Case Studies of Medical Device Adverse Events

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Presented here are case studies* of medical device adverse events. They serve two purposes: First, they are examples for study in recognizing the types of adverse events in healthcare that involve medical devices. Second, it can be seen from their review that many medical devices are typically involved in a single device-related adverse event. The cases also highlight many of the adverse event causes and mechanisms of injury previously discussed in the previous section on medical device accident recognition and investigation. It addresses a wide variety of device types and areas of clinical use. The case study topics are listed below.

CASE STUDIES Page

Published actual case reports of hazards with medical devices are available for further study at the ECRI free clinical Web site called Medical Device Safety Reports (MDSR) at **www.mdsr.ecri.org**. MDSR is a repository of medical device incident and hazard

* These case studies are deidentified, fictionalized cases. Though they derive from ECRI's broad base of experience in performing field and laboratory investigations of medical device adverse events and from publicly available adverse event database reports, they do not represent a specific incident, accident, adverse event, or close call. Any resemblance to persons living or dead, to objects or commercial products, or to specific situations of device use is purely coincidental.

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information independently investigated by ECRI and published in its monthly journal *Health Devices*. It derives from thousands of ECRI investigations of medical device failures and related injuries and deaths over several decades. Periodically updated, it focuses on the steps that medical device users can take to prevent or reduce medical device risks to patient care and healthcare worker safety. It contains recommendations that can help to avoid design and quality-assurance problems and human factors limitations that increase the incidence of medical device adverse events and medical errors. The incident described, type of device involved, lessons learned, and ECRI's safety recommendations remain relevant and timeless. The citation to the original published *Health Devices* report is given. MDSR is searchable by cause of incident, device type, and clinical specialty/department.

LEARNING OBJECTIVES

There are several objectives to keep in mind when reviewing these examples with staff and comparing them to adverse events at a facility. First, user facilities should broadly consider which devices were potentially involved in the adverse event. Use of these cases in teaching should try to focus on helping staff to recognize that a medical device was involved in an adverse event. Informing staff of how best to report on that device involvement within the facility is also critical to another primary objective of these studies.

User facilities should look for and explore the links (the "interfaces" discussed previously in Section 3) between the suspect medical device and other related devices that were used. Of course, potential root causes should be explored at the device, policy/procedure, and organizational levels. Although most medical device cases are fairly straightforward, the device that is first considered in the investigation of an adverse event is frequently not the device to which the event is ultimately attributed.

Another primary objective of these cases is to help the user facility determine if and how the adverse event was attributable to (i.e., caused by) the suspect device or devices, including the labeling, instructions, and packaging, or whether some other major

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causative factor, such as an error in device use, was involved. When reviewing these cases studies, user facilities should note the investigational approaches described related to testing of device performance, searching of informational resources; interview findings also may be used in coming to conclusions about the cause of the event. Concerning "cause," facilities must remember that a patient is a variable biological system. In some cases, what appears to be a device-related adverse event is found to be an adverse patient reaction to an otherwise normal set of conditions of use and performance for the suspect device.

In regard to "close calls," "near misses," or "no-harm events" involving medical devices, it is recommended that they, too, be reported through the facility's internal reporting program. Several definitions and perspectives on such adverse events have been presented elsewhere (Battles and Shea 2001). Herein, adverse events that do not result in harm to the patient will be referred to as close calls. Within any one facility, a close call on one day may prove to be a fatality with the same device in another setting. As such, identifying and studying close calls with medical devices is encouraged.

CASE FORMAT

Each case study begins with a case abstract followed by a list of the devices that needed to be considered by those involved in the incident and by the team that performs an investigation. An analysis of the case is then presented. The analysis discusses the involved medical technology, the nature of the suspected problem being investigated, and the investigative findings. The causative factors are then listed, though these are not necessarily the root causes in all cases. The injury mechanism is also given.

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Case Study 1: Apheresis/Dialysis Machine Air Embolism

A 64-year-old woman who died in a critical care unit after approximately 10 minutes of plasma exchange (PE) therapy using an apheresis machine for hemofiltration. She was to undergo PE with human albumin solution (HAS) over the course of a 60-minute treatment, with 2 L of plasma to be removed and replaced with 1.5 L of HAS. The patient had a central venous (CV) pressure cannula inserted in the right jugular vein for pressure monitoring, but it was not clear whether this catheter was used upon her admission to the intensive care unit for the PE therapy. During treatment, segments of air bubbles were seen in the venous PE line that was returning blood to the patient by the treating physician and by another physician: this air was seen entering the patient. About two minutes later, she went into respiratory arrest, and cardiopulmonary resuscitation (CPR) was initiated. During CPR, air was reportedly again seen in the venous blood line. Despite the resuscitation attempts, the patient died. Postmortem examination indicated that the patient died of a fatal venous air embolus, probably of a volume greater than 250 ml. Air was determined to be in the brachiocephalic veins, superior vena cava, inferior vena cava, and the right ventricle. At the time of the treatment, the patient was in a semireclining position with the back of the bed raised to about 40°.

Devices Considered

Apheresis/dialysis machine
Plasma separator blood filter (disposable)
Dual lumen, 11 Fr, 180 mm catheter (disposable)
Arterial blood line (disposable)
Venous blood line (disposable)
Filtrate line (disposable)
Drainage bag set (disposable)
Substitution fluid line (disposable)

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4-way cluster tubing set (disposable)
Human albumin solution (consumable)

Analysis

The investigation attempted to explain how the large quantity of air diagnosed on postmortem examination (at least 250 ml) in the patient's venous vasculature could have been introduced into to this patient during setup or use of the involved hemofiltration machine and its numerous disposable tubing and fluid components.

Personnel from both the hospital and the manufacturer tested the machine immediately after the incident. They found it to be working satisfactorily and were unable to explain the incident from a standpoint of the technology. Two factors hampered the investigation. One factor was that the disposable blood circuit and tubing had been discarded shortly after the incident (exemplar components and tubing were used during all initial and subsequent examination and testing). The other factor was that the machine's data memory of its history of operation from the incident treatment had been erased through some undetermined sequence of events. Initial investigation failed to explain how air could have originated in the machine and its solution bags, much less be able to bypass a bubble trap and ultrasonic bubble detector equipped with an automatic tubing safety clamp.

Before the interviews and further device testing that was to take place, the following case documents were reviewed:

- Operator Manual
- Technical Manual
- Coroner's report and exhibits
- Patient's medical records
- Pre- and postmortem chest x-rays

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The incident-related personnel with whom the hospital's investigation team met included the treating physician, the assisting physician, the staff nurse, and the clinical engineer, who had responsibility for routine inspection, maintenance, and repair of the machine. The investigation included a physical re-creation of the setting in which the treatment took place. This included placement of the apheresis machine in the same location on the right side at the head of a bed (as viewed from the foot of the bed), placement of the lines in the same fashion, and placement of a cardiopulmonary resuscitation (CPR) training manikin on the bed that represent the location of the patient.

The initial investigations had unsuccessfully attempted to print the data from the incident treatment, which should have been stored automatically in the machine's memory. The memory is designed to include data such as treatment mode, parameter settings, cumulative volumes, alarm summaries. Tests were performed to investigate why the machine lacked the data from the incident treatment. The possibility of an intermittent fault or failure of an electrical circuit board, component, or connector may have caused or contributed to the incident.

The root cause analysis (RCA) included establishing a detailed sequence of events and led to more than 50 potential user- or machine-related contributing factors that could cause the introduction of air into this patient with this equipment. Among these factors were the following:

- The patient was anxious and was fidgeting with and tugging on the femoral vein PE blood lines leading to the machine.
- The machine was in a position next to the bed that permitted accidental dislodgment of the venous blood line from the safety clamp with minimal tugging force.
- The machine may have been switched to standby mode during the performance of CPR, which would have permitted retrograde introduction of air from the vena cava into the venous blood line.

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- The CV pressure catheter extended down the vena cava at least to the level of the right atrium, according to the x-rays examined.

After equipment inspection and testing and consideration of many potential causes and contributing factors for this incident, it was concluded that the air that was seen actually came from the patient (having entered via an open jugular CV-line stopcock) but was seen in the machine's venous blood return tubing line based on how the machine was operated. The RCA correctly segregated the potential sources of air into a biological side (i.e., the patient) and a machine side.

Further machine inspections and testing proved that it was operating according to manufacturer's specifications, including the operation of the air detectors and alarms. The air protection circuits and devices in the machine worked effectively. This strongly discounts consideration that the air seen in the tubing originated within the machine. There was no evidence to suggest that an intermittent failure of an electrical component or circuit board played a role in the incident. The loss of the memory data appears to have been an unfortunate consequence of the technical inspection that took place shortly after the incident. There was no evidence to suggest tampering of the machine or its tubing.

