What Happened? Investigating Adverse Events

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The call can come in at any time...3 p.m....4 a.m....during lunch...that a medical device was involved in an incident that harmed a patient. A safety variance (incident) report is written up and all eyes are on your department. Who is to blame? How do you proceed? When was the last inspection?

The questions are coming fast and furious and attorneys for the hospital and the patient's family may be knocking on your door. When something like this occurs it is a natural reaction to try to shift the blame to someone or something else. The supplies, the device user, the process, or even the supplier or equipment manufacturer could be at fault. Fingers are pointing everywhere, but your job is to determine the root cause of the problem, take responsibility if it did rest with you or your department, and develop a plan for how can it be prevented in the future.

As medical technology professionals, we need to take a lead role in the investigation any time an incident involves a device. The medical device itself tends to take the blame when an incident first occurs, before a thorough investigation has begun. Working alongside the risk management department, the end user department, and the Environment of Care (EOC) committee, we need to investigate and resolve the issues that present themselves along the way. Investigating an incident is similar to investigating a crime scene; several specialties are called for their expertise and isolate what caused the problem (the perpetrator) and how it happened (the crime itself). Experience has shown that there is generally more than one factor that led to the problem. So, where to begin?

Managing an Investigation

The first step in determining the cause of an incident is to build an interdisciplinary investigation team. Each organization has a procedure that identifies who should be involved.

As an equipment subject matter expert, you know the equipment and therefore are the logical choice to be part of the investigation. You may not know the clinical side of the incident, however, and therefore need to have a medical professional on the team. This should be somebody who knows the procedure or protocol for the device use with the patient and understands what the particulars of the patient were prior to use. There are instances when the patient may have a condition that required additional preparation for the device to be used on him or her, but that preparation did not happen.

Having access to other disciplines beyond your knowledge base can help piece together a full picture of the events that led to the incident. The team may grow as the investigation proceeds—one piece of evidence may reveal a new subject area you need expertise on. For example, if the incident involved a power failure or surge, you may want to include facilities in the investigation.

Next, you have to identify the circumstances surrounding the incident. Determine what products were used in conjunction with the equipment, who was present, and what they experienced. What did they see? What did they hear? Was there an odor? As this information is gathered, it is important to be objective. Without objectivity, you could lose vital pieces of information that could cause you to overlook or miss important information. The key here is to keep an open mind. Listen to what was said and investigate each piece of information to arrive at the truth.

Check Points

How an adverse event is handled depends on the nature of the event and your employer's policies, but the best way to investigate is to avoid having one in the first place. As you study for your certification exam:

- Pay close attention to what can go wrong with a device and how you can prevent it.
- Learn how clinicians use the device and on what types of patients.
- Become familiar with other departments in the hospital (risk management, facilities, housekeeping) and their roles in patient safety.
The investigation is not about assigning blame. As equipment caretakers, we do not want to blame the equipment or how it was or was not maintained. If the equipment is found to be at fault, though, we need to understand what the problem is and ensure that the same incident does not occur again. Processes may need to be changed, frequencies of inspections may need to be adjusted, or additional education for the staff may be in order.

Always contact the product and/or equipment manufacturer to determine if other users have experienced similar problems with that device. This is another avenue in which you may experience resistance. Just as the user will not want to admit a problem on the clinical side, the manufacturer might be skeptical about what happened during use or maintenance of the device. It is important to ask all the questions necessary to be clear that you understand what could have caused a problem.

Putting the Pieces Together
If you follow the steps above, you should have a good idea of what has occurred. The next step is to piece it all together.

You probably have done this already as the investigation progressed, but you need to evaluate all the pieces of information and create a clear picture for all to understand. Discussions with risk management, end users of the devices, and eventually the EOC will ensue to determine the actual cause of the incident. You may have to demonstrate for them what you believe happened so they can see for themselves and understand the root cause. However you present the information, the end result—determining the cause—must be the same.

Based on your findings, changes may have to occur. If modifications are called for—a product, procedure, or equipment change—all involved need to be educated about those changes. Follow up on an incident is one of the most important steps, if not the most important. Carrying out the change may be difficult, but it is necessary. After all, healthcare is about patient care and patient safety.

Follow Through
What we do in response to these incidents is just as important as how we maintain the equipment. When an incident occurs it is our responsibility to step up and take the lead on equipment investigations to help all involved understand what happened and reach the truth of the matter. If it involves reporting to FDA under the Safe Medical Device Act of 1990, follow your employer’s policies. We have an important role in healthcare and should not shirk away from any expectation placed on us by those who rely on us.

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Test Your Knowledge
A surgeon reports that the electrosurgery unit (ESU) control settings required to achieve effective cutting are considerably higher than usual. The surgeon should be advised to

A: Carefully check the ESU return electrode and its cable before continuing to use the machine
B: Turn up the control setting as much as necessary—such variations are normal
C: Use a different surgical pencil
D: Make sure the machine is in the blend mode

Explanation: The need to turn up the power level on an electrosurgical unit above normal levels indicates that the impedance seen by the output of the ESU is significantly higher than normal, and so the current produced by the ESU is lower than normal.

By far the most common reason for this is a defect in the patient return electrode. Common reasons for the impedance in this circuit to be high include that the electrode has become detached from the patient, or there is a broken wire in the cable attaching the return electrode to the ESU. Either one of these conditions is unsafe, and could lead to a patient injury. For this reason, the surgeon should be asked to check the return electrode before proceeding with the surgery.