RFID in Healthcare –
A panacea for the regulations and issues affecting the industry?

UPS Supply Chain Solutions℠

Our Insight.
A UPS Supply Chain Solutions White Paper

Patients at a hospital in England were exposed to the human version of mad cow disease when infected equipment was used. Human error caused patients at the hospital to be exposed to the infected equipment. How can health care organizations avoid catastrophic situations like this?[1]

Proper protocols and the use of radio frequency identification (RFID) technology could prevent such outbreaks by ensuring instruments are properly tracked and classified. This and other RFID applications can provide significant benefits to the healthcare industry to ensure patient safety and improve supply chain efficiency. RFID is now generating significant interest in the marketplace because of its robust application capabilities. RFID enables healthcare facilities improve overall safety and operational efficiency because it operates without line-of-sight while providing read/write capabilities for dynamic item tracking.

This and other RFID applications can provide significant benefits to the healthcare industry in terms of ensuring patient safety and improving supply chain efficiency.

Why RFID Adoption Has Been Slow

For a variety of reasons, adoption of RFID technology by the healthcare industry has been sluggish because payback is less immediately visible than what most companies prefer. Although costs are decreasing, many companies are reluctant to invest in a technology not yet widely adopted.

Maximizing RFID benefits also requires modifying existing business processes, a daunting task that usually entails changes in technology investment strategies. Without clear RFID standards and data ownership policies, investment in RFID has been a difficult proposition.

Compelling Developments

However, recent developments have made RFID applications more compelling.

1) RFID costs are expected to decline significantly. RFID tags costs dropped from $1 in 2000 to 20 cents in 2004, and are expected to fall to 5 cents by 2006. In 2004, readers cost about $1,000 but are expected to fall to only $200 by 2006.[2]

[1]"Can RFID Cure Healthcare's III's?" RFID Journal, November 12, 2002.
[2]"The True Cost of Radio Frequency Identification (RFID)," High Jump Software, a 3M Company, February 2004.

2) Coupling RFID technology with the electronic product code (EPC) will provide the capability to locate and track items throughout the supply chain, allowing significantly more data to be attached to items at the pallet and case level. EPC Global, a subsidiary of the Uniform Code Council (UCC), is leading the development of industry-driven standards for the EPC Network to support the use of RFID in today's fast-moving, information-rich trading networks. EPC Global and EAN International are writing specifications on the content for 96-bit EPC tags. EAN International is the global not-for-profit organization that creates, develops and manages the EAN-UCC standards jointly with the UCC, one of its member organizations.

3) New regulatory requirements such as the Florida Pedigree Act mandate that important information accompany each drug throughout the supply chain. Using RFID will allow healthcare companies to capture required information such as drug name, dosage, container size, number of containers, lot/control numbers, etc.

RFID technology can improve the tracking of drug usage throughout the clinical-phase testing protocols.

4) Tampered or adulterated products entering the healthcare supply chain is a growing concern. In light of the 9-11 terrorist attacks and the anthrax-tainted mail found in the United States, both consumers and manufacturers are looking for ways to keep drugs safe.

Overall, healthcare companies need the types of solutions that RFID can provide. Numerous RFID applications for both hospitals and pharmaceutical companies can benefit customers and patients.

Healthcare Marketplace Needs and RFID Solutions

Pharmaceutical Applications

Drug Counterfeiting
Pharmaceutical companies, distributors, and hospitals need technology to deter drug counterfeiting. The World Health Organization estimates that between 5 to 8 percent of global pharmaceuticals are counterfeit. In some countries, the percentage of counterfeit drugs is significantly higher at between 25 to 40 percent. Thus, the pharmaceutical industry reports that it loses $2 billion per year due to counterfeit drugs.[3]

[3]"Pharmaceutical Product Tampering News Media Factsheet," HDMA, April 2004.

