HRC
VOLUME 2

Risk Analysis

Incident Reporting and Management 2

Medical Device Adverse Event Recognition and Investigation

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 this Risk Analysis.

This Risk Analysis covers the following basic areas of medical device accident investigation:

- General causes of medical device accidents
- Device interfaces
- Investigation guidelines
- Information collection
- Equipment inspection and testing
- Interviewing

Presentations on the tracking and analysis of general problems related to any one technology, to device-related techniques, or to a manufacturers product line are not included.

The Investigator's Perspective

Most serious or fatal medical-device-related accidents occur in the healthcare facility, although accidents in the home setting with devices that are provided and maintained by the healthcare facility (or possibly a durable medical equipment [DME] supplier) are becoming more common. Healthcare facilities 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 healthcare facilities and their contracted independent investigators are then in the best position to quickly and fully investigate most aspects of an accident.

Internal Accident Investigation versus Forensic Investigation

The goals of an internal 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 event and typically include a review of event reports, medical records, equipment-related documentation, and healthcare facility 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.

A nonpunitive environment is essential to a successful investigation. Otherwise, healthcare workers who were involved in a device-related event, regardless of whether user error contributed to the accident, may be reluctant to participate in an investigation. Reasons for this reluctance

HRC TOOLS FOR THIS TOPIC

The following tools and resources on this topic are available in your *HRC System.* Refer to this article, your *HRC* Index, the *HRC* Members' Web site, and other *HRC* resources for help.

— **Form**

— **Guidance**

— **Action Recommendations**

— **Also Available on *HRC* Web Site**

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include fear, possibility of record spoiling or repercussions, embarrassment, ignorance, "red tape," or lack of management feedback.[1] Healthcare workers may be concerned about damaging their own or their department's reputation. The threat of management retribution in the form of discipline, loss of position, or employment termination may be intimidating to healthcare workers. Real or perceived management unresponsiveness can also hinder healthcare worker cooperation.

When patient injury results from a medical device accident, medical malpractice and/or product liability litigation may ensue. Consequently, risk managers should take steps to protect the findings of an internal accident investigation from discovery. The scope of attorney-client privilege, which varies among jurisdictions, will have a bearing on what, if any, documents and communications will be discoverable in any subsequent litigation. Generally, the underlying facts of any accident investigation will be discoverable by an opposing party. However, it may be possible to limit disclosure of statements, interviews, conversations, and documents that may turn out to be critical to the defense of a malpractice case against the hospital and/or its employees. Risk managers should consult with healthcare facility counsel concerning how the attorney-client privilege, or its extension, the work-product doctrine, may apply to prevent disclosure.

The early investigation of an accident, including the risk manager's role in assisting in the investigation, should be directed by the facility's legal counsel in anticipation of litigation. In order to gain the maximum protection of any privilege from disclosure in future litigation, correspondence and other documentation concerning an outside investigator should include a brief objective statement of the reasons why litigation is anticipated but should not include any statement that may be deemed an admission of liability.

Risk managers should become familiar with their jurisdiction's relevant court opinions concerning the opposing counsel's access to potentially damaging statements made by employees during the course of an internal investigation. It is important to safeguard and keep confidential information related to the internal investigation, particularly in jurisdictions that permit opposing counsel to interview employees involved in the internal investigation. The facility's risk manager and legal counsel should identify who within the organization should have access to information concerning the internal investigation and should control the flow and access of information to those individuals.

In contrast to an internal investigation, forensic investigation takes place within the context of a lawsuit, or in rare cases, a criminal prosecution. Each party will be entitled to discovery concerning the opinions of any forensic investigators retained to give testimony at trial.

