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IMPROVING PATIENT CARE BY REPORTING PROBLEMS WITH MEDICAL DEVICES

Learning Objectives:

Upon completion of this program, health professionals should be able to:

- Describe what constitutes a medical device
- Explain the importance of medical device postmarket surveillance
- List the three broad types of medical device adverse events
- Define their responsibility to report medical device adverse events
- Define the user facility's responsibility to report to FDA and/or manufacturers
- Describe methods used by FDA to inform health professionals regarding medical device safety

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Healthcare practitioners are the primary users of medical devices for direct patient care. As such, they are in the best position to recognize problems (such as in the example above) that result from the use of medical devices. 82% of all device-related incidents are discovered by nurses or physicians. The outcome of a device-related adverse event or product problem, as with any other medical product (i.e., drug, biologic, or special nutritional product), can be serious and result in illness, injury, or even death.

The active monitoring and reporting of medical device problems by health professionals and the facilities in which they work leads to improved patient care and increased safety, both for the patient and for the operator of the device. The reporting of device problems to the manufacturer and/or the Food and Drug Administration (FDA), the federal agency which regulates medical devices, is a critical communication link to ensure the safety and effectiveness of medical devices marketed in the United States.

The sooner that FDA learns about a problem, the sooner the agency can take action to protect patient and user safety. Sometimes a single report can initiate this action. Several case examples, based on actual reports received by FDA, are found throughout this article.

DEFINITION OF A MEDICAL DEVICE

"There probably are not many terms in the English language that cover as much ground as 'medical devices.' Those words encompass a great diversity of products from bandages to heart valves, from thermometers to the most advanced therapeutic and diagnostic machinery" David A. Kessler, MD , Former Commissioner Food and Drugs

The Federal Food, Drug, and Cosmetic Act) defines a medical device a "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article,...which is...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease...,or intended to affect the structure or any function of the body..., and which does not achieve any of its principal intended purposes through chemical action within or on the body...and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes." Therefore, medical devices are different from drugs, which work by chemical or metabolic reactions within or on the body to achieve their principal intended effects.

There are over 1800 categories of medical devices, and they vary in both complexity and risk potential. Some of the more common medical devices include ventilators , heart valves , pacemakers, X-ray machines, infusion pumps, implants, biopsy equipment, and ultrasound. Accessories to devices such as hoses, tubing, or software controlling a device are also regulated as devices. Less complicated devices include sutures, bedpans, thermometers, sharps containers, and medical gloves. Examples of lesser known products that are also regulated as devices are laboratory diagnostic tests; sterilants and disinfectants used for medical devices; water treatment used for dialysis; cementing agents; sunglasses; topical wound dressings; home diagnostic kits; and even leeches.

CASE EXAMPLE: An 81 year old female was undergoing surgery for a left hip implant. The surgery was proceeding routinely until the surgeon placed bone cement into the acetabular area in preparation to fit the hip implant. The patient went into anaphylactic shock and died.

Q - Is bone cement a medical device?
A - Yes.

Simply, if a product is not a medication (drug or biologic) and is used for diagnosis or treatment, it is probably a medical device.

An understanding of the routes by which medical devices come to be marketed, and the limitations of what is known about a device before it is marketed, offers valuable insight into why it is so important that health professionals closely monitor medical devices which they use in their clinical practice.

THE PREMARKET REVIEW

Before medical devices can be made available for use by the healthcare community, the manufacturer must first gain approval or permission for marketing by F DA. Part of the premarket review requires that device manufacturers develop good testing and manufacturing practices (which are inspected by FDA). The desired outcome of this process is the production of a consistently well-made, reliable, safe, and effective medical device which the user can depend upon to function for the specified life of the product.

In 1976, Congress amended the Food, Drug, and Cosmetic Act, and the FDA received the authority to require that new medical devices be proven safe and effective before being marketed. Prior to that time, FDA could only take action against hazardous or misrepresented devices after they were in the marketplace. The 1976 law created two primary routes to market medical devices, based on risk potential and product complexity:

1) **The 510(k) or premarket notification** is the simplest and most common route. For a device to be cleared via this route, the manufacturer must demonstrate t h at the new product is "substantially equivalent" to a device that is already on the market (the assumption is that the new product is safe and effective for the intended use, performs consistently, and is as good as what is currently available on the market). FDA then reviews the device by assessing the similarities to a device(s) already on the market. Examples include infusion pumps, foley catheters, and endotracheal tubes.

