The media reports on 2 patients who died in a cath lab after receiving anesthetic gases instead of oxygen. A staff person had misconnected the gas line, overcoming the specific fittings.

The state health department issues an alert on endoscope reprocessing after lapses compel facilities to offer hepatitis and HIV testing to thousands of patients.

The Centers for Disease Control and Prevention (CDC) issues an advisory not to use a medication linked with bacterial infections.

When notices like these arrive in your facility, do they get into the proper hands? Every facility needs a process to make sure that device-related information, including recall notices and hazard alerts, doesn’t fall through the cracks, says Jim Keller, director of the Health Devices Group at ECRI, an independent nonprofit organization that researches health care technology.

All of the above incidents actually happened. The cath lab case, reported in early 2002, occurred in a New Haven, Conn, hospital. The endoscope alert came in October from the California State Department of Health Services after 8 facilities notified over 5,000 patients about problems with endoscope reprocessing. The CDC advisory, issued in April, concerned magnesium sulfate solution from PharMEDium Services, linked with Serratia marcescens bacteremia.

The Joint Commission on Accreditation of Healthcare Organizations Environment of Care Standard EC.6.10 requires health care organizations to manage medical equipment risks by having processes for monitoring and acting on equipment hazard notices and recalls.

The information isn’t confined just to recalls, Keller cautions. Some of the most serious problems are never classified as recalls. There also are advisories, alerts, articles from the clinical literature, notices from device manufacturers such as updates to reprocessing instructions, and even newspaper articles about patients harmed by a device-related accident.

“Say your hospital has a problem after a widely publicized story in the lay press. Just imagine what the headlines would be like if your hospital has to admit it wasn’t aware of the previous incident or didn’t take action,” he says.

Keller offered these 5 best practices for managing device-related information:

1. Have clearly defined roles and responsibilities.

There should be a process for handling device-related information consistently throughout the organization.

“You need a coordinator or administrator of device-related information who decides what information needs to be processed and disseminated. This person should also be responsible for forwarding the information to the relevant departments,” he says.

Often the responsibility is assigned to the materials manager, the biomedical engineer, the risk manager, or a person designated by the Patient Safety Committee.

“You also need a formal, centralized list of devices used in your institution, with a corresponding list of department heads or other staff assigned to each device category,” Keller says. They should receive the safety notices for devices on their list. For example, the OR manager would receive notices about surgical lasers or pneumatic drills.

Some common areas that can be overlooked:
• not including devices used at satellite facilities, such as an ambulatory surgery center or clinics
• failing to assign responsibilities for rental equipment, equipment on loan, and physician-owned equipment
• not assigning responsibilities for “cross-over devices,” such as drug-eluting stents and computer-based devices.

“If you ask the pharmacy, ‘Who is responsible for hazards and recall notices for drug-eluting stents?’ they might say, ‘That’s a device. That’s materials management’s responsibility,’” says Keller. “But if you talked to the materials manager, they might say, ‘That has drugs in it, so the pharmacy takes care of that.’” The same is true for devices with software: Is that information technology’s responsibility? Or is it biomedical engineering or the department using the device?

“You need to communicate about who is going to handle these cross-over devices,” he advises. “Get a list together and make sure people are assigned.”

2. Have a consistent naming convention and an inventory for your devices.

What is an electrosurgical unit called in your facility—a Bovie, a cautery, an ESU, or all of these?

“If you get a notice about a problem with an ESU—the formal name for this technology—but your facility calls it a cautery, you might not find the relevant devices in your inventory,” Keller notes. It is not uncommon for a hospital to have 6 different names for some types of devices, and even more names for some medical device vendors.

“The problem can be even worse for hospital systems, especially when each hospital in the system manages its own inventory,” he says.

Ideally, the inventory should be accessible from a centralized location and cover the full range of devices used in the organization.

Check to see if your organization is using consistent, up-to-date terminology. ECRI has a naming convention called the Universal Medical Device Nomenclature System (UMDNS), promulgated by the World Health Organization and used in more than 40 countries. The system has standardized device names, definitions, and manufacturers’ names that can be applied to your inventory to help resolve inconsistent naming. The UMDNS is harmonized with the nomenclature of the US Food and Drug Administration (FDA).

