Medical Device Accidents: Recognition and Investigation

For Saudi Food and Drug Authority

Educational Sessions on Medical Device Accident Investigation

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INTRODUCTION

Any general discussion of investigating medical device accidents is necessarily limited due to the vast diversity of technologies and devices. Chapters or entire texts could be dedicated to the techniques and subtleties of investigating individual technologies (such as anesthesia machines, physiologic monitors, infusion pumps, heart-lung bypass systems, electrosurgical units, and critical care ventilators), as well as for disposable devices (including catheters, breathing circuits, electrodes, oxygenators, and trocars). Generic classes of device-related accidents could also be addressed for topics such as surgical fires, skin “burns,” and gas embolism. Accidents involving perceived failures of implants (e.g., cardiac valves, pacemakers, silicone prostheses, orthopedic implants) require further unique investigative approaches beyond the scope of these materials.

Published treatises that address some of these medical-device-specific topics are available (Bruley 1994, Cooper 1993, Dyro 1998, ECRI 1991, Forsell 1993, Gaba 1989, Geddes 2002, Hyman 1994, Hyman 2002, Senders 1994, Shepherd 1992). These references can serve to further guide an investigator in the pursuit of the cause of a suspected medical device accident. However, it is recommended that the user facility investigators seek first to develop a working knowledge of the following basics covered in this section:

- General causes of medical device accidents
- Device interfaces
- Investigation guidelines
Presentations on the tracking and analysis of general problems related to any one technology, to device-related techniques, or to a manufacturer’s product line are not included.

THE INVESTIGATOR’S PERSPECTIVE

Most serious or fatal medical-device-related accidents occur in the acute care hospital setting, although accidents in the home setting with devices that are provided and maintained by the hospital (or possibly a durable medical equipment [DME] supplier) are becoming more common. Hospitals and other user facilities are usually the first ones aware of an accident and have the best access to the device(s), equipment purchasing, maintenance and repair records involved, personnel involved, and relevant patient records. Both hospitals and their contracted independent investigators are then in the best position to quickly and fully investigate most aspects of an accident.

ACCIDENT VERSUS FORENSIC INVESTIGATIONS

The goals of an accident investigation are to determine what happened, why it happened, and which corrective actions and preventive measures can be taken: The goal is not to assign blame. Accident investigations are performed soon after the incident and typically include a review of incident reports, medical records, equipment-related documentation, and hospital procedures. Involved personnel are interviewed. Equipment is examined and tested, frequently under conditions similar or identical to the accident and often in the presence of interested parties.

Forensic investigations are performed in relation to litigation, arbitration, and contract issues. In medical malpractice/product liability cases, the goal of a forensic investigation is to
provide a clearly stated, reasonable biomedical engineering or medical opinion on the cause of the accident at deposition or trial. The opinion defines the involvement, or lack of involvement, of the suspect device. Information analysis closely parallels that for accident investigations: additional activities include review of legal case documents, analysis of equipment design philosophies, accident reenactment, and specialized analysis and testing in preparation for testimony. Some investigators see the assignment of blame as one fundamental goal of a forensic investigation. In this regard, however, it is important to remember that in the end, legal liability is determined by juries and courts. Their verdicts, as do out-of-court settlements, have less to do with enhancing safe medical device design and use than with determining who compensates a patient for real or imagined injuries.

CAUSES OF MEDICAL DEVICE ADVERSE EVENTS

The failure of medical devices to fulfill their intended purpose with reasonable safety and reliability has several classes of causation, as discussed below.

Invalid Device Foundation

One type of basic failure to perform properly or effectively is due to an invalid physiological or theoretical foundation for the device. This may have come about from the device designer’s ignorance of existing knowledge or an insufficiently developed base of scientific knowledge within the healthcare and research communities. Widespread use of gastric hypothermia in the early 1960s to medically cure ulcers and avoid surgical intervention is an example. Most such examples are self-eliminating within several years. Since clinical experience demonstrates a failure to meet diagnostic or therapeutic goals, the technology is soon abandoned.

Design Errors

Some manufacturers fail to apply the existing knowledge base to the device development process carefully. This failure includes inadequate testing of the design before use on
humans and inadequate evaluation of the device and its safety and performance in the hands of the typical user as part of the design, evaluation, and development process. Even in high-quality engineering organizations, design errors cannot always be eliminated. Through testing and clinical evaluation in the normal use environment, errors are unmasked and corrected. There is often a fine line between design error and “suboptimal” design (e.g., panel indicators or controls that require counterintuitive interpretation or manipulation by an operator, such as violating the convention that turning a rotating control clockwise increases the amplitude of a signal or increases pressure; failure to provide a guard or lock for an easily bumped and inadvertently changed critical control, such as an anesthesia machine flowmeter valve).

Grosser examples of design errors include failure to provide adequate mechanical clearance between active electrical components or failure to provide fusing or effective grounding, either of which may cause electric shocks or fire hazards.

In practice, some design deficiencies are apparent only after long use of a device. While in retrospect, they could have been anticipated, there are practical limits to human perception and to how long a product can be tested before it is formally introduced into the marketplace (the very slow weakening and ultimate failure of an implanted orthopedic joint or plate due to corrosion and metal fatigue may occur only after several years; a statistical cluster of such failures points to a systematic rather than random failure).

Manufacturing Errors

These device failures are the easiest to prevent because, unlike design errors, they are not based on conceptual failures. Instead, they are based on the failure to devote sufficient priority devoted to purchasing, inspection, and testing of raw materials and components or on failures in inspection, testing, and related record keeping and quality-control analysis for components, subassemblies, and systems. Typical examples include failure to both bore a hole and check for its presence before packaging and shipping tracheostomy
tube adapters, thereby blocking a patient’s airway. Some manufacturing defects take time to be manifested (e.g., an electrical relay rated for 800,000 operating cycles fails after 1,000 cycles, perhaps due to impurities in a metal supplied by a primary source to a metal fabricator, then to a relay manufacturer four or five times removed from the medical device manufacturer).

**Random Failures**

Some device failures are caused by random, unpredictable malfunctions of materials or a component. Because random failures are inevitable, an effective design validation effort undertakes a fault tree or similar analysis to determine the effect of the failure on individual components or subassemblies and the associated risks to patients and operators. If the risk is significant, redesign to achieve a fail-safe device is essential. The investigator must apply similar efforts. For example, a patient was crushed to death by a descending motorized radiotherapy gantry that did not stop in response to its normal operating control, its operator’s emergency stop control, or its automatic limit switch. All three controls operated through the same electrical relay, which had failed. Redundant design for safety would have required that independent relays be used for each of the three modes of controlling gantry descent or that relay failure in any mode would stop gantry movement.

In the traditional application of most medical devices, there has been an interplay between three elements: the device, the patient, and the professional user(s) of the device. However, two major elements have recently been added to many devices. More and more devices are now incorporating computers or microprocessors, which, in turn, require software. The software or instruction sets that control what the devices do and when they do it present special complexities in understanding and failure prediction/analysis. They create a whole new arena for design and human error and assignment of responsibility. Lethal overradiation of several patients caused by an intermittent software problem in a computer-controlled linear accelerator is a classic example. Software “glitches” and “bugs” are common to virtually all software. Corrections, improvements, and
“enhancements” are usually part of software development for some time, often long after the software is first marketed. In the future, as more medical devices incorporate microprocessors and accompanying software, one can expect deficiencies and failures in software to increasingly develop as the fundamental reason a device fails to fulfill its intended purpose. Discerning the difference among corrected, improved, and enhanced software, determining which software, associated with the device, isolating responsibility, and determining when the software product was really complete or merchandisable may prove a significant challenge.

**EXTERNAL FACTORS LEADING TO FAILURES**

*Electrical Power Supplies*

The quality and consistency of electric power affects device function. Despite the electric safety scare of the late 1960s and early 1970s in North American hospitals, more damage has been done by having too little electricity when and where it was needed than by having too much where and when it was not wanted (i.e., electric shock). Power failures and outages, brownouts (i.e., reduced voltage), overloaded circuits, and failures of batteries, battery chargers, standby electrical generators, and transfer switches cause many more device failures and harm to patients than do inadvertent electric shocks associated with medical devices.

*Medical Gas Supplies*

Failures in medical gas supplies and systems supporting anesthesia machines, ventilators, resuscitators, and oxygen administration devices cause more preventable deaths among patients than does electric shock. Accidental exchange of certain medical gases (e.g., using nitrous oxide, an anesthetic, in place of oxygen) has killed scores of patients. The usual cause is crossed medical gas plumbing/fittings during construction, maintenance, or repair and failure to inspect each individual medical gas outlet for the type of gas it emits following such activities.
Electromagnetic Interference (EMI) or Radio-Frequency Interference (RFI)

EMI or RFI has caused failure in some electric or electronic medical devices. Electromagnetic energy from nearby transformers, motors, radio stations, electrosurgical units, hospital central clock controllers, and communications systems may cause a medical device to stop functioning properly. EMI may be radiated through the air or conducted through power lines or other conductors. EMI is difficult to detect and prove as a cause of failure because it is usually intermittent. Not only are relatively few devices susceptible to EMI, but a given device may be susceptible only at a specific control setting or in a particular mode of operation.

Historical examples of EMI with medical devices include failure of life-support ventilators because of conducted EMI from a hospital’s central clock controller, changes in infusion and drug administration rates for an infusion pump because of radiated EMI from electrosurgical units on another floor of the hospital, inhibition of cardiac pacemakers by radiated EMI from microwave diathermy, and signal distortion on electrocardiographic monitors from a nearby electric transformer.

Environmental Controls

Inadequate control of environmental conditions, such as temperature and humidity, can result in device failures. High-humidity environments may cause electric or electronic equipment to fail. Low-humidity environments may cause failures from electrostatic discharges that damage microelectronics.

Systems Errors

Some accidents occur because the systems designed to prevent their occurrence have not been implemented. Such system failures include the following:

- Failure to implement incident reporting systems, hazard and recall systems, or
other communications systems, policies, and procedures

- Failure to have systems to impound possible defective devices for detailed examination
- Failure to follow through with competent investigation, to understand causes of incidents, and to implement corrective actions
- Failure to document appropriate device-related information
- Failure to undertake prudent prepurchase evaluations of devices
- Failure to provide appropriate devices (not just provide them improperly or in defective condition)

A taxonomy, or list of classification terms, has been developed to classify medical device adverse events and aid in the investigation of their cause. It is based on ECRI’s more than three decades of investigating adverse events, patient injuries, deaths, and close calls from errors and accidents associated with healthcare technology, instruments, devices, and systems. In this regard, five broad categories are at the heart of all adverse events and medical errors involving a healthcare technology.