2) **The PMA or premarket approval application** route must be used if the new medical device is not similar to a device already on the market. In this case, the manufacturer must conduct clinical and pre clinical scientific studies to demonstrate that the device is safe and effective for its intended uses. Examples of devices in which a PMA was filed include stentless heart valves, coated vascular grafts, and implantable devices that combine cardiac pacing with defibrillation.

Note: Medical devices which were on the market prior to 1976 were "grandfathered," which means they were allowed to remain in general use, but are subject to an FDA request for safety and effectiveness data from studies.

In spite of a rigorous premarket review process, medical devices (or any other medical products) are only as safe as the information known at that moment in time. For example, clinical trials for a medical device may involve only a few hundred patients; medical devices are typically "bench-tested" (rather than tested in real-life clinical situations); and unlike drugs, most durable medical devices have no established end-of-life (i.e. it is unknown how long a device can be used and how frequently it can be used). **Therefore, healthcare professionals cannot assume that FDA has determined definitively that a device cleared for marketing is absolutely safe for human use.**

The accumulation, review, and evaluation of information that is gained about a product once it is cleared and available for marketing is called **Postmarket Surveillance.**

THE IMPORTANCE OF POSTMARKET SURVEILLANCE

Once the premarket process is completed and a device goes into widespread use, unforeseen problems can still arise. For example, adverse effects that occur relatively rarely or relate to product labeling (including instructions) or user technique and skill, cannot always be detected during the premarket review. Furthermore, questions related to durability, biocompatibility, and toxicology in humans may not be answered with certainty until a device has been on the market for a number of years.

Hospitals and other clinical settings monitor for problems with devices and other products within their facilities . These internal surveillance systems help to track and trend problems within the facility to improve the delivery of patient care.

FDA and manufacturers utilize a variety of postmarket surveillance tools to signal important events or trends in order to help identify the cause of device failures and to take appropriate action. In addition, medical devices continue to be tested by the manufacturer even after approval. FDA also performs in-house laboratory research to further analyze problems related to device safety.

To optimize postmarket surveillance in the detection of medical device problems, FDA and manufacturers are dependent upon individual healthcare professionals and the facilities in which they work to report problems with medical devices.

IDENTIFYING AND AVOIDING PROBLEMS WITH MEDICAL DEVICES

Types of Problems

Problems with medical devices generally fall into one of the following three broad categories:

- **Device Problems:**

Device problems include malfunctions (e.g., mechanical, electrical, or software - related) , manufacturing defects in product design or development, or material problems such as product instability.

- **Use Problems:**

Use problems may be caused by inadequate or misleading labeling, confusing instructions, inadequate

confusing instructions, inadequate packaging, design problems which make the device difficult to use, or inadequate training in the use of the device.

Use problems can cause or induce user errors. (See boxed information "Human Factors" on this page).

• Clinical Problems:
Clinical problems can occur with a patient who is sensitive or allergic to a device, has a preexisting condition that makes the device difficult or risky to use, or in whom the device would have an inherent risk.

Avoiding problems

Healthcare professionals can do some simple things to avoid common problems with medical devices:

- understand how a device should be used, and for which patients it is probably not safe
- be familiar with the instructions and other labeling
- inspect and test equipment prior to use make sure that devices are properly maintained and serviced
- do not use a device that has malfunctioned until it has been "cleared" by the appropriate facility staff (i.e., biomedical engineering)
- understand that the manufacturer may not be held liable for patient injury if a medical device is used in a manner not specified in the labeling (8,9,10)
- do not use a device past its expiration date

REPORTING DEVICE-RELATED PROBLEMS:

Healthcare professionals are **encouraged** to report medical device problems directly to the manufacturer and/or FDA whenever it is suspected that the product caused or contributed to an adverse outcome. However, health professionals who practice in hospitals, outpatient treatment, diagnostic, and surgical facilities, or long term care facilities need to be aware that **their facility is responsible** for reporting serious device-related events to the manufacturer and/or FDA. These types of facilities are called device "user facilities." The key to effective reporting is to understand the two complementary avenues for national adverse event reporting:

- Medical Device Reporting (MDR) **requires** device user facilities, manufacturers, and distributors to promptly notify FDA about device-related events that may have caused or contributed to a death, serious illness or injury; and
- MedWatch, the FDA Medical Products Reporting Program, which **encourages** individual health professionals to notify FDA and/or the manufacturer about serious adverse events and product problems with medical products. (i.e., events not reportable under MDR).