Counterfeit drugs adversely affect people's lives by preventing patients from receiving needed medication. Fortunately, RFID/EPC tags can help detect products that are:

- Counterfeit or fake
- Tampered with, adulterated or substituted
- Unacceptable (i.e., expired, discarded, returned, recalled, etc.)[4]

Clinical Trials

The pharmaceutical drug approval process is rigorous and dependent on meticulous documentation. As new drugs go through the clinical trial phase, accurately tracking patient usage is crucial. RFID technology can improve the tracking of drug usage throughout the clinical-phase testing protocols. Improved tracking and accountability can improve the reliability and speed of the United States Food and Drug Administration (FDA) drug approval process.

RFID technology that improves visibility into returns could enable faster redeployment.

Inventory Management

Manufacturers and distributors need improved visibility throughout the supply chain to gain an accurate account of inventory. Lack of visibility of customer orders results in increased inventory because healthcare practitioners often keep buffer stocks to avoid stock outs. Increased inventory visibility could reduce buffer stocks by substituting knowledge for inventory, thereby reducing total inventory costs.

Hospital and Medical Device Company Applications

Medical Device and Asset Tracking

RFID has strong application potential with medical device companies. The FDA requires medical device companies to be able to identify each unit by serial number. Medical device companies need better control of implants on consignment with hospitals because returns can occur more than 50 percent of the time. RFID technology that improves visibility into returns could enable faster redeployment since the company would know sooner when an unused product could be returned.

Surgical instruments and other devices must be properly cleaned and packaged between uses. Tags on the instruments and readers on the sterilization chambers and storage cabinets can validate proper cleaning and help locate needed instruments. Since medical devices are often mounted on portable carts, smart tags placed on the devices and readers installed in the doorways can enable personnel to quickly locate a crucial piece of equipment and immediately determine its fitness for use.

[4] Koh R., E.M. Schuster, I Chackrabarti, and A. Bellman, "Securing the Pharmaceutical Supply Chain," Auto-ID Center, June 1, 2003.

Similarly, catastrophic errors would be completely traceable from manufacture to use, and preventative maintenance on equipment could be more accurately tracked.

Patient Tracking
Patient identification and location assistance are often needed to ensure patient safety when urgent medical attention is needed. Patient tags with RFID chips will meet this need.

Product Tracking
Hospitals currently have to track radioactive isotopes throughout the facility from storage to transport and then from administration to disposal. RFID tags and readers can automate these tasks thereby saving time and resources.

Realizing the full benefits of the technology will require companies to make changes in their business processes.

Active RFID tags with read/write capabilities can be used to detect seal integrity for containers and individual packages. The tag can record the time and duration of seal loss, allowing even problems that occur mid-shipment to be detected.

Inventory Management
Large amounts of inventory typically can be found in hospital operating rooms. Lack of visibility in the supply chain coupled with the unauthorized purchase of certain items often results in the proliferation of "unofficial" inventory that could be reduced by properly managing the materiel ordering process. RFID technology can provide an accurate account of both official and unofficial inventory levels. Proper diagnosis of the problem will drive the implementation of corrective solutions.

Following the example of leading retailers, hospitals could move to the next generation of supply chain management by having their suppliers manage product ordering and inventory levels. Hospital suppliers would then be responsible for providing product on a timely basis through RFID technology. A dramatic shift in how hospital supplies are ordered could drive down hospital inventory levels assuming the proper processes and metrics are in place.

Barriers to RFID Adoption

Key barriers to RFID adoption stem from previously high technology costs. Payback periods have typically been too long. Companies are waiting for RFID technology to drop in price, thus making it a more affordable investment. Lean information technology budgets mean that new technologies need to demonstrate compelling business cases and short paybacks on investments. Companies are skeptical if the costs cannot be offset by the promised benefits.

Realizing the full benefits of the technology will require companies to make changes in their business processes. For example, tagging medical devices and placing readers in doorways at hospitals will require an initial deployment and a change in protocols for locating assets. While the initial training will require coordination and effort, the decrease in time spent looking for assets and increased asset utilization will improve the overall efficiency of the hospital.