Forensic investigations may be performed in relation to litigation, arbitration, mediation, 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 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 achieve an intended diagnostic or therapeutic goal 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 intended 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 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 several elements: the device, the patient, the professional user(s) of the device, and 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. 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 Failure

Electrical Power Supplies

The quality and consistency of electric power affects device function. 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. In July 2001, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a *Sentinel Event Alert* on medical gas mix-ups, which stated that common causes of such mix-ups are related to lack of proper training of personnel responsible for the delivery, connection, or identification of medical-grade gas vessels; removal of gas-specific connectors; and/or improper labeling (in one case) or storage of medical gas vessels.[2]

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 healthcare facility, inhibition of cardiac pacemakers by radiated EMI from microwave diathermy, and signal distortion on electrocardiographic monitors from a nearby electric transformer. More recently, cell phones have been identified as culprits in causing EMI interference. See the Risk Analysis "Electromagnetic Interference and Medical Devices" in the *Medical Technology* section of the *HRC System* for more information on this topic.

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 event 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 events, 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

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:

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

Errors during Use (Further detail on this subject is provided later in this Risk Analysis.)

- 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

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)

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.

Support System Failure

- Poor prepurchase evaluation
- Poor event/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. They are complimentary to, but more succinct than, the terminology used in the approximately 2,200 coded categories in the U.S. Food and Drug Administration's (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 803).

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.

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 include the following:

- Barotrauma
- Burn (electrical, thermal, chemical)
- Coagulopathy
- Electrical shock/electrocution
- Embolism (gaseous/particulate)
- Exsanguination
- Extravasation
- Failure to deliver therapy
- Fire
- Hemorrhage
- Hyperthermia
- Hypothermia
- 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 event, 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 events 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 result in precipitous treatment if the patient's true physiological status is not first confirmed. In more than one case, a sleeping patient has apparently 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 event.

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

ECRI has found that events of improper equipment maintenance, testing, or repair leading to a patient injury or death are extremely rare. In investigating such cases, the level of training and experience of the person performing a repair or other service 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 intra-aortic 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 unintended 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 cost-prohibitive (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 ECRI's 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 Events

The investigation of a medical-device-related event need not be a threatening experience for anyone. It will involve the examination and documentation of all facets of the event. But medical-device-related events pose unique investigative demands. Thus, prerequisites for an effective investigation are an understanding of the factors that cause events (as discussed above) and an understanding of how the device interfaces with the patient and users. The case studies included in Appendix A of this Risk Analysis illustrate pitfalls common to medical-device event investigations and how risk managers can draw lessons to prevent future events.

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 healthcare facility) to diagnose, treat, or monitor another person. Medical devices have four primary interfaces that must be considered in any investigation of a medical-device-related adverse event:

- User/device
- Device/patient
- Device/disposables
- Device/environment
  - — User Facility
  - — Ambulance
  - — Home

A common mistake made when investigating a device-related event 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 event.

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 event but are frequently not considered during the initial reporting of an event 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 and deprive the healthcare facility of learning important information to prevent future occurrences. (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 event. 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 event. 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 healthcare facilities, an immediate report to the risk manager or patient safety officer should trigger action by an interdisciplinary investigation team that includes staff members who are familiar with the equipment used and the environment in which the event occurred (e.g., a clinical engineer, a nurse manager or supervisor from the department where the event 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 event 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 events do not result in serious injury, and an investigation can often be appropriately and effectively conducted by a facility's own staff members. JCAHO considers events that do involve serious injury or death to patients or staff to be sentinel events. JCAHO requires the performance of a root-cause analysis to reveal problems that contribute to the occurrence of a sentinel event. Root-cause analysis, a multidisciplinary process intended to identify the base (or root) cause of an adverse event, is thus applicable to the investigation of device-related events that have caused injury or death. Refer to "Systems Analysis" in Supplement A of the *HRC System* for more information on this topic.

Events 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.

However, when outside investigators are summoned, the Health Insurance Portability and Accountability Act (HIPAA) requirements on patient healthcare information privacy must be considered. Depending on circumstances, the HIPAA privacy rule may require a business agreement with third parties who may have access to or use individually identifiable health information. See "Health Information and Privacy Standards" in Supplement A of the *HRC System* for more information on HIPAA requirements.

