Reducing Patient Safety Risks Through Innovations in Managing Recalls

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Some health care organizations have leveraged their improved alert management environments to extend their benefits in innovative ways that incorporate both administrative and clinical staff.

A major academic medical center received a notice of a human tissue recall at 6:00 p.m. on a Friday. A rapid response team began investigating the alert and blocking the specific tissue from use in scheduled surgery beginning the next day. By Monday evening, all surgeons who use such tissue had been contacted and all patients were identified who might have been affected by the suspect tissue prior to the recall. By the next day, patients were informed of free testing to determine whether there was any disease exposure.

And when Inova Health System received the human tissue recall, their recall and safety manager developed an action plan that included removing the recalled products from inventory, consulting with the hospital’s epidemiologist and infection control practitioners, establishing a lab testing plan, and identifying the affected patients and their surgeons. The tissue processors and distributors were contacted to obtain complete information. A communication plan was developed for contacting patients and their surgeons with a clear, consistent message. Throughout the process, Materials Management and Risk Management coordinated their efforts and maintained a dialog with the Department of Surgery and with senior leadership.

How did these two health care organizations succeed in managing a major patient safety risk so rapidly and effectively, when, in so many organizations, safety alerts and recall notices do not make it to the accountable staff for days, weeks, or in some cases, even months? The answer, it turns out, is multi-faceted.

An Important Process with Big Problems

The process used by many hospitals to obtain and manage product alerts (e.g., recalls and bulletins) is seriously flawed. There are multiple alert sources and formats, diverse methods of alert distribution to the hospitals, and poorly functioning paper-based systems within the hospitals. Critical alerts are mishandled or lost, weeks can pass before recalled products are removed, and little timely data is available on the status of the alerts. In just one instance of a widespread problem, a widely publicized breakdown of the paper-based process occurred at Johns Hopkins Hospital when a manufacturer’s notice of a bronchoscope defect was misplaced for 13 weeks. The result was two patient deaths and another 400 patients with suspected injuries.

Problems in the business process of alert management in health care organizations fall into three general areas:

- Organization—the structures, roles, responsibilities, and relationships of the alert management staff
- Infrastructure—the supporting and enabling mechanisms (manual or automated) of alert management
- Process—the sequence of related tasks that use organizational resources in performing alert management
Organizationally, alert management is often performed by individual departments, each with their own scope of product domains. For example, Materials Management, Biomedical Devices, and Pharmacy departments each handle recalls for products that are their responsibility. There is no overall coordination and responsibility for alert management and no assurance that all product domains are accounted for. The infrastructure tends to consist of manual mechanisms (e.g., mail and routed documents) and limited automation (e.g., spreadsheets and e-mail). This arrangement does not support efficient workflow or timely, comprehensive reporting. Since the work is performed by independent departments, the process is fragmented and inconsistent across the organization. With limited communication mechanisms, it is difficult to determine accountability and to ensure appropriate remediation actions and closeout.

Using IT to Improve Alert Management

In introducing an alert management information technology (IT) solution, each of these areas is transformed resulting in improved performance overall. One IT solution is the Risk and Safety Management Alert System (RASMAS) (see sidebar “RASMAS: A Response to the Alert Management Need”). Developed in response to the alert processing problems, RASMAS provides health care organizations with a new infrastructure that allows for major business process improvement. In the remainder of this article, the benefits that accrue to an organization as a result of implementing an automated system are described. Although the analyses in this article are based on organizations’ experience with RASMAS, RASMAS is not the only system to support product alert management.

RASMAS: A Response to the Alert Management Need

In response to the alert processing problems, Mitretek Healthcare developed the Risk and Safety Management Alert System (RASMAS). The objective of RASMAS is to provide health care organizations with an enterprise-wide, flexible, and inexpensive subscription service that will improve patient safety. Currently RASMAS is used in over 100 hospitals.