MEDICAL DEVICE REPORTING (MDR) BY USER FACILITIES

The purpose of MDR is to ensure that the most serious problems with medical devices will be identified at the level of the user and will be reported by the user facility to the manufacturer and/or the FDA. The MDR regulation was published on December 11, 1995 and became effective on July 31, 1996. This regulation facilitates the implementation of the user facility reporting requirements of the Safe Medical Devices Act of 1990 (11) and adds new requirements for (12) manufacturers and user facilities, as well as requirements for written procedures, complaint files, and reporting forms. Since the user facility has direct access to the patient and the device, it is in the best position to obtain the information that manufacturers and FDA need to determine whether the event presents a public health risk (13)

What is a device user facility?

Healthcare professionals who practice in any of the following types of clinical settings are working in a device user facility (i.e., facilities which are subject to MDR reporting):

• Hospitals (providers of diagnostic, therapeutic, surgical, and other patient services which include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities)

• Long-Term Care Facilities (providers of skilled nursing care, hospice care, or rehabilitation services)

• Ambulatory Surgical Facilities (providers of same-day outpatient surgical services)

• Outpatient Treatment Facilities (providers of nonsurgical therapeutic care on an outpatient basis, which includes ambulance providers, rescue services, and home healthcare services)

• Outpatient Diagnostic Facilities (providers of diagnostic testing on an outpatient basis, such as diagnostic radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and *invitro* testing services).

HUMAN FACTORS

(the study of the interaction between the user and the device) FDA is interested in knowing about device use problems in order to minimize error and patient injuries that result from user error (5) Human factors problems are more likely to occur with technologically advanced devices, such as programmable devices (6) Device use problems can happen in spite of adequate training and a high level of caution.

Examples of design problems that tend to induce user error include: 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 or confusing device operating procedures; inadequate device feedback or status indication that causes user uncertainty; and poorly designed labeling (7)

On the other hand, well-designed devices are those that are consistent with the user's experience; are logical and 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 the user to device-related problems; prevent users from making fatal errors that could otherwise occur easily; and are supported by readable and understandable labeling (7)

Health care practitioners can play an active role in device design by reporting information that they believe will help a manufacturer make a better device.

There are clinical settings which are **exempt** from MDR reporting requirement. These facilities include offices of physicians, dentists,

chiropractors, optometrists,nurse practitioners, school-based clinics, employee health clinics, and freestanding care units. **However, health professionals who work under the auspices of a user facility are subject to their facility's mandatory reporting requirements.**

How and what must user facilities report?

User facilities are required to complete a mandatory reporting form (FDA 3500A) whenever they receive or otherwise become aware of information that reasonably suggests that a device has or may have caused or contributed to the **death, serious illness, or serious injury** of a patient in the facility. Mandatory reporting requirements by user facilities could also include **device malfunctions** and/or **user error** which results in **death or serious illness/injury.** See TABLE 1 for further clarification of the meaning of "caused or contributed" and TABLE 2 for the FDA definition of "serious illness/serious injury" related to device reporting.

The user facility has the responsibility for determining if the **device-related event** is reportable based on the facts and circumstances observed by its medical or nursing personnel

User facilities have an additional responsibility to report, on a semiannual basis, all reports they submitted to FDA and the manufacturer within the previous 6 months. FDA uses these reports to monitor the compliance of the manufacturer with their reporting requirements.

Note: There are no mandatory reporting requirements for user facilities to report adverse events or problems with other medical products, such as medications. However, healthcare professionals a re encouraged to report these occurrences via the voluntary MedWatch reporting mechanism.

Death: Must be reported by the user facility to the **FDA and the manufacturer** of the device within 10 working days of the facility becoming aware of the event.

CASE EXAMPLE: A 35 year old female suffered a severe head injury in a car accident. Upon discharge from the hospital, she remained disoriented and easily agitated, and was followed by a home care agency for further care. Her physician's orders included IV medications to be infused via an infusion pump, physical therapy, and an electric hospital bed for long-term use. The patient was unattended one day for about 45 minutes, after which time the caregiver entered the room and found the patient's body hanging between the side rail of the bed and the floor. It appeared that the patient had attempted to get out of bed by slipping through the side rails. Her head became entrapped between the side rails and, unable to extricate herself, she was strangled.
Q - Is this death a reportable event?
A - Yes. Since the electric hospital bed (a medical device) might have caused or contributed to the patient's death, the event is reportable by the home care agency (the user facility) to FDA and the manufacturer within 10 working days of becoming aware of the event.

TABLE 1

CAUSED OR CONTRIBUTED

"Caused or contributed" means that an incident was or may be attributable to a medical device. The medical device may have been a factor in a death or serious injury, including events which occurred as a result of:

Device failure
Manufacturer defect
Malfunction
Improper/inadequate design
Improper/inadequate labeling
User error

TABLE 2

DEVICE-RELATED SERIOUS ILLNESS/INJURY

FDA defines a device-related serious injury as an injury or illness that:

- Is life-threatening;
- Results in permanent impairment/ damage to body function or structure; or
- Necessitates medical/surgical intervention to prevent permanent impairment/damage of body function/structure

Serious illness/injury: Must be reported by the user facility to the device manufacturer within 10 working days of the facility becoming aware of the event. (If the manufacturer is unknown, the report should be sent to the FDA.)

FDA encourages **user facilities** to submit reports of device malfunctions that **do not result in death or serious injury** directly to the **manufacturer** using the mandatory reporting form (FDA 3500A). Although these reports are not mandatory under the law, they provide important information that can result in product recalls and other types of corrective action.

CASE EXAMPLE: A 56 year old male entered an outpatient treatment facility to receive radiation therapy for throat cancer. He subsequently sustained burns central to and bordering the treatment area. Upon further investigation by the facility, it was discovered that the Radiation Treatment Planning System (RTP) had a software problem which included an algorithmic error resulting in irregular field settings. Due to this error, the patient received a 22% overdose of radiation to areas outside of the central beam axis during the course of his linear accelerator-based therapy. His radiation therapy was suspended, and he received treatment for his burns.
Q - Is this injury a reportable event? A - Yes. A software problem with the RTP (medical device) resulted in a serious burn injury to the patient, which required medical intervention to prevent permanent damage to body structure. The outpatient treatment facility (the user facility) should report this event to the manufacturer within 10 working days of becoming aware of the event.

CASE EXAMPLE: During a routine angioplasty procedure in a hospital, the tip of apercutaneous transluminal angioplasty catheter detached. The patient experienced no electrocardio -graphic changes or chest pain and was transferred to the medical intensive care unit. He ultimately underwent surgery to remove the wire tip of the catheter.
Q - Is this a reportable event?
A - Yes. Medical intervention was necessary (one of the definitions of "serious"), after the device (catheter) malfunctioned, to prevent permanent impairment to body function. The hospital (the user facility) should report this event to the manufacturer of the device (within the 10 working day limit).

CASE EXAMPLE: A 40 year old female undergoing a laminectomy was administered what the anesthesiologist thought to be 100% oxygen (to bring her out of anesthesia).When the patient became cyanotic, the anesthesiologist immediately removed her from the ventilator, believing it was malfunctioning. The patient was manually resuscitated. Three hours later, in the same operating room, a four month old premature infant was in surgery for a ventriculoperitoneal shunt. When the same ventilator was used, and oxygenation had been initiated, the infant became cyanotic and CPR had to be administered. Upon investigation by the hospital, it was found that the oxygen hose was inappropriately assembled into the nitrous oxide inlet and the nitrous oxide hose was inappropriately assembled into the oxygen inlet. The biomedical engineering department documented that the manufacturing firm had delivered and set up the device for use. Subsequently, no one had checked the ventilator connections prior to use of the device. *Q - Is this a reportable event? A - Yes. The incorrect assembly of the ventilator connections (medical device) resulted in a life-threatening event (one of the definitions of "serious"). This event should be reported by the hospital (the user facility) to the manufacturer (within the 10 working day limit).*

CASE EXAMPLE: A flash fire occurred during a blepharoplasty procedure being performed on a 40 year old male in an outpatient surgical facility. The patient was receiving oxygen via nasal cannula. The surgeon was cauterizing with an electrosurgical cutting and coagulation device when a " golf ball-sized" flash occurred. The patient's eyelashes, face, and cornea were burned. The burns were treated by debridement and ointment, and the patient ultimately required treatment by an ophthalmologist. The electrosurgical device was evaluated by the manufacturing firm and found to be functioning properly. The instruction manual contained warnings regarding fire hazards specifically with the use of electrosurgery in an oxygen enriched environment. *Q - Is this event reportable even though the labeling warns of potential fires? A - Yes. The patient required medical intervention to prevent permanent impairment after receiving an injury attributed to the use of the device. The outpatient surgical facility (the user facility) should report this event to the manufacturer within 10 working days of becoming aware of the event.*

CASE EXAMPLE: A 34 year old female with a nonpalpable breast lesion discovered by mammography entered an outpatient diagnostic facility for a large core needle biopsy under stereotactic guidance. The patient experienced no discomfort after the procedure, but a subsequent mammogram revealed that metal shavings and fragments from the 14 gauge needle had remained in the breast tissue after the biopsy was performed. This was due to multiple firings of the biopsy gun into the tissue that resulted in the needle hitting the cannula, causing the burring. *Q - Is this event reportable under the law by the user facility? A - No. This is a device malfunction which did not meet the definition of a serious illness / i n j u ry. However, F DA strongly encourages user facilities to report device malfunctions to the manufacturer and/or MedWatch so that they can take appropriate action if needed.*

CASE EXAMPLE: A nurse in a hospital was preparing to draw up a medication into a 5 cc syringe. In the process, he noticed the markings on the syringe were at an angle that made it impossible to draw up the medication accurately. He then checked the drawer where the syringes were stored and noticed at least 10 other syringes that were mismarked. Upon opening a new box of syringes, he discovered all the syringes were correctly marked. *Q - Is this event reportable under the law by the user facility? A - No. Although this device problem is not reportable under the law, FDA would encourage the user facility to report it to the manufacturer and/or MedWatch*

Of special note:

• Health professionals need to be aware that if a patient brings his/her own medical device (i.e.,a wheelchair) into a user facility for personal use and the device causes or contributes to the patient's injury or death, the event is reportable under MDR (even though the device is not owned or leased by the user facility) because it occurred in a user facility (14)

. • Healthcare professionals who work in user facilities and sustain a device-related illness/injury (or death) are considered "patients" of that user facility and any serious adverse event reportable under the law would be reported as if it had happened to a patient in that facility.

The role of the healthcare professional in user facility reporting:

It is critical that health professionals working in user facilities monitor and report all device problems in accordance with the procedures established by their facility.

These procedures will probably include:
• Removing the defective device from the patient area;
• Labeling the device with a description of the problem and the date;
• Recording the name, model number, and manufacturer of the device;
• Notifying the appropriate personnel;
• Filling out an incident report, and submitting all the evidence with the written report.

CASE EXAMPLE: A 2 year old female was admitted to the hospital with a fever of unknown origin and diagnosed with sickle cell anemia. The child was receiving D5W with potassium IV at 20 cc/hr per a large volume infusion pump. The mother, who was in the room with the child, heard the pump alarm and turned on the nurse call light. The nurse heard the pump alarming upon entering the room. The child was coughing and having difficulty breathing. When the nurse attempted to better open the patient's airway, the child became limp and unresponsive. A code was called and CPR was initiated. The patient was removed from the pump and transferred to the ICU, where she died several hours later. *Q - What would be some of the device-related actions which should be taken? A - A health professional witnessing this event needs to identify that the infusion pump might have contributed to the death of the pat i e n t . Established procedures within that facility must be followed. These procedures may include that the pump be labeled, removed from the clinical area , a n d checked to evaluate why it was alarming (whether it was programmed correctly, whether there appeared to be over/under infusion, whether the tubing was properly i n s t a l l e d, e t c.). The healthcare professional should also notify the appropriate personnel within his/her facility (such as the risk manage r) , and complete the necessary written report.*

Although the healthcare professional might be the one to discover the problem, the ultimate responsibility for reporting device-related events to the manufacturer and/or FDA rests with the user facility. The healthcare professional does not need to determine if a device-related incident is reportable to FDA or the manufacturer. The user facility investigating team will make this determination within the requirements of MDR.

Above and beyond following internal reporting policies in their user facility, healthcare professionals are encouraged to take an active role in developing the mandatory device monitoring system which will provide an effective mechanism for data collection, documentation, and evaluation.

The MDR regulation specifies that the following be done in all user facilities :

• Obtain copies of the MDR regulation, reporting forms and instructions, and coding manual.

• Designate an MDR contact person (e.g., the facility administrator, risk manager, or biomedical/clinical engineer). The contact person can rely on a committee to determine reportablility of events.

• Develop written procedures explaining how the user facility intends to comply with MDR requirements (usually these procedures have been added to the monitoring systems already present in the facility)

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• Start a file of reports and information that is sent to FDA and the manufacturer. Files must be kept not only for events which were reported, but for those not reported, and must be maintained for two years.

• Develop internal systems to identify device-related events, determine which events must be reported, provide documentation of decisions, and ensure that forms are properly completed and submitted within the required time frame.

N o t e : The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will be reviewing compliance with MDR during their site visits. User facilities can also be visited by FDA investigators to determine whether they are in compliance with MDR.

VOLUNTARY REPORTING BY HEALTH CARE PROFESSIONALS

The second reporting mechanism , voluntary reporting by healthcare professionals, is just as vital as mandatory MDR in protecting the safety of patients and device operators.

Under MEDWATCH, FDA's Medical Products Reporting Program, health professionals are encouraged to report serious adverse events and product problems with all medical products (i.e., drugs, biologics, medical devices, and special nutritional pro d u c t s , including dietary supplements , infant formulas , and medical foods) to FDA and/or the manufacturer. Health professionals use the voluntary reporting form (FDA 3500). Whenever a device fails to perform as expected, it should be kept, as well as any other material evidence that could be used if an investigation of the product is made (15)

Medical devices should not be sent to FDA.

The definition of a serious adverse event is broadly defined within voluntary reporting to include any patient outcome that results in death, a life-threatening eve n t , hospitalization (initial or prolonged), disability, a congenital anomaly, or if medical or surgical intervention was required to prevent permanent damage. Health professionals do not need to prove causality; a suspected possible association between a product and an adverse patient outcome is sufficient reason to report.

FDA is also interested in reports of product problems such as inaccurate or unreadable labeling, packaging or product mix-up, contamination or stability problems, defective devices, or product confusion (caused by name, labeling, design, or packaging).

When can the voluntary system be used to report problems with medical devices?

1. To report medical device events occurring in clinical settings which are **exempt** from user facility reporting (such as the office of a physician, nurse practitioner, or dentist). Events that are particularly important to report are serious device malfunctions that result in a death or injury, or when a device-related condition is created that may be unsafe, hazardous, or otherwise presents a public health concern. FDA is not interested in reports from health professionals if personal preference is at issue rather than device performance.

2. To report some medical device events occurring within a user facility (it is usually the user facility that makes the decision to file a voluntary device report). User facilities are encouraged to use the mandatory version of the form , **F DA 3500A**, even though the reporting is voluntary, because the 3500A requests additional necessary information about the device incident.

• Voluntary reporting is appropriate for a "near miss" (i.e., under slightly different circumstances, a serious injury or death might have occurred) When a potential hazard is recognized, corrective action should always be taken. FDA encourages the voluntary reporting of "near misses" to the device manufacturer (16)

• The voluntary reporting mechanism can also be used for reporting user error not resulting in death or serious illness/injury, because such events may indicate that the labeling for a device does not provide adequate directions for use or adequate warnings (17)

• Finally, voluntary reporting of device-related problems in a user facility is appropriate for device-related events not reportable under the law (i.e., not causing or contributing to serious illness/injury or death) which affect product quality such as defective devices, inaccurate or unreadable product labeling, packaging or product mix-up, contamination, or stability problems.

It is important to note that voluntary reporting on the FDA 3500 by health professionals does not satisfy their user facility's medical device reporting requirements under MDR. Health professionals should follow the intern a l incident reporting procedures within their facilities for all device - related events. However, health professionals can file an individual report using the FDA 3500 form.

WHAT HAPPENS TO YOUR REPORT?

Reports sent to the device manufacturers:

Upon receiving a report from a user facility or an individual healthcare professional, a manufacturer must investigate, evaluate, and identify the underlying causes of any adverse event reported to them. (The manufacturer usually contacts the reporter to obtain as much information as possible so that the manufacturer can investigate the event and complete their report to FDA.) FDA periodically inspects manufacturers for compliance with manufacturing and reporting requirements. In addition , device distributors must also report device-related deaths, serious injuries , serious illnesses, a n d malfunctions to FDA with a copy to the manufacturer .
(18) In some cases the problem might be resolved by means of relabeling or a recall. For example, 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 recall. (1)

Reports Sent to FDA:

When FDA receives a report from a user facility or an individual health professional, it is entered in the medical device postmarket surveillance database, and subsequently compared to other information. Part of this review is to evaluate any past problems with the device, particularly those which may present an immediate risk to the public health. All voluntary reports that are received by MedWatch are sent to the manufacturer for follow-up. FDA staff also look at actual or potential risk, and ensure that appropriate corrective action is initiated. Not all reports involve problems that re q u i re immediate resolution. FDA continually reviews the database to detect problems, trends, and potential hazards.

As a result of such trend analysis, FDA staff noticed a gradual increase in the number of deaths associated with the use of hospital bed side rails (19)

Between January 1990 and June 1995, F DA received 102 reports of head and body entrapment incidents involving hospital bed side rails. Although one entrapment occurred with a 2 year old patient, the majority of deaths and injuries involved elderly patients. This prompted FDA to mail a Safety Alert entitled *Entrapment Hazards with Hospital Bed Side Rails* on August 23, 1995 to over 94,000 hospitals, nursing homes, hospices, nursing associations, and home healthcare agencies.

E ach ye a r, F DA receives approximately 100,000 reports through the MDR route and 5,000 device reports through the voluntary MedWatch route. Nurses are active device reporters, submitting about 25% of the voluntary device reports (biomedical engineers and other technicians/ technologists submit about 21%, risk managers about 13%, and physicians about 8%). The remainder of the voluntary reports are submitted by pharmacists and dentists, with about 17% from non-health professionals.

Confidentiality and Public Availability of Reports

FDA is aware that health professionals are concerned about the issue of confidentiality and public availability of reports.

Voluntary Reports (reported on FDA 3500) from health professionals:

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not release any patient identifiers to the public. Healthcare professionals can assist in this process by not using the patient's name, initials, or other identifying information in block A1 (patient identifier) on the reporting form (i.e., leave it blank).

The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise (there is a check-off box on the form). However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

On July 3, 1995, FDA published a regulation that extends this protection by preempting state discovery laws for voluntary reports held by drug, biologic, and medical device manufacturers (20)

Mandatory Reports (reported on FDA 3500A) from user facilities:

Certain information from user facility reports is available for public disclosure. Prior to public disclosure, F DA will delete:

- Any information that constitutes trade secret or confidential commercial or financial information;

- Any personal, medical, and similar information (including the serial number of implanted devices) which would constitute an unwarranted invasion of privacy; and

- Any names and other identifying information of a third party voluntarily submitting an MDR report. This includes physicians, nurses, other healthcare professionals, or other hospital employees, unless they are the designated MDR contact person.

