Risk Management Tips for Device-Related Events

As risk managers know, clinical staff sometimes do not preserve all equipment involved in an event, especially disposable devices and associated packaging. Staff may not understand the need to preserve the equipment or they are concerned about time constraints. In addition, staff often do not record all relevant device-related information in the event report, such as the device's manufacturer and model number, date of application, placement, lot and/or serial number, and date used on or removed from the patient. This means that information necessary to an investigation of an event that may involve patient injury or death is often lost or unavailable to the risk manager and investigators when it is needed.

This Risk Analysis describes procedures for handling medical devices involved in events or accidents, including documentation and impounding of devices, and maintaining a chain of custody. A sample letter to send to manufacturers to secure their cooperation in preserving devices when they must be returned is also included.

Documentation

Ideally, all device-identifying information should be recorded in the patient's chart so that it is readily available. It is unrealistic, however, to assume that healthcare facilities can accomplish this rather burdensome record-keeping task. Therefore, we recommend that identifying information (serial, control, or lot number) be recorded for life-support devices, both equipment and accessories, which may or may not be disposable. Such devices include the following:

- Intra-aortic balloons and balloon pumps
- Heart-lung bypass units
- Ventilators
- Anesthesia breathing circuit (including the endotracheal tube and other accessories)
- Anesthesia units

Healthcare facilities should also consider recording information about devices that, though not necessarily involved in life support, are commonly involved in recalls or incidents. Such devices include the following (detailed information on implanted devices should always be recorded as well):

- Hypo-/hyperthermia units and accessories
- Electrosurgical units and accessories
- Infusion pumps and accessories
- Intravenous administration sets
- Beds
- Wheelchairs

Risk managers can also help educate clinical staff about device-related problems. For example, see "Top 10 Medical Devices Associated with Injury and Error" for a brief description of what ECRI's accident investigators have identified as the most frequently occurring device-related problems. Additionally, reports of medical device problems, hazards, and recalls from ECRI's *Health Devices Alerts* (*HDA*) database are published regularly in *Action Items for Risk Managers*, which is mailed bimonthly along with the *Risk Management Reporter*. The *HDA* reports are also available online from the *HRC* Members' Web site.

Device-related information is important for several reasons, including the following:

- If a device fails or malfunctions, the record (lot and serial numbers) will facilitate communication with

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.

— **Sample Letter**

— **Action Recommendations**

— **Also Available on HRC Web Site**

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Top 10 Medical Devices Associated with Injury and Error

The following list has emerged as a product of ECRI's 30-plus years of conducting medical device evaluations. Risk managers should ensure that stringent safety precautions accompany the use of these devices or practices in their facilities. Keep in mind that some sources estimate that user error is associated with up to 90% of device-related events.

1. Infusion pumps: problems result from lack of free-flow protection (Facilities accredited by the Joint Commission on Accreditation of Healthcare Organizations [JCAHO] were required to remove from service pumps without free-flow protection as part of JCAHO's National Patient Safety Goals.)
2. Ventilators and anesthesia systems: problems related to breathing circuit leaks, disconnections, and failure to set problem-detecting alarms properly
3. Patient monitors: problems associated with improper settings
4. Defibrillators: problems associated with lack of familiarity with devices preventing the needed split-second response
5. Electrosurgical units and lasers: fires often occur due to excessive supplementary oxygen or improper preparation procedures
6. Heart-lung bypass and circulatory-assist devices: problems arise when staff fail to detect perforations or leaks or take appropriate action when they occur
7. Catheters and needlestick prevention devices: problems related to failure to use needlestick prevention devices and shearing when a catheter is inserted in a vessel
8. Trocars and staplers: patient injury resulting from staff not fully understanding equipment and resulting improper use
9. Endoscopy instruments: infection due to staff's failure to adhere to reprocessing protocols or lack of understanding of endoscope design, preventing effective cleaning
10. Magnetic resonance imaging (MRI) equipment: accidents related to ferrous metal objects entering the MRI suite

the manufacturer and/or problem reporting networks such as ECRI, the U.S. Food and Drug Administration (FDA), or the U.S. Pharmacopeia. If the device becomes the subject of litigation against the facility, the completeness of the healthcare facility's records on the event will help the healthcare facility prepare its case.