Underlying the service is an alert management business process which was formulated in collaboration with several health care organizations. It is now used effectively in hospitals of all sizes, whether free-standing or part of a health system. It was designed to address fundamental problems with the existing paper-based process:

Alert identification and creation. Mitretek standardized and centralized the identification and creation of alerts. Multiple sources are scanned by software and analyzed by a clinical team. Duplicate alerts are eliminated. New alerts are placed into a standardized format, clarifying information is added, and a product domain (e.g., pharmacy or food) is assigned. Most alerts are released within four business hours of identification.

Alert distribution. Alerts are released to coordinators at each hospital who have been designated as responsible for products in particular domains. This targeted dissemination of information minimizes the possibility that the alert will be missed.

Alert processing. A flexible and easily used computer-based workflow process enables rapid, controlled communication of activities on an alert between all involved parties, replacing the error prone mix of phone calls, faxes, and sticky notes.

Delay detection and notification. Each hospital subscriber specifies their work flow and management standards to the system. Included is the maximum allowable time permitted in each phase of alert handling. RASMAS managers are then provided reports and e-mail notices to inform them whenever an alert is delayed.

On-going process improvement. A library of reports is available to identify problems in processing alerts in individual facilities and domains; these reports are used for on-going process improvement. An audit report that shows every action that is taken on an alert is also available for management scrutiny or to answer queries from outside parties.

Endnote

1. In January 2004, RASMAS was endorsed by the AHA, which stated that “the service will help the nation’s health care providers efficiently manage important health care product and safety alerts that are impacting key issues in health care today such as patient safety.”
Alert management is performed within the context of an enterprise-wide organization with a defined management structure and responsibilities. Management assures that the full range of relevant product domains is addressed. The automated infrastructure supports effective workflow and provides immediate and comprehensive reporting. Audits are supported by a repository containing the full history of all actions on an alert. The process is now comprehensive and standardized across the organization, and management can monitor adherence to the process and to the organizational standards. Accountability is well defined, and staff adapt to the requirements of their specific responsibilities within the process. Figure 1 summarizes the alert management business process improvement that occurs with the introduction of an automated system.

As with any business process improvement, there are challenges that must be addressed in the implementation. Organizationally, with the formation of an enterprise-wide team, alert coordinators in some product domains must enlist the cooperation of responders who work in other departments. The system managers, who are often from Materials Management and Risk Management, become responsible for oversight of staff who represent a cross section of hospital departments. The new automated infrastructure requires that all users have a minimal comfort with e-mail and with a Web browser. Finally, some staff may initially be resistant to changes in their work process and must be supported in making the transition.

Regardless of the challenges, the benefits to health care organizations upon implementation of the automated system have been marked. Though the degree of improvement varies among institutions, alert management performance is reliably improved in several areas:

- Increased scope—the range of products covered by alert management generally expands from a limited number to most or all of the 14 product domains covered in RASMAS; in addition, the number of alerts processed increases significantly.
- Improved timeliness—within several months of implementation, the average time for processing and closing alerts drops from 20 days using a manual process to 2.6 days using the automated process, an 87 percent improvement.
- Improved diligence—the actions taken on alerts are more thorough and spur development of a more stringent corporate policy. Alerts cannot be closed by coordinators until all designated staff have completed their assignments.
- Reduced risk—each day that a recalled product remains in a hospital may be considered an “at-risk” day. In expediting the processing of recalls, health care organizations remove potentially hazardous products in a more timely way and therefore reduce the risk of harm to patients, visitors, and staff.

Figure 2 displays the reduced closing times resulting from the automation of alert management and the associated avoided product “at-risk” days.

Since the automation of alert management is relatively new, performance metrics are still in the formative stages of development. As the metrics are conceived and developed, they are made available to subscribing hospitals as standard reports to support monitoring of performance. Eventually metrics will be established as standards so that members of various hospital communities will be able to compare their performance against others in their cohort.

**New Capability Spurs Further Innovations**

Some health care organizations have gone beyond the provided transformations and leveraged their improved environments to further enhance alert management. They have done this through innovations in or-
Organizational structure and in business processes. They have pioneered new approaches that improve patient safety and serve as a model for other organizations seeking best practices in alert management. Three such health care organizations are:

- Children's Hospital of Wisconsin (CHW). A major pediatric medical center located in Milwaukee, this hospital is a private, independent, not-for-profit, pediatric medical center that serves children with all types of illnesses, injuries, and other disorders. It is a leading center for pediatric health care in the United States. The hospital has approximately 300 beds. It has implemented RASMAS at two facilities and defined 44 users.