The unique incident was explainable with the assumptions that the venous blood line was accidentally pulled out of its safety clamp and that the air in the venous blood line actually came from the patient secondary to an air leak in the central venous pressure catheter at the right neck. This scenario was consistent with the recollections of the treating physician and was successfully tested and replicated in vitro.

CV catheters and pressure lines, especially in the jugular site, are a common source of passive venous air embolism. Each time the patient inhales, the contraction of the diaphragm creates a vacuum (negative pressure) in the thorax that can draw air into an open or poorly sealed venous line. Being in a seated position, as this patient was, also created a hydraulic vacuum at the jugular site since it was above the level of the heart. The air came out of the catheter in the form of bubbles at the tip, which ended in the vena

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cava. As the patient exhaled, the thoracic venous pressure returned to zero or became slightly positive and the CV line partially refilled with blood. As the catheter refilled with blood, it essentially became a one-way air-inlet valve that allows air into the superior vena cava and bracheocephalic vein but did not let blood leak out at the exit site at the neck. This was due to the hydraulic pressure of the blood, combined with the pneumatic pressure generated in the thorax during breathing.

Causative factors: improper connection by user, possible connector failure.

Injury mechanism: gas embolism.

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Case Study 2: Centrifuge Contents Ejection

A medical technologist had loaded a centrifuge with blood samples for processing. When the spinning cycle was completed, she opened the lid and attempted to slow the rotor by pressing on it with a pen cap. The rotor's speed was faster than she expected, and the pen top was pulled from her hand. The cap ricocheted off the centrifuge bowl wall and smashed the sample tubes. The debris of glass and blood was flung from the centrifuge onto the technologist's chest. Fortunately, the technologist was uninjured and uncontaminated.

Devices Considered

Centrifuge
Test tubes (disposable)
Personal protective equipment (e.g., face shield, gloves, gown)

Analysis

When interviewed about this adverse event, the medical technologist stated that she was following universal precautions in handling blood products. She was wearing gloves, a nonpermeable gown, and a face shield. She admitted that she was foolish in trying to stop the rotor but excused her actions because she was being pressed for lab results. She understood that she could have been seriously injured from the broken glass or spinning rotor or infected by contaminated blood.

The centrifuge was examined and found to be over 15 years old with a noninterlocked lid. This allowed the lid to be opened independent of the rotor's speed. The rotor itself was undamaged, but it and the bowl were contaminated with blood and glass. Also, the centrifuge had a two-wire ungrounded power cord and no inspection label. It had never been inspected for electrical safety or proper and safe operation.

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A review of databases and new product literature pointed out that modern centrifuges are required to have interlocked lids to prevent access to the bowl while the rotor is moving to prevent such an adverse event.

The centrifuge was inherently unsafe despite the technologist's ill-conceived and dangerous attempt to stop the rotor. Additionally, the investigation revealed that some laboratory equipment was not on routine inspection and preventive maintenance schedules. Such an inspection may have discovered the unsafe centrifuge. Also, the laboratory schedules were adjusted to more evenly divide the workload and allow faster return of result to clinicians.

Causative factors: incorrect use, lack of incoming and ongoing inspection, design and labeling errors.

Injury mechanism: potential for infection and mechanical injury.

References

International Electrotechnical Commission (IEC). *Safety requirements for electrical equipment for measurement, control, and laboratory use—part 2-2: Particular requirements for laboratory centrifuges.* Draft Standard 66E (Central Office) 11. (to be used in conjunction with IEC 1010-1).

Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens: final rule. CFR § 1910.1030. *Fed Regist* 1991 Dec 6;56(235):64004-182.

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Case Study 3: Defibrillator Failure to Discharge

During a cardiac arrest, several attempts were made to defibrillate a patient. The defibrillation was done using paddles. The staff noted that the defibrillator was not discharging into the patient. Reviewing the electrocardiogram (ECG) strips after the event revealed no electrical activity. The ECG strips recorded only a dotted line and documented "no shock delivered." The dotted line and "no shock delivered" implied no paddle contact with the patient. The patient died. Based on a postmortem examination, the death was not attributed to the inability of the defibrillator to discharge.

Devices Considered

Defibrillator
Defibrillator paddle electrodes (disposable)
Defibrillator electrodes (hand-free style) (disposable)

Analysis

Investigation revealed that the staff had used adult-sized disposable defibrillation electrodes with the paddles rather than with the hands-free cable attached to the disposable electrodes. The disposable electrodes adhere to the patient and are intended to connect directly to the defibrillator and be used in place of the paddles.

In this case, the paddles were placed on the nonconductive foam backing of the disposable electrodes, and the wires for those electrodes were ignored. For defibrillation with paddles, the staff should have used the supplied defibrillation electrode pads that are designed to be a conductive interface between the patient and paddles. The defibrillator was removed from service and tested by the clinical engineering department and found to be functioning properly. A mandatory in-service was arranged for all staff. The storage of the hands-free pads and cable was rearranged to prevent a recurrence of the mistake.

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Despite the error in use, the design of the hands-free pads may not clearly differentiate them from other types of commonly used interface pads.

Causative factors: labeling ignored, incorrect clinical use, failure to train and credential, systems problems in equipment storage.

Injury mechanism: failure to deliver therapy.

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Case Study 4: Dialysis Machine Contamination

A community hospital has a dialysis unit for treating both acute and chronic dialysis patients. The unit is equipped with several dialysis machines of the same make and model, and staff had been trained in using the equipment and recognizing signs of malfunction. For several years, the hospital has been using disposable dialysis tubing sets supplied by one particular supplier.

The hospital began using new tubing sets that had been unexpectedly supplied by the tubing supplier and that were represented as being compatible with their machines. The tubing was equipped with a different brand of disposable transducer protector. Nurses soon noticed that they were having trouble maintaining proper blood flow and pressure during treatments. Also, the disposable transducer protectors were being wetted with blood much more than normal. Further, nurses administering dialysis continually had to adjust pressure knobs to maintained proper blood level in the tubing. However, no patients experienced medical problems.

Several months later, when staff began using tubing from a different manufacturer, the problem stopped, and the machine easily maintained the proper blood flows and pressures. Neither the hospital nor the equipment suppliers had submitted problem reports to the U.S. Food and Drug Administration (FDA) until this time.

Devices Considered

Hemodialysis machine
Dialyzer (single patient use)
Dialysis tubing set
Pressure transducer protectors
Cannulae

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Analysis

Dialysis machines are used to cleanse the blood of patients whose kidneys no longer function. The machine draws blood from one of a patient's arteries through a cannula; passes it via disposable tubing through a series of filters, called an artificial kidney, to clean it; and brings it back into the patient through a second needle in the same artery. When the machine is functioning properly, the blood never actually passes through the machine; the blood merely passes through the tubing and the artificial kidney and reenters the patient. The machine's main function is to maintain proper pressure and flow in the tubing to ensure that the blood passes through the artificial kidney at the proper rate. After each patient, the single-use tubing and artificial kidney are removed and replaced, and the machine is sterilized.

During the time that the blood pressure and flow problems were being experienced, the hospital had continued using the new tubing on all its machines while the dialysis unit staff discussed the problems with the tubing and transducer protector manufacturers. Based on the continuing problems, hospital staff contacted the supplier to inquire about the new tubing sets; the supplier assured the hospital staff that the devices were compatible with their machines and stated that it had not received any complaints of problems with the new tubing sets from any other hospital. It was later discovered that at least two other hospitals had complained of tubing set performance problems and incompatibility with the dialysis machines, but the supplier had not alerted tubing purchasers or FDA. The hospital staff also noted that FDA approved the tubing for use with their dialysis machines. Separately, the hospital biomedical engineering department staff was discussing the problems with the manufacturer of the dialysis machines. Different manufacturers had produced all the machines, tubing sets, and transducer protectors (which prevent contamination of the machine's internal blood pressure sensors). During this period of new tubing set use, dialysis treatment was administered to scores of patients, including hepatitis C virus and human immunodeficiency virus patients who were transferred from a nearby hospice to the hospital for acute dialysis.

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During a routine maintenance check of the dialysis machines after having switched over to a third supplier's tubing, which stopped the blood pressure and flow problems, a nurse noticed that tubing within the chassis of one of the dialysis machines was contaminated with several small droplets of blood. This tubing led to the internal blood pressure sensors and was not visible during normal machine setup or treatment procedures. She reported her findings to her supervisor.