An additional barrier to RFID technology investment stems from the view that applicable standards are lacking. EPC Global, however, is working to create the EPC which will provide significantly more data capabilities for the 96-bit EPC tags. The EPC will enable more information to be captured than the current Universal Product Code (UPC) which can only contain 12 bits of information. The EPC will enable more salient and detailed information to be captured for a product down to the item level. The tag can then be programmed to hold information such as an item's serial number, size, manufacture date, price, and its distribution touch points, thus enabling greater product accountability and safety.

RFID Decision Factors

Pharmaceutical industry leaders such as Pfizer, CVS/pharmacy, Abbott Laboratories, Cardinal Health, Johnson & Johnson, and McKesson are studying the safety and security of the pharmaceutical supply chain. They are also interested in knowing how to improve returns management and increasing the efficiency of distribution operations.[5]

The adoption of RFID technology in the pharmaceutical industry depends on the creation of open standards, FDA approval, packaging redesign, and technology validation. Freeing up enough capital for investment in RFID/EPC technology can occur if in-house consolidation across servers, networks and data storage occurs.

Many companies are also waiting for RFID technology prices to drop and for case studies that strongly illustrate the benefits of RFID in business operations. As the RFID technology prices decline and applications become more robust, RFID technology will be increasingly adopted.

[5]"SupplyLinx: Target Issues RFID Mandate; Other Positive RFID Data Points," Bear Stearns Equity Research, February 23, 2004.

Mandates

Retail companies are leading RFID adopters. Wal-Mart, for example, has mandated their top 100 suppliers to adopt RFID technology, enabling increased inventory visibility and management. Similarly, Target has required its suppliers to use RFID technology at the pallet and case levels for some of its regional distribution centers by 2005. Target then expects the rest of its suppliers to adopt RFID by 2007.[6] The Department of Defense has also mandated that its top 100 suppliers utilize RFID technology.

While mandates for utilizing RFID technology are occurring, the ultimate responsibility for adopting RFID will depend upon a company's ability to develop a compelling business case and effectively pilot RFID applications.

Companies will have to weigh a host of considerations before deciding to invest in RFID technology.

Companies will have to weigh a host of considerations before deciding to invest in RFID technology. Considerations to balance will include tag readability, tag price points, system integration costs, hardware and setup costs, management, ownership and sharing of data, business process changes, privacy concerns, and standards, i.e., EPC vs. the International Organization of Standards (ISO), a non-governmental network of the national standards institutes of 148 countries.

Companies will be looking for favorable payback periods because competing priorities for financial expenditures warrant careful consideration before investing in new technology applications.

RFID and Bar Coding

While the bar code is widely accepted in the marketplace, RFID offers some distinct benefits:

- No "line of sight" requirements
- More automated reading
- Less labor required
- Improved read rates
- Larger data capacity
- Ability to "write" information on a tag
- Effectiveness in harsh environments (e.g., temperature extremes, dusty and dirty conditions)

Companies will have to consider the cost of either implementing RFID as a way to augment bar coding or to replace it. Bar coding, however, is a mature and proven technology that works well in numerous applications such as inventory management. Adopting RFID requires careful analysis to demonstrate that the incremental advantages significantly outweigh the benefits derived from bar code technology.

[6]"SupplyLinx: Target Issues RFID Mandate; Other Positive RFID Data Points," Bear Stearns Equity Research, February 23, 2004.

Organizations and Associations Supporting RFID

Although the FDA has not yet mandated RFID adoption, it has recommended tagging of unit-level drugs that are likely to be counterfeited by 2006 and has called for the tagging of all drugs at the pallet, case and unit levels by 2007.[7] The Healthcare Distribution Management Association (HDMA), a non-profit organization for distributors of pharmaceutical drugs, also issued a position statement in November 2003 recommending that pharmaceutical manufacturers and wholesalers begin putting RFID tags with EPC on cases in 2005 and deploy the infrastructure needed to take advantage of those tags. The recommendation also included the incorporation of EPC tags at the selling unit level by 2007.