- If the device is the subject of a recall or hazard report, the healthcare facility will have a record of which patients have had the device used in their care, and clinical judgments about replacing or monitoring the device can be made. The healthcare facility will also be able to more easily trace devices that are not in use but may be in stock and thus make decisions on proper handling. See "Medical Device Hazards and Recalls" in the *Medical Technology* section of the *HRC System* for further information on this topic.

Risk managers should monitor the effectiveness of the healthcare facility's event reporting system in capturing essential device-related information. Event reports should be filed whenever a device failure or user error during treatment or diagnosis has or may have adversely affected patients or personnel. An actual injury does not necessarily have to occur; the potential for injury is enough because it is important for patient safety purposes. The report should identify the device that was used to monitor, treat, diagnose, or care for the patient at the time of the event. The manufacturer, model, and lot, serial, or control number should be documented on or along with the event report. These reports should be discussed in detail with the director of clinical engineering, and summaries should be presented to the healthcare facility's safety committee. A medical device report must be filed with the device manufacturer or, if the manufacturer is unknown, with FDA in cases in which a medical device has contributed to serious injury or death.

Like other events, device-related events should be analyzed to detect problem areas or trends. Identified problems should be carefully examined to take proper corrective action. More than half of all device-related accidents result from user error; according to some estimates, up to 90% of device-related events are attributable to human error.[1] Thus, in addition to pre-use checklists

Sequestering Devices

For risk managers, deciding that a device needs to be removed from service may be one of the most difficult choices to make. For instance, if an intra-aortic balloon pump is suspected of malfunctioning, a risk manager may want to remove it from service to have it inspected and to prevent potential harm to another patient. However, that pump may be the only one available in the hospital at the time, and another patient may need it to survive. Risk managers, together with the medical staff and institutional ethics committee, are faced with the unpleasant task of trying to quickly determine the likely role the medical device played in an accident and the safety of returning it to service.

In such situations, facilities should make every attempt to lease replacement equipment, borrow equipment from other facilities, or transfer patients to other facilities where care can be continued appropriately. The medical staff can be encouraged to search for alternative therapies. Ultimately, risk managers and other decision makers must weigh the probability that the device was involved in an accident (in the example above, could the malfunction have been a result of the disposable balloon itself and not the pump?) against other patients' need for the device when making these decisions. Guidance from the facility's ethics committee may be appropriate or even necessary. In addition, risk managers should be prepared to face pressure from the medical staff to return the device to service. Remember, all parties are attempting to provide the best patient care to the most patients.

Risk managers should also consider the likelihood of litigation and the severity of the injury when deciding how to proceed with the device. There are no clear-cut guidelines that can be followed. Risk managers have to use their judgment, be firm, and proceed along a course that will minimize patient harm to the extent possible, documenting the reason for the decision.

and system-user redundancies, better user orientation and ongoing education may be a key risk management tool.

ECRI has identified five categories of human errors that lead to device-related accidents: device misassembly; inappropriate reliance on automated features or alarms; accidental misconnections; improper maintenance, testing, or repair; and incorrect clinical use of a device, such as unintentional activation. For further information on investigating medical-device-related events, see "Medical Device Adverse Event Recognition and Investigation" in this section of the *HRC System*.

Impounding and Examining Equipment

If a device is involved in an event, it should be impounded, without changing any control settings, so that an analysis can be performed. It should not simply be sent to the biomedical engineer for repair. Disposable devices are no exception and must be saved for later analysis.

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

Most equipment can soon be returned to service because it will be obvious that it played no role in the injury. However, no suspect device should be returned to service until it has been properly tested and eliminated as a possible cause of injury. See "Sequestering Devices" for a discussion on making decisions regarding impounded equipment.

Establish a Chain of Custody

Medical devices involved in an event should be handled via a chain-of-custody procedure to monitor the devices' integrity and prevent devices from becoming lost, particularly if patient injury has occurred. Devices that have been involved in an event should not be cleaned or processed before such procedures have been discussed with an experienced, independent third-party investigator. Cleaning or processing could seriously hinder any subsequent investigation. Similarly, storage and shipment conditions must be considered to prevent damage to the device. For example, a membrane oxygenator involved in an event should be protected from freezing because ice could rupture the membranes, making subsequent leak testing invalid.