**CLASSIFYING MEDICAL-DEVICE-RELATED ADVERSE EVENTS**

The taxonomy presented here differs in content from US-FDA’s historical MedWatch codes for device failures. The MedWatch codes number in the hundreds and were designed to aid in database analysis of the reported problems. The classification lists below have a primary purpose of aiding investigation but can also be used for initial coding. Focusing on these broad classifications of cause during a medical device adverse event investigation will aid investigators as they wend their way through what may at first appear to be a myriad of possible contributing causes of a medical-device-related adverse event. The broad categories and subcategories for classification of the causes of medical device adverse events (some of which have been discussed above) are as follows:
I. Device Factors

- Device failure
- Design/labeling error
- Manufacturing error
- Software deficiency
- Random component failure
- Device interaction
- Failure of accessory
- Invalid device foundation
- Packaging error
- Improper maintenance, testing, repair
- Lack of incoming inspection

II. Errors During Use

(Discussion and examples of these use-related causes are presented below, after the classification lists.)

- Labeling ignored
- Device misassembly
- Improper (“bad”) connection
- Accidental misconnections
- Incorrect clinical use
- Incorrect control settings
- Incorrect programming
- Inappropriate reliance on an automated feature
- Failure to monitor
- Abuse
- Spills
- Preuse inspection not performed
- Maintenance or incoming inspection error
III. External Factors

- Power supply failure (including piped medical gases)
- Medical gas and vacuum supplies
- Electromagnetic or radio-frequency interference (EMI and RFI, respectively)
- Environmental controls (temperature, humidity, light)

IV. Tampering/Sabotage — interference with the function or operation of a medical device or accessory, which results in the reckless endangerment of the patient (tampering) or which was performed with the intent to do harm (sabotage). Tampering may be due to carelessness or extremely poor judgment.

V. Support System Failure

- Poor prepurchase evaluation
- Poor incident/recall reporting systems
- Failure to impound
- Lack of competent accident investigation
- Failure to train and credential
- Use of inappropriate devices
- Lack or failure of incoming and preuse inspections
- Improper cleaning, sterilization, storage
- Error in facility policy

These categories and terms have proven useful in application during clinical, administrative, risk management, and laboratory investigations of medical device accidents (1, 2). As mentioned, they are complimentary to, but more succinct than, the terminology used in the approximately 2,200 coded categories in the FDA Form 3500A Device Coding Manual used by medical device manufacturers.
and healthcare facilities to comply with the MedWatch Medical Device Reporting regulation (21 CFR Part 804).

Beyond these causes of medical device adverse events, ECRI has developed and used the following taxonomy to classify the proximate causes of injury or death related to medical device adverse events. “Proximate cause” is a term commonly used in root cause analysis and refers to the more readily apparent or obvious causes of an adverse event. “Root causes” underlie proximate causes. This is discussed more in the Healthcare Risk Control article titled “Root Cause Analysis.”

In addition to the list of causes of adverse events, the list of mechanisms of injury is also important to consider during the investigation. Many times, what appears to be an injury caused by a medical device has other etiologies. The investigation may rule out the suspect device and implicate an idiopathic physiologic response by the patient.

**Proximate Causes of Healthcare Technology-Related Injuries**

- Barotrauma
- Burn (electrical, thermal, chemical)
- Coagulopathy
- Electrical Shock/electrocution
- Embolism (gaseous/particulate)
- Exsanguination
- Extravasation
- Failure to deliver therapy
- Fire
- Hemorrhage
- Hypothermia
• Hyperthermia
• Infection
• Infiltration
• Ischemia
• Mechanical (puncture, laceration, tear, etc.)
• Misdiagnosis
• Monitoring failure
• Overdose
• Pressure necrosis
• Suffocation
• Underdose
• Wrong drug

ERRORS DURING USE

Many medical devices present risks if they are not set up, checked, used, cleaned, or serviced properly. Device manufacturers assume a basic level of knowledge, skill, and care on the part of the healthcare user or servicer and, as a result, place on users certain responsibilities for the safe use of a device. Nonetheless, even with the most experienced user, mishaps occur. Are such mishaps “human error,” “use error,” or “user error?” How do we best address this aspect of proximate cause for a medical device adverse event during an investigation and in reporting our conclusions? The terms can be helpful or inhibiting in an investigation, depending on how they are perceived.

Terminology from the field of human factors research proves useful in discussing such errors. In classical terms there are errors, slips, and mistake as defined below:

• **Error**—Actions or omissions leading to results that were neither foreseen or intended. Most errors are benign or close calls. Combinations of errors lead to accidents.
• **Slip**—Correct action done incorrectly.

• **Mistake**—Wrong action done correctly or incorrectly.

In the broadest sense, “human error” as a cause of medical device adverse events encompasses all individuals who have a potential role in the education, setup, maintenance, repair, reprocessing, and use of a medical device or system. Sometimes the human contributing to the cause of the adverse event is the patient. “Use error” is more specific in that the adverse event is directly associated with the application (“use”) or preparation of the device to patient care, treatment, or diagnosis. Inadequate training or poor human factors, software, or labeling can be major precursors to an error occurring during medical device use as can the systems errors mentioned above. Inevitably, however, many adverse events are the result of a “user error” where attribution for an error, slip, or mistake rests with the device user. An important caveat is that user error does not automatically mean that the error is attributable to the user. As with use error, user errors usually have an underlying cause that should be investigated. Investigation into the cause of such errors should focus on the system within which the user works.

It is generally accepted that more than half the medical device adverse events are caused by some aspect of an error on the part of the device user. Rather than leaving use error as a proximate cause of an incident, examination of the systems within which the user works, though a potentially complex task, is required to get to the root causes of the adverse events. Errors during medical device use result from inadequate training, lack of experience and supervision, and/or inadequate or unavailable instruction manuals, all of which are reinforced by the natural risks, time pressures, psychological pressure, and rapidly changing priorities inherent to the healthcare environment. Sabotage, though rare, has occurred and led to deaths, as has nonmalicious tampering. Maintenance and service errors (e.g., misassembly of anesthesia machine flowmeters following preventive maintenance; incorrect calibration of infant incubator thermostats) must be considered as well. Finally, the patient as “user” is a consideration. Patient errors with devices (e.g., stressing an artificial hip by ignoring instructions to avoid jogging, tampering with a -
medication reservoir) may require investigation. An example or two from the major use-error categories will help refine the investigator’s awareness of user problems.

**Device Misassembly**

Medical device misassembly is frequently contributed to by poor human factors design, device wear, or user inattention. Consider the case where a reusable cranial perforator drill bit is designed with an internal clutch that disengages the cutting mechanisms at the very instant the tip of the drill perforates the inner table of the skull. It has five working components that must be disassembled for cleaning and then reassembled before use. The manufacturer provides written recommendations for ensuring that the perforator has been correctly reassembled. However, it is easy to misassemble this perforator in such a way that the clutch mechanism does not function. In such cases, once through the bone, the ½-inch drill bit will instantly bore into the brain to a depth of approximately 2½ inches. Subsequent designs of cranial perforators use the container in which they are stored and sterilized as a guide to prevent misassembly. If the guide is used, misassembly is impossible. Manufacturers have also eliminated the problem of user misassembly by developing disposable perforators that do not require any disassembly or reassembly by the user.

This cranial perforator example is noteworthy because some incidents of suspected “perforator failure,” even with those that can be misassembled, are actually caused by anatomic anomalies in the patient’s bone or dura. As such, the device’s design and the user’s technique may not have been the true causes of the accident. Even so, from an overall user standpoint, the initial perforator design was poor because it easily permitted the user to misassemble it.

**Inappropriate Reliance on an Automated Feature**

The response of healthcare personnel to an automated alarm on a physiologic monitor may results in precipitous treatment if the patient’s true physiological status is not first
confirmed. In more than one case, a sleeping patient has been defibrillated when a physiologic monitor displayed a cardiac waveform that appeared to be ventricular tachycardia; in reality, one of the ECG electrodes had detached. The nurses saw the apparent ventricular tachycardia and treated the patient based on what the machine indicated. The patient’s actual condition was markedly different. In some of the cases, the patient did not survive. Though the users could well have chosen to employ more thorough clinical protocols, the monitoring technology itself contributed to this incident.

**Accidental Misconnections**

Accidental misconnections are a common problem, especially with respiratory therapy and anesthesia equipment. Some positive end-expiratory pressure (PEEP) valves are not clearly labeled as to the direction of their flow, and others are not bidirectional. If placed in a breathing circuit in the wrong direction or if placed in the wrong limb of a breathing or anesthesia circuit, high pressures can develop in the circuit and cause lung damage. Another example in this category is the accidental connection of electrode lead wires to line power. This proved to be a problem with electrode lead wires connected to apnea monitors used in the home care setting. The lead-wire plugs fit very easily into extension cords; the color coding of white, black, and green for ECG leads corresponded to the white, black, and green color coding of power cords. In one case investigated, the white, black, and green leads were plugged into the transparent extension cord plug from an infusion pump. Changes in the design of the lead-wire plugs were ultimately made and have tended to eliminate this problem.

**Improper Maintenance, Testing, or Repair**

Incidents of improper equipment maintenance, testing, or repair leading to a patient injury or death are extremely rare based on research presented by ECRI staff at a 1998 FDA conference on refurbishing and servicing of medical equipment. In investigating such cases, the level of training and experience of the person performing a repair, etc., may seem to play a role in the cause of the adverse event. However, even an experienced
servicer may make a mistake. Consider the case where the tubing leading to a surgical pneumatic tourniquet had been repaired by operating room nurses using a female Luer connector. The nurses had cut out a dry-rotted section of tubing because it was leaking. As a result of the improper repair, the tourniquet accidentally deflated a minute or two after the patient had been injected with regional anesthesia in his arm. He suffered grand mal seizures and brain damage from the bolus of anesthetic entering his systemic circulation.

In contrast to this case, an experienced servicer of an intraaortic balloon pump switched high and low pressure gas feed lines within the chassis of the machine during repair and failed to perform a post-repair performance verification check. The next use of the pump resulted in balloon over-inflation, aortic rupture, and patient death.

Incorrect Clinical Use

This category includes improper checkout or unintentional activation. Examples in this category include the accidental activation of a surgical laser, which caused a fire that seriously burned a patient, and the accidental activation of an electrosurgical active electrode by a surgical resident’s forearm as he held a retractor. The failure to use an appropriate holster for the active electrode is an obvious user error and has caused a number of significant burns.

Labeling

Some risks cannot be eliminated through product design, either because the risk is a necessary part of the device’s function (e.g., the sharpness of hypodermic needles, the power of lasers) or because the technology to eliminate risk does not exist or is prohibitively costly (e.g., with anesthesia machines and apnea monitors). Manufacturers must then rely on the user and convey this reliance through instructions, warnings, or checkout procedures. However, these must be reasonable or they will not affect the problems that users will experience with the device. Some user manuals are replete with
warnings whose primary effect may be more to decrease the manufacturer’s liability in case of user error than to minimize the chance of an accident.

In cases of seeming use error, the investigator must consider the possible contribution of the labeling. User error by one person’s interpretation is a labeling deficiency in the view of another. The perspective can be influenced by the viewer’s investigative approach and understanding of both the technology and the user environment.

The more complex a device, the more labeling can play a role in contributing to an accident. An example of inadequate design labeling was found on a defibrillator with a three-position power switch labeled OFF, MONITOR REC ONLY, and ON. ON actually designated on for both the monitor and defibrillator but did not say so. It took three times as much force to move the switch to the heavily detented ON position as it did to reach the intermediate position in which only the monitor would function. Thus, until operators were made aware of the problem by a new label, it was quite likely that the critically needed defibrillator charge would be delayed while an operator who had not pushed the switch hard enough to move it to the third position tried to discover why the defibrillator would not charge. In fact, all five of our test panel members, including two physicians, two nurses, and an EMT, had difficulty energizing the unit, typically taking more than one minute or failing completely.

**INVESTIGATING DEVICE-RELATED INCIDENTS**

The investigation of a medical-device-related incident need not be a threatening experience for anyone. It will involve the examination and documentation of all facets of the incident. But medical-device-related incidents pose unique investigative demands. Thus, prerequisites for an effective investigation are an understanding of the factors that cause incidents (as discussed above) and an understanding of how the device interfaces with the patient and users.
DEVICE INTERFACES

A consumer product usually has one interface: between the user and the device. In contrast, medical devices are used by one or more individuals in a specialized setting (the hospital) to diagnose, treat, or monitor another person. Medical devices have four primary interfaces (see Figure 1) that are considered in any investigation of a medical-device-related adverse event:

Device – User

Device – Patient

Device – Accessories (including disposables)

Device – Environment

- User Facility
- Ambulance
- Home
Device Interfaces

Environment:
User Facility / Home/Ambulance

- Electric Power
- Medical Gas
- Heat, Humidity, Light

Patient

User

Accessories/Disposables

- Breathing Circuit
- Heated Humidifier
- Exhalation Filter
- Tracheal Tube
- Water trap

— Figure 1 —
A common mistake made when investigating a device-related incident is simply inspecting the device or equipment without regard to all the applicable interfaces. Such investigations tend to overlook the following:

- How the device was used
- How it was connected to the patient
- How it responded to feedback from the patient (e.g., ECG signals, temperatures, respired volumes or pressures)
- Whether the control settings were appropriate for the intended therapy or procedure (localized electrical or pneumatic power disturbances)
- Electromagnetic interference from nearby devices
- Patient drug therapy and related sensitivities
- Human factors of use

These are only a few of the possible variables. Eliminating such considerations from the investigation and simply testing the device will frequently show that it was operating as designed and lacks any manufacturing or design flaws. This approach will typically fail to provide useful information as to how the device failed or how it was or was not involved in the incident.

The interface between the user and the device is the human-factors interface where the device design aids or hinders safe and effective use. The user may prepare, program, and adjust the machine. The machine gives feedback to the user about its functional status, the status of the patient, and the delivered therapy. Obviously, this user interface is typically central to most medical device adverse events.

Frequently overlooked is the interface between the device and the disposables used with it. Such disposables include leads, electrodes, reagents, infusion sets, plastic tubing, filters, reservoirs, and breathing circuits. Unfortunately, these may have been responsible for the incident but are frequently not considered during the initial reporting of an incident or the initial phases of a user facility’s investigation. In many cases, facility personnel have
inadvertently discarded these disposables. Not only does this complicate the investigation, but it may also make it impossible to discover the cause, depriving the facility, physician, or manufacturer of the chance to share liability with or transfer it to a third party should litigation ensue. (In many cases, disposables are produced or sold by a company other than that which made the device initially thought to be responsible for the accident.) An attempt should always be made to obtain and investigate the disposables associated with an implicated device.

The fourth interface is between the device and the healthcare facility. This is more relevant when capital equipment, rather than disposables, is involved but should always be considered in the initial phases of the investigation. The facility will typically be the source of electric power, pneumatic power (medical gases or vacuum) and interconnecting signal or data-transmission wiring. Variations in the electric power distribution system and electromagnetic interference with this system, as well as the signal or data systems, may be the cause of aberrant device performance that leads to an incident. Likewise, the medical gas distribution systems are subject to contamination, cross-connection, or depletion and could thereby affect the performance of the attached devices.

All four interfaces—user/device, device/patient, device/disposables, device/user facility—must be considered when assessing risks or determining the cause of an incident. In the absence of a thorough investigation that considers these interfaces, testing may reveal that the device functioned as designed; thus, the cause of the accident may not be thoroughly understood, appropriate recommendations for prevention cannot be fully developed, and the accident may recur.

**INVESTIGATION GUIDELINES**

In a user facility, an incident report should trigger action by an interdisciplinary investigation team that includes the risk manager and staff members who are familiar with the equipment used and the environment in which the incident occurred (e.g., a clinical engineer, a nurse
manager or supervisor from the department where the incident occurred, a physician, and an equipment technician). A member of the safety committee may also be included in some cases.

To ensure objectivity, no one who was directly involved with the incident should be included in the team. Of all of these personnel, the risk manager and clinical engineer will usually be involved in virtually all investigations. The team coordinator (typically the risk manager, clinical engineer, or outside investigator) should understand the investigative process and all of its elements.

Most medical-device-related incidents do not result in serious injury, and an investigation can often be appropriately and effectively conducted by a facility’s own staff members. Incidents that have or may have caused serious injury or death should be considered by an independent investigator to help ensure objectivity and thoroughness. Such an investigation can augment, parallel, or substitute for the user facility’s own investigation. External investigators can be helpful in exploring both technical and legal issues because they have broad experience, objectivity, a lack of preconceived notions, and a cooperative rather than defensive or adversarial attitude.