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.

ECRI's Accident and Forensic Investigation Group

Since 1968, ECRI has investigated thousands of accidents at healthcare facilities around the world. ECRI's Accident and Forensic Investigation Group staff function as independent third-party investigators who can provide unbiased analysis of device-related incidents.

In addition to on-site and in-laboratory investigations, ECRI staff can assist with root-cause analyses, risk-reduction strategies, forensic engineering investigations, database searches, and litigation reference files. All investigations are undertaken in strict confidence within the limits of ethical and legal confidentiality principles.

For more information on ECRI's Accident and Forensic Investigation Group, call (610) 825-6000, ext. 5223, or e-mail accidents@ecri.org.

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.

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 event investigation should involve the following:

- Preservation of evidence and impoundment of equipment (For more information on this topic, see "Risk Management Tips for Device-Related Events," located in this section of the *HRC System*.)
- 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 event, especially disposable devices, the associated packaging, and identifying data.

When an event 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 event, preferably before the equipment is impounded. Control settings should not be changed on devices that have been involved in an event unless it is necessary to minimize injury at the time the event occurs. "Risk Management Tips for Device-Related Events," located in this section of the *HRC System*, provides further discussion on this topic.

Information Collection

ECRI's Medical Device Event Investigation Form (see Appendix B) is a data-collection tool designed to capture relevant information concerning a device-related event and investigation, including the information required to be reported to some governmental agencies. One person at the healthcare facility (e.g., risk manager) should be responsible for completing the form, which can serve as a collection point for information that may be gathered from several sources. Another form is used by the FDA program for medical device adverse event reporting called MedSun. The forms are useful supplements to the user facility's event 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. Also see "Event Reporting," located in this section of the *HRC System*.

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 event will help investigators determine the facts of the case. But just as clinical staff may fail to save disposables and packaging that could be crucial to an event investigation, they often fail to record all relevant device-related information in the event report. This means that information necessary to an investigation of an event 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 event 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) should 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 events. Such devices include hypo-/hyperthermia units and accessories, electrosurgical units and accessories, infusion pumps and accessories, intravenous administration sets, bed-exit devices, dialysis units, patient/resident lifts, and motorized scooters. (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 event, 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 event 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 event?
- Were any inspections or repairs performed before or after the event? 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?

Medical Device Reporting

When a medical device contributes to the death or serious injury of a patient or staff member, the healthcare facility must report the event to the device manufacturer or to FDA. See "Medical Device Reporting" in the *Laws, Regulations, and Standards* section of the *HRC System* for a detailed discussion of this topic.

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 event with the patient or their family should follow the guidelines of the facility, including facility policies on disclosure. Risk managers must also ensure that such discussions adhere to requirements under JCAHO's disclosure standard for informing patients and there families of all unanticipated care outcomes. See the Risk Analysis "Disclosure of Unanticipated Outcomes" in Supplement A of the *HRC System* for further information on this topic.

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 event. 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.

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 events have occurred and, if so, what caused them. ECRI's Health Devices Alerts database, which contains hundreds of thousands of abstracts on device-related problems, hazards, and recalls, as well as action items, is available to *HRC System* members through the *HRC* Members' Web site. 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 event 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.

Conducting Interviews

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 event may cause difficulties in obtaining timely information. Fortunately, in most investigations, the goal to quickly resolve an event's cause in an effort to develop preventive recommendations is usually an incentive of greater import than potential issues of personal or institutional liability.

Whom to Interview

When deciding whom to interview, refer to the event 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 event 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 event. 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 event 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 interviewee 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 individual or his or her friends or coworkers? Have others influenced the individual'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 events and the four device interfaces, a good basis for a list of questions is the classic who, what, when, where, why, and how.

Taking notes is preferable to using a tape recorder, which can 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. Tapes and transcripts, if they are made, may be subject to discovery by an adverse party in the event of litigation. Other tips for conducting interviews include asking open-ended questions, probing for details, rephrasing questions, ending on a positive note, and rephrasing responses to ensure the individual's correct meaning is interpreted. Refer to

"Event-Report Interviews" in this section of the *HRC System* for a more in-depth discussion of interviewing strategy.

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 interviewer should sign and date the interview notes. If the event 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 event investigation — the event 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 event is questioned is also important for only then will it be possible to determine the contributing factors and causes of the event.

A thorough event investigation considers all possible device interactions. Hasty conclusions that a device or operator was at fault may bias the investigation, mislead the patient into bringing suit, and unjustly impugn personnel, equipment, service organizations, or manufacturers.

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.

ACTION RECOMMENDATIONS

- Review information in this Risk Analysis and others in the *HRC System*, such as "Event-Report Interviews" and "Risk Management Tips for Device-Related Events."
- Conduct investigations of medical device-related events with the goals of determining the cause(s) and drawing lessons to help prevent future events — not with the goal of assigning blame.
- Implement policies and procedures to help ensure that all appropriate checks are performed before any device is used in a procedure.
- Ensure that medical staff members are trained on the proper use of medical devices before they are allowed to use them to perform procedures.
- Review requirements under the HIPAA privacy rule when outside experts are called in to investigate.
- Use the form in Appendix B of this Risk Analysis to ensure proper data collection during investigations of device-related events.
- Adopt a procedure to ensure the facility complies with federal requirements for medical device reporting when device-related events occur.

Notes

1. Cunningham J, Kane A. Accident reporting — part 1: key to prevention. *Saf Health* 1989 Apr;139(4):70-1.
2. Joint Commission on Accreditation of Healthcare Organizations. Sentinel event alert: medical gas mix-ups [online]. 2001 Jul [cited 2004 Mar]. Available from Internet: http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_21.htm.

GUIDANCE Appendix A

Medical Device Investigation Case Studies

ECRI's accident investigation experts have discovered some themes common to many investigations: false assumptions made early in investigations can mislead investigators and delay, or even prevent, discovery of the true cause of an accident; staff may ignore policies related to incident reporting or may fail to detect that an injury has occurred; and pre-use checks may be improperly performed or skipped altogether for critical equipment.

The following case studies are drawn from ECRI's Accident and Forensic Investigation Group. The first two cases discuss how investigations are conducted and the risk manager's role in keeping investigations on track; the last two cases discuss lessons risk managers can use to help prevent future errors.

Case Study 1: Red Herrings

All investigations involving medical devices have potential red herrings (characteristics that lead investigators to inaccurate conclusions) because of the numerous ways in which a device interfaces with personnel, patients, and support systems. With a strategy of questioning and testing all assumptions, experienced investigators are less likely to be misled.

In one case, a hospital reported to ECRI that anesthesia ventilator failures had occurred in nearly every operating room (OR). The failure mode was the same in each case. Other devices in use, such as electrocardiograph and electromyograph monitors, were not affected when the ventilators failed.

The anesthesia gas machines were operated using oxygen and nitrous oxide from the piped medical gas system. Notably, the medical gas supplier had installed a liquid oxygen tank just before the failure episodes began. During the failures, no abnormalities with oxygen concentration, flow, or pressure were observed. Nevertheless, as a precaution, the anesthesia department decided to operate the anesthesia machines using bottled gas.

Based on its own investigation, the hospital concluded that the occurrence of the ventilator failures just after the installation of a liquid oxygen tank was more than a coincidence. This conclusion was supported by the absence of problems with the sensitive intraoperative patient monitoring equipment, which was all electrically powered and independent of the piped medical gas system. Also, no ventilators failed when operated on bottled gas. However, the medical gas supplier and the ventilator manufacturer (as well as its independent expert) disagreed with the hospital's conclusion but offered no additional perspectives on the problem's cause. At this point, ECRI was contacted to act as an independent investigator.