Chain-of-custody protocols should outline proper device collection and handling. For example, a chain-of-custody policy might include the following requirements:

- Keep sequestered devices in a sealed container (when possible) labeled with the patient's name, date, time,

and the signature of the person responsible for collecting and securing the device.[2]
- Store sequestered items in a locked storage area, separate from where routine maintenance takes place so that they will not be confused with devices in use.
- If the device is to be released externally (e.g., to independent investigators), require the third party to sign a chain-of-custody form specifying the item and date of return.
- Use a login/logout procedure for internal access to sequestered devices.

Ensuring that all individuals who are granted access to sequestered devices understand and comply with the chain-of-custody process is key to its success.

When Should Devices Be Sent Back to the Manufacturer?

When notified of a potential problem with a device, a manufacturer may offer to examine the device free of charge and/or exchange, replace, or offer a refund for the device. If healthcare facilities decide to accept this offer and send the device back to the manufacturer, they must ensure that the device and the suspected problem have first been thoroughly analyzed and documented. Healthcare facilities have reported to ECRI the following responses when devices involved in events were returned to the manufacturer:
- The manufacturer claims the device was never received, although it was picked up by a salesperson and/or shipped to the factory.
- The device was inadvertently damaged during shipment, making any possible testing of doubtful validity.
- The device was accidentally damaged during testing.
- The device was tested, and there was nothing wrong with it (no information on what was tested or how the device was tested is ever provided).
- The device was sent back to the hospital months ago. Didn't you receive it?
- The original complaint was never received.

While most manufacturers are committed to producing safe and effective products, it is naive to assume that all reported problems will result in constructive action by the manufacturer. Healthcare facilities have to protect their own interests. All communication with manufacturers should be carefully and completely documented, and a written acknowledgment should be requested from the manufacturer. We recommend sending ECRI a copy of all correspondence and/or using the Problem Reporting Form. See "Reporting Medical Device Events" below for further discussion on this topic and information on how to obtain the Problem Reporting Form.

If the device-related event has involved significant injury or death of a patient or staff member, sending the device to the manufacturer for testing usually will not be in the healthcare facility's best interest. If litigation occurs, the healthcare facility and the manufacturer may each be defendants and, as such, adversaries. In such cases, an independent investigator should be engaged, and examination of the device may be witnessed by all parties concerned.

In cases in which injury is known and litigation unlikely, returning equipment to the manufacturer may be appropriate. Before sending any device to the manufacturer, however, the healthcare facility should document its own or any associated independent testing. (It is easier to investigate problems immediately after their occurrence when details are more easily recalled and involved equipment and personnel are available.) As outlined in the sample letter in Appendix A of this Risk Analysis, the manufacturer should agree to and sign off on several conditions before the healthcare facility returns the device for testing. Correspondence with the manufacturer and shipment of the device should be done by certified mail, with a return receipt requested. Shipping documents should be carefully filed.

The risk manager's investigation of device-related events will be significantly aided by cooperation from the manufacturer. In the event of litigation, complete records of all correspondence between the healthcare facility and manufacturer, as well as evidence that the healthcare facility had its own procedures for event investigations and followed them, may strengthen the healthcare facility's position. If a manufacturer discovers a defect in its product that results in the issuing of a hazard or recall, the healthcare facility will have contributed to the prevention of similar events in other healthcare facilities.

Again it must be stressed that a device that has been involved in serious patient injury or death should not be sent back to the manufacturer before an outside investigator tests the device.

