

# ***Improving Patient Safety by Eliminating Problems in the Product Alert Process***

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## ***Overview***

At The Johns Hopkins Hospital (JHH) in Baltimore, two patients died and an additional 400 may have been exposed to dangerous bacteria because of a design flaw in the bronchoscopes used at the hospital. On November 30, 2001, the manufacturer issued a product recall stating that the bronchoscope had a defect that prevented full sterilization. JHH did not receive the recall notice and was not aware of the recall until late January 2002. Instead of being sent to the department that used the bronchoscope, the notice was addressed to a loading dock at another department across the street. This recall had significant national impact; numerous medical facilities around the country experienced a situation similar to what happened at JHH.

This product recall episode is not an isolated incident. There are serious shortcomings in the existing system for alerting healthcare facilities of a potential danger in using a given product. The alert system does not use standard terminology or processes. Furthermore, inefficient manual processes are regularly used to distribute and track alerts at clinical facilities. As shown in the bronchoscope incident, delays of this vital information can have serious consequences. Clearly, the time has come to eliminate this risk to patient safety.

## ***Purpose of this Paper***

The process of receiving and taking action on healthcare product alerts is one that is frequently overlooked within the healthcare community. There have been breakdowns in the process that the majority of healthcare institutions use to administer the more than 6,000 alerts received annually. This paper examines the shortcomings of the current product recall process and describes an information system that may eliminate many of these problems.

## ***Background***

Mitretek Systems began examining the shortcomings in the product alert process in 2001. This examination began with an internal research and development project that was designed to determine whether knowledge management software and new Internet tools could be used to create a system that would improve the product alert process. As a result of this research, Mitretek developed a prototype designed to improve the product alert process and consequently improve patient safety.

Staff responsible for patient safety at Johns Hopkins Health System (JHHS) reviewed the prototype system and concluded that it offered significant potential for use in their hospitals, as well as in most U.S. hospitals. Mitretek and the JHHS Center for Innovation in Quality Patient Care (CIQPC) agreed to work together to refine the prototype system. At the same time, JHHS conducted a parallel study of the product alert process at the JHH.

## ***Shortcomings of the Existing Product Alert Process***

Clinical facilities use thousands of biomedical devices, pharmaceuticals, blood products, biologics, and medical supplies, as well as foods, food additives, herbals products, and other dietary products. Every product is subject to potential problems in its use, including malfunctions, tampering, contamination, and labeling errors. Whenever a problem is identified, an alert is ultimately sent to the product users.

There are numerous types of healthcare product alerts, and there is little consistency in the terminology used to describe the various types of alerts. The most serious alert—and the one that receives the most attention—is the recall alert. Other types of alerts specify actions the product user should take or

provide information that is felt to be of interest to the product users. Unless otherwise defined in this paper, the term "alert" is used in the broadest sense; it includes recalls, advisories, public health notices, field corrections, and any other type of written alert pertaining to the use of a product.

The product alert process has two components. The first covers the communication of alerts from the manufacturers to the clinical facilities; this component involves manufacturers and information aggregators. The second component involves the clinical facility, which must review the alerts and resolve all alerts that are relevant to the facility. In the U.S. healthcare industry, there are numerous problems in both components.

A number of experts agree that the process has major problems that must be addressed:

"We've had many, many cases of recall notices being sent to the wrong place. It's a common problem," said Maryanne Spicer, director of corporate compliance at Massachusetts General Hospital in Boston. "The recall system should really be improved."

In the May 27th edition of the Baltimore Sun, Dr. Steven Schonfeld, director of pulmonary medicine at Sinai Hospital in Baltimore, said "It doesn't make any sense. We get better recall notices for our cars than our medical devices.... There has to be a much more rigorous process that we could use for device recalls."

"It's obviously a problem," said Dr. David Kirschke, an investigator with the Federal Centers for Disease Control and Prevention. He went on to say that the process needs to be handled in a "more efficient and effective way in the future."

Figure 1 illustrates the complexity of the current product alert notification process.