The anesthesiologists believed that the ventilators were failing because of particulate introduced into the piped medical oxygen system when the liquid oxygen tank was installed; however, ECRI examined the oxygen gas filter of each anesthesia machine for particulate and found the machines to be very clean. The investigators also thought it unlikely that clogging would cause intermittent problems that could be resolved by switching the power off and on.

In an earlier comparative evaluation, ECRI had tested the performance of the anesthesia machine and ventilator model used at the hospital. Those tests revealed that the ventilator ceased to operate at line voltage below 95 volts (V). Duplicating this test with one of the hospital's ventilators yielded the same results.

After measuring the voltage at the 115 V outlets in the ORs, ECRI found that in some of them, it was only 107 V. When in use, the voltage dropped; during ECRI's visit, it dipped as low as 100 V. Further investigations revealed that the voltage was related to isolation transformer problems. Once these were corrected, no further ventilator problems occurred, and confidence in the medical gas system and ventilators was restored.

The hospital made some assumptions that, while reasonable, misled the investigation in its early stages. The red herring in this case was the coinciding of the liquid oxygen tank installation and the ventilator failures. Also critical was the mistaken assumption that because the monitoring devices continued to operate during the ventilator failures, the line voltage was sufficient. Red herrings swim in a sea of assumptions. When an assumption can be easily tested, it should be.

Case Study 2: Risk Management Processes

If a policy-related problem occurs, it is most likely that the policies were not followed by caregivers, members of the biomedical department, or someone else in the investigation process. Thus, continually educating caregivers and others about the policies and emphasizing the need for risk sensitivity takes on significant importance. The following hypothetical case, drawn from

several ECRI investigations, shows how overlooking a facility's policies can make an investigation more difficult than it has to be.

A patient was scheduled to undergo laparoscopic cholecystectomy. In the OR, she was intubated, and the anesthesiologist began anesthesia induction via machine. The anesthesiologist noted difficulty ventilating the patient, reintubated the patient, and eventually had to manually ventilate her with a bag mask. Due to a lack of oxygen during the initial attempt to ventilate, the patient experienced bradycardia and subsequent brain injury.

Following the incident, the anesthesiologist unplugged the anesthesia machine and sent the breathing circuit to the hospital's biomedical department, telling the staff that there was a problem with the breathing circuit and asking them to check it out. The breathing circuit was taken to a workstation in the hospital's maintenance area, examined by several staff members, and discarded.

By this time, ECRI had been contacted as an independent investigator because the hospital feared that the injured patient's family would file suit. ECRI's investigator tested the anesthesia machine, which seemed to be functioning appropriately. He was unable to examine the breathing circuit, which had been discarded. Given the facts of the case, the investigator was able to speculate that there were three possible causes for the patient's injury: a physiological difficulty on the patient's part, an esophageal intubation, or an obstruction in the airway.

Because the anesthesia machine had been unplugged following the procedure, all data and settings that would have been recorded during the procedure were lost. Thus, the investigator had no way of knowing whether the machine was set properly during the procedure. In addition, ECRI's investigator wanted to examine records of oxygen saturation and exhaled carbon dioxide monitoring data because this could have given him some insight into whether the patient was properly intubated. Notes from the procedure indicate that a pre-use check of the breathing circuit revealed no problems, but the investigator was skeptical about the reliability of the notes, given the anesthesiologist's failure to handle devices properly following the accident. In the absence of evidence, the investigator was unable to test his hypotheses.

Several compounding lapses in adherence to hospital policies significantly hampered this investigation. The anesthesiologist clearly ignored the standard chain of communication by sending the breathing circuit directly to the biomedical department without indicating that it had been involved in an accident. Likewise, the biomedical staff failed to react to this deviation from standard operations. By failing to preserve monitoring data and settings from the anesthesia machine, the anesthesiologist further complicated matters. By the time ECRI's investigator arrived, the most he could do was test the anesthesia machine under standard operating conditions — and, as it turned out, this did not yield helpful information. If the biomedical staff had been sensitive to the situation, at least the breathing circuit could have been saved for examination by an investigator.

Case Study 3: New Technologies

Before clinical staff are allowed to use new technology, proper training in its use should be ensured. Unfortunately, this does not always happen, as the following case illustrates.

A patient was scheduled for an endoscopic retrograde cholangiopancreatography and sphincterotomy at a small, rural hospital. The surgeon in the case had seen the procedure performed but had never performed it himself and was unfamiliar with the electrosurgical unit (ESU) necessary for the procedure. During the procedure, the sphincterotome cutting wire broke when power was applied through it. In trying to pull the wire out, the surgeon caused significant trauma. The accident apparently led to fatal pancreatitis in the patient.

The surgeon claimed that the ESU had malfunctioned, causing the wire breakage and resultant injuries. ECRI's investigation, however, revealed that the cutting wire would have to have been subject to excessive current to melt and that other sphincterotomes of the same model operated properly when exposed to the typically recommended power. It became apparent that the inexperienced surgeon had used excessive ESU power settings and that this had caused the accident.

Following the investigation, the surgeon argued that the manufacturer's labeling was vague as to the appropriate power settings that should have been used. ECRI's investigators agreed that the labeling, which had been approved by the U.S. Food and Drug Administration, was insufficient. However, the label's shortcomings did not absolve the surgeon of responsibility. A more experienced surgeon would have known that it was proper to start the procedure on a low power and increase only to the point needed to make a cut.

From a legal perspective, it may have made sense to attempt to shift blame to the manufacturer for the label's shortcomings. However, a more complete risk management assessment of the situation makes it clear that the surgeon should never have attempted to perform this procedure. Risk managers should ensure that physicians have received adequate training and, when appropriate, are credentialed before they use devices on patients when

any new technology is deployed in their facilities. Risk managers should be especially cautious about any new procedure using minimally invasive techniques or any procedure involving a laser, which will typically require specialized training and credentialing. Even devices that are simply upgrades of older versions may have nuances that require new training to be fully understood.

Case Study 4: Pre-Use Checks

As the case below illustrates, failing to completely perform pre-use checks of all medical devices used throughout a procedure can lead to significant patient injury. If devices are to be added to the procedure unexpectedly, they must also be completely checked.

The patient was to receive inhalation anesthesia for an elective surgical procedure, and the anesthesiologist correctly performed complete pre-use checks on the breathing circuit. The circuit functioned appropriately before and after assembly, and this fact was noted in the patient's record. However, once the patient was in the OR, the surgical team realized that the breathing circuit needed to be longer than they had anticipated. The anesthesiologist obtained the extensions he needed for the breathing circuit, added them, and began attempting induction via anesthesia machine and mask.

The anesthesiologist's notes indicated that the patient was difficult to ventilate by mask. He was then intubated; that intubation was believed to be an esophageal intubation. A second intubation was performed successfully. Ventilation from the anesthesia machine was still unsuccessful, and the patient became hypoxic and bradycardic. The patient was eventually ventilated using a manual resuscitator, and his vital signs stabilized, but he suffered an hypoxic brain injury.

Following the incident, the anesthesia machine and breathing circuit were isolated. The anesthesia machine proved to be working appropriately, and it was eventually determined that one of the extensions added to the breathing circuit was obstructed. An ECRI investigator determined that the obstruction was caused by a flaw in the manufacturing process that left a fine film across part of the breathing circuit, completely blocking airflow through the circuit. The film was clear and could not have been seen during a visual inspection unless the light hit it at a certain angle; only complete pre-use checking, including testing airflow through the circuit, would have revealed the obstruction.

ECRI's investigator concluded that the anesthesiologist likely failed to perform a pre-use check on the components added to the breathing circuit. Had he done so, the anesthesiologist almost certainly would have discovered that airflow through the breathing circuit was blocked. In addition, regularly used patient monitors should have detected that the airflow was blocked.

