**Introduction**

Imagine a large and extremely busy perioperative services department that performs over thirty cases per day. Hundreds of clinical staff and physicians are constantly in and out of surgical suites, with patients under constant surveillance and care. Operating rooms are turned around in a matter of minutes and thousands of medical devices and supplies are stored within the rooms, the hallways and central supply areas. Time is of the essence, both in terms of attending to the immediate needs of patients in critical states of surgical care but also in maintaining an efficient and productive service line.

Now imagine the department is informed that a major recall has occurred for a commonly used medical device. The manufacturer has provided a series of lot numbers for the product and now the staff is forced to navigate through the myriad of shelves, cabinets, closets and rooms to find the small number of items with the lot numbers that match those being subject to the recall. For some, it may remind them of the old adage of 'finding a needle in a haystack'. Clearly a time consuming and arduous task, but a task that requires a thorough and detailed approach to identify and remove those items that were included in the recall to maintain the highest levels of quality and safety.

Unfortunately, it's easy to imagine this type of a scenario as it has become a common occurrence in the healthcare marketplace. Over the past year, more than 600 medical device recalls were issued for a wide range of items including implantable devices for interventional cardiology, infusion pumps, orthopedic implants and many more (1). Given an FDA estimate that over 110,000 injuries and deaths occur annually as a result of problems due to medical device malfunction, these recalls create risks for all care providers to sustain the highest levels of quality in care provision (2).

**Challenges to Managing Recalls in Perioperative Care**

Care providers in the perioperative setting are not immune to the concerns and challenges of recall management, particularly as it applies to physician preference items such as implants and devices. There have been several examples over the years of large scale recall campaigns from a variety of manufacturers, with a recent example involving the recall of cardiac rhythm management devices from Boston Scientific in 2006.

Although most organizations have created policies and procedures to respond to medical device recalls as part of their compliance with JCAHO Environment of Care standards, these approaches are often completely reliant on manual process. Through the manual approaches, a few significant concerns arise:

- For a recall impacting a large inventory volume, labor time can be significant as large quantities of inventory located in multiple locations must be pulled, verified, and removed.

- Due to large inventories that are carried in multiple locations, an oversight can occur in the attempt to locate all storage locations, creating an opportunity for missing the identification and removal of all items.

- The accuracy of manually reviewing and reconciling lot numbers on all products is prone to create instances of oversight and error, thus allowing recalled items to remain within departmental inventory and pose safety and quality risks.

In addition to the identification of items carried within the organization, another significant challenge is to identify those patients who have already been recipients of a recalled item. Although documentation tools are available in the form of operative records and implant logs, they are commonly developed and maintained by manual documentation processes. As cited in research related to manual documentation error rates in the clinical setting, the reliance on manual, paper-based processes can lead to documentation error or oversight near a rate of 10% (3).

To address the challenges in maintaining an accurate and comprehensive approach in responding to a device recall, many organizations are now seeking assistance from information technology. More specifically, the unique attributes of radio frequency identification (RFID) enabled device and supply management systems have proven to offer an opportunity to improve the efficiency, accuracy, and quality of device recall management processes.

**RFID: A Better Solution to Manage Medical Devices and Supplies**

Although developed nearly sixty years ago, only recently have RFID technologies started to gain increased levels of attention within the healthcare industry as hospitals, physicians, and other care providers turn towards innovative technologies to solve critical business needs. Due to it's characteristics of effectively locating and tracking objects, examples of it's application within the healthcare setting have included monitoring patient locations, tracking the location and utilization of assets such as beds and monitors, and even tracking employees within the organization.

In addition, a powerful use of RFID's properties has been to support the tracking and management of medical devices and supplies. The following provides a brief description of the workflow of the technology and a picture is provided in Figure A below.

**Workflow for Medical Device and Supply Management:**

- As items are received within the department, the barcodes on the unit-of-use packaging are scanned to create RFID tags which will be affixed to the package of the individual item. As part of the tag generation, all item information such as product description, lot number, serial number, and expiration date is stored in a database.

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Once tagged, items are placed in a secure, cabinet-based storage technology which has RFID enabled shelving that supports the location tracking and management of all items. At this point, information on the location, quantity, expiration date, or other unit-of-use level information is readily available within seconds by using a software tool to access information on any items within the cabinet inventory.

When items are needed for a procedure, the clinical staff logs into the system using a common identification and authentication mechanism such as an identification badge. Once logged in, the user selects the patient from a list of the day’s cases and then opens the doors and retrieves the necessary medical devices and supplies for the procedure.

After all items have been acquired, the doors are shut and a summary of all items removed for use on the patient is captured and displayed to the user. This data is added to the database to create an easily accessible record of item utilization by user, patient, procedure, physician, and other relevant information.

When instances of a recall occur, identifying the items subject to recall as well as their specific location within the cabinet-based storage system is simple, efficient, and accurate.

Through query capabilities within the system software, a user can access information such as product type, lot number, or other descriptive characteristics of the items and match those to the recall information provided from the manufacturer. From there, the process of identifying items for removal can occur. The following case study provides an illustration.

Case Study: Responding to a Medical Device Recall

The Michigan Congenital Heart Center (MCHC), located within C.S. Mott Children’s Hospital at the University of Michigan, has earned the reputation as a national and international leader in providing comprehensive care for congenital heart patients from infancy through adulthood. An example of the Heart Center’s leadership was seen in their decision to implement an RFID-based medical device and supply management system to address challenges in their utilization processes for items used to address complex heart conditions. A picture of an installation within one of MCHC’s cath labs is showing Figure B.

With products monitored at the item level, an accurate and real-time set of data is available including the specific cabinet and shelf location for each item. Upon receiving notification of a recall from a manufacturer for an implantable medical device used to address the condition of atrial septal defect (ASD), the staff managing the inventory at MCHC worked efficiently to identify and remove all items that posed a risk towards patient care.

Normally, completing a thorough inventory search would have taken several hours for the staff. Their efforts would have consisted of manually pulling all of the devices and then cross-referencing their lot numbers with the list of fifty (50) lot numbers provided by the manufacturer. Not only is the process time and labor intensive, but it can also have downstream effects of delaying or rescheduling cases in which these items are required for use.

Figure B: Installation within an MCHC cath lab

Instead of using manual processes to identify and remove the recalled items, MCHC was able to leverage the RFID enabled system to efficiently complete the process. The steps involved searching for the manufacturer’s products through a simple query in the system’s software application. Once the products were identified, all lot numbers for the products were displayed and quickly cross-referenced with those provided by the manufacturer.

Following this short step, the search was quickly narrowed down to identify eleven (11) items that were subject to the recall. Included in this list of eleven were the exact cabinet and shelving locations for a quick and efficient removal of the items. Furthermore, data was also available to identify any patient who may have been already implanted with the recalled devices.

In total, a process that used to take several hours to complete was shortened dramatically. More importantly, the staff could be confident that all items subject to the recall had been identified and the risks to patient care were eliminated.

Conclusion

As the use of medical devices and implants continue to play a role in the provision of perioperative care, it’s likely that incidences of device recalls will also continue. Through the use of technology to automate manual processes and improve the storage and access of important information, there are opportunities to improve the responses to a recall. With the use of RFID-based technology to support these automation needs, healthcare providers can develop a more efficient, accurate, and comprehensive approach in managing device recall processes to maintain the highest levels of quality and safety for their patients.

Sources: