How do some healthcare organizations succeed in managing a major patient safety risk rapidly and effectively, when in so many others, safety alerts and recall notices do not reach the accountable staff for days, weeks, or in some cases, even months? The answer, it turns out, is multi-faceted. Success requires a coordinated, integrated approach that improves organization, infrastructure, and process.

**Alert Management Is Critically Deficient**

The process used by many hospitals to obtain and manage product alerts (e.g., recalls and bulletins) is seriously flawed. Hospitals receive alerts from multiple sources and in different formats. They frequently use diverse methods of distribution that rely on poorly-functioning, paper-based processes. Critical alerts may be mishandled or lost, and weeks can pass before recalled products are removed from service. Timely data on the status of the alerts is difficult or sometimes impossible to obtain. A number of high-profile cases have demonstrated that these weak links in the alert management process can have fatal results.

Problems in the process of alert management in healthcare organizations fall into three general areas:

- **Organization**: The structures, roles, responsibilities, and relationships of the alert management staff are not clear or coordinated.
- **Infrastructure**: The supporting and enabling mechanisms of alert management are inadequate.
- **Process**: The sequence of tasks related to alert management is fragmented and inconsistent.

Organizational, alert management is often performed by individual departments, and the scope of their responsibilities does not extend beyond the products used in their departments. For example, Materials Management, Clinical Engineering, and Pharmacy departments frequently handle recalls only for products that fall within their designated areas of responsibility. Many hospitals have no centralized coordination and responsibility for alert management, and no way of assuring that all product domains affected by an alert are accounted for.

The infrastructure for managing alerts 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. Paper documents can easily be misplaced or misrouted and summary data is not readily available.

Finally, since the work is performed by independent departments, the process is fragmented and inconsistent across the organization. With limited communication mechanisms and organizational oversight, it is difficult to determine accountability or to document that appropriate remediation actions and closeout have taken place. The workflow may be interrupted without anyone even being aware of the breakdown.
Organizational Benefits Flow from Automation

The use of an automated alert management solution supported by information technology (IT) provides the framework for addressing all of the weaknesses in existing alert management systems and offers the potential for subsequent organizational innovation. First, when an automated system is implemented, an enterprise-wide strategy is developed that involves the entire organization, introducing a defined structure and responsibilities that were previously lacking. This approach bridges the separation that typically exists between different departments and ensures that each product domain has coverage.

Second, the new IT infrastructure provides an effective, automated workflow that replaces a multitude of manual and semi-automated mechanisms. It also provides comprehensive reporting so that the status of any recall can be immediately determined. Audits are supported by a repository containing the full history of all actions taken on an alert.

Third, the process is improved with automation because alert management becomes standardized across the organization. Responsible staff can monitor adherence to the process and to organizational standards. Accountability is well defined, and staff is aware 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.

Once the drawbacks in non-automated systems are addressed, the organization is in a good position to initiate more sophisticated measures to improve patient safety. Among the potential organizational innovations that can be supported by automated alert management are:

- Evaluation of the clinical implications of recalls,
- Development of performance standards, and
- Establishment of new procedures for risk assessment.

Each of these is highlighted in case studies discussed below.


The experiences of leading health care organizations using automation effectively to enhance their alert management provide insights into the factors that lead to success. These organizations have pioneered new approaches that improve patient safety, and serve as a model for others seeking best practices in alert management.

The following case studies demonstrate how three health care organizations instituted process changes following implementation of enterprise-wide alert management. They each took a holistic look at their recall practices and went on to establish policies that formalized the assessment, planning, and execution activities related to alert management. In addition, they established mechanisms to involve risk management, clinical staff, and other relevant parties.

Clinical Impact: Using a Checklist to Drive Action

A Midwestern children's hospital and health system struggled with a multitude of alerts and how to manage them consistently across their many inpatient and outpatient facilities. To address these challenges, the health system began using automated recall management in the spring of 2004. Under the guidance of the director of Medical Technology and Safety, the hospital established an Alert Management Committee to improve hospital policies associated with recalls and the use of automated alert management. Automation provides a global view of alert management, allowing the Committee to fully define and monitor all of the hospital's recall processes.
A simple yet powerful adjunct tool that evolved from the Committee’s work is a checklist that provides guidelines to coordinators in determining whether an alert may have a clinical impact. The coordinator answers a series of questions on potential clinical impact and, if any answers are affirmative, notifies the risk manager. The risk manager assembles an appropriate team that further analyzes the impact of the alert 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.

Use of the checklist allowed the hospital to go beyond the stage of monitoring and responding to alerts and evaluate the clinical implications. The Committee continues to oversee alert management activities and the refinement of the hospital’s alert management policies and procedures. After having automated its alert management process, the hospital is now in a better position to implement continuous improvement policies.

Performance Standards: Improving Recall Management through Smart Staffing

A not-for-profit health system on the East Coast began using an automated system in the winter of 2003. In response to the increased volume and complexity of product recalls, senior leadership determined that they needed one individual to maintain oversight of alert management across the health system. As a result, the position of Recall and Safety Manager, under the supervision of the assistant vice president of Materials Management, was created. The Recall and Safety Manager is responsible for ensuring that an effective recall process is in place throughout the health system.

Prior to automation, recalls were handled separately at the facility level, and recall processes were governed by the policies in place at those facilities. One of the first jobs that the Recall and Safety Manager tackled was reviewing the independent facility processes and standardizing them into a single consistent approach. Now each facility’s alert management team communicates process standards and sets performance expectations. Performance results, obtained from the automated recall management reports, are presented to patient safety committees, and non-compliant staff is reported to facility management.

The Recall and Safety Manager, who has a clinical background, also determined that removing recalled products from inventory was not sufficient and that remediation of these alerts frequently required greater clinical oversight. One example where clinicians needed to become entrenched in alert management processes was the Biomedical Tissue Services recall that occurred in October of 2005. When notified of the human tissue recall, the Recall and Safety Manager immediately 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 health system contacted the tissue processors and distributors to verify that they had the most up-to-date information and that it was accurate and complete. They
worked with their media relations department to develop a communication plan 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 senior leadership. The effectiveness of these organizational and process changes was evident in this hospital’s handling of the human tissue recall: Their 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.

Risk Assessment: Centralized Accountability, Decentralized Remediation

In early 2005, an academic medical center began using an automated system to standardize and manage its recall procedures. At this medical center, alert management is the responsibility of the Procurement and Supply Chain Department under the direction of an assistant vice president. The medical system chose to adopt an approach of centralized 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.

In this organization, senior leadership is responsible for assuring that staff adheres to corporate alert management policies and the chief operating officers of the facilities communicate with staffs who do not comply. A Senior Recall Team was established to oversee critical alerts that may impact patient safety. 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. This medical center has demonstrated a clear organizational commitment to recall management by establishing programs with defined executive responsibility. The programs include senior-level leadership, standardization of work processes, and monitoring of operations.

By using a standard procedure for rapid assessment of alert risk, this medical center processes alerts quickly and methodically. People at all levels of the recall chain have the authority to request that the Senior Recall Team convene if they believe that an alert may impact the ongoing health of a population of exposed patients. 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. 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.

Conclusion

In response to problems in product alert management, many of our nation’s hospitals have implemented automated alert management, which has transformed their alert management culture 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 organizational innovation. The advances include evaluating the clinical impact of recalls, setting performance standards for recall management, and improving risk assessment. The institutions implementing these steps have advanced their culture of patient safety and demonstrated the potential for continued improvement.

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