Time is a significant factor. The longer it takes to mount and complete an investigation, the greater the probability that evidence will be lost, memories will dim, and speculation and self-justification will cloud the process.

In this regard, it is important to realize that product defects are often discovered by physicians, nurses, or other user-facility personnel who use or maintain the products. It is essential that all user-facility personnel, including all physicians, understand the importance of immediately reporting all product defects and device-related adverse events to the risk manager, who should then coordinate an investigation with the product safety coordinator. Sometimes the defect may not be an integral part of the product; for example, it may be poor packaging or inadequate labeling or instructions. Other times, the “defect” may be caused by an error in the way it was used. If a report is sent immediately to the risk manager, the
process for determining cause can be initiated, improving patient care and healthcare organization procedures. The poster entitled “Accidents Happen—An Immediate Action Plan” is a model for use in educating user-facility staff about reporting needs.

After the risk manager receives the report, he or she should decide whether to investigate and who should investigate. The investigation team should work closely with the risk manager in this investigation, especially if a patient or staff member injury occurred for which the user facility could be held liable.

A thorough incident investigation should involve the following:

- Preservation of evidence and impoundment of equipment
- Collection of patient and equipment information
- Assessment of the injury
- Inspection and testing of the equipment used
- Interviews with involved personnel (which is discussed separately)

**Preservation of Evidence and Impoundment of Equipment**

Whether it is for a lack of understanding or simply a lack of time, clinical staff often neglect to preserve all equipment involved in an incident, especially disposable devices, the associated packaging, and identifying data.

When an incident occurs, all devices and disposables that might have been involved should be impounded until they can be inspected. Photographs of the equipment, the room in which it was used, and the injury (where applicable) should be taken as soon as possible after the incident, preferably before the equipment is impounded. Control settings should not be changed on devices that have been involved in an incident unless it is necessary to minimize injury at the time the incident occurs.

For many microprocessor-controlled devices, whether battery or line powered, error codes
may be stored in the device’s memory. These codes are usually essential to a thorough investigation. For such a device, clinical engineering should be consulted before turning off the device, unplugging it, or removing its battery.

Likewise, devices should not be cleaned or processed without first discussing the procedures with an experienced, independent third-party investigator or manufacturer. Cleaning or processing could seriously hinder any subsequent investigation. Similarly, storage and shipment conditions must be considered to prevent damage to the device. For example, a membrane oxygenator involved in an incident should be protected from freezing because ice could rupture the membranes, making subsequent leak testing invalid.

Most equipment can soon be returned to service because it will be obvious that it played no role in the injury. However, no suspect device should be returned to service until it has been properly tested and eliminated as a possible cause of patient injury.

When notified of a potential problem with a device, a manufacturer may offer to examine the device without charge to the user facility and/or exchange, replace, or offer a refund for the device. If the device-related incident has involved death or significant injury to a patient or staff member, the decision to release the medical device should involve discussion between the healthcare facility’s administrative, risk management, and, possibly, legal counsel.

The investigation of device-related incidents can be significantly aided by cooperation from the manufacturer. In the event of litigation, a user facility’s position may be strengthened if it has complete records of all correspondence with the manufacturer, as well as evidence that the user facility’s procedures for incident investigations were followed. If a manufacturer discovers a defect in its product and issues a hazard or recall, the facility will have contributed to the prevention of similar incidents in other institutions.

**Information Collection**

The Medical Device Incident Investigation Form is a data-collection tool designed to
capture relevant information concerning a device-related incident and investigation, including the information required to be reported to some governmental agencies. The form is a useful supplements to the user facility’s incident reporting forms and are especially useful for capturing data to be included in a medical device report.

A discussion of the elements on the ECRI form follows.

**Device and Service Information**

Equipment information is important for several reasons. If a device fails or malfunctions, the record (lot and serial numbers) will facilitate communication with the manufacturer and/or device problem reporting networks. If the device has been involved in litigation, the completeness of the facility’s records on the incident will help investigators determine the facts of the case. But just as clinical staff fail to save disposables and packaging that could be crucial to an incident investigation, they often fail to record all relevant device-related information in the incident report. This means that information necessary to an investigation of an incident that may involve patient injury or death is often lost or not available when it is needed. Thus, user facilities should ensure that an effective equipment control program is in place to capture equipment information before an incident occurs. Ideally, information such as the device’s name, manufacturer and model number, date of application, lot and/or serial numbers, and the date used or removed from the patient should be recorded in the patient’s chart so that it is readily available. It is unrealistic, however, to assume that user facilities can accomplish this rather burdensome record-keeping task. Therefore, identifying information (serial, control, or lot number) be recorded for life-support devices, both equipment and accessories, which may or may not be disposable (e.g., intra-aortic balloons and balloon pumps, heart-lung bypass units, ventilators, anesthesia units, anesthesia breathing circuits).

User facilities are also encouraged to consider recording information about devices that, though not necessarily involved in life support, are commonly involved in recalls or
incidents. Such devices include hypo-/hyperthermia units and accessories, electrosurgical units and accessories, infusion pumps and accessories, and intravenous administration sets. (Of course, detailed information on implanted devices should always be recorded at the time of implantation and be kept in a separate surgical suite implant log.) The investigator should make sure that equipment information is recorded for all devices involved in the incident, including disposables. Any expiration or “use before” date should be noted. For devices that are routinely inspected, the date of the last inspection and the due date must be recorded. For reusables, the method of sterilization or cleaning should be noted. During the incident investigation, the positions and conditions of the equipment, accessories (e.g., cables, connectors, sensors), and disposables should be noted. Positions should be sketched relative to the patient, personnel, and other equipment. Investigators should also address the following questions:

- Were the switch, control, and indicator settings typical for the procedure?
- Who had contact with the suspect equipment after the incident?
- Were any inspections or repairs performed before or after the incident? What were the results?
- Have there been any recent device malfunctions? Does the injury possibly relate to device malfunctions recently experienced? Were there any malfunctions during the procedure? (Review equipment service records for possible information.)
- Was packaging from suspect disposables saved?