Upon investigation with outside consultants, infection control concerns were raised that blood could have entered the internal tubing during previous procedures and could have contacted and contaminated blood of previous patients. The hospital promptly notified FDA, state health department officials, the tubing supplier, and the dialysis machine manufacturer of the possibility of cross-contamination between hemodialysis patients.

The tubing manufacturer voluntarily recalled all its tubing sets released in the United States. FDA issued a Safety Alert because the spot where the blood was discovered is not visible during routine operation or maintenance of the dialysis machine. The hospital sent all remaining sets of tubing to FDA and others for testing and investigation but had already disposed of the tubing that was on the machine when the incident(s) occurred.

It is not known if any cross-infections occurred. A lack of a coordinated investigation at the hospital may have contributed to delays in discovering the potential for cross-contamination. More timely reporting by the suppliers or the hospital of what were initially perceived as no-harm events may have resulted in a quicker resolution of the problem.

Causative factors: device design, failure of accessory, lack of competent accident investigation, poor incident/recall reporting system.

Injury mechanism: infection.

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Case Study 5: Electrosurgical Grounding Pad Burn

A patient undergoing gynecologic surgery was found to have a 1 x 2 cm third-degree skin burn under the edge of the electrosurgical dispersive electrode on her right flank at the end of the procedure. The patient been prepped in the flat position on the operating table, including placement of the electrode, and then repositioned into lithotomy position. In the incident reported here, a burn was detected after the surgeon attempted to activate an electrosurgical unit (ESU) several times with no surgical effect. The burn occurred directly underneath the dispersive (i.e., return) electrode and corresponded to a charred section near the edge of the electrode's conductive adhesive surface, which indicates that arcing probably occurred between that section of the dispersive electrode and the patient's skin.

Devices Considered

Electrosurgical unit
Electrosurgical active electrode (disposable)
Electrosurgical dispersive (return) electrode (disposable)
Electrosurgical probe electrode (disposable)

Analysis

Upon examination, the dispersive pad appeared to have been adequately attached to the patient, the electrode did not appear to be defective (other than the charred section of the pad), and the conductive adhesive was not dried out. However, the site underneath the pad had not been shaved.

A database search found several other electrosurgical burns attributed to improper shaving of the area underneath the patient return electrode. Indeed, manufacturers of dispersive electrodes are aware of this problem and provide application instructions and warning labels on their packages, which typically state that the area underneath the dispersive electrode should be cleaned and shaved as necessary. However, operating room scrub or circulating nurses may neglect to shave the area to save time, despite

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hospital policy, or because they are unaware of the need for shaving or patients object to shaving for cosmetic reasons.

An electrosurgical burn following an ESU activation that produces little or no surgical effect typically indicates poor electrical contact between the dispersive electrode and the patient. Poor electrode placement, inadequate site preparation, defective materials on the return electrode, dried-out conductive gel or adhesive, or the dispersive-electrode losing contact with the patient can cause poor electrode/patient electrical contact. In this case, the patient's hair most likely inhibited complete dispersive electrode skin contact, resulting in high patient/electrode contact impedance. The burn most likely occurred at a small contact point between the patient's skin and the conductive layer of the return electrode.

The electrosurgical unit used in this case was an older unit that did not have a return-electrode contact quality monitor, which actively measures the patient/electrode connection and signals poor contact. Had a newer unit—most of which have this monitor—been used, the poor contact would have been identified before an injury occurred.

The adverse event's proximal cause was inadequate dispersive-electrode site preparation—essentially a user error. The dispersive electrode's labeling was ignored and unread, and the need for site preparation may need to be more clearly defined to the user community. The continued use of an older electrosurgical unit when newer safer technology is available should be reviewed. This incident would not have occurred with newer model electrosurgical units with dispersive-electrode monitoring.

Causative factors: labeling ignored, improper connection, error in facility policy.

Injury mechanism: electrical burn.

Reference: See "Investigating Device-Related Skin 'Burns'" in Appendix A.

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Case Study 6: Epidural Catheter Breaks

Over the course of two months, five incidents of epidural catheter breakage were reported at a teaching hospital. The events occurred in both the obstetrical and surgical wards, and all involved the same brand of catheter. Lot numbers were obtainable for only two of the catheters. They were not from the same lot. In each incident, the catheter broke during removal after several days in place delivering pain medication.

Two of the catheters broke at a point of what appeared to be a partial angled slicing cut. Two separated from the junction with the hub. The last catheter broke in midsection and appeared to have broken at a crease, with a small remnant tag of plastic hanging off. The first four catheters were removed without difficulty. This last incident resulted in a 5 cm fragment of catheter remaining in the patient, which had to be surgically removed.

Devices Considered

Epidural catheters (disposable)
Introducer needles (disposable)

Analysis

Damage and breakage of epidural catheters secondary to being pulled back through the introducer needle is a known and common problem. The two catheters with the angled slices were likely damaged during introduction due to the technique of use.

It was determined that the catheter that had broken, leaving a fragment in the patient, had been left in too long. Bending while in situ caused the crease and weakened the catheter. Excessive force applied during a hasty removal contributed to the breakage. This is also a known complication.

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The two catheters that separated from the hub are of concern. The weldment of a catheter to its hub should be strong enough to withstand reasonable pulling forces during withdrawal. Manufacturing error or hub weldment damage from storage conditions were considered as the two possible root causes.

Causative factors: device abuse, possible manufacturing error, improper storage.

Injury mechanism: particulate embolism.

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Case Study 7: Heating Pad "Burn"

A diabetic patient with severe acute cellulitis of the left lower leg was admitted for observation and treatment. A warming lamp was briefly used for about 20 minutes to stimulate blood flow in the leg. In order to allow the patient to sleep, the warming lamp was removed and a circulating hot-water heating pad set to 40°C (104°F) was applied for 30-minute intervals every few hours. Skin integrity checks were unremarkable through the course of the heat therapy. On the third day of admission, about 10 hours after the last use of the heating pad, the patient was discovered to have red mottled areas on the right calf extending laterally. Similar mottled areas were seen on the medial left calf although that leg had not received heating pad treatment. The lesions progressed over the course of the next day to blisters and partial-thickness skin injury. Thermal burns from the heating pad or warming lamp were suspected.

Devices Considered

Circulating hot-water heating pad controller
Heating pad (disposable)
Warming lamp

Analysis

Testing of the heating pad showed it to be operating properly and within specified temperature limits. The backup safety thermostats were also tested and found to be operating properly. Circulating water temperature was 39.4°C (103°F) when set to 40°C (104°F), and the pad surface temperature was approximately 38.3° to 38.9°C (101° to 102°F) due to the thermal losses in the pad plastic.

Investigation of the use of the heat lamp revealed that the patient's wife was present throughout its use and stated that the lamp was always at least three feet from the leg. The

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hospital's clinical engineer made qualitative tests of the heat lamp on his own leg, under these conditions of distance. The tests proved unremarkable after two hours.

Review of the medial literature revealed that research* on pigs and human volunteers has resulted in the generally recognized threshold temperature for causing partial-thickness thermal burns to human skin as being 43.3°C (110°F) after six hours of continuous application. Frank thermal burns have not been demonstrated at temperatures below this. The few reports in the FDA databases of alleged burns with this model of heating pad were all related to observed failures of the thermostats. The two heat sources were discounted as having burned the patient.

Further review of the patient's medications revealed that he was on warfarin blood-thinning medication. The prescribed dosage of 10 mg once per day was incorrectly recorded in his medical records, and he received at least twice that amount per day after admission. The lesions were realized to be adverse skin reactions to the drug overdose and not attributable to the heat-therapy devices.

Causative factors: none related to devices.

Injury mechanism: overdose.

* Moritz AR, Henriques JR. Studies of thermal injury II: the relative importance of time and surface temperature in the causation of coetaneous burns. *Am J Pathology* 1947;23:695-719.

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Case Study 8: Infant Incubator Overheated

A two-week-old neonate at a tertiary care teaching hospital died while under therapy in an infant incubator in a neonatal intensive care unit (NICU). Nurse staffing levels were low at the time of the incident. Although a nurse was in the room with the infant, other critical duties diverted her attention from the child and the incubator. She did not hear any alarms sound. Her attention was drawn to the incubator when she noticed abnormal readings on the main display panel from across the room.