- Inova Health System. A regional health care system, this not-for-profit health care organization is based in Northern Virginia and consists of hospitals and other health services, including emergency and urgent care centers, home care, hospice, skilled nursing care, and community-based clinical partnerships. It has been ranked among the top 10 health care institutions nationwide for many years. It has nearly 1,600 beds. It has implemented RASMAS at 79 locations and defined 332 users.

- A major academic medical center. This health system includes a medical center, two regional hospitals, primary and specialty care clinics, home care, hospice, skilled nursing care, and community-based clinical partnerships. It has been ranked among the top 10 health care institutions nationwide for many years. It has nearly 1,600 beds. It has implemented RASMAS at 79 locations and defined 332 users.

Innovations in Organizational Structure
Each of the three organizations has instituted innovations in organizational structure that have improved alert management. They have established programs with defined executive responsibility that demonstrate a clear organizational commitment to alert management. The programs include senior-level leadership, standardization of work processes, and monitoring of operations.

CHW began using the automated system in the spring of 2004. At CHW, alert management is the responsibility of the director of Medical Technology and Safety. The hospital established an Alert Management Committee to improve hospital policies associated with the system implementation. The committee adopted a global view of alert management, since the new technology provided the opportunity to define and monitor the business process more fully. The committee’s Safety Policy and Procedures, released in the summer of 2005, defined the hospital’s new approach to alert management. It continues to oversee alert management and the refinement of the hospital’s business process.

Inova began using the automated system in the winter of 2003. At Inova, alert management is the responsibility of the Materials Management Department. In the summer of 2005, in response to the increased volume and complexity of product recalls, senior leadership established the position of recall and safety manager. They determined that one individual was needed to maintain oversight across the health system. The position was created in the Materials Management Department under the assistant vice president. The person selected to fill that position has a law degree and is a Certified Professional in Healthcare Quality. She is responsible for ensuring that an effective recall process is in place throughout the health system. Prior to automation, recalls were handled separately at hospital facilities each of which had its own policy. The recall and safety manager has been reviewing the independent facility processes and standardizing them into one consistent approach.

The academic medical center began using the automated system in early 2005. At this health system, alert management is the responsibility of the Procurement and Supply Chain Department under the direction of an assistant vice president. The medical system adopted an approach of central-
ized accountability for initial alert assessment and decentralized accountability for product remediation. A small team performs the initial assessment, which includes a look-up in the relevant purchasing/inventory system, documentation of the results in the system, and notification of appropriate staff at the facilities. Senior leadership has assumed responsibility for assuring staff adherence to corporate alert management policies—the chief operating officers of the facilities communicate with staff who do not comply. In addition, they have established a Senior Recall Team that is responsible for oversight of critical alerts that may impact on patient safety.

Innovations in Clinical Business Processes

The three organizations have also instituted process changes that address the clinical impact of alerts. They have established policies which formalize the assessment, planning, and execution activities related to alert clinical impact. They have established mechanisms to involve risk management, clinical staff, and other relevant parties.

CHW pioneered the concept of a coordination checklist that provides guidelines to coordinators in determining whether an alert may have a clinical impact. Figure 3 presents a generic coordination checklist derived from the hospital's version. The coordinator answers a series of questions on potential clinical impact and, if any answers are affirmative, they notify the risk manager. The risk manager assembles an appropriate team that analyzes the impact and develops a plan of action based on considerations such as the type of alert, the number of patients affected, physician implications, potential exposures of staff or patients, compliance issues, and public health risks. The response team includes representatives from appropriate clinical departments as well as hospital administration, support services, public relations, and legal services. An action plan is developed with a schedule and assigned responsibilities. The plan is executed, communicated to leadership, and documented in the alert management system.

