Recall Management: Best Practice Basics

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The 1999 landmark Institute of Medicine study, *To Err is Human: Building a Safer Health System* alerted the healthcare community to the high number of preventable medical errors that occur each year in U.S. hospitals and clinics[1]. The recall process is one important area in which patient safety can be significantly improved by following best practices. Without a formal process and the appropriate tools, product recalls can quickly turn into a crisis that can impact care delivery, patient safety, and create enormous financial burdens on the hospital.

Manufacturers of food products, prescription drugs, and automobiles have a standard methodology for dealing with product recalls efficiently. It is imperative that hospitals do the same. By putting operational, legal, and public relations plans in place and identifying recall teams and their roles, hospitals will be prepared for recalls when they occur.

Understanding the Recall Process

Every day healthcare facilities use thousands of biomedical instruments and devices, pharmaceuticals, blood products, biologics, and medical supplies. Every product could be subject to potential problems that would necessitate recalls including malfunctions, tampering, contamination, labeling errors, and counterfeiting.

In the United States, the Food and Drug Administration (FDA) is the regulatory body that oversees the safety and effectiveness of food, drugs, and cosmetics. FDA regulations state that products that are in violation of the law by being mislabeled, defective, or potentially harmful must be recalled. The FDA evaluates, classifies, monitors, and audits product recalls

Recalls are typically voluntary and may result when a company discovers a problem with a product and then contacts the FDA. In other instances, a company recalls the product after the FDA raises concerns. This action could occur after the agency inspects a manufacturing facility or evaluates reports of health problems. In rare cases, the FDA "requests" a recall.

Whatever the reason for a recall, the FDA's role is to oversee the company's recall strategy. An evaluation of the health hazard by the FDA helps companies determine the strategy for communicating risks associated with a recalled product. As part of reviewing a company's proposed recall strategy, the FDA looks at the depth of the recall; the extent of public warnings needed; and whether the recall is being extended to the wholesale, hospital, pharmacy, retail, patient, or consumer levels. The notification to the public may be in the form of a national press release or a letter to the consumer or user community. In a letter to physicians, for example, Guidant gave recommendations about how to identify a leak-related malfunction and other advice for minimizing the risk of pacemaker failure.

Recall notices may also be posted on the web on the FDA's weekly Enforcement Report (www.fda.gov/opacom/Enforce.html) or other FDA agency websites

Check Points

Consistent recall management practices should be followed, including:

- ✓ Formation of recall teams
- ✓ Widespread and prompt dissemination of recall notices
- ✓ Tracking of all recall communications and actions

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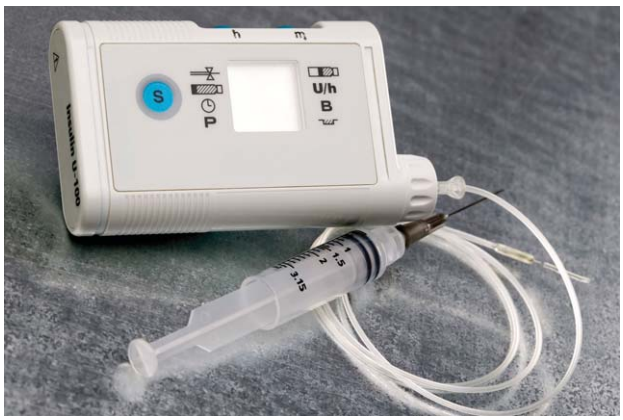

Thousands of products used in healthcare delivery are recalled annually.

such MedWatch, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research.

It should be noted that the FDA is not involved in all recalls. Many recalls are issued voluntary by the manufacturer and are not reported to the FDA. As a result, the FDA websites and listservs do not represent 100% of the recalls that occur each year. Also, recalls may not involve returning products. A technical service bulletin or field correction, for example, is a notification that includes the steps to address a problem where the product resides, particularly for larger biomedical equipment where shipping it back to the manufacturer for the repair would not be practical.

Create a Recall Team

In most hospitals, the medical equipment professionals and the materials management personnel are typically the most informed about recall activities because of the volume of products they oversee. These professionals should share their insights with other departments and help to create a cross-departmental recall management team that includes risk management personnel, patient safety staff, physicians, and the executive community. The team should be expanded to include clinical, legal, and communication departments when the recall impacts care delivery or requires patient notification.