The incubator had severely overheated, and hyperthermia was ruled as the cause of death. Temperatures within the incubator were hot enough to melt and distort the plastic mattress tray. At the time of the incident, the incubator was in its second month of prepurchase clinical evaluation. An investigation by hospital medical and engineering personnel was performed and could not determine the cause of the incident or duplicate anything other than normal performance. The manufacturer of the incubator could offer no explanation for the apparent overheating incident and stated that this was the first and only incident of this type of which they were aware. This perspective was supported by independent searches of relevant medical device problem report databases.

Devices Considered

Incubator
Skin temperature probe
Detachable power cord

Analysis

Further investigation involving clinical engineering specialists determined that the incubator overheated due to a brief power interruption that disrupted the programming of the unit's microprocessor controller. (The manufacturer was present during this investigation.) The cause of the brief power disruption was the loose hot and neutral

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wires inside a replacement three-pin power plug that had been installed on the detachable power cord. The nature of the programming disruption caused the incubator's heater to continuously heat and to blank out most, if not all, of the control panel display (as was observed by the nurse). Under this condition of errant heater operation, an audible alarm sounded continuously but was easily missed in the background noise of the crowded NICU and not heard by hospital personnel.

Within the one-hour timeline of the baby's exposure to overheating, the temperature of the air entering the incubator from below the mattress would have been approximately 82.2°C (180°F), with a corresponding temperature within the chamber at the location of the baby of at least 51.7°C (125°F). These temperatures continued to climb over the following hour, during which the baby was undergoing resuscitation outside the incubator, resulting in an incoming air temperature in excess 93.3°C (200°F) and melting of the plastic mattress tray. Such high temperatures were possible due to the high-temperature backup thermostat having been improperly serviced.

Further examination of the power plug wires revealed that they had been improperly installed in a way that predisposed them to loosening. The combination of two servicing errors was the proximate cause of the adverse event. Both errors had occurred before the incubator had been delivered to the hospital. Failure of the hospital to perform an incoming inspection, which would have included testing the backup thermostat, was a root cause of the incident. The failure to do the needed inspection resulted from a communication breakdown within the equipment acquisition committee. The clinical engineering department had not been made aware that the incubator had arrived and therefore could not apply their standard inspection procedures.

Causative factors: lack of incoming inspection, error in facility policy, manufacturing error, failure of accessory, environmental noise.

Injury mechanism: hyperthermia.

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Case Study 9: Infusion Pump Infiltration

While using an infusion pump to deliver a saline bolus to an infant, staff noticed swelling and discoloration an the infant's forearm caused by infiltration. The infusion was stopped, and the pump was removed from service for inspection. The infusion set and catheter were discarded accidentally and not available for inspection. The pump did not alarm during the infiltration. The facility did not detect any performance problems with the device when they tested it. The supplier informed us that the device was not intended to detect or prevent infiltration.

Devices Considered

Infusion pump
Infusion tubing set
Venous catheter
Injection port needle

Analysis

Infiltration—also called extravasation—is the extravascular accumulation of a solution being infused. One consequence of infiltration is that it can lead to necrosis; however, the primary consequence is that the patient is denied necessary fluids or medications. Because vital intravenous (IV) medications are frequently delivered to a patient by means of infusion therapy, infiltration can have serious effects on a patient's health.

Infiltration incidents have been reported with all types of infusion pumps. However, infusion pumps typically play only an ancillary role in such incidents, and the belief that the pumps produce infiltration is inaccurate. Rather, the usual causes of infiltration are dislodgment or improper insertion of either a catheter or, in the case of a subcutaneous injection port, a needle. Thus, to avoid problems, staff members should monitor IV sites

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of patients who are receiving infusions through pumps at least hourly to ensure that catheter or needle dislodgment and subsequent infiltration do not occur.

Another common misconception is that occlusion alarms on infusion pumps will signal infiltration. In fact, pumps will alarm only when downstream pressure reaches a specified value and elevated pressures resulting from infiltration are typically far lower than occlusion alarm triggering levels.

However, there is no currently marketed infusion pump that can reliably detect infiltration. It would not have been possible for the clinical engineering department to test for infiltration prevention in their inspection of the pump. It is important to instruct staff members that infusion pumps do not detect infiltration and that patients receiving infusions through these devices should therefore be supervised closely and IV sites should be assessed hourly.

Pumps submitted for maintenance following infiltration incidents can be returned to service after routine inspection and documentation. The facility should monitor the trends of repair requests that involve infiltration. If this problem persists, additional staff training on avoiding infiltration may be needed.

Causative factors: incorrect clinical use, inappropriate reliance on automated feature, failure to train.

Injury mechanism: extravasation.

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Case Study 10: Laser Eye Injury

During orthopedic surgery, a neodymium:yttrium-aluminum-garnet (Nd:YAG) laser was used through a fiber with a right-angled probe. The procedure was routine, and, because it was closed, only pink-rimmed safety glasses were worn. Also, the circulating nurse did double duty as the laser operator. At the end of the procedure, the surgeon said he was finished, removed the probe, and handed it off to the scrub nurse. The circulating nurse was not near the laser and was unable to put the laser in standby mode when the surgeon indicated that he was finished with it. As the probe was handed off, the surgeon accidentally pressed the laser footswitch and fired a burst of laser energy into the scrub nurse's face. The Nd:YAG's near-infrared light energy is focused by the eye's lens onto the retina. The exposed nurse sustained a retinal burn that fortunately healed with no loss of vision.

Devices Considered

Nd:YAG surgical laser
Laser fiber and probe (disposable although sometimes reprocessed)
Laser safety eyewear (reusable)
Safety eyewear (reusable)

Analysis

The laser was checked by the manufacturer and was found to be operating properly with all the federally mandated safety features in place and functioning. The laser fiber and probe were likewise found to be functional although they had been reprocessed.

When interviewed, the staff was astounded that such an incident could occur. They had used Nd:YAG lasers endoscopically for years with no problems. They had been told that pink-rimmed eyewear was safe for use with lasers. They believed that because the laser light was in the fiber and inside the patient, no light could escape and harm them. One

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staff member even stated that he had been flashed once in a similar case and was uninjured.

Discussions with the laser manufacturer pointed out that laser safety standards existed and should be maintained to prevent such incidents. A review of laser safety standards pointed out that the hospital should have a laser safety committee as well as a laser safety officer to determine laser hazards and define laser safety protocols. The standards recommend the use of a laser operator, who should be concerned only with the safe operation of the laser operation. The laser operator and the surgeon should communicate about laser use to help prevent unwanted laser emissions. The standards also direct that laser safety eyewear suitable for protection from the laser in use should always be worn during laser use.

A database search revealed only a tens of cases of eye injury in over 35 years of medical laser use. In virtually all these cases, the laser eye injuries occurred because **proper** laser safety eyewear was **not** worn. Laser flashes are reportedly common in some user circles but are not reported for fear of job loss, legal action, and embarrassment. The low incidence of reported laser eye injuries may conceal a more common problem that accurate and nonblaming reporting could reveal. Proper laser safety eyewear is critical to preventing these injuries

An examination of the safety glasses used in this case found that they offered no protection from Nd:YAG laser energy. The glasses were not marked with the wavelength and optical density for any laser. Purchasing records indicated that pink-rimmed laser safety eyewear had been used with carbon dioxide lasers. As the glasses wore out, they had been replaced with similar safety eyewear that was not intended or labeled for any laser protection.

The proximate cause of this incident was ignorance of proper laser safety eyewear. However, a lack of adherence to standard laser safety protocols was the root cause of this incident. A laser operator is critical to protecting the patient and staff from laser injuries

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and laser-induced fires. An understanding of proper laser safety measures should be required of all staff that works with lasers. The requirements of the laser safety standards were designed to allow the safe use of lasers and should always be followed.

Causative factors: labeling ignored, use of inappropriate device, incorrect clinical use, failure to monitor, failure of incoming inspection, errors in facility policy, failure to train and credential, poor incident reporting system.

Injury mechanism: thermal burn.

Reference:

American National Standards Institute (ANSI). *Safe use of lasers*. ANSI Z136.1. 2000.

American National Standards Institute (ANSI). *Safe use of lasers in health care facilities*. ANSI Z136.3. 1996.

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Case Study 11: Low-Air-Loss Pressure Sore Treatment Bed

A hemiplegic elderly male patient in a long-term care facility was found face down and unresponsive in his low-air-loss bed during late evening rounds. He was found lying somewhat on his right side, with his torso slightly turned toward the mattress surface. His face was buried in the mattress. His right arm, the one that he could weakly use, was trapped under him. His left arm, though free, was not functional. Nurses commented that the air-filled mattress appeared to be too soft and that it had allowed him to roll over and become smothered. His back was found to be just touching the bedrail on one side but not forced against it. It was not believed that he had been entrapped by the rail. Postmortem examination revealed death by asphyxiation.