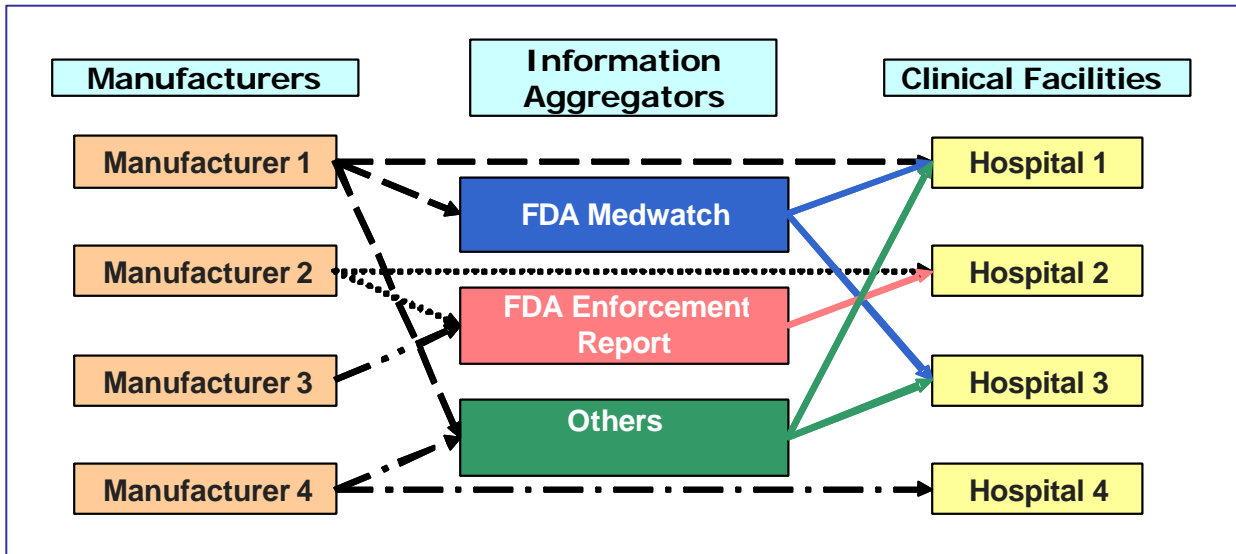


Figure 1. Current Product Alert Process

### ***Manufacturer Alert Notices***

Manufacturers and distributors of pharmaceuticals, biomedical devices, supplies, and biologics are the initiating source for the majority of alert notices. Typically, the manufacturer determines through its purchasing records which clinical facilities may have the product and notifies those facilities via a variety of mediums—typically fax, mail, or phone call, and occasionally through a sales representative, email, or web site. The manufacturer is also responsible for notifying the Food and Drug Administration (FDA) and other information aggregators of certain product alert situations.

The current process has many deficiencies:

- Manufacturers send initial product alerts by letters or faxes without any assurance that contact information is current or that the information is received.
- There is no consistent process across manufacturers of an alert format, terminology, or severity criteria; this lack of a standard for product alert content may result in confusing or incomplete information.

The current process for disseminating product alerts is loosely structured and executed. There is no standardization or consistency in the communication process. Too often, alerts do not reach the person in the clinical facility that needs to initiate an action to respond to the alert. An unnecessary error or delay can have a critical impact on patient care.

### ***Alert Information Aggregators***

Organizations such as the FDA and ECRI (formerly the Emergency Care Research Institute) aggregate the alerts for certain types of products. These aggregated alerts are posted on web sites or distributed via electronic mailing lists or paper reports. It should be noted that aggregators—including the FDA—do not necessarily receive all manufacturers' notices or post all of the notices that they receive.

While there are some benefits to this approach, there are also a number of shortcomings:

- There can be significant delays between a manufacturer's first issuance of an alert and its posting on a web site. 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 May 8, 2002, almost six months after the November 30, 2001 initial notification from Olympus.
- Because web sites are passive, individuals must remember to access the web site; in addition, to receive notifications from list servs, interested individuals must enroll for the service.
- The needed product alert information may not appear on every web site, so multiple web sites must be scanned.
- There is no consistency in product alert format and terminology between web sites and information aggregators.
- There is no consistent use of indicators to designate the severity of an alert. The indicators that are used are loosely modeled on the FDA's recall class structure, but the level of urgency is not always apparent.
- Valuable staff time is wasted because each individual receiving a printed report must scan the entire report to identify any alerts that are relevant to their facility. Printed reports can be up to 80 pages in length and often have different physical formats and information.

- Staff time is also wasted identifying new alerts within some printed reports because the report does not clearly separate new alerts from alerts being carried forward from a previous report.