When the recall and safety manager assumed her position at Inova, she determined that greater clinical oversight of alerts was needed. For example, the health system needed to ensure that it understood the patient implications of false negative readings with recalled lab test kits and defective stains. Just removing products from inventory was not sufficient. The previously described coordination checklist was customized and incorporated into the alert management process. When coordinators working with clinical staff determine that there is a clinical impact, they notify the risk and safety manager and the appropriate risk manager. A response team is assembled, and a plan is developed and executed.

The new process has produced a better educated front line staff and resulted in the elimination of many “rogue” buying habits.

The ability to rapidly implement an organization-wide plan and to keep the senior leadership involved throughout the recall process was a direct result of having an organizational focal point with the authority to act in a coordinated mode.

At the academic medical center, there are standard procedures for rapid assessment of alert risk. Anyone involved in alert processing can request the convening of the senior recall team if an alert “may impact the on-going health of a population of exposed patients or as needed otherwise.” The team, led by the vice president for medical affairs, conducts an evaluation and identifies short-term and long-term actions needed to respond to the alert. Possible response measures may include identification of impacted patients, staff, and providers; determination of an appropriate clinical response; development of a communication plan; designation of limited contact points for the relevant manufacturer or distributor; and tracking of recall-related costs. Under the guidance of senior leadership, the team works with the relevant administrative and clinical entities to ensure appropriate and consistent responses.

At the academic medical center, the timeliness of their response to the tissue recall was impressive. According to the vice president for medical affairs, the use of the automated system in combination with the actions of the Senior Recall Team allowed the health system to be “out in front in responding to this issue” and “quickly minimized the number of affected patients.”

Innovations in Administrative Business Processes

Additional process changes were instituted that were either directly or indirectly related...
## ALERT COORDINATION CHECKLIST

**RASMAS Alert Number:**

Use this form as a guide for processing alerts according to hospital policy. All alerts received shall be tracked and documented in RASMAS. It is important to enter the actions into RASMAS at the time they are performed so that the dates reflect when the actions are taken.

### General Guidelines

- **☐** If not affected by the alert, document your comments in RASMAS and close the alert.
- **☐** Follow all instructions as defined in the alert. (For example: remove from service, repair, replace, return, dispose of, label, educate, or complete response form to vendor.)
- **☐** Communicate information to staff and physicians as appropriate.
- **☐** Review actions taken by alert responders, and verify that no further action is needed. Close the alert in RASMAS.

### Clinical Assessment

- **☐** Observe if the alert is Class I, Urgent, or Life threatening and expedite the actions to resolve.
- **☐** Partner with an appropriate clinician to answer the following questions. Contact the Risk Manager if you answered YES to any of the questions.
  - **☐** Name of the clinician that reviewed this alert
    - **☐** Y or N Does the alert require notification of patient(s)?
    - **☐** Y or N Does the alert involve any potential for infection contamination or other body/liquid exposure?
    - **☐** Y or N Does the alert pose a significant public health risk?
    - **☐** Y or N Does the alert have other potential adverse affect on hospital operations?
    - **☐** Y or N Does the alert require physician intervention?
    - **☐** Y or N Does the alert have implications for corporate compliance with state or federal laws, regulations or accreditation standards?
    - **☐** Y or N Will the actions of the alert affect the hospital’s supply of crucial equipment/medications or other supplies that could have an affect on operations or delivery of care?

- **☐** Consider similar products that may be susceptible to the same type of hazard.

### Documentation

- **☐** The system automatically records the following information according to user actions:
  - **☐** The date the alert was received.
  - **☐** List of all persons involved or notified within the system (including system users and FYI recipients).
  - **☐** Date and description of each action taken by users to resolve the issue.
  - **☐** The record of product disposition when closed. (For product disposals, there must be a documented witness. For alerts with no action, there must be an explanatory comment.)

- **☐** Enter the following information in the system using a work note or comment.
  - **☐** List of all persons involved or notified outside of the system (including staff and physicians).
  - **☐** Date and description of each action taken by non-system users to resolve the issue. Include a record of phone calls made.

- **☐** Separately maintain a file of independent paperwork associated with alerts for ____ years.
  - **☐** Copy of response card and return receipt for responses sent to manufacturer/distributor.
  - **☐** List of patients notified.
  - Related press releases to the public.