Devices Considered

Low-air-loss bed
Replaceable mattress bladders
Bedrails

Analysis

Low-air-loss beds are designed to treat or prevent decubitus ulcers (bed sores) by providing a low-pressure mattress support surface and by keeping the patient's skin dry. One common technique that low-air-loss beds apply to achieve this is to use pillow-shaped bladders that are the width of the bed and oriented in a vertical position. Typically, more than a dozen such bladders are required to cover the length of the bed frame. The vertical bladders have air-inlet jacks that latch into mating air-supply connectors on the bed frame. A compressor built into the bed provides the air to fill the bladders. Bladder pressure can be adjusted for optimum support or cushioning effect based on the patient's weight and stature. The bladder fabric is porous and designed to allow the filling air to leak through the mattress. This gentle, low flow of leaking air keeps the skin dry. The air is also slightly warmed to keep from cooling the patient.

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In this case, it was determined that two of the air bladders that supported the patient's upper chest and shoulder areas had become deflated. This caused the patient to roll to one side and come to rest in a position with his face buried in the mattress sheets. His paralysis, combined with the extreme softness of the mattress, prevented him from moving or rolling to a position where he could breathe.

Inspection of the bed frame revealed that repairs had been made to the air-supply connectors on one side. Two replacement connectors had been installed. The replaced connectors aligned with one side of each of the two bladders that had deflated. Although the connectors were the correct part number, they had been installed incorrectly using the wrong type of screws. The head of the screws that were used sat above the otherwise flush surface of the connector and prevented full latching of the bladder jack when it was plugged in, unless extraordinary pressure was used to press on the connector. It was determined that a maintenance error was the cause of the bladder deflations, combined with poor installation instructions for the new air connectors. The bedrail was found to be properly applied and secure. It did not play a role in the incident.

A review of the maintenance records for the bed revealed that two other patients had been found in a compromised position on that same bed due to partial bladder deflation. However, these patients were not injured and cursory inspection of the beds after each incident did not reveal any bladder inflation problems. Failure to find the problems occurred because the bed inspection took place with the fitted sheet over the full mattress. The sheet kept the loose connectors in place even when a patient was not on the bed. It was also found that when housekeeping changed the bed linens, they often found loose bladders on this bed but would simply try to plug them back in as best they could. They did not know that the connectors were supposed to latch in place.

Causative factors: maintenance error, repair part labeling error, poor incident reporting system.
Injury mechanism: suffocation.

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Case Study 12: Manual Resuscitator Failure

A patient was being transferred from the postanesthesia care unit (PACU) to the intensive care unit following surgery. During the transfer, a manual resuscitator was connected to the patient's tracheal tube for ventilation. Approximately 1½ minutes after the beginning of manual ventilation (the time required to reach the PACU door), the nurse using the resuscitator noticed that the patient was cyanotic and that squeezing the bag had become difficult. The patient was then suctioned to clear any possible mucus plugs and was also extubated and reintubated to verify that the tracheal tube was positioned correctly. Another manual resuscitator was then used to resume manual ventilation. The patient was diagnosed with a pneumothorax and anoxia.

Devices Considered

Manual resuscitator (disposable)
Tracheal tube (disposable)
Tracheal tube connector (disposable)

Analysis

Subsequent testing of the manual resuscitator at the hospital revealed a malfunctioning exhalation valve, but the cause of the valve malfunction was not determined at that time. The nonrebreathing valve contains a diaphragm duck-billed valve, which opens when the bag is compressed to direct gas to the patient. When the patient exhales, the gas flow lifts and closes the duck-billed valve, which prevents gas from returning to the bag and opens a path for the expired gas to vent to ambient air through slots in the valve's housing. Later examination of the incident resuscitator by an independent investigator revealed that there were two duck-billed diaphragms in the device where there should only be one. Since the exhalation-valve housing is sealed, the extra diaphragm must have been placed in the valve during manufacturing and assembly of the device.

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Based on a review of problem reporting databases, the problem experienced with this resuscitator was likely an isolated incident. There was only one other published report, which appeared in the British medical literature, wherein the exhalation valve of another manufacturer's manual resuscitator became blocked because two exhalation-valve diaphragms were accidentally placed in the device.

Further, the manufacturer's recommended preuse testing procedure may not necessarily detect this insidious problem. At low ventilation pressures, which occur when the bag is squeezed slowly, the exhalation valve can function properly with the extra duck-billed diaphragm. However, at high pressures achieved during quick bag squeezing, the two diaphragms separate, and the expiratory pathway becomes occluded. Thus, as the patient received each breath, if each exhalation was not complete, pressure would build up in the lungs and cause the resuscitator to become harder to squeeze because the valve became occluded and the lungs became pressurized. This pressurization caused the pneumothorax, and the patient became anoxic because exhalation was inhibited. Had the nurse been more aware of the manual ventilation technique and potential problems (e.g., difficulty in squeezing the bag), she may have more quickly noticed the patient's distress and avoided the incident.

Timely reporting of such events help discover lot-specific manufacturing defects. This is especially critical for disposable devices, including those related to respiratory care (e.g., breathing circuits, bacterial filter, water traps, connectors, heated humidifier components, tracheostomy and tracheal tubes).

Causative factors: manufacturing error, lack or failure of incoming and preuse inspections, failure to train.

Injury mechanism: barotrauma, suffocation, failure to deliver therapy.

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Case Study 13: Medical Gas Mix-up

In preparation for laparoscopic surgery, a technician was directed to obtain a full "E" cylinder of carbon dioxide for the laparoscopic insufflator. From the storage area, the technician obtained a cylinder that was mostly gray with part of its top end painted green. The cylinder had only part of a label that read "Carbon Dioxide." The technician inserted the cylinder into the insufflation cart's cylinder holder tube and connected the cylinder to the gas yoke of the insufflator, and the surgery proceeded. No one checked or questioned the technician's choice of gas.

Near the end of the procedure, a small flame appeared at the tip of the electrosurgical probe, and the video screen flashed orange-red. After quickly withdrawing the electrosurgical probe, the surgeon found that the probe's insulation had burned away and that the trocar sheath had partially burned and melted. The laparoscopic surgery was converted to an open procedure to inspect for injuries, but patient was only slightly burned on the internal abdominal wall and recovered.

It was later determined that a gas mixture of 20% carbon dioxide and 80% oxygen, a respiratory therapy gas, was used in this case. The oxygen-enriched atmosphere allowed an incandescent tissue ember, typically produced by electrosurgery, to ignite the probe's insulation and then the trocar.

Devices Considered

Medical gas cylinder
Insufflator
Electrosurgical probe (disposable)
Trocar (disposable)

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Analysis

A medical gas cylinder's primary identifier is its label. A cylinder with a torn and incomplete label should not have been used. While gas-specific cylinder color codes are often used, nonstandard color schemes are also widely used and can lead to confusion. Color coding should not be relied on as an indicator of a cylinder's contents. The technician was unaware of these well-publicized and longstanding compressed gas safety rules and standards, and thus he chose and installed the wrong cylinder. The operating room procedures were also lacking requirements to verify the installation of the proper cylinder.

The pin index system was designed to prevent use of inappropriate gases with a device, and the pins had been removed from the insufflator's gas yoke, making it able to accept any gas cylinder. Initial investigation gave reason to believe that had the pins been in place, the mix-up would have been prevented. However, in this case, the same pin index for carbon dioxide—as defined by a national standard—was also used for the gas mixture. Thus, the presence of index pins would not have prevented the adverse event, and the availability of similar cylinders for two different gases used for two different medical specialties in the gas storage locker was found to be a compounding problem.

The investigation concluded that the proximate cause of the fire in this case was the technician's ignorance of cylinder safety and was not related to the devices. Essentially, it was a "use error" on the technician's part. But deeper causes with systems were also present; for example, cylinders were not being stored separately to prevent mix-ups, and the operating room procedures did not include checking for use of the proper gas before the start of surgery. The removed index pins in the insufflator's yoke suggested that other problems with gas cylinders could occur with other gas-using devices in the facility.

Alteration of devices, such as removing index pins, can be the cause of adverse events and should be discouraged. Also, existing safety standards may need to be widely reinforced and reiterated to help minimize the occurrence of adverse events. In addition,

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minimally invasive surgery is becoming more widespread, even in physician offices, and safety precautions may need to be more widely promulgated.

Causative factors: use of inappropriate device, accidental misconnection, preuse inspection not performed, incorrect clinical use, errors in facility policy, failure to train, maintenance or incoming inspection error.

Injury mechanism: fire, thermal burns.

Reference: Compressed Gas Association pamphlets on medical gases and cylinders. National Fire Protection Association (NFPA). *NFPA99—Standard for healthcare facilities.* 2002.

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Case Study 14: Pharmacy Intravenous Solution Compounder Improper Mixing

A parenteral solution of dextrose and water was mixed in a hospital pharmacy using an automated solution compounder. A solution was to be mixed containing 150 ml of dextrose 50% and 1,350 ml of water. This was to yield a 1.5 liter-bag filled with dextrose solution in the concentration of 4,500 mg/dl. When the solution bag was used, the patient did not respond to the intended dextrose therapy and sustained a neurologic injury. There had been two other recent incidents of suspected improper mixing with the compounder that had not resulted in patient injury.

The solution in the incident bag was analyzed by the hospital's clinical laboratory. The analysis revealed a dextrose concentration of 2.5 mg/dl, suggesting that virtually no dextrose had been mixed into the solution bag. The compounders had been in use for several years. However, a new hospitalwide patient data management system had been recently installed and was linked to the pharmacy's compounder at the time of the incidents.

Devices Considered

Intravenous (IV) solution compounder
Patient data management system
Compounder tubing set (disposable)
Bags of IV solution (consumable)

Analysis

Initially, hospital investigators considered a possible software flaw. Testing of the compounder revealed that it operated according to manufacturer specifications, both with and without being connected to the patient data management system. Nonetheless, given

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that software errors may require a unique or aberrant sequence of events to be problematic, the investigation continued along these lines.

Despite initial suspicions and recollections, it was found that two of the incidents had occurred before full installation of the software link to the patient data management system. One of these involved a dispensed solution. For these two incidents, the pharmacy data link software had been installed in the patient data management system, but the corresponding software had not been installed in the compounder. As such, there was no physical or electrical linkage of the two systems at the time of the two incidents.

Further investigation revealed that a total of six incidents of suspected miscompounding had occurred in the previous ten months but that only three miscompounded solutions were dispensed by the pharmacy. Interviews of the pharmacy staff revealed that the pharmacy caught the errors in compounding of the other three solutions at the time of compounding. Those solutions had been discarded without detailed investigation or review of pharmacy policies and procedures. It was also discovered that all the incidents occurred after employment of two new pharmacy staff involved in compounding and after changing suppliers of IV solution bags. The causes of these nondispensed miscompoundings were, at the time of their occurrence, generally attributed to errors by the users in setting up the equipment tubing or in placement of the source solution IV bags.

The investigation turned toward the causes related to the twisting of kinked tubing, user misprogramming of the compounder, improper compounder calibration at the beginning of each day, the use of incorrect IV solution bags, and the use of the correct IV solution bags on the wrong compounder locations. Unfortunately, the memory in the compounder had not been downloaded before tests were performed on the unit. Had the memory been intact and reviewed, determination of misprogramming for the incident solution would have been a quick task. Examination of the new IV source solution bags revealed that they were very distinctively marked as to contents, and it was judged that error in placement on the compounder hanging racks was not likely.

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A search of the FDA and ECRI *Health Devices Alerts* databases, as well as the National Library of Medicine, revealed no reports of miscompoundings with the incident unit. However, the search did reveal several articles in the medical literature that made general recommendations for modifying discussed pharmacy policies and procedures to avoid miscompounding accidents. Pharmacy medication logs documented that on the day of the incident, the compounder had been used to mix other dextrose/water solutions immediately before and after the incident compounding. There were no reported adverse events related to other dispensed solutions on that day.

It was concluded that the likely cause of the improper mixing of the incident dextrose/water solution was a programming error by the user. Since the compounder cannot be programmed to deliver a volume of dextrose 50% low enough to result in the actual observed concentration of 2.5 mg/dl, it was concluded that no dextrose had been programmed to be infused. The root cause of the incident was determined to be a lack of adequate staffing at critical times of the day, compounded by poor management of STAT orders for compounded solutions.

IV solution compounders had been in use in hospitals for only a few years at the time of the incident. The databases were not helpful in assessing the incident due to the newness of the technology. Reporting on what may otherwise be viewed as a use error is indicated to help determine possible trends in hazards with new technologies.

Causative factors: incorrect programming, poor incident reporting, error in facility policy.

Injury mechanism: underdose, failure to deliver therapy.

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Case Study 15: Pressure Monitor/Transducer Inaccuracy and Fluid Overload

A community hospital had traditionally used reusable quartz pressure transducers of the same brand as the physiologic monitors with which they were used. Wishing to cut reprocessing costs for the reusable transducers, the hospital began to evaluate disposable pressure transducers for use in clinical areas—namely, anesthesia, recovery, intensive care, and cardiac care.

The decision to evaluate disposable transducers was initiated by one of the hospital's departmental purchasing agents who gained physician approval and coordinated the purchase process on his own. He contacted a manufacturer of disposable transducers and met with one of its sales representatives, and arrangements were made for an in-service presentation by the transducer manufacturer. All nurses from the intensive care unit (ICU), cardiac care unit (CCU), anesthesia unit, and postanesthesia care unit attended. The sales representative presented an on-site program for day-shift nurses; evening- and night-shift nurses watched a manufacturer-produced videotape. These programs did not include an actual setup of a transducer to a patient monitor. The facility subsequently received shipment of the disposable transducers and began an in-house trial of the device.

One use during the in-house trial was on a 70-year-old female patient with a diagnosis of metastatic cancer of the breast, who was transferred to the hospital's CCU. Her attending physician inserted a Swan-Ganz catheter into the right pulmonary artery, as well as an arterial line catheter. The Swan-Ganz catheter was connected to a newly introduced disposable transducer. The arterial line catheter was connected to one of the old-style reusable quartz transducers. Both lines were connected to the blood pressure module housed within the physiologic monitor made by the manufacturer of the reusable quartz transducer. This was the first time that the CCU had ever used a disposable blood pressure transducer.

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Upon insertion, the invasive pulmonary artery blood pressure readings from the Swan-Ganz line were very low. The digital numbers on the display monitor were low, and the graphically displayed waveform appeared "damped." Pressure readings from the arterial pressure line were within normal physiologic range. Nurses rezeroed the disposable transducer on the Swan-Ganz catheter three times, but the readings remained low. IV fluid therapy was immediately initiated.

The disposable transducers being used for the first time in other areas of the hospital were also exhibiting problems at this time, but not necessarily the same ones. Anesthesia personnel attempted to use one during surgery. They could not zero the transducer and switched back to the old-style reusable transducer. After this incident, the hospital contacted the disposable transducer representative, who corrected the problem by changing the cable. No hospital staff other than those present were made aware of the problem. The physiologic monitor used in surgery is of the same brand but is a newer model than those used in the CCU and ICU.

Coincident with this patient's seemingly problematic pressure readings, the ICU contacted both the departmental purchasing agent responsible for the purchase of the disposable transducers and the hospital's on-call biomedical technician about an inability to get an accurate waveform and digital readout from an arterial line connected to a new disposable transducer. The biomedical technician was unable to correct the problem. He substituted the disposable transducer with one of the newer model physiologic monitors that were being used in the surgical suite. This was the first time that the biomedical technician learned that the hospital was using disposable transducers. No further action was taken at the time.

The evening house supervisor (on the 3:00 p.m. to 11:00 p.m. shift) was aware of the ICU problem and informed the incoming night supervisor not to use disposable transducers for arterial lines. Nothing was said about using the disposable transducers for Swan-Ganz lines used for monitoring venous or pulmonary artery pressures.

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The disposable transducer used on the CCU patient was not changed.

At about 36 hours after the low pulmonary artery pressures had been seen and fluid therapy started, the CCU patient's Swan-Ganz catheter waveform became completely flat. A nurse who had previously heard about the ICU's problem with the disposable transducer replaced the disposable transducer with a reusable Hewlett-Packard transducer. A good waveform was immediately obtained, and the Swan-Ganz readings were within normal range. No further action was taken.

The CCU patient died approximately three hours later. Postmortem examination determined that the cause of death was from massive fluid overload.

Devices Considered

Blood pressure transducers (reusable and disposable)
Blood pressure modules of two different physiologic monitors
Swan-Ganz catheter
Arterial blood pressure catheter

Analysis

Investigation by the risk manager and clinical engineer revealed that the older model physiologic monitors have an internal blood pressure transducer sensitivity selector switch, which is accessible to engineering staff only through the top metal plate of the pressure module. The switch on the older-style CCU monitor was set for reusable transducers, not disposable transducers, thus yielding erroneously low Swan-Ganz readings. The clinical engineer knew of this feature of the older—but still clinically acceptable—monitors. Unfortunately, he had not been consulted during the purchasing process for the disposable transducers that were to be used with the capital equipment monitors. The newer monitors had a sensing circuit that would automatically adjust the monitor's transducer sensitivity setting.

