INTRODUCTION
In late 2001, two patients died at The Johns Hopkins Hospital (JHH) in Baltimore and an additional 400 may have been exposed to dangerous bacteria caused by a design flaw in the bronchoscopes used at the hospital.

On Nov. 30, 2001, the bronchoscope manufacturer used by JHH issued a product recall by direct mail, stating that the bronchoscope had a defect that prevented full sterilization. At the time of this recall, Johns Hopkins noted almost a threefold increase in the number of patients with pseudomonas.

By early February 2002, JHH determined the bronchoscope devices were the probable cause of the increased infection rates. Unfortunately, JHH did not become aware of the recall notification until late January because the notice was addressed to the wrong department in the wrong building. This failure to direct the notice to the right department in the correct building resulted in the continued use of the defective devices for months after the original recall was issued.

This episode was not an isolated incident. Health care organizations deal with thousands of alerts annually. Alerts include product recalls, field corrections, bulletins and public health notifications that affect items used in health care – from blood and biologics to pharmaceuticals, biomedical devices, supplies and more.

This article describes shortcomings of the typical manually driven product alert process and the attributes of a tool specifically designed to address these shortcomings.

Facing the problem
Stemming from a Y2K biomedical device identification project, Mitretek Systems, a non-profit scientific research and systems engineering organization, began an internal research and development project designed to assess the feasibility of utilizing knowledge management software and Web-based tools in alert management processes. By June 2002, Mitretek had created a prototype of a Web-based system that held promise as a solution to the problem. Mitretek demonstrated the prototype system to the staff responsible for patient safety at Johns Hopkins Health System (JHHS). Mitretek and the JHHS Center for Innovation in Quality Patient Care (CIQPC) then agreed to work together on the tool.

In June 2003, JHHS began live use of the first operational version of the Risk and Safety Management Alert System (RASMAS). Success in using this Web-based product alert communication and management tool, coupled with the interest shown by other health care organizations, led Mitretek Systems to develop a subscription-based version of the system for widespread use in U.S. hospitals.

Challenges in reacting to product alert using manual processes
There are four major steps in properly reacting to a product alert. An overview of the steps appears in Figure 1 on the next page.

Typically, the manufacturer utilizes purchasing records to identify and notify clinical facilities of an alert. The notices are then distributed through a variety of media – typically fax, mail, phone, e-mail or Web site posting; occasionally through a sales representative. There are critical deficiencies in this process.

• When manufacturers send initial product alerts by letters or faxes, there may be no assurance that the contact information is current or confirmation that the information is even received by intended recipient.

• There is no consistent process across manufacturers of a product alert format, terminology or severity criteria; this lack of a standard for product alert content may result in confusing or incomplete information.

Health care organizations can also receive alerts from organizations such as the U.S. Food and Drug Administration (FDA) that act as alert aggregators. Aggregated alerts are usually posted on Web sites or distributed via electronic mailing lists or paper reports. While there are benefits to this approach, there are a number of shortcomings.

• There can be significant delays between a manufacturer’s first issuance of an alert and its posting on aggregators’ Web sites. The highly publicized Olympus bronchoscope incident, for example, was not posted on the FDA’s Center for Devices and Radiological Health (CDRH) Web site until March 20, 2002, almost four months after the Nov. 30, 2001, initial notification from Olympus.

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Because Web sites are passive, individuals must remember to access them; in addition, to receive notifications from electronic mailing lists, interested individuals must enroll for each service.

All relevant product alert information may not appear on each aggregator’s Web site, so multiple Web sites must be scanned. (The FDA has 12 separate Web sites that may house alerts.)

There is no consistency in product alert format and terminology between Web sites and information aggregators.

While redundancy can be a good patient safety practice, valuable staff time can be spent unnecessarily when each individual receiving a printed report must scan the entire report to identify any relevant alerts. Printed reports can be up to 80 pages and have varying physical formats and information.