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*Figure 3. Alert coordination checklist.*
to implementation of the alert management system. These changes have standardized and strengthened the alert management process and helped to instill a culture of patient safety within the Materials Management Department.

Both Inova and the academic medical center have trained their staff in their multiple facilities in the use of the system and their institution’s specific policies regarding recalls. They have met with the individual alert management teams at each facility to communicate process standards and to set expectations of performance. Performance results, readily available in the system, are reported to patient safety committees, and non-compliant staff are reported to facility management. Both organizations have begun to calculate hospital costs associated with significant product recalls.

At Inova, several efforts were initiated by the recall and safety manager to foster the concept that Materials Management plays a significant role in hospital safety. A Recall Blast List was implemented to notify senior management quickly when a major recall has been issued. An executive summary of significant recalls is provided to senior leadership every three weeks. Materials Management also publishes the intranet newsletter Material Messages each quarter. The newsletter includes safety-related articles with topics such as Counterfeit Products in Health Care, which warned staff not to purchase products through Internet auction sites or trade bulletin boards. In addition, a “Safety Star” is awarded to a staff member who has originated safety improvements within Materials Management.

The academic medical center identified several success factors for their improved alert management process. Procurement and Supply Chain Management is responsible for initial alert analysis and for notification to affected facilities which are responsible for taking the appropriate action. The new process has produced a better educated front line staff and resulted in the elimination of many “rogue” buying habits. There are now clear guidelines regarding patient communication related to recalls. The same alert management process is now used for internal alerts that only affect the medical center’s community. Finally, centralized oversight has been established for accountability in “closing the loop.”

The three health care organizations have built on the initial improvements in their environments resulting from the alert system implementation and further enhanced alert management and patient safety. Their additionally improved performance can be examined in the context of the previously identified areas:

- Increased scope—participation in alert management and associated activities has been expanded to include senior management and clinical staff; in addition, Materials Management staff have come to recognize their contribution to hospital patient safety.
- Improved timeliness—while no data is available on this, it could be inferred that with increased executive oversight, there will be fewer instances of non-cooperating staff and thus reduced processing times.
- Improved diligence—the concerted effort to involve clinical staff in addressing the issue of patient impact indicates a more serious commitment by the institutions to formulate comprehensive responses to product recalls.
- Reduced risk—in methodically addressing clinical impact, the organizations are reducing the risk of harm to patients who would otherwise be potentially exposed to adverse effects or may have been exposed prior to the recall.

Conclusion
In response to problems in product alert management, health care organizations have implemented automated systems that have transformed their alert management organizations and associated processes. The new enterprise-wide alert management systems have resulted in consistent performance improvements across a wide range of health care organizations. Some institutions, enabled by their improved environments, have further enhanced their management of alerts. Through initiatives within materials management, these institutions have advanced their culture of patient safety and demonstrated the potential for continued improvement.

Endnotes
1. Analysis of hospital survey data indicates that all respondents were receiving alerts for 5 of the 14 domains prior to automation. Various numbers of respondents received alerts for each of the remaining 9 domains.
2. RASMAS releases approximately 38 alerts per week across the 14 product domains. Limited survey information coupled with anecdotal comments indicates that this represents a significant increase over those received in the manual process.
3. One emerging measure of diligence is the percent of released alerts that require remediation action—direct action to remove or modify a recalled product. An analysis of subscribers who have used an automated system for at least three months indicates that approximately 10 percent of processed alerts require remediation action. Organizations with significantly lower remediation rates are more likely to be closing alerts prematurely without appropriate evaluation. It has also been observed that over time managers exercise increasing oversight of the alert management process and become less tolerant of deviation from corporate policy.
4. This health system was not able to provide approval for this article in time to meet the publication schedule and so it is not identified.
5. Members of the committee include directors and/or managers of safety, risk, pharmacy, clinical engineering, materials services, radiology, lab, information systems, facilities, nutrition, and respiratory therapy.
6. Team members include the chief medical officer, the patient safety officer, the vice president for medical affairs, the assistant vice president for procurement and supply chain, and the director of accreditation and regulatory affairs.
7. From a presentation by the medical center published in March 2006.