Reporting Medical Device Events

Under the Safe Medical Devices Act of 1990, FDA requires that healthcare facilities report any information that reasonably suggests that a medical device has or may have caused death or serious injury to patients or employees. FDA requires that facilities submit a MedWatch mandatory report (Form 3500A) to the manufacturer — or to FDA if the manufacturer is unknown — within 10 working days of "becoming aware" of the event. *HRC System* members can file mandatory 3500A reports through ECRI's password-protected Computerized Problem Reporting

System (CPRS). They can also use the system to file voluntary MedWatch reports. *HRC* members can access CPRS by selecting "Report a Medical Device Problem" from the *HRC* Members' Web site; they can then select the option for "Reporting a Problem to FDA." For security purposes, CPRS requires that *HRC* members sign on with a separate username and password. Members can obtain these from ECRI's help desk by telephone at (610) 825-6000, ext. 5555, or by e-mail at helpdesk@ecri.org. A sample MedWatch Form 3500A is also reprinted in Volume 1 of the *HRC System* under the *Medical Device Alerting System* tab.

ECRI encourages reporting of medical-device-related incidents and deficiencies to ECRI's Problem Reporting System so we can determine whether a report reflects a random failure or one that is likely to recur and cause harm.

Each confidential report is logged into our Problem Reporting System database and individually discussed at weekly triage meetings to review problem reports. ECRI acknowledges receipt of each report and informs the reporting party of its findings and opinions in cases in which it can provide guidance related to the report. Otherwise, we monitor the situation for developing trends of similar problems.

As soon as members of ECRI's staff determine that specific device hazards and problems may exist, ECRI informs the manufacturers and encourages them to respond constructively and correct the problem. The reporter's identity and institution is never revealed without permission. In many cases, we publish the results of our investigations of reported problems — along with appropriate warnings and recommendations — in *HDA* and other ECRI publications.

Copies of ECRI's Problem Reporting Form are available in Volume 1 of the *HRC System* under the *Medical Device Alerting System. HRC* members can also report online from the *HRC* Members' Web site. From the Web site, select "Report a Medical Device Problem" from the left navigation bar. Next select "Reporting a Problem to ECRI" to submit the information electronically. A downloadable Problem Reporting Form is also available from this section of the Web site.

Risk managers must also be aware of other possible reporting requirements. For example, if a medical-device-related event involves serious injury or death, it must be reported to the Joint Commission on Accreditation of Healthcare Organizations as a sentinel event. State-mandated reporting requirements may also apply; risk managers should review any applicable state regulations.

ACTION RECOMMENDATIONS

- Monitor the healthcare facility's event reporting system to see whether it is capturing essential device-related data.
- Discuss all device-related events with the director of clinical engineering.
- Ensure that there is a system for impounding and examining event-related devices that may have malfunctioned.
- Establish chain-of-custody procedures to preserve the integrity of medical devices involved in events.
- Review all event-related correspondence that is sent to or received from the manufacturer.
- Ensure that summaries of device-related events are presented to the healthcare facility's safety committee.
- Collaborate with the director of clinical engineering to ensure that effective orientation, ongoing education, and user protocols are developed and provided to all appropriate personnel.
- Ensure that device-related events are reported through the proper channels.

Notes

1. Bogner MS. Medical devices and human error. In: Mouloua M, Parasuraman R, eds. *Human performance in automated systems: current research and trends*. Hillsdale (NJ): Lawrence Erlbaum; 1994:6467.
2. Evans MM, Stagner PA. Maintaining the chain of custody: evidence handling in forensic cases. *AORN J* 2003 Oct; 78(4):563-9.

SAMPLE LETTER Appendix A

Manufacturer Inspection of Incident-Related Device

Sirs:

We are prepared to return (describe product) for your evaluation. During its use, the following occurred:

(describe the malfunction)

We request that you review this device for defects that may be associated with the incident described above. However, before we return the device, we would appreciate your acceptance of the following conditions:

1. You will notify us by letter immediately upon your receipt of the device.
2. Within 30 days of your receipt of the device, you will provide us with a complete report of your findings, conclusions, and recommendations concerning the device in question, as well as a description of test preparation, test methods, and results.
3. No testing that results in the destruction of the device will be undertaken without written authorization from myself to proceed.
4. The device and all related accessories sent to you will be returned to us promptly upon the completion of your examination, or sooner, at our request.

We await your written acceptance of these terms and appropriate packing and shipping instructions. Please return a signed copy of this agreement. Thank you for your cooperation.

Sincerely,

Jane Doe
Risk Manager

Agreed and accepted on [date]
by
(name)
(title)

cc: ECRI