Monthly reporting of recall activities should be instituted to provide insights into areas where process improvements can be achieved. These reports should be shared with the recall team, executive management, and other departments such as risk management or the patient safety committee if these departments are not represented on the recall team. Minimally, these reports should capture:

- The number of alerts received by department
- The number of alerts requiring action by the hospital
- The length of time from receipt of the alert until closing actions are complete
- The number of patients affected, or potentially affected, when applicable
- The number of products located for return/replacement

The Tool Chest

Arm your recall team with various tools to execute an effective recall. Your tool chest should include workflow diagrams, detailed coordination checklists, a recall team staff directory, and a policy and procedure document. The tools should capture the roles and responsibilities of staff and should include a staffing and action plan for handling recalls that occur on weekends.

Share the News of Recalls

Recall notices can arrive at hospitals through faxes, certified mail, standard letters, and e-mails from manufacturers and distributors. At other times, hospital personnel learn about recalls from sales representatives or through websites and listservs.

To streamline notification channels, hospitals should communicate recall practices and policies to all vendors and distributors in writing. Request that vendors include product, lot, and serial numbers on invoices to aid in tracking products. And ensure that vendor purchase agreements designate the person, department, or service that handles recall notifications for your facility.

Once aware that a recall exists, healthcare organizations should distribute the recall information throughout the hospital and subsequently capture and record the actions taken. Recall management services have recently become available to the healthcare market to streamline these processes. One web-based service, the Risk and Safety Management Alert System (RASMAS) developed by Mitretek Systems, takes on the task of alert discovery, de-duplication, as well as automated alert dissemination directly to the departments that are most likely affected. Workflow tracking ensures the alert is managed in a timely fashion and provides delay and escalation notices to management should an alert fall behind. Reports aid management with assessment and process improvement opportunities.

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Optimize Storage Practices

Being able to quickly identify affected products is imperative. To facilitate these activities, store items so that model, lot, and serial numbers are readily accessible. Ensure appropriate members of the recall team have authority to check inventory systems to identify if the product has been purchased by the hospital. Developing a systemwide standardized nomenclature for inventories will aid inventory look-up and product identification. Databases and log books of items that enter the hospital through alternative purchasing means should be maintained. Integrate use of bar code scanners or automated supply systems to locate items and quantities.

Patient risk days can be dramatically reduced through alert management best practices.

Not Safe to Use? Label It!

When defective products have been located, storing them in your office is not an ideal solution. Staff may have noted that product and, in a pinch, may raid your office for the item unaware that it is a recalled product. Instead, clearly tag the items and move them to a designated, locked area while awaiting repair or return to prevent accidental re-introduction into the clinical area. There have also been instances where recalling firms have accidentally shipped back out recalled products it has received from hospitals. Proper labeling goes one step further in preventing this type of error.

For large devices or fixed location equipment, create an area to post technical service bulletins in a highly-visible manner. Include a note regarding the anticipated date for scheduled repair.

Product Returns/Replacement

The manufacturer's reply card is an important component in the recall process. This card or the related letter provides the instructions to staff to ensure proper credit and reimbursement when applicable. There are typically three options—return the product to the supplier, return the product to the distributor or manufacturer, or destroy the product.

Staff should be educated to complete the product return reply card and return it even if you do not have the product in inventory. The FDA measures the effectiveness of the recall based upon card return rates and recalling firms use this information for product reconciliation. A copy of the reply card should be maintained as part of the complete recall record. Use certified mail and retain the receipt for all reply cards returned through the U.S. postal system.

Educate & Communicate

In 2005, the FDA posted more than 5,000 alerts for products that are used every day by doctors and hospitals[2]. Historical data show that the number of recalls grows each year. With the number of alerts on the rise, it is wise to include recall management practices for your organization in new employee orientation programs. Conduct annual in-services and utilize proficiency tests to ensure your staff is confident in use of the tools and that recall activities and documentation are as comprehensive as possible.

The Total Package

Having well-defined recall processes and an active recall team are the first steps to better recall management. Combining strategy with tools and sound best practices helps hospitals efficiently and knowledgably manage recalls and, more importantly, reduces patient exposure to potentially dangerous products. The benefits of an organized recall program include organizational efficiency, reduced alert processing time, and top-notch patient safety outcomes. ■

References

1. **Institute of Medicine.** To Err Is Human: Building a Safer Health System, Janet Corrigan, Linda T. Kohn, Molla S. Donaldson, National Academies Press, 2000.
2. **US Food and Drug Administration, "The FDA and Product Recalls,"** http://www.fda.gov/fdac/features/2006/306_recalls.htm.