RASMAS: A Web-Based Product Alert & Recall Management Service

Organization Name: Noblis Health Innovation
Type: Acute Care Hospital
Specialty Hospital
Long Term Care
Outpatient Clinics

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IDENTIFICATION:
Problem: What can your organization do to identify and respond to product recalls more quickly and effectively and protect patient safety?

There are a growing number of product alerts and recalls that impact healthcare providers. The longer recalled product remains on the shelf; the greater risk to patient safety. In addition, identifying, tracking, and removing recalled product from the supply chain can be cumbersome and time consuming. Many problems are identified when a recalled product is given to a patient and that product causes patient injury or death.

Historically, healthcare providers tracked product alerts and recalls by searching available public sources (e.g., FDA, Consumer Product Safety Commission, etc.), and these alerts and recalls were tracked manually. In November 2001, a predominant hospital in Baltimore, Maryland had two patients die and an additional 400 may have been exposed to dangerous bacteria because of a design flaw in the bronchoscopes used at the hospital. The manufacturer issued a product recall stating that the bronchoscopes had a defect that prevented full sterilization. The hospital did not receive the recall notice and was not aware of the recall until late January 2002. Instead of the recall notice being sent to the department that used the bronchoscopes, the notice was addressed to a loading dock at another department across the street. The recall had significant national impact; numerous medical facilities around the country experienced a situation similar to what happened at this leading hospital.

This product recall episode is not an isolated incident. There are serious shortcomings in the existing process for alerting healthcare facilities of potential danger in using a given product. Furthermore, inefficient manual processes are regularly used to distributed and track alerts at clinical facilities. Delays of vital information can have serious consequences.

Since 2004, the number of product recalls and safety alerts that impact hospitals and healthcare systems in the US continues to rise. Our studies show that facilities using a manual alert processing system were not aware of 87% of available product alerts, therefore exposing patients, staff, and visitors to risk of injury from defective products.
RASMAS is a web-based service that allows healthcare providers to receive alert and recall content in a consistent manner and track all activity taken by the hospital to quarantine or remove defective product from the supply chain. Baseline data that existed prior to RASMAS included hospitals maintaining manual records of alerts or recalled product. The average days to close an alert without the automated RASMAS tracking system was approximately 22 days. The average days to close an alert two months after a facility implements the RASMAS system is approximately 3 days.

**PROCESS:**

The problems of tracking product alerts and recalls manually and the impact this approach has on patient safety was first identified in 2001. 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 3,000 alerts received annually.

Noblis, the non-profit science, strategy, and technology firm that developed RASMAS conducted research on what capabilities should be included in an automated recall management system. Product development for RASMAS began in 2002. In 2002, a major hospital in the Northeast had an incident where recalled product was not pulled from the shelf, and the patient was treated with recalled product resulting in the patient’s death. This major hospital became an integral part in developing and testing the RASMAS prototype in 2002 and 2003. In 2003 and 2004, the commercial RASMAS system was developed, and RASMAS was put into commercial use in January 2004. In 2005, RASMAS was awarded a National Patient Safety Award.

**SOLUTION:**

RASMAS is a web-based service that provides comprehensive notification, distribution, and management of product alerts and recalls for products used in healthcare facilities. RASMAS streamlines the way the healthcare supply-chain communicates and manages product alerts and recalls. RASMAS provides an immediate improvement in patient safety by automating many of the manual processes currently used by healthcare organizations to handle product and safety alerts.

- RASMAS clinical staff searches more than 100 sources, publicly available and non-public sources, daily.
- Staff reviews, categorizes and standardizes alerts to identify the product, remove duplicates, and denote alerts urgency and required actions.
- Alerts are categorized into specific domains to direct the information to the appropriate point of contact in the affected hospital department.
- RASMAS provides its members with a centralized database to document the actions taken in response to the alert or recall notification.
- If an alert or recall notification has not been attended to, there is an inherent process for escalation to ensure that each notification has been acknowledged and reviewed.
• A complete documentation trail is established for each alert and the course of action taken.
• RASMAS offers an array of reporting tools or query capabilities that can be quickly generated for review by management for internal audits or to respond to regulatory bodies such as the FDA or the Joint Commission.

To date, our repository of alerts and recalls contains over 19,000 alerts.

The key benefits of RASMAS are:
• Standardized alert content via a web-based service
• Closed loop responsibility model
• Member-defined escalation triggers
• Detailed workflow history for 'on the spot' audits
• Comprehensive dynamic reports
• A robust Community focused on advancing product safety and recall management

Since 2004, over 775 healthcare organizations have subscribed to RASMAS to increase patient safety, improve clinical effectiveness, and heighten operational efficiencies. RASMAS has reduced alert processing time by up to 80% in many of our member hospital and healthcare organizations.

OUTCOMES:

Since 2004, leading healthcare providers have subscribed to RASMAS to increase patient safety, improve clinical effectiveness, and heighten operational efficiencies and many healthcare providers see that it is imperative to have procedures in place to handle recalls. From our experience, having an electronic system with specific procedures in place has reduced alert processing time by up to 80% in many of our member hospital and healthcare organizations. Prior to utilizing RASMAS, the time it took the organization to identify the alert and complete all necessary actions was on average 20 days. After implementing the RASMAS service, the same organization needed an average of 3 days to receive, address, and close the alert.
Today, many healthcare facilities, including 8 of the top 10 hospitals on the 2009 US News and World Report’s Best Hospitals Honor Roll are RASMAS members. These organizations have determined the best practice for recall management is one that includes a web-based service that provides alerts in a timely manner and includes complete audit trail tracking and full accountability.