FORM Appendix B

ECRI's Medical Device Event Investigation Form

The following form is a data-collection tool designed to capture relevant information about a medical device-related event. This form may be reproduced for use in your institution. The completed form should not be photocopied or filed in the patient's medical record.

CONFIDENTIAL — FOR INTERNAL RISK MANAGEMENT PURPOSES ONLY. DO NOT PHOTOCOPY OR FILE IN MEDICAL RECORD.*

Case identifier no._____

DEVICE INFORMATION

Record for each device involved in incident, including disposables. Use separate forms as necessary.

Manufacturer name _____

Brand name _____

Generic product name _____

Model no. _____

Catalog no. _____

Serial no. _____

Lot no. _____

Internal equipment control number _____

Expiration date _____

Purchase date _____

Labeled for single use? _____

Previously used? _____

Implanted device? _____

Implantation date _____

Reusable device? _____

Cleaning/sterilization method used _____

Create a file with the following information: purchase contract, package insert, user/operator manual, maintenance contracts, and recall notices. Forward to the patient safety officer and/or risk manager.

SERVICE INFORMATION

Last date serviced _____

Service performed by _____

Was service on schedule? _____

Attach service records.

EVENT INFORMATION

Event result (e.g., death, injury, illness, device malfunction)

Date of event _____

Specific injury incurred _____

Date that medical personnel became aware of the event

Date reported to manufacturer _____

Was device used as labeled/intended? (Attach copy of label.)

Device operator when event occurred (name, title) _____

Location of event _____

Other devices in use at time of the event _____

Brief description of event (e.g., what happened, how the device was involved). Attach expanded narrative, if needed. _____

Witnesses to event (name, title, phone)

PATIENT INFORMATION

Record for each patient involved. Use separate forms as necessary.

Name _____

Address _____

Phone _____

Classification (e.g., inpatient, outpatient, visitor, employee) _____

Patient identification number _____

* This heading should be modified to include appropriate language that may provide protection from discovery in the healthcare facility's jurisdiction.

Room no._____

Age_____ Sex_____ Weight_____

Attending physician _____

Known allergies_____

Diagnosis before event _____

_____

Medical status before event (e.g., stable, critical, fair) _____

Was more than one patient involved? _____

If so, collect information for all patients._____

INJURY ASSESSMENT

Time of discovery _____

Elapsed time from placement of device _____

Description of injury_____

_____

_____

Location of injury on patient (e.g., head) _____

Location of suspect device in relation to injury_____

Extent of injury at time of discovery

_____

_____

Were photos of injury taken? (If yes, attach to this form.)

_____

Patient treatment _____

_____

_____

Patient follow-up (current status)

_____

EVENT INVESTIGATION

Collect relevant data for all devices involved in event, including disposables. Use separate forms as necessary.

Date reported to risk management

_____

Date investigation initiated

_____

Switch/control/indicator settings at time of incident (indicate whether typical — yes or no)

_____

_____

_____

_____

_____

Relevant environmental conditions

_____

_____

Has device malfunctioned before?

_____

When? _____

Description of malfunction _____

Was report filed? _____

Was corrective action taken or repair performed? (describe)

_____

_____

_____

Positions and conditions of device, accessories, and disposables

_____

_____

_____

_____

_____

On a separate sheet, sketch positions relative to patient.

Who inspected the device following the event? _____

Did the device manufacturer witness the inspection? _____

Name of witness _____

Types of tests performed (e.g., electrical) _____

Inspection findings (Did device fail? How? What components or subassemblies failed? Was the device used correctly?) Attach expanded narrative if needed. _____

_____

_____

_____

_____

_____

_____

INVESTIGATION CONCLUSIONS

Was the device the direct cause of the event?_____

How did the device cause or contribute to the event?_____

_____

_____

_____

_____

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_____

Immediate actions required _____

_____

_____

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_____

_____

_____

Follow-up required _____

_____

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_____

_____

_____

Signature _____

Date _____