AdvaMed, an advanced medical technology association, supports the use of automatic identification for medical devices on a voluntary basis. AdvaMed also recommends that reprocessed or refurbished items should be treated no differently than other medical devices. AdvaMed believes it is up to manufacturers to apply automatic identification to items where it makes sense economically and technically.[8]

Clearly, organizations and associations support RFID technology as a means for addressing product safety and accountability. However, companies that adopt the new technology will have to carefully update their internal processes and protocols to take advantage of the benefits that can be realized from RFID.

Case Studies

Companies are currently using RFID technology in the healthcare industry as a way to enhance patient safety and improve inventory management capabilities. For example, the United States Navy replaced a labor-intensive, manual patient location system in Pensacola Fleet Hospital in Iraq with an RFID system. Hospital personnel are using RFID-enabled wrist bands to identify, locate, and obtain status updates on their patients. According to Hospital Corpsman Chief Petty Officer Michael Stiney, U.S. Navy, "The ability to keep important information with each patient, and to track his or her whereabouts automatically have helped medical professionals at this facility better manage patient care."[9]

[7] "SupplyLinx: Target Issues RFID Mandate; Other Positive RFID Data Points," Bear Stearns Equity Research, February 23, 2004.
[8] "A Position Paper on Automatic Identification for Medical Devices," AdvaMed, September 12, 2002.

RFID is often used on patient wristbands to provide accurate identification and maintain the safety of newborn infants. Alzheimer facilities have RFID readers installed at doors to help determine patients' locations and maintain their safety should they enter unauthorized areas.[10]

Three Virginia hospitals operated by Bon Secours Richmond Health System will use an RFID network in each hospital to determine the exact location of tagged medical equipment and mobile assets. The RFID network will enable each hospital to determine if an item is in use, available, or if it needs servicing. Approximately 10,000 pieces of equipment will be handled by the inventory management system.[11]

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Another application for RFID tags exists in prescription bottles used by blind or visually-impaired individuals. Patients can use devices placed on prescription containers to "read" the prescriptions and learn dosage amounts verbally through the use of speech conversion technology.[12]

A reliable and cost-effective packaging solution for medication tracking exists in using RFID technology to record patient usage when the tablet is expelled from the packaging, enabling accurate capture of clinical data without manual data entry.[13]

In Summary

Although healthcare companies are slowly adopting RFID, usage is expected to accelerate when RFID technology prices drop and companies become more confident of the applications. RFID's strong functionality can improve a company's operational efficiency by reducing labor and enhancing product visibility, thus reducing overall inventory levels.

FDA and HDMA recommendations for tagging drugs in the next few years should have a ripple effect on the pharmaceutical industry. Patient safety and product tracking requirements will necessitate the adoption of RFID technology. Accounting for drugs' authenticity and status (e.g., expired, discarded, recalled) will be accomplished through RFID/EPC tags that meet identification and anti-counterfeit

[9]"United States Navy Tracks Wounded in Iraq With ScenPro's TacMedCS Program Using RFID Technology from Precision Dynamics Corp. and Texas Instruments," http://www.pdcorp.com/company/archives/2003/052003.html, May 20, 2003.
[10]"RFID: The Next Generation of AIDC," Zebra Technologies, 2003.
[11]"Hospitals Get Healthy Dose of RFID," RFID Journal, April 27, 2004.
[12]"RFID: The Next Generation of AIDC," Zebra Technologies, 2003.
[13]"Med-ic™ ECM™ Packaging," International Paper Smart Packaging, www.ipsmartpackaging.com.

requirements. Thus, pharmaceutical companies will continue to study RFID technology and discover that the applications warrant capital investment supported by strong business cases.

Hospitals already have strong RFID applications which include asset and medical device tracking to promote patient safety and increase operational efficiency. In addition, some hospitals that have not yet adopted bar code technology can use RFID technology to leapfrog their competition in maintaining better asset visibility while reducing inventory levels.

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