the adverse reaction to MedWatch, FDA's **voluntary** reporting program. Your report might provide important information about why these adverse events are occurring. You can submit these reports by telephone (1-800-FDA-1088), by FAX (1-800-FDA-0178), or by mail (MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857).❀

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*Deborah Blum is a Nurse Consultant in the Office of Surveillance and Biometrics. If you have questions about this article, please contact Deborah Blum, R.N. Office of Surveillance and Biometrics, HFZ-520, 1350 Piccard Dr., Rockville, MD 20850; FAX (301) 594-1967; e-mail dyb@cdrh.fda.gov.*

# INTERFERENCE BETWEEN DIGITAL TV TRANSMISSIONS AND MEDICAL TELEMETRY SYSTEMS

*By Nancy Pressly, BS Engineering*

The Food and Drug Administration (FDA) wants to alert you about recent incidents involving digital television (DTV) transmissions interfering with medical telemetry systems that use TV channels. These devices are secondary users of the radio-frequency (RF) spectrum. Licensed users such as television stations are the primary users. As a secondary user, your telemetry devices could be subject to interference from the primary user at any time. Your systems, how-ever, must not cause interference with the signal of the primary user. If your telemetry devices are operating on frequencies licensed to a primary user, you must take any steps necessary to avoid device malfunctions due to interference.

In one city, the telemetry systems at two hospitals had been operating on a TV channel unused for many years. Recently, however, the Federal Communications Commission (FCC) reassigned the channel to a TV station near these hospitals. The new TV signal interfered with the hospitals' telemetry systems and rendered them unusable.

Medical telemetry devices have shared the TV RF spectrum on channels 7-13 for many years. In October 1997, the FCC authorized operation of medical telemetry devices on a wider RF spectrum. However, at this time most medical telemetry systems are believed to still be operating on the original channels 7-13. In the next few months, 10 major market areas for DTV will begin transmitting signals on previously unused channels, some within the 7-13 channel band.

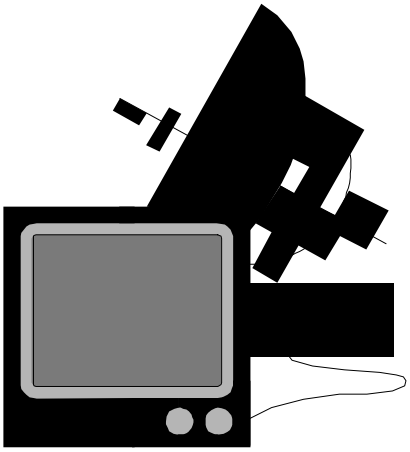
The FCC has developed a website for information concerning digital TV and medical telemetry. Included on this page is a table of channel allocations and their geographic location. The FCC website is www.fcc.gov/healthnet/dtv.html.

Facilities using medical telemetry systems should consult the table to determine channel allotments that might be potential problems in their area. If you find that your telemetry systems are transmitting on channels that remain unused, you should have no problems with DTV transmissions. However, you should periodically check the FCC table to assure that those channels remain available.

If your telemetry systems are transmitting on channels that are scheduled to be used by a local station, you should work with the manufacturer of your telemetry systems to:

- determine when the TV station plans to begin broadcasting on those channels, and
- change your telemetry channels to unused channels prior to that date to avoid telemetry interference.

If DTV interference results in a death or serious injury, you must follow the mandatory adverse event reporting procedures established by your facility to comply with the Safe Medical Devices Act of 1990 and use Form 3500A to report. If a telemetry system ***malfunctions*** due to this type of electromagnetic interference, please



report it to MedWatch, FDA's voluntary reporting program. You can submit these reports by telephone (1-800-FDA-1088), by FAX (1-800-FDA-0178), or by mail (MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857).

A copy of the full text of the March 20, 1998 Public Health Advisory is available on the FDA webpage at www.fda.gov/cdrh/safety.html. Additional information regarding electromagnetic interference and medical devices can be found on our EMC webpage at www.fda.gov/cdrh/emc/index.html. ❀

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Nancy Pressly is a Biomedical Engineer in CDRH's Office of Surveillance and Biometrics. If you have questions about this article, please contact Nancy Pressly, Office of Surveillance and Biometrics, HFZ-510, 1350 Piccard Dr., Rockville, MD 20850; FAX 301-594-2968; e-mail nap@cdrh.fda.gov.

## Use Error And Human Factors - *(from page 1)*

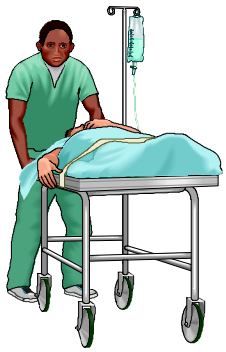
If so, it should be reported. In addition to use error, an adverse event can result from many factors such as poor manufacture or biomaterial incompatibility (e.g., as experienced with latex or silicone).