**Event Information**

The information requested on the form related to the event itself is relatively self-explanatory. However, it is important to note that when investigating medical device
adverse events, any other medical devices used at the time of the adverse event must be explored while filling out the form. Accessory devices and disposable equipment that may have been used should be especially sought out. In medical device adverse event investigations, there is a tendency of the beginning investigators to let the focus of their attention rest solely on a piece of capital equipment. This must be avoided. Investigators must broaden their perspective to the full range of potentially involved devices.

**Patient Information**

Much of the baseline patient information will come from the patient’s chart (e.g., the patient’s name, hospital ID number, sex, age, weight, diagnosis, known allergies). Discussion of the incident with the patient or their family should follow the guidelines of the facility.

**Injury Assessment**

Characteristics of the injury are frequently the best indicators of its cause. They include the following:

- Time of injury discovery in relation to application of a suspect device (The actual elapsed time is very important.)

- When and where the injury was discovered and by whom

- Characteristics of the injury at the time of discovery

- Location of the injury on the body and relation to placement of suspect devices

- Estimation of injury extent upon discovery (e.g., if a burn, whether first, second, or third degree)
• Treatment and medication applied to the injury

• Changes in the injury as they occur (Color photographs are the best way to document changes in the condition of the injury. The time and date should be recorded for each photograph.)

**Investigation, Equipment Inspection, and Testing**

The inspection and testing process differs for each technology and device type. However, some general perspectives will prove useful. To maintain objectivity in the investigation, staff members who last serviced or repaired the suspect equipment should not be the ones to inspect it following an incident. Other qualified staff from the appropriate department can be called upon to perform such inspections. An outside, independent examination of equipment may be most effective if alternate technical personnel are not available. The manufacturer may want to witness equipment inspections. It is usually in everyone’s best interest to permit the manufacturer to observe the equipment inspections. Device inspections are best undertaken by the facility’s investigation team, the outside investigator (if used), and the manufacturer simultaneously. An issue relating to investigator safety is worthy of mention. Many devices, especially disposables, may be contaminated. Investigators should always employ universal precautions for handling infectious or contaminated devices. In addition, vaccination against hepatitis B virus is recommended for personnel routinely involved in medical device investigation. See the document in entitled “Safety during Equipment Inspections” for infection control and other electrical and mechanical safety recommendations to consider during inspections.

**Database Searches**
A thorough investigation of an accident will also include a search of relevant databases that contain information on medical device problems, hazards, and recalls. Such information is useful in determining if similar incidents have occurred and, if so, what caused them. Valuable information on prevention of similar accidents or equipment modification may also be presented, especially in the published recall and hazards alerts. Investigators are cautioned about placing too much significance on unpublished database problem reports submitted by users or manufacturers directly to regulatory authorities. These should be considered as unverified, anecdotal reports unless the entire set of facts surrounding the reported incident is obtained and reviewed by the investigator. Such complete facts about these reports are very difficult to obtain in a timely fashion and are frequently prohibited from use in litigation.

These reports can be very useful for tracking failure trends or the incidence of lot-specific problems and for determining if the problem or complication encountered in your investigation case is a known complication with the device or a rare event. Investigators should be aware that these reports are frequently of limited value during accident investigation.

**Investigation Conclusions**

The consideration of the investigation’s findings are discussed at the end of this section on page 34.

**INTERVIEWS: TIPS AND TECHNIQUES**

For user-facility medical device accident investigators, the patient’s medical and surgical records typically provide information that is only marginally useful in determining the cause of a device-related injury. However, the record can indicate which healthcare personnel should be interviewed. The investigation team should strive to interview all involved medical and nursing staff. It may also be necessary to question technicians and other personnel (including third-party service personnel) responsible for cleaning,
sterilizing, inspecting, and maintaining the equipment and linens used on the injured patient. Legal considerations related to the potential liability of some medical or surgical staff involved in an incident may cause difficulties in obtaining timely information. Fortunately, in most investigations, the goal to quickly resolve an incident’s cause in an effort to develop preventive recommendations is usually an incentive of greater import than potential issues of personal liability. The interview process is not always easy; even when the interviewer stresses that the objective is to prevent future problems and assess potential liabilities, there is no guarantee that individuals who are interviewed are going to be cooperative or even honest. And those who do want to help may unintentionally give inaccurate information or omit important facts.

**Whom to Interview**

When deciding who to interview, investigators should refer to the incident report. Obviously, the person initiating the report and those directly involved must be interviewed; it may also be a good idea to talk with others who might have been in the area, who work with the people involved, or who perform the same sort of tasks in other areas of the facility.

Interviewing all those present during the incident will enable corroboration of details and establishment of a sequence of events. Interviewers must remember that in a critical clinical situation, participants may have a poor concept of the passage of time and may confuse the sequence of events, what drugs were administered, or even who was present. Only one person should be interviewed at a time, starting with the person most directly involved in the incident. When two or more people are interviewed together, problems arise related to interpersonal relationships (e.g., peers, subordinate/supervisor). An exception to this is during equipment setup and incident recreations. In such cases, collaboration among personnel is typically the best way to arrive at conclusions. Because each person will act in what he or she perceives to be his or her own best interests, interviewers should try to see the interview from the other side. Will the subject have a reason for hiding or not emphasizing certain information? Does he or she seem to note
and remember events accurately? Is there the potential of disciplinary action, criminal or civil liability, or discharge from employment, for either the subject or his or her friends or coworkers? Have others influenced the subject’s recollection of events?