Currently, there is no central product alert information aggregator, the product alert information is inconsistent in content and format, there can be significant time delays between the manufacturers' first release of an alert and its appearance on a web site, duplicate alerts identification is not done, and neither Internet-based services nor traditional printed reports offer effective communication mechanisms. Without a doubt, the medical community needs a system to help them track alerts more effectively.

### ***The Clinical Facility***

When an institution receives an alert, a labor-intensive process is set in motion. First, staff must determine whether the product is currently being used at the facility. Staff must manually look up the product in the materials management/inventory systems. If the product shows up in these systems, the organization knows it must pull the item or conduct a physical search of the inventory to determine if the specific lot numbers cited in the alert are in inventory. However, no data match on the product is not a guarantee that the product is not in use at the facility. Typically, inventory systems used in clinical facilities have an incomplete record of products purchased by the institution. Some departments may have independently purchased or been loaned products/equipment by vendors for trial or research; these items would not show up on central databases.

According to research, there is not a widespread use of computerized information systems in hospitals to handle product alerts. The labor-intensive manual process used by most facilities is subject to error and has many serious shortcomings:

- Staff spend significant time identifying and analyzing alerts only to discover that the alert has no significance to their facility. It may be a duplicate of a previously received alert, an alert for a product not used in the clinical facility, an alert—such as a food alert—not handled by the clinical staff, or an alert that is limited to a geographic area of no interest to the facility.
- Staff searching for an alert on a particular type of product must wade through a large paper report to identify relevant alerts.

- Staff spend time reading through a revised alert only to find that—except for a single piece of new information, such as a new lot number—it is identical to an existing alert.
- Alerts sent to an individual on extended leave can cause lengthy delays in response, with potentially serious consequences.
- Alerts sent from multiple sources increase the potential for not acting on an alert; each person that receives an alert may assume that another person is acting on it.
- Management spends too much time tracking the organization's progress in removing recalled products or notifying staff of completed action to close out an alert.
- The management of a large healthcare organization with multiple facilities around the region or country, large administrative staffs, and significant rates of staff turnover cannot be certain that the staff know about and follow the organization's paper-based product alert policies and procedures.

In summary, the manual process currently used to distribute, track, and manage alerts requires excessive staff and management time. Moreover, it exposes the organization to unnecessary risk from law suits and negative publicity due to the mishandling of an alert. A computerized system would streamline the tracking process, saving staff time and other resources, as well as minimizing the facility's risk of legal actions and adverse publicity.

### ***Volume of Product Alerts***

There is no definitive source on the number of product alerts that occur in the healthcare industry during a year. Mitretek and JHHS have estimated the annual number of alerts based on certain definitions and assumptions.

Mitretek and JHHS analyzed two sources of alert volume data—the FDA and JHHS. Most pharmaceutical, biomedical device, blood, and biologics alerts, along with food product alerts, are reported to four centers within the FDA; each center posts alerts on their respective web sites.

The FDA places the 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 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 highly publicized Olympus Bronchoscope alert was initially classified as an FDA Class II alert.

Table 1 presents the actual Fiscal Year (FY) 2001 annual, monthly, and weekly volume of recall (by class) and warning letter alerts from the four FDA web sites.

**Table 1. FY01 FDA Volume of Alerts for Biologics, Devices, Drugs, and Foods**

Alert	Annual	Monthly	Weekly
Class1	244	20	5
Class2	2,930	244	56
Class3	984	82	19
Warning Letter	948	79	18
<b>Total</b>	<b>5,106</b>	<b>426</b>	<b>98</b>

The data in Table 1 includes food alerts. Clinical facilities often ignore food alerts assuming that their food-services contractor is receiving these alerts as well. The FY01 recall and warning letter alert volumes excluding food alerts appear in Table 2.

**Table 2. FY01 FDA Volume of Alerts Excluding Food Alerts**

Alert	Annual	Monthly	Weekly
Class1	30	2.5	0.6
Class2	2,641	220	51
Class3	855	71	16
Warning Letter	657	55	13
<b>Total</b>	<b>4,183</b>	<b>349</b>	<b>80</b>

These volumes, however, do not really reflect the number of alerts that a clinical facility must review. Institutions often receive the same alert from multiple sources, necessitating redundant reviews. For instance, a facility may receive notices from manufacturers, review the FDA Enforcement Report and MedWatch web sites, and receive publications from ECRI for medical devices and reagents. The same alert may be included in each of these sources. Further, if different departments in an institution purchase the same product, the manufacturer may send a notice to each department. The net result is that institutions may have to review and evaluate the same alert multiple times.