FDA is interested in another type of event -- a "near miss" or potential adverse event. More narrowly interpreted, "near misses" are events that could have caused serious injury or death, if timely corrective action had not been taken. To illustrate, a clinician may be busy in an intensive care unit. The device is already connected to the patient, so the clinician intuitively turns the dial clockwise to change the setting. When the patient's blood pressure drops, the clinician turns the dials back and corrects a potentially dangerous situation and thinks, "I turned the dials this way because dials normally turn clockwise to increase the output, but this manufacturer has designed it to turn counter-clockwise to increase the output." At this point, the clinician should consider that there is something wrong with the design. Because of the clinician's vigilance, no patient injury resulted, but it was a "near miss." If it is an ongoing problem, the next similar occurrence could be a "hit" instead of a "miss."

Clinicians often do not perceive devices as sources of problems. Because of their training, they try to make them work flawlessly. As a result, clinicians often blame themselves for adverse events when, in fact, device design or other human factors may have been involved. FDA is striving to educate medical and healthcare personnel to ask themselves to think more carefully about the role of human factors when problems occur with devices.

Perhaps you have experienced adverse events related to one or more of the following categories of device problems.

- *Control display arrangement and design.* Are the controls appropriately displayed? Are they in a logical sequence? Are they quick and easy to access?



- *Device operating logic.* Is the data entry difficult? Is the sequencing of functions intuitive? Is it difficult to navigate through multiple functions?

- *Component installation or accessory installation.* Is it easy or difficult? Does it result in faulty, loose, or incorrect connections?

- *Alarms.* Has the manufacturer taken the environment into account when designing its alarms? Can the alarm be heard over the noise encountered in the typical use environment? Is the alarm too intrusive? Does the alarm clearly convey what has gone wrong?

- *Transfer of training.* Are similar devices designed to operate very differently, thus causing confusion? FDA has received reports of adverse incidents related to a type of infusion pump which looks very much like most other infusion pumps except that the tubing threads from bottom to top. This is counterintuitive. If a nurse is accustomed to putting in the tubing from top to bottom and begins to use an infusion pump which looks similar to most other infusion pumps but threads differently, an adverse event may occur.

FDA is constantly trying to improve the ways we analyze post-market problems caused by use error. For example, we have fifteen analysts, primarily nurses, who look daily at the adverse events reported to FDA's Medical Device Reporting (MDR) system. They have device-specific expertise in areas such as cardiology, urology, and ophthalmology. When assessing the nature, scope, and magnitude of each adverse event, they use their knowledge and expertise. They research the device history, using FDA databases and the published literature. We are also developing a human factors checklist as an aid in determining the nature of use error. This checklist will assist our analysts in identifying and categorizing use error problems. *(Continued on page 7)*

## Use Error And Human Factors In Adverse Event Reporting - *(from page 1)*

Finally, we have identified certain terms in the coding manual (*Medical Device Reporting: Instructions for Completing Form 3500A with Coding Manual for Form 3500 A*) that may reflect use error problems. These terms can be used to search the MDR database for event problems. Examples of terms that may be directly related to design problems are "difficult to deflate", "difficult to position", "difficult to program", "misreading of display", or "miscalibration." All these terms and others reflect potential use error problems.

The following are some actual reports of use error taken from our MDR database.

- Some infusion pumps have recessed displays that are difficult to read. The clinician thinks the fluid is infusing at 1 ml/minute when it is actually infusing at 7 ml/minute. Due to the viewing angle and the fact that the display is recessed, the top of the seven is cut off.

- A ventilator alarm malfunctions because of improper installation of the batteries. If it is too difficult or complicated to install the batteries safely and correctly, the design should be changed to prevent this type of use error.

- An oxygen delivery system causes hypoxia, because the user misunderstood the control settings. FDA has received reports describing control knobs that move smoothly in a clockwise fashion without stopping or clicking on intermediate settings. If the control is set between 1 and 2, the clinician may think 1.5 liters/minute of oxygen is being delivered, but in fact the device is delivering absolutely no oxygen at that setting. At the 1-setting and at the 2-setting, it is delivering oxygen, but between these two settings there is nothing to alert the user that **no** oxygen is being delivered. There are no digital displays to recognize the fact that the dial is not ratcheted. Again, the design induced the error.

We would like to emphasize that FDA is becoming increasingly sensitive to human factors concepts and use error in particular. We are analyzing adverse event reports more systematically, developing a use error checklist, and using the MDR coding manual as a tool to search our MDR database. Our goal is to identify safety concerns and prevent use errors. This systematic analysis is in its early development, but we are making increasing use of these kinds of tools.

Safety data about marketed devices ("postmarket") is also used by FDA scientists when evaluating new product submissions ("premarket"). What we find on the postmarket side is increasingly being shared with our colleagues who conduct premarket analysis. It is also helpful when talking with manufacturers. We are working with and encouraging manufacturers to consider the user's responsibilities and limitations in the use environment and to make sure their devices are easy to operate. Finally, we need the device user to alert us to potential use error.❀

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*Thomas Gross, M.D., is the Director, Division of Postmarket Surveillance, Center for Devices and Radiological Health.*

# Coming in the Summer Issue

*Need for Caution When Using Vacuum Assisted Delivery Devices*

*Implanted Pacemakers: Avoiding Electromagnetic Interference*

*Safeguarding Cardiac Guidewires: Follow These Tips to Avoid Breakage*

*Device Tracking*


*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.





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| Editor: | Nancy Lowe |
| Assistant Editors: | Herb Spark |
| | 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