**How to Interview**

Preparation by the investigator or interviewer is important for effective interviewing. Some research and reading may be necessary to become familiar with technical details. The interviewer should prepare a list of questions for each interview, keeping in mind the causes of device-related incidents (see pages 3 to 10) and the four device interfaces (see pages 17 to 18). A good basis for a list of questions is the classic who, what, when, where, why, and how.

It is best to take notes rather than use a tape recorder during the interview. A tape recorder may have an inhibiting effect on the interview subject. Also, the tape will have to be transcribed later, which is time-consuming and can be very difficult if there is any background noise or if the subject did not speak clearly and loudly. People who are ill-at-ease may tense up when the interviewer takes notes, but there are ways to overcome this problem. The interviewer can begin by emphasizing his or her role as a fact finder, then ask general questions that do not require note taking (e.g., “How long have you had your current responsibilities?”); this should put the subject at ease. When the conversation gets under way, the interviewer can say, “Let me make a few notes. I want to be sure I have gotten your comments right.” The interviewer should try to jot down notes while maintaining eye contact and should avoid staring at the notepad and scrawling furiously. An open mind is essential throughout the interviewing process. The interviewer should not accept the first account heard as accurate and should weigh subsequent versions accordingly. Likewise, he or she should avoid drawing conclusions until everyone involved has been interviewed. Discrepancies should be noted throughout the process, but judgments should be deferred.

The following are some other hints for effective interviewing.
Ask open-ended questions. “What happened next?” will likely elicit more information than “Did you then call the pharmacy?” The interviewer should allow the subject to tell his or her story in his or her own words and at his or her own pace. Even seemingly irrelevant details may become important later. The interviewer should unobtrusively guide the conversation toward the points that should be addressed.

Probe for details. Interviewers should pay special attention to information concerning any unusual occurrences surrounding the incident. They should ask about changes in device performance, unattended devices, peculiar sounds, smells, alarms, and sudden changes in either the patient’s condition or physical position. Interviewers should be careful not to interrupt the subject’s train of thought to ask for details. Instead, they should make notes and tie up the loose ends later.

Rephrase the questions. By asking similar questions in slightly different ways at different points in the interview, an interviewer can verify the accuracy of a statement. For example, during investigation of a ventilator failure that appeared to be related to line voltage. When the respiratory therapist was asked whether the ventilator had ever failed, he said no. Later, when asked if the ventilator had ever stopped spontaneously, he said yes. In his mind, the failure was not in the ventilator, but in the power-distribution system. The first question elicited a judgment rather than an observation.

End on a positive note. Before completing an interview, the interviewer should ask the subject if any points have been overlooked or if there is anything he or she wants to add. Especially with interviews that have been stressful for the subject, the interviewer should try to end on a positive note by reemphasizing his or her role as a fact finder rather than a blame fixer, thanking the subject, and urging him or her to call if anything further occurs.

Rephrase the responses. Jargon and differing perspectives of various disciplines can lead to false conclusions. Thus, the interviewer must understand the subject’s intended meaning. For example, if a physician is asked whether any nurses were present when an
incident occurred, he or she might assume that the interviewer means registered nurses and answer No, when, in fact, a licensed practical nurse was present. A good way to check is to rephrase the subject’s response—“So you and Dr. Jones were the only ones in the room?”—to which the subject might respond, “Well, no, Sue Smith was there too, but she’s just an aide.”

**Document the Interview**

The interviewer should summarize each interview as soon as it concludes and before the next one begins. In addition to summarizing what the subject said, the interviewer should note impressions about the subject’s demeanor and candor and any other relevant information. The interview notes should be signed and dated. If the incident involved a serious injury or death, or if there is any other reason to suspect that a claim might be filed, it is especially important to preserve all evidence of the interview, including the interviewer’s original handwritten notes. The interview notes and summary should never be entered into a patient’s medical record or employee’s personnel file.

**Consideration of the Findings and Results**

At this point, the investigator must consider all elements of the incident investigation—the incident report, collected evidence, equipment testing results, photographs, and interview notes—to determine the cause, develop corrective actions where indicated, and ensure that they are implemented. The investigator must make sure that all possibilities are explored to the fullest extent possible (based on the available information and access to the equipment). The investigator must also be prepared to consider that the device that was the focus of the investigation is not the device that caused the adverse event ensuring that everyone involved in the incident is questioned is also important for only then will it be possible to determine the contributing factors and causes of the incident.

A thorough incident investigation considers all possible device interactions. Hasty conclusions that a device or operator was at fault may bias the investigation, mislead the
Summary

The investigation of medical device accidents is an integral part of the continuing effort to improve the quality of patient care. The investigator of medical device adverse events needs to understand the technology involved, the causes of such accidents, and basic investigational methodology. Perhaps most importantly, the investigator must be familiar with the constraints and demands on the device user that lead to accidents resulting from user error.

The following section addresses those aspects of root cause analysis that can be applied to the investigation of healthcare technology adverse events. It gives a perspective on digging deeper into the underlying causes of the adverse event. Investigators must remember that even for incidents that appear to have been caused by a straightforward error in the use of the device, there is usually a more basic contributing cause.