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Equipment evaluation and purchasing processes were changed at the facility to ensure that any disposable device that is connected to a piece of capital equipment was tested for compatibility. Further, hands-on, in-service training for use of such disposables was mandated.

Causative factors: device incompatibility, poor equipment acquisition process, failure to perform device compatibility testing, poor incident reporting systems, inappropriate user reliance on an automated feature, failure to train.

Injury mechanism: fluid overdose.

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Case Study 16: Radiation Therapy Overdose

A radiation therapy patient received the wrong dose of radiation (different from what was ordered) on repeated treatments due to an error in manually entering dosage data into the software used to program a linear accelerator (LINAC). A serious injury resulted.

Devices Considered

Linear accelerator
Treatment planning computer
Treatment planning software

Analysis

An investigation determined that the problem was not solely that of data entry by hospital personnel. Poor human factors design of the data-entry menus of the LINAC contributed to the error; otherwise, the LINAC functioned appropriately. Real-time dosimeters that would have alerted staff to the error during the first and subsequent treatments were not available at the facility.

The radiation technicians who delivered the therapy did not check the prescribed dosage with the displayed dosage from the LINAC's memory before each treatment—the pre-programmed dosage was assumed to have been correct. Although staffing levels in the radiation oncology department of the user facility were low, sufficient time had been available during initial use of the treatment planning computers for proper review and sign-off by a second oncologist of the calculated dosages. Nonetheless, an error was made when the calculated data was manually entered. Those entries were not double-checked.

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The user facility felt strongly that the LINAC's software should have caught the human error. However, the erroneous dosage that had been entered was found to be a viable treatment dosage for a different type of patient, and the LINAC was not faulted.

Computer software is present in a vast number of medical devices today. In most instances, that software is integral to the functioning of the device and would be considered a component of the device. Software defects can cause or contribute to serious injury or death and should be considered in investigations.

Causative factors: design error, incorrect programming, inappropriate reliance on an automated feature, poor prepurchase evaluation, failure to monitor, error in facility policy.

Injury mechanism: overdose.

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Case Study 17: Rongeur Break in Spinal Surgery

During a lumbar laminectomy, the articulating jaw of an intervertebral disk rongeur broke off while being used by the surgeon. The tip was retrieved with minor difficulty during that same surgical procedure. The surgeon and the instrument nurse did not note any problems with the functioning of the rongeur before the break. The patient had some neurologic complications during recovery associated with the spinal level at which the surgery took place. It is not known if the complications were related to the instrument breakage. The instrument was a straight, seven-inch Cushing style intervertebral disk rongeur. The jaw cups measured 2 mm x 10 mm. There were no specific serial numbers on the unit, but it did have "No. 67" stamped on the handle. It had likely been purchased three to five years before the incident.

Devices Considered

Laminectomy rongeur

Analysis

The hospital's clinical engineer and risk manager visually examined the rongeur. They compared it to another of the same make, model, and size. The rongeur was intact and operated smoothly, except for the missing upper articulating jaw. The broken jaw was not provided. The articulating jaw tip was later given to the patient by the surgeon. It was clear that the incident rongeur's jaws had been subjected to bending and twisting forces during use. It appeared that the rongeur had applied forces sufficient to exceed the strength of the jaw's base (i.e., the user was heavy handed and it broke under otherwise normal conditions of use).

The engineer further nondestructively examined the rongeur using a stereomicroscope in the pathology department. He saw no evidence of significant dulling to the cutting edges of the fixed lower jaw. The lower jaw on this rongeur does not articulate. The articulating jaw broke from its base through the upper hinge pinhole. The fracture surface was entirely clean with no discoloration. It did not appear as though there had been a

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preexisting crack at the hinge pin before surgery. Even assuming that there had been a preexisting crack, it is not likely that such a crack would have been visible to the naked eye. Preexisting fracture lines are difficult to see without the aid of a microscope, and such microscopic inspection of surgical instruments is not a common practice in hospitals. General visual inspection and functional manipulation are usually considered sufficient.

There were no readily apparent metallurgic defects, but the clinical engineer recommended that a specialist in metallurgic failure analysis be consulted if the case was to be further investigated on the technical level.

A review of the user facility's operating rooms instrument repair records showed that the rongeur had been resharpened 18 months before the incident but had never been repaired. User-facility incident reports were reviewed for similar problems with this rongeur. None were found, although several other incidents of instrument breakage had been reported involving this surgeon over a span of about 10 years.

A search of the FDA and ECRI *Health Devices Alerts* databases revealed approximately 130 reports of problems with all manufacturers' rongeurs over the past 10 years. However, only six of these related to similar reported breaks of this model of Cushing rongeur. There were no published recalls of the device. The six reports spanned the last decade, the most recent being two years before the incident. For this type of surgical instrument, six reports do not represent a remarkable number of citations given its small size and popularity in use.

The rongeur had been used beyond the limits of its strength. This brand and model of device also lacked a remarkable problem history and was likely not properly designed for its intended use.

Causative factors: abuse.
Injury mechanism: mechanical, particulate embolism.

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Case Study 18: Surgical Drape and Oxygen Mask Fire

An obese patient was to have a lymphectomy of the nodes on her right neck with sedation and local anesthetic. A single-use facemask was placed and delivered eight liters per minute (Lpm) of oxygen to the patient. She was prepped using an alcohol-based skin-prep solution from chin to nipple line and right shoulder to left neck. After the surgeon had scrubbed, he entered the operating room, was gowned, checked the prep, and draped the patient with a towel, a transverse laparotomy drape, and an incise drape. The surgeon used a scalpel to make the skin incision and then used blunt dissection to expose the lymph nodes. The patient was somewhat restless during this part of the procedure and was further sedated. About 20 minutes into the surgery, the surgeon used electrosurgery to cauterize bleeding vessels around the lymph nodes. During this process he noted sparking and a flame on the end of the electrosurgical probe. Shortly thereafter, smoke appeared from under the drapes, and the patient attempted to sit up. The burning drapes and facemask were quickly removed, and the fire on pillow around the patient's head, on her gown, and in her hair and hair net was extinguished with sterile water. The patient sustained first- and second-degree burns on her face, neck, and chest and the loss of her eyelashes, eyebrows, and some head hair.

Devices Considered

Electrosurgical unit
Electrosurgical pencil (disposable)
Electrosurgical probe electrode (disposable)
Oxygen facemask (disposable)
Skin prep solution and applicator (disposable)
Surgical drapes (disposable)
Surgical head positioning pillow (disposable)
Patient, gown, and hair net (disposable)

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Analysis

Initially, the alcohol skin-prepping solution was believed to have caught fire. However, both the prep nurse and the surgeon noted that the prep was dry and had not dripped into hair or linens. Also, the time between the prep application and the fire was longer than 20 minutes, and any liquid would likely have evaporated. The facemask was covered by surgical towels and the drape and was isolated from the surgical site by the incise drape. At 8 Lpm over 20 minutes, the mask would have flowed 160 L of oxygen under the drapes—enough to enrich the underdrape space several times over and to wash out any lingering alcohol vapors. The surgical drape was so positioned that the patient's head and the table were fully covered and that it trapped oxygen under the drapes and retarded its dissipation. Patient restlessness and retraction of the wound allowed a gap in the drapes to form with resulting gas communication of the surgical site with the underdrape space. Oxygen was then able to enrich the surgical site through the gap. The sparking and flaming were the result of the patient's tissue burning intensely during electrosurgical use in the oxygen-enriched atmosphere. The sparking most likely ignited the fine hairs on the patient's skin or the fine fibers on the towels and flashed back throughout the oxygen-enriched space. The fire on the edges of the linens and the loss of hair from the fire supported the likelihood of an underdrape oxygen-enriched atmosphere.

Use of electrosurgery in an oxygen-enriched atmosphere was the proximate cause of this incident. The use of 8 Lpm of oxygen rather than medical-grade air and oxygen or air alone could be justified on the patient's physiologic need for excess oxygen during sedation. However, the facemask would direct an oxygen flow toward the surgical site, and any opening to the site would allow the oxygen to enrich the site, making electrosurgical use a fire hazard. Most surgical draping techniques are capable of isolating the incision from the underdrape space, and any gases or vapors therein, from the surgical site, but they were not proof against any communication. Perhaps the incise drape was not adhered to a sufficient area of skin, or perhaps the incision was too close to the towel edges. These circumstances could allow an opening to the underdrape space,

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especially if the patient moved. The ignorance of the hazards and lack of coordination of procedures between the anesthesiologist and the surgeon were the root causes of this fire.

The cause of the adverse event was attributable to the techniques of use of the several devices involved and not to the devices themselves. Essentially, it was a use error on the part of members of the surgical team. New hazards may arise as new surgical materials, prepping agents, and anesthesia gas delivery techniques are introduced. Surgical fires present risks not only to patients, but also to clinical staff and the facility.

Causative factors: incorrect clinical use, error in facility policy.

Injury mechanism: fire, thermal burns.

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Case Study 19: Tracheal Tube Fire

In a large metropolitan medical center, a patient was suffering from chronic obstructive pulmonary disease (COPD) with almost no pulmonary function reserves. The patient had been ventilator dependent in the hospital for one week at which time it was decided to perform a tracheostomy. The patient arrived in the operating room intubated, and anesthesia was induced using isoflurane (forane) at 0.5% with 7 L/min of 100% oxygen. The patient was maintained on an anesthesia ventilator.

Prepping was carried out using an alcohol-based iodophor. After draping, the incision was made and the tissue was dissected down to the trachea. During dissection, bleeders were cauterized uneventfully with the electrosurgical unit (ESU). Unknown to the anesthesiologist and the surgeon at this time, the tracheal tube had risen in the trachea to a point where the distal end of the cuff was just underneath the center of the incision site. The surgeon then used the ESU in the coagulate mode to cut laterally between two of the tracheal cartilage rings; he then attempted to cut (with some difficulty) through the superior ring. As the superior tracheal ring was being cut, sparks and flames were seen shooting out of the incision site. Flames were also seen at this time burning on the surgical drapes at the edge of the fenestration. The drape fire was quickly patted out as the anesthesiologist immediately disconnected the breathing circuit from the tracheal tube, causing the fire in the incision to apparently extinguish spontaneously. The breathing circuit was reconnected to the tracheal tube, and the breathing bag was squeezed, ventilating the patient with 100% oxygen. Flames again erupted from the operative site. The breathing circuit was disconnected from the tracheal tube, and water was squirted into the incision site. The breathing circuit was reconnected, and the breathing bag squeezed, resulting in flames again erupting from the incision site. At this point, the breathing circuit was disconnected and water was delivered down the tracheal tube. This final deluge of water extinguished the fire. The patient died several weeks later due to severe tracheal burn injuries from the fire.

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Devices Considered

Tracheal tube (disposable)
Electrosurgical unit
Electrosurgical pencil (disposable)
Electrosurgical pencil electrode tip (disposable)
Skin-prep solution and applicator (disposable)
Surgical drapes (disposable)

Analysis

Initial medical device concerns focused on questioning the power output level of the ESU and the flammability of the surgical drapes. Ignition of latent alcohol vapors was also considered. Testing of the ESU by the hospital's clinical engineering department revealed that it was within specification for power output at all settings and modes of operation. Review of the prepping techniques did not indicate any pooling of the flammable prep and that more than five minutes had passed between the time of prepping-agent application and draping. This was sufficient for the prep to dry and alcohol vapors to dissipate. Published evaluations of surgical drapes revealed that although some have a certain degree of ignition resistance from some heat sources based on their base fabric material, all surgical drapes are flammable, especially in high oxygen concentrations.

The high oxygen concentrations present within and flowing out of the surgical site at the time of tracheal entry was the predisposing factor to the fire. Had the surgical team realized that there was a fire in the airway, and had the patient not been ventilated with 100% oxygen while the team tried to extinguish the fire, the patient may have suffered only minor burns, as has happened in other cases of tracheal tube fire during tracheostomy. After reviewing the manufacturer's warnings and cautions for the tracheal tube and the ESU, it was subsequently realized by the anesthesia and surgical staffs that electrosurgical units should *not* be used to enter the airway during tracheostomy, especially with 100% oxygen and a polyvinyl chloride plastic tracheal tube present.

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Causative factors: labeling ignored, incorrect clinical use, failure to train.

Injury mechanism: fire, chemical and thermal burns, suffocation.

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Case Study 20: Ventilator Barotrauma

A patient was recovering from thoracic surgery and was being ventilated via a tracheal tube with a critical care ventilator. The breathing circuit contained a heat/moisture exchanger (HME) and bacteria filter.

Approximately 2 hours and 20 minutes after the surgery, a respiratory therapist lowered the positive end-expiratory pressure (PEEP) setting because the patient's blood pressure readings were unstable. The respiratory therapist was watching the ventilator's manometer and noticed that it jumped to 25 cm H_2O immediately after the PEEP dial was turned to zero. The therapist immediately disconnected the patient from the ventilator, and a nurse manually ventilated the patient while the therapist examined the ventilator. The manometer dial was at 0 cm H_2O with the breathing circuit disconnected. When the patient was placed back on the ventilator, the pressure manometer jumped to 20 cm H_2O. The patient was successfully switched to another ventilator but was subsequently found to have complications from an air embolism.

Later, the physician ordered that the patient be placed on a different brand of ventilator because of similar reports of problems with the incident model ventilators at the hospital. The hospital removed all 34 of their incident model ventilators from service and rented other brands of ventilators because of this incident and because of reports of other incidents in which the incident ventilators reportedly held high levels of PEEP.

Devices Considered

Intensive care ventilator
Breathing circuit (disposable)
Pressure transducer protector (disposable)
Tracheal tube (disposable)
Bacterial filter (disposable)
HME (disposable)

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Analysis

Review of incident reports and equipment repair records revealed that the hospital had had about 15 incidents of higher-than-set PEEP with 5 of its 34 incident model ventilators. The incident ventilator had been involved in a similar incident the previous year; it allegedly held high PEEP on a postsurgical patient. At that time, the ventilator was returned to the manufacturer for testing; however, they did not find anything wrong with it. The ventilator was then operated for three weeks continuously in the clinical engineering department without incident before it was returned to service. Also, a week before the incident, it was noted that another incident model ventilator, which had been on a patient for seven days, was holding erroneously high levels of PEEP. The hospital was not able to find a common link between the incidents (e.g., the ventilators differed in age and in number of operating hours before the problem appeared).

Using the ventilator settings used at the time of the incident, arrangements were made to test the incident ventilator for accuracy of its volume, rate, and PEEP settings; accuracy of its internal monitors; and its ability to deliver a breath when a pressure that exceeded the sensitivity setting was detected. Proper operation of the ventilator's exhalation valve was verified, as was the operation of the high-pressure, exhaled volume, and oxygen concentration alarms.

The ventilator immediately malfunctioned when it was turned on. The ventilator's analog meter displayed a PEEP level of 20 to 25 cm H_2O when 0 cm H_2O was set on the ventilator, and the breathing circuit was holding pressure. The bacteria filter was bypassed to discount its contribution to the problem, and the ventilator continued to show an expiratory pressure of approximately 25 cm H_2O.

When the ventilator's cover was lifted to access the internal components, it was observed that critical connectors and valves appeared to be installed correctly and that the components appeared to be assembled properly. The inspiratory valve was opening

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intermittently in unison with the patient triggering indicator, suggesting a leak in the breathing circuit or its pressure-sensing lines.

Disassembly and reassembly of the inspiratory and expiratory pathways' internal tubing and pressure-sensing lines and replacement of the breathing-circuit pressure transducer protector resolved the problem. The machine then passed all other performance tests.

Further detailed investigation included interviews of all the hospital's respiratory therapists and revealed that the ventilator manufacturer had performed an informal "silent recall" of the internal breathing-circuit pressure transducer protectors about two years earlier due to a leaking problem with the protectors. A leaking protector could cause the PEEP problems observed. Old protectors had been switched out for new ones by a local sales representative. There was no charge to the hospital, and there was no documentation given to the hospital by the manufacturer or local sales representative about the replacements. However, many old protectors remained available for use within the hospital. The protectors are replaced for each new patient application, but old potentially leaking protectors would sporadically make their way into service, resulting in the episodic problems.

Aside from the manufacturer's poorly handled recall process, the hospital respiratory therapy staff was not sensitive to the need to inform risk management or clinical engineering about the exchange of product. Had they been made aware of the need for such alerting, the sporadic problems that seemed so insolvable and spanned many months may have been quickly resolved.

Causative factors: failure of an accessory, poor incident/recall reporting systems, failure to train.

Injury mechanism: air embolism.

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