Nonprofit organizations, government agencies, and device manufacturers can download a UMDNS file with device and vendor names free of charge if they sign a licensing agreement and abide by certain conditions. Information is at www.ecri.org under Products and Services.

Downloading the file is just the first step. “To get it right, you have to match each item in your inventory with the nomenclature,” Keller says. “Unfortu-nately, there isn’t an easy, automated way of doing this data cleaning.”

3. Have an approved, comprehensive source of information.

There needs to be an approved list of sources for recall notices, hazard alerts, and other device-related information. Sources can include device manufacturers, regulatory agencies such as the FDA, the clinical literature, and hazard and recall notification services. ECRI provides a clearinghouse for this type of information through its Health Device Alerts program.

“The information you use should be clear and accurate with specific action steps to help your staff decide how to resolve reported problems,” Keller says. “If your hospital uses a clearinghouse, it would be a good idea to gather the data from multiple sources, analyze the significance of the reported problems, and verify the accuracy of information from original sources.”

“We find that as many as 25% of the recall notices in the FDA’s enforcement report need to be corrected,” says Keller. For example, there may be a missing or incorrect model number, or information may be lacking on how to resolve the reported problem.

Verifying the information can save time and avoid the risk of having critical information slip through the cracks, he says.
4. Have a reliable and consistent process for dissemination.

“You need to have a process to make sure device-related information is forwarded to the right people,” Keller says.

As a test, he suggests managers check their databases to see if they have a record of the cath lab incident in New Haven, Conn. Is there documentation that the information was forwarded to the cath lab and other relevant departments? ECRI wrote a report about this incident and recommended specific training for cath lab professionals.

Is there evidence the recommended training was done? If your institution decided more training wasn’t needed, was that decision documented with justification? If not, there may be gaps in your notification process that need to be addressed.

5. Have follow-through and accountability.

Your notification process should include an easy method for departments to acknowledge that they received the notices and either removed the devices from service or implemented the corrective actions or recommendations.

In addition to this mechanism, “we have suggested that the hazard and recall notice process needs high-level support,” he says. “That way, the managers and staff who receive the reports know they are being overseen. I think that gives them a greater incentive to follow through.”

Information on ECRI is available at www.ecri.org or by calling 610/825-6000.

Patients notified after colonoscope reprocessing lapse

Endoscope reprocessing instructions need to be device specific—that’s the lesson learned from a recent incident in Pennsylvania.

A community hospital notified about 200 patients in March that they may have been exposed to hepatitis and HIV because colonoscopes were not reprocessed correctly. The lapse occurred because technicians did not follow model-specific reprocessing instructions for 2 new Olympus scopes, notes Jim Keller, head of the Health Devices Group at ECRI, a nonprofit organization that researches health care technology.

The risk of disease transmission was low, and the state health department had not identified any cases linked to the colonoscopies.

The new colonoscopes, purchased in late 2004, had a water-jet channel that was not in the hospital’s previous scopes. Technicians did not recognize the difference and failed to disinfect the water-jet channel, ECRI reported.

The key is to have reprocessing instructions that are specific to each model of endoscope your facility uses, Keller explains.

Recall notices and alerts

This is how the US Food and Drug Administration defines recalls and alerts.

Recall and field correction

Action taken by a firm to either remove a product from the market or to conduct a field correction. Recalls may be conducted on a firm’s own initiative, by FDA request, or by an FDA order.

- **Class I recall**: There is a reasonable probability that use of a product will cause serious adverse health consequences or death.
- **Class II recall**: Use of a product may cause temporary or medically reversible
adverse health consequences, or the probability of serious adverse health consequences is remote.

- **Class III recall**: Use of product is not likely to cause adverse health consequences.

### Medical device notification or safety alert

Any communication by a manufacturer, distributor, or other responsible party or FDA to inform health professionals or others of a risk of substantial harm from a medical device in commercial use. Notifications are issued at the request of FDA. Safety Alerts are voluntary.