PROVIDING FEEDBACK TO HEALTH CARE PROFESSIONALS

Reports from health professionals and other sources provide valuable information about device problems. When risks or potential risks associated with the use of medical devices are identified by FDA, the agency issues a Notice (or letter), a Public Health Advisory, or a Safety Alert. This information is then mailed to hospital administrators, risk managers, biomedical engineers, pharmacists, and other agencies. It is also sent (via email or fax) to the M e d Watch Partners , rep resenting more than 130 health professional specialty organizations.

A Notice is usually a letter to healthcare professionals or healthcare organizations from FDA. Two recent examples are the April 17, 1997 Notice alerting health professionals to a potential infection problem with medical devices that are rented or leased by healthcare facilities, and the June 13, 1997 Notice entitled *Radioactivity in Radiation Protection Devices.*

A Public Health Advisory is generally issued when there has been a problem identified with a device and describes potential risk. For example, FDA issued a Public Health Advisory on March 21, 1994 entitled *Avoiding Injuries fro m Rapid Drug or IV Fluid Administration*.identified with a device and describes potential risk.

HOW TO OBTAIN FORMS AND INSTRUCTIONS

Voluntary (FDA 3500) form for reporting by **health professionals :**

- By mail or fax : call 1-800-FDA-1088 (fol low instructions for health professional or press "0" during the initial message)

- By intern e t : www. f da.gov / medwatch (cl i ck on "How to Report " , then "Reporting by Health Professionals"). Print the form or download as a PDF file. There is also form software which can be downloaded and used to complete the forms using a personal computer. After the initial entries are m a d e, the completed form can be printed and mailed to FDA and/or the manufacture r. This software does not permit electronic submission of reports. If you prefer a copy of the free software on disk, call 1 - 8 0 0 - F DA-1088 (press 0), or e-mail MedWatch (medwatch @ bangate.fda.gov). Note: the form software contains both the FDA 3500 and the FDA 3500A forms.

Mandatory (F DA 3500A) form for reporting by **user facilities :**
- By mail or fa x : call 1-800-FDA-1088 (press "0" during the initial message)
- By intern e t : www.f da.gov (cl i ck on “Medical Dev i c e s / Radiological Health,” “ Program Are a s ,” “Medical Device Reporting,” and "Forms and Instructions." Print the form or download as a PDF file. There is also form software which can be downloaded and used to complete the forms using a personal c o m p u t e r. After the initial entries are made, the completed form can be printed and mailed to FDA and/ or the manufacturer. This software does not permit electronic submission of reports. If you prefer a copy of the free software on disk, call 1-800-FDA-1088 (press 0), or e-mail MedWatch (medwatch @ b a n gat e. f d a . gov). Note: the form software contains both the FDA 3500 and the F DA 3500A forms .

HOW TO REPORT TO FDA

Voluntary (3500):

- By mail (postage-paid form)
  Med Watch
  The FDA Medical Products Reporting Program
  Food and Drug Administration
  5600 Fishers Lane
  Rockville, MD 20852-9787
- By phone: 1-800-FDA-1088
- By fax: 1-800-FDA-0178
- By internet: available late 1997

Mandatory (3500A):

- By mail:
  FDA Center for Devices & Radiological Health
  MDR Reporting
  PO Box 3002
  Rockville, MD 20847-3002

  Mark the envelope:
  "User Facility Report"

QUESTIONS ABOUT REPORTING?

Voluntary:

Contact the MedWatch office
Phone: 1-800-FDA-1088 (press 0) or (301) 443-0117 (local)
Fax: 1-800-FDA-0178 or (301) 443-5776 (local)
E-mail: medwatch@bangate.fda.gov
Mail: MedWatch
FDA, HF-2
5600 Fishers Lane, Room 9-57
Rockville, MD 20857

Mandatory:

Reporting Systems & Monitoring Branch (HFZ-533)
FDA, CDRH
1350 Piccard Drive
Rockville, MD 20850

Phone numbers for specific questions (Please use fax numbers except for emergencies): Interpretation of policy
(301) 827-0038 (fax) (301) 594-2735 (voice)

Individual 3500A or semi-annual reports
(301) 827-0038 (fax) (301) 594-2731 (voice)

Emergencies outside of normal East Coast business hours
(301) 443-1240 (fax) (301) 443-3757 (voice - 24 hours/day)