**Circuitous route of a product alert**

When a health care organization receives an alert, another labor-intensive and error-prone process is set in motion.

First, the alert must be routed to the person(s) in the organization with responsibility for managing the reaction to the alert. The responsible person must determine if the alert duplicates a previous alert or if the product is even utilized by the health care organization.

When a product alert has been deemed relevant, a second round of activities begins. The person responsible for handling alerts needs to communicate this information to individuals who may need to take action. Complicating this task is the fact that there can be many individuals who need to be notified across various hospital clinical departments, purchasing departments and warehouses.

Once the alert has reached the appropriate person or department, documentation of actions taken can begin. Often this may be through notations written on the alert or perhaps with sticky notes. This poorly formalized approach to detailed documentation becomes a hindrance to risk management when an audit or legal issue regarding the alert arises at a future date.

Follow-up to ensure all actions have been taken can also be an inefficient process involving a flurry of faxes, e-mails, hallway meetings and phone calls. Tickler files, written notes and basic spreadsheets are often used to monitor the overall progress on the alert.
An automated approach to recall management

It became clear to Mitretek and JHHS that a comprehensive and adaptable alert management and communication service needed to be created if there was to be significant improvement in the ability to react to product alerts. The final version of the service is shown in Figure 2.

To centralize the acquisition and refinement of alerts, Mitretek operates the National RASMAS Center (NRC). The NRC staff, using both manual and automated processes, locates as many alerts as possible that could place a patient, visitor or hospital staff at risk. Alerts are also downloaded automatically for the NRC staff from many of the aggregator Web sites and listservs. Duplicates are identified and filtered out; the NRC staff reviews and associates the alerts to an appropriate domain area (e.g., pharmaceuticals, medical supplies, blood products, etc.). Where possible, additional information that can help hospital staffs react to the alert is added to the core alert information. All alerts are set in a standardized format and released to health care organizations that subscribe to the service.

There can be a number of benefits with this alert management and communication service.

- A full-time (NRC) staff is devoted solely to finding and preparing alerts, so there is less risk to the health care organization that staff burdened with other responsibilities will miss a particular alert.
- There is a standardization of the alerts’ format, reducing the time it takes for staff to read and understand alerts.
- All collected alerts are archived in one Web-based repository where they are always available for review and use.

Pre-process assessment is required

Before health care organizations can process alerts by subscribing to this sort of alert management and communication service, they must assess their organizational alert workflow process. This assessment should include identification of the facilities and staff who will be receiving or managing the alerts and their role(s).

With Mitretek’s RASMAS, health care organization staff responsible for a domain area receive an e-mail notification of a new alert. These people can then decide on the appropriate actions. They can immediately close the alert if they determine that their domain area doesn’t use the product, they can handle the required actions themselves or they can forward the alerts to other people within the organization to take action. An automated delay notification feature ensures the alerts are acted upon within the specified time frame. In the event of delays, notices are sent up the designated management chain. Additional features such as alert re-assignment and real-time reporting round out the recall management process. All notes, actions taken and system notifications are captured at the alert level for historical review, auditing and reports.

Significance to risk management

One of the first issues that Mitretek and JHHS faced when they initiated their alert management and communication service was determining the scope of the problem.

Mitretek and JHHS could find no data on how many product alerts were being issued annually in the United States. After some analysis, an initial estimate based on FDA data was published in the white paper “Improving Patient Safety by Eliminating Problems in the Product Alert Process,” published by Mitretek and JHHS in June 2003.

After a year of NRC operations, it was possible to set a more accurate estimate. From Nov. 1, 2003, through Oct. 30, 2004, Mitretek’s alert acquisition staff acquired 3,400 alerts. Approximately 1,900 of these alerts required an action on the part of the product user. Of these 1,900 alerts, 189 were FDA Class I alerts. The remaining 1,500 alerts were “recall complete” notices (announcements from the manufacturer that a product recall was completed and that no further action was needed).

These volumes, however, do not really reflect the number of product alerts that a health care organization could receive. For instance, a health care organization may receive notices from manufacturers and review the FDA Enforcement Report and MedWatch Web sites — and the same alert may be included in each of these sources. Further, if different departments in the organization purchase the same product, the manufacturer may send a notice to each...
The FDA places product recall alerts into one of three classes.

**Class I:** There is a reasonable probability that use of or exposure to a product will cause serious adverse health consequences or death.

**Class II:** Use of or exposure to a product may cause temporary or medically reversible adverse health consequences; the probability of serious adverse health consequences is remote.

**Class III:** Use of or exposure to a product is not likely to cause adverse health consequences; information-only product alerts are placed in this category. The FDA also issues warning letters for regulatory violations in which a manufacturer is required to take corrective action on a product. Alerts requiring an action on the part of a clinical facility appear in all three classes, as well as in the warning letters. It is assumed that a Class I alert demands rapid action by the clinical facility. In theory, the Class II and III alerts that require action do not have the urgency of a Class I alert. However, in practice, a delay in taking action on Class II and III alerts can result in serious harm to patients. (The Olympus bronchoscope alert was initially classified as an FDA Class II alert.)

Department. The net result is that the organization will need to review and evaluate the same alert multiple times. A study by JHH revealed that this redundancy increases the number of alerts that must be reviewed by approximately 10 percent.

Additionally, many alerts reference multiple products, yet each product must be addressed individually. A representative sampling of JHH alerts indicated that when the multiple product alerts were averaged across all alerts, 1.72 products were included in an alert. If duplicate- and multiple-alert factors were included in estimates of alert volumes, the annual volume of alerts to be managed increased by 89 percent.

Over the past decade, the healthcare product manufacturing industry has undergone dramatic growth. Accordingly, the volume of product alerts received by the FDA has increased, and this trend can be expected to continue. According to FDA data, the growth for the period fiscal year 1992 through fiscal year 2001 was 56 percent, which represents an annual growth rate of approximately 6 percent.

**Benefits of an automated system**

The main benefit of an automated alert management and communication system such as RASMAS is its potential to reduce the time it takes a healthcare organization to close an alert. Based on a JHH study, alerts required an average of 36 days from date of issuance by the manufacturer to closure of the alert when using a manual process. Minimum time was one day; maximum was 126 days. Post implementation of an automated process, all RASMAS subscribers, regardless of institution size or number of users, have reduced the typical time to complete all actions internally and close alerts to under four days.

Aside from enhancing patient safety, the use of an effective automated alert management system can reduce the risk to the hospital of a sentinel event caused by the use of a product known to be defective. While little hard data are available on the cost incurred when a product alert is overlooked or mishandled, JHH found that it cost Johns Hopkins Hospital approximately $200,000 in labor alone to track and rectify the 2001 Olympus bronchoscope recall. This estimate does not include any costs associated with insurance claims, changes to insurance premiums or resulting litigation. The costs of alert-specific activities are not generally tracked by health care organizations, so the total cost of an alert-created safety error cannot be estimated with any degree of certainty.

Another value of an automated alert management system is its impact on staff time. JHH studied the work effort to review, distribute and track actions performed by its staff in response to alerts, as well as to monitor the alert-related activities. The study revealed that the equivalent of at least nine staff months was required to process alerts at the hospital. (This figure does not include time spent finding and removing items from the supply area or the time spent performing the same functions at other Johns Hopkins facilities.) A follow-up study revealed that there was an 80 percent decrease in staff time to handle alerts after RASMAS was implemented.

**CONCLUSION**

Throughout this article, descriptions of the many shortcomings of the traditional product recall process have been identified. A comprehensive and adaptable alert management and communication service can make significant improvement in the ability to react to alerts by eliminating most of the existing problems of a manually based process, resulting in a positive impact on patient safety and loss control.

**ABOUT THE AUTHORS**

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Mitretek Systems’ RASMAS system has been endorsed by the American Hospital Association.