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Taking Recalls from the Basement to the C-Suite: Automating Alert Management

By Brooke Berson

At Duke University Health System, the implementation of an automated management service for product alerts and recalls has enhanced patient safety and improved efficiency.

Recall management is truly a patient safety initiative that requires participation of employees from the basement to the executive suite. At Duke University Health System (DUHS), what began as a desire to improve alert management efficiency and efficacy through an automated service has resulted not only in reduced response time for alerts and improved follow-up with patients, but also the development and clarification of hospital policies related to recalls and product issues within the supply chain.

Automating Recalls within Hospitals

Product alerts are issued when clinical experience or ongoing research indicates that a problem exists in the use of a product. An alert can notify the hospital about an update in software used in medical equipment, describe a new process for use of the product, or mandate the recall

of a medical product or drug. Alerts are issued by manufacturers and may be posted on an FDA web site.

Typically, alerts are sent to hospitals through several channels, including mail, fax, and e-mail. Once received, the goal is to route alerts to the individual responsible for taking action to resolve the alert. Depending on the product in question, this individual may be in the operating room, cath lab, materials management department, radiology, or anywhere patient care occurs. A final step, when applicable, is to complete and return the reply card that indicates to the manufacturer the quantities of product involved for that hospital and/or actions taken to resolve the alert.

This process has many weaknesses, and despite the best efforts of health care

providers, delays and disruptions occur, thus creating more days that patients may be at risk. Among the factors that cause problems:

- > No industry standard exists for the issuance of alerts. Each manufacturer or government agency devises its own notification format and selects its own contact method. Therefore, hospitals must be prepared to monitor multiple channels and review each alert to extract key information.
- > Manufacturers generally send notices and alerts to the location to which the product was shipped. Although that shipping location might target the correct department, the procedure does not ensure that the communication reaches the appropriate product user. This risk is especially high if the receiving department services multiple departments within the facility. As a result, delays can occur until all of the proper recipients for the alert are located.
- > Purchasing functions may not be integrated across different facilities within

an Integrated Delivery Network (IDN), so coordination to ensure product removal and locating the specific product may be difficult.

- > Rogue purchasing patterns can hinder product tracking, as the documentation associated with buying outside the normal supply chain process is often missing.
- > At many hospitals, senior leadership is not directly involved in alert management. Response to high-priority or complex alerts may not have executive support, and therefore may not achieve the efficiencies necessary for quick action.
- > If medical leadership is not involved in the process, communication with patients about the nature of the alert can be inconsistent.

The cumulative effect of these factors is a series of delays and incomplete responses that potentially can affect patient safety.

Finding a Better Option

DUHS began taking a close look at its management of alerts in 2004 to achieve a more systematic and timely response.

At the time, one of its pharmacy departments was the designated warehouse for drug and product alerts and recalls.

The alerts were gathered from various sources, compiled, sent weekly, and tracked by number. The notification process involved a “broadcast” e-mail that was sent to about 500 employees. However, for the recipients, the weekly e-mails included all alerts; the e-mails were not targeted to specific product domains. Employees therefore had to contend with a large volume of material that might not have been relevant to their areas.

Each department then had to search independently in order to determine whether the products were among the inventory in their locations. If the affected product was found, an e-mail with the recall number and follow up actions was sent to the pharmacy, where it was printed and filed. This manual process made information retrieval burdensome. Although DUHS was able to close the loop, the process was not efficient with regard to documentation, monitoring, or information retrieval. Finally, senior leaders were not directly involved with the recall process.

DUHS was committed to improving patient safety and wanted to streamline the process so the organization could identify products as closely as possible to the time of the announcement. DUHS explored a variety of options. A safety officer discovered a web-based subscription service that provides comprehensive notification, distribution, and management of product alerts for healthcare organization at a conference and asked DUHS to explore this option. A meeting was arranged with the company that provides the service and key stakeholders at DUHS. Other options were vetted; however, this particular service offered the ease, organization, and accountability DUHS was looking for.

Implementing the New Process

DUHS recognized that success depended on buy-in from all the stakeholders. Before DUHS fully committed to the new alert management service, the organization opted to test it by receiving sample alerts and comparing the information with that received from its current system. DUHS quickly realized that the service notified the organization more

Success Beyond Alert Management or A Culture of Safety

The heightened awareness of safety resulting from implementing an automated alert management service has extended past responding to alerts. One example involved resource technicians who work in DUHS's materials management department, who on three different occasions observed that boxes from one manufacturer were adulterated on one side by a foreign substance. These boxes were received at two of DUHS's hospitals. At each hospital, the materials management staff immediately noticed and reported the issue, sequestered the boxes, labeled them as rejected, and contacted the manufacturer. The manufacturer did have an issue at a warehouse, and the boxes were supposed to have

been destroyed. These packages never made it into the hospital, protecting patient safety.

A second example involved an astute administrative assistant who was unpacking boxes in nuclear pharmacy. She noted that the label on a box of needles did not match the size of the needles contained in the box. Subsequently, she contacted the automated recall service administrator, defaced the box, and returned it. The assistant recognized that the box should have had a new label over the old one, and the manifest should have reflected the change. This attention to detail regarding products and safety repeats itself daily at DUHS.

One last example is the attention that “internal recalls” are commanding. In the past, if a product malfunctioned, it may have been locally sequestered at one hospital, but the response would have been limited to that hospital. The inculcation of an environment of safety has created a new level of vigilance about identifying and reporting product issues. When products malfunction, staff report the internal recalls. DUHS then checks to confirm other locations where the product is used, and informs staff of the potential product problem. The affected product with the specific lot number is removed from inventory within minutes.

quickly, provided alerts that were easier to read, and targeted the alerts in such a way that DUHS could enable reduce time formerly spent combing through lengthy e-mail alerts. The service also has a built-in accountability feature requiring employees to close the alert, along with a notice escalation feature that notified DUHS if an alert was not closed. After the success of the trial, DUHS's senior executive team endorsed the new alert management service. Additionally, senior leadership involvement and oversight was built into the new process, supporting the priority of a culture of safety.

The initial list of responders at each facility was based on the contact list from the pharmacy. Those who received the pharmacy list of alerts ranged from directors to managers and clerks. The list was revised to include primarily those individuals who order and receive products, since they are in the best position to quickly locate the products. Department directors assisted in identifying additional responders and establishing back-up responders. The coordinator function was centralized within purchasing and clinical engineering so that searching DUHS's enterprise-wide materials management system for the product was the responsibility of a few. This relieved the 300+ responders of that burden.

DUHS found that a brief, on-line tutorial gave its employees all the training they needed to use the service. Now, when a new responder is added, the employee is trained via the tutorial. Instruction on the web-based alert system is now provided to all new employees during their orientation.

The new recall alert service went live at DUHS in February 2005, and the launch went smoothly. Initially, DUHS ran the old system in parallel with the new one.

After several months, DUHS was able to confirm that the new service was picking up all the notifications provided by the pharmacy plus many more. Once DUHS realized the integrity of the new system for the end-to-end alerting process, the organization felt comfortable terminating the old notification system.

The automated alert service was rolled out to acute care first, followed by the outlying clinics and physician practices including home care and hospice. Every entity within DUHS is included in the alert process. Now, DUHS has more than 300 users at 81 separate sites.

Results, Expected and Unexpected

Within three months, the time required to resolve alerts dropped from more than 30 days to approximately three days. (These figures exclude large medical equipment and certain other products that by their nature have a longer close-out cycle.) This reduced response time has remained consistent over several years, despite the fact that the alert volume has grown at an average rate of over 25 percent each year, and has now reached 3,600 alerts per year. The increase in alerts is a combination of an improved capture rate achieved through the service, and a rising rate for the issuing of alerts. The rapid and significant reduction in response time was the outcome that DHUS had hoped for.

Accountability was improved as a result of the closed-loop system DUHS had in place, enhanced further by an escalation process that kept management well informed of an alert's status at all times. Because every action taken regarding the alert is documented in the system, reporting and responding to U.S. Food and Drug Administration audits is much easier and is consistent from department to department. Responders receive guidance about the importance of arranging

for backup responders when they are absent. Lapses in response are rare, and an e-mail reminder generally results in resolution of the alert.

In addition to improving management of the alert itself, DUHS also benefited from putting other procedures in place as part of the implementation. The organization has established a senior recall team to make decisions and provide oversight of the safety impact and patient communication strategy for alerts. Headed by the DUHS vice president for medical affairs, the team is convened when a recall, process change, or alert is believed to impact the ongoing health of a population of exposed patients or for a number of other safety reasons.

The senior recall team evaluates information related to the alert and identifies both short- and long-term actions to be taken along with strategies for patient communication related to any recalled product. To ensure that the message to patients is consistent, a standard set of talking points is developed for each recalled product that directly affects patients. Direct patient contact is coordinated through clinical risk management and/or the attending physician. In most cases, one informative letter can be sent to all patients. However, in some instances, patients must meet individually with their physician to assess the risks of the recall and to develop a plan for action. Finally, collaboration with revenue management allows physicians or risk managers to address patient concerns or issues regarding reimbursement.

Reimbursement implications of certain recalls can be significant, especially when follow up involves more than a single doctor's visit, but requires multiple appointments, tests or explantations (removal of an implant). Recalls that

have an impact on reimbursements, whether Medicare or private insurance, are now managed through an explicit policy illustrated in a flow chart. Revenue management devised an algorithm that includes notification strategy, and finance assumptions in order to ensure a consistent process for managing all aspects of recalls.

Increased awareness of safety by staff members at all levels of DUHS has rippled through to other activities beyond the processing of alerts. For example, proactive responses by employees receiving shipments of products, as well as outreach regarding internal recalls (see sidebar), reflect a heightened

vigilance that reduces risk and enhances patient safety.

Improved Safety and Efficiency

DUHS has experienced significant improvement in alert processing time and quality. Standardizing the workflow and providing feedback mechanisms for open alerts have increased efficiency. Since staff members see only the alerts for which they are responsible, the tasks are clearly delineated, and administrative tasks such as reporting and audits have become much less labor intensive.

Just as important, however, are the management structures now in place that have had additional benefits in terms of

fostering more explicit policies and consistent education and follow-up of alerts with patients. Both clinical actions and financial management have been enhanced, and a culture of safety has become pervasive. The net effect of the changes has been enhanced patient safety and improved operational performance—a win-win situation for all concerned. ☺

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