Examination of product alert data at JHHS indicates that this redundancy increases the number of alerts that must be reviewed by approximately 10 percent.

Many alerts reference multiple products, yet each product must be addressed individually. A representative sampling of JHHS alerts indicates that when the multiple product alerts are averaged across all alerts, 1.72 products are included in an alert.

The numbers provided in Tables 1 and 2 do not take these complicating factors into account. If duplicate- and multiple-alert factors are included in estimates of alert volumes, the annual volume of alerts that a clinical facility must manage increases by 89 percent.

Over the last decade, the healthcare product manufacturing industry has undergone dramatic growth both in the number of companies doing business and in the number of products being brought to market. Accordingly, the volume of product alerts received by the FDA has increased, and this trend is expected to continue. According to FDA data, the growth for the period FY92 through FY01 was 56 percent, which represents an annual growth rate of approximately 6 percent. The impact of duplicate- and multiple-product alerts and the growth rate in alert are shown in Table 3.

**Table 3. Adjusted and Projected Product Alert Volumes Reflecting Duplicates, Multiple Products and Alert Growth Rate**

<b>Fiscal Year</b>	<b>Annual</b>	<b>Monthly</b>	<b>Weekly</b>
<b>2001 Actual</b>	4,183	349	80
<b>2001 Adjusted</b>	7,914	660	152
<b>2002 Projected</b>	8,389	699	161
<b>2003 Projected</b>	8,892	741	171
<b>2004 Projected</b>	9,426	785	181
<b>2005 Projected</b>	9,992	833	192

## ***JHHS Alert Time Delay and Cost Study***

Based on the JHH study, alerts required an average of 36 days from date of issuance by the manufacturer to closure of the alert by the Alert Coordinator. The minimum time was 1 day; the maximum was 126 days.

JHHS studied the work effort to review, distribute, and track actions performed by the staff in response to the alert, as well as to monitor the alert-related activities. The study revealed that the equivalent of at least 9 staff months were required to process alerts at the hospital; this 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.

The study also examined the cost incurred by non-receipt or non-handling of an alert. It was found that it cost JHH 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 hospitals, so the total cost of an alert-created safety error cannot be estimated with any degree of certainty.

## ***System Requirements to Improve Product Alert Process***

Clearly, the current methods and practices used to disseminate, record, and process alerts are largely unsatisfactory and add to national concerns for patient safety. A system-based approach can provide product alert aggregation, normalization, and dissemination through the use of various features:

- A single national repository of healthcare product alerts
- Standard terminology and categorization methods to ensure clear communication
- A standard format for all alerts
- A standard product numbering scheme to facilitate an automated process that would search the clinical facility's materials management and inventory systems to determine whether the product is in use in the facility
- Cost-effective integrated product alert management systems for clinical facilities

These are complicated objectives that will take years to fully implement.

Currently, Mitretek is working with JHHS to test a system that applies knowledge management and other advanced software technologies to the problem to address the shortcomings of the existing product alert process. Using a blend of software and human inputs, the system can accomplish the following:

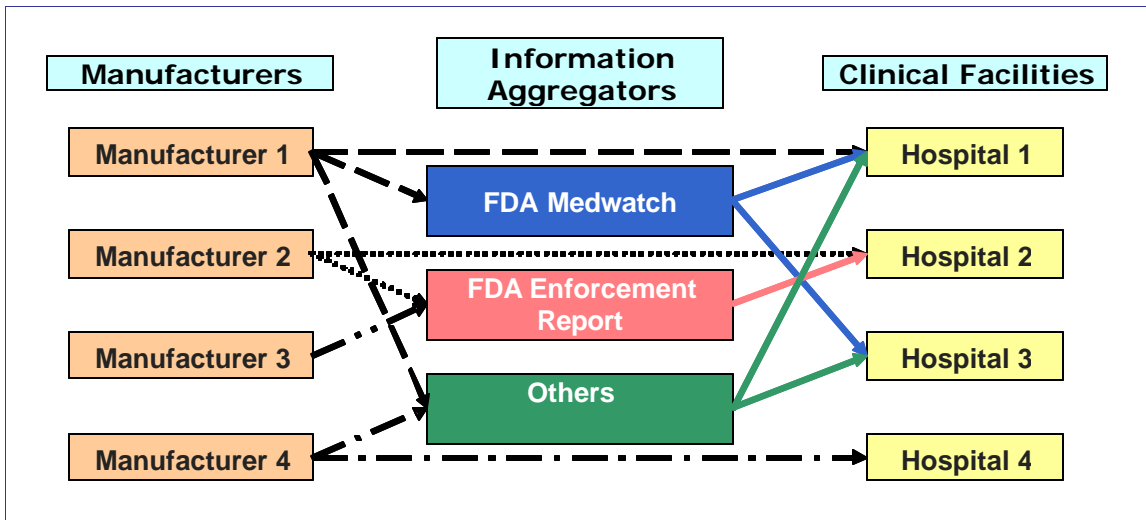
- Discover and acquire product alerts from varied sources
- Convert alerts into a standardized format
- Automatically and manually add critical or useful information to the alerts
- Distribute the alerts using profiles
- Send value-added alerts to clinical facilities
- Automate key aspects of alert distribution, tracking, and management

Figure 2 describes the product alert process with the incorporation of The Risk and Safety Management Alert System (RASMAS). The system requirements and the current process shortcomings that they address are listed in Table 4. Information about RASMAS can be found at <http://rasmus.mitretek.org>.

A follow-up study is planned for summer 2003 to determine the impact of the system on JHH alert-processing operations.

## ***Conclusion***

Clearly, the current product-alert process is compromising patient safety because of its many shortcomings and failures. Recent innovations in information technology and systems engineering offer great potential to improve the product-alert process and to restore a higher level of confidence to professionals working in the healthcare community. Time-saving tracking capabilities can streamline the recall process, minimizing the time spent with recall data and increasing the amount of time that staff can devote to patient care.



**Figure 2. Product Alert Process with RASMAS**

**Table 4. Alert Processing Shortcomings and System Requirements**

Shortcomings	Requirements
No standard product alert record	Convert all product alerts, regardless of source, into a standard format
Multiple methods for communicating alerts	Have all system users transmit paper and fax alerts to a central location where they are placed into a managed and monitored alert queue
Inconsistent indicators of severity and other key alert characteristics	Augment original alert category information with standard terminology and recommended action statements
No single repository of alerts	New system becomes central repository
Delays in posting alerts on web sites	Attempt first to acquire and process initial alert from manufacturer in order to eliminate web site posting delay
Passive nature of web sites	Use software to constantly scan web sites for alerts and push new alert to clinical facilities (after appropriate filtering)
No single repository for alerts relevant to a clinical facility	Maintain facility-specific repository of relevant alerts
Lengthy and inconsistent reports from alert information aggregators in varied formats	Replace reports with individual normalized alert records
Facilities waste time identifying duplicate alerts	Use software, augmented by human review, to identify and discard duplicate alerts
Individuals waste time identifying alerts of interest or concern	Send relevant alerts only, based on an individual's alert interest profile
Management time wasted using manual methods to track alert resolution activities	Provide system functions to automate the internal distribution and tracking of alerts
Ineffectiveness of paper-based internal alert processing	Base the product alert business process on a structured and controlled computer-based process
Alert-processing delays when staff are unavailable	Use system to notify management of alert-processing delays and points of delay.

## ***About Mitretek Systems and Johns Hopkins Health System***

Mitretek conducts basic and applied research, undertakes systems engineering analyses, and develops software solutions that strengthen the nation and benefit the public in the areas of health, safety, criminal justice, environment, energy, homeland security and counter-terrorism, space, transportation, and telecommunications.

Mitretek is distinguished from other scientific research and engineering companies by its position of complete independence and objectivity. Since it refrains from establishing alliances for commercial purposes or competing with vendors, it is free from organizational conflict of interest.

In the healthcare area, Mitretek provides information technology and management consulting services to a number of federal agencies, as well as to numerous private-sector hospitals.

The Johns Hopkins Center for Innovation in Quality Patient Care has been established to help patient care units quickly transform grassroots ideas into innovative pilot programs designed according to

rigorous scientific standards and reviewed for quantitative outcomes that improve the care that patients receive. The CIQPC provides Hopkins employees with the tools they need to make a difference—to patients, to co-workers, and to the healthcare profession.

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