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Fall 2016

Could the Pharmaceutical Industry Benefit from Full-Scale Adoption of Radio-Frequency Identification (RFID) Technology with New Regulations?

Alberto Coustasse DrPH, MD, MBA, MPH Marshall University, coustassehen@marshall.edu

Craig Kimble PharmD, MBA, MS, BCACP kimble7@marshall.edu

Robert B. Stanton MBA, PharmD Marshall University, rstanton@marshall.edu

Mariah Naylor

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Recommended Citation

Coustasse A, Kimble CA, Stanton RB, Naylor M. Could the Pharmaceutical Industry Benefit from Full-Scale Adoption of Radio-Frequency Identification (RFID) Technology with New Regulations? Perspectives in Health Information Management. Fall, 2016. http://perspectives.ahima.org/couldpharmabenefit/

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by Alberto Coustasse, DrPH, MD, MBA, MPH; Craig A. Kimble, PharmD, MBA, MS, BCACP; Robert B. Stanton, MBA, PharmD, and Mariah Naylor, MS

Abstract

Healthcare regulators are directing attention to the pharmaceutical supply chain with the passage of the Drug Quality and Security Act (DQSA) and the Drug Supply Chain Security Act (DSCSA). Adoption of Radio-Frequency Identification (RFID) technology has the ability to improve compliance, reduce costs, and improve safety in the supply chain but its implementation has been limited; primarily because of hardware and tag costs. The purpose of this research study was to analyze the benefits to the pharmaceutical industry and healthcare system of the adoption of RFID technology as a result of newly implemented supply chain regulations. The methodology was a review following the steps of a systematic review with a total of 96 sources used. With the DSCSA, pharmaceutical companies must track and trace prescription drugs across the supply chain, and RFID can resolve many track-and-trace issues with manufacturer control of data. The practical implication of this study is that pharmaceutical companies must continue to have the potential to increase revenues, decrease associated costs, and increase compliance with new FDA regulations with RFID. Still, challenges related to regulatory statute wording, implementation of two-dimensional barcode technology, and the variety of interfaces within the pharmaceutical supply chain have delayed adoption and its full implementation.

Keywords: costs, Drug Quality and Security Act, Drug Supply Chain Security Act, pharmaceuticals, radio-frequency identification, RFID

Introduction

Healthcare expenditures in the United States neared \$2.6 trillion or 17.9 percent of the gross domestic product (GDP) in 2012.^{1, 2} Healthcare expenditures are much higher in the United States than in other western countries such as the United Kingdom (9.4 percent), France (11.7 percent), and Canada (10.9 percent). In the United States, it has been forecasted that healthcare expenditures, if they continue on their current track, may exceed 20 to 25 percent of GDP by 2020.³ This cost shows the need for innovation that can drive the United States toward a more cost-efficient healthcare system. Currently, prescription drug costs total approximately \$250 billion and are the third leading healthcare expense.⁴ To decrease total overall drug spending, which is a significant portion of the total overall healthcare expenditures, it is necessary to reduce expenditures in the pharmaceutical industry, such as those that result from process inefficiencies and lack of patient safety.⁵

Radio-frequency identification (RFID) can help provide a quick way to retrieve information, track pharmaceuticals or items in the supply chain, and help avoid the costs associated with counterfeit or adulterated medications.⁶ RFID is a technology that uses radio waves to automatically track people or objects and associate programmed information with these people or objects. This system is composed of a tag, a reader, an antenna, and software. The tag is placed on an individual object, which allows for unique identification. When an RFID-tagged item is sent through a reader's field of view, a distinct data code is transmitted. The antenna transfers the information from the tag to the reader or vice versa.⁷ RFID tags are classified as active or passive.⁸ Active tags are battery powered and transmit a signal over 100 feet at predetermined intervals and in healthcare are commonly used for the tracking of equipment or bins. Passive tags are activated by an outside power source when they are swiped within the field of a reader. The tags can be read-only or read-write. Read-only tags transmit data from the RFID reader to the database, whereas read-write tags can retrieve or send data.⁹

RFID technology was invented in 1948 but was not applied commercially until the 1990s, when standards for the technology were developed. Between 2000 and 2010, wide-scale adoption of RFID technology began.¹⁰ Large retail companies were leading RFID adopters. In 2003, Wal-Mart began implementation of a plan that was supposed to result in all suppliers using RFID tagging on products distributed by 2006. The technology was expected to increase inventory visibility and management. Initial phases of the plan showed a 16 percent reduction in out-of-stock items. As the Wal-Mart implementation continued, supplier compliance diminished, largely because of suppliers not wanting to implement multiple systems, variances in state regulations, and comparatively high tag costs compared to the costs of linear and matrix bar codes, which challenged the success of the plan. Wal-Mart's implementation of RFID gained groundbreaking recognition and served as an example for other companies that desired to implement the technology, but the technology never quite caught on with pharmaceutical manufacturers.¹¹

Although RFID is a more reliable technology, the use of bar coding (especially two-dimensional [2D] bar coding) has been a more widely accepted form of electronic identification in the pharmaceutical industry.¹² RFID, however, has many advantages over linear 2D bar coding. A barcode on a pharmaceutical bottle contains a stock-keeping unit (SKU) representing the national drug code (NDC) and may contain other information such as expiration date, package size, and lot number, but it does not change without being replaced with a new sticker or package requiring a direct line of sight. In addition, the barcode is easily counterfeited, whereas an RFID tag is almost impossible to counterfeit. An RFID tag contains an electronic product code, which is a unique identifier for each item or serial number (no two items are identical). This identifier can be associated with all kinds of information, such as specific dates on which it was held in a warehouse, transferred to another supplier, or returned to the manufacturer. RFID eliminates the need for a direct line of sight to the tag. While traditional linear 2D barcodes and matrix barcodes can contain a lot of information, they are still limited in the total amount of information stored and must be replaced if changes are made. The major limitations of barcodes are that they are printed, so a new barcode has to be applied to the product to update the product, and they also require a line of sight. In contrast, RFID tags offer track-and-trace technology that can be programed by the manufacturer and secured for information governance (read-only tags) and is virtually impossible to copy or counterfeit, which is vital for the drug pedigree.^{13, 14} They also can come in other forms including readwrite, write-once, and read-many, which can be valuable if information needs to be adjusted or circumstances vary. Exposure to the outdoors, package tears, external markings, stickers, chemicals, moisture and extreme temperatures renders traditional 2D barcodes unreadable, thus requiring frequent replacement and opening the door to potential errors. RFID tags are more resistant to environmental conditions and are also embedded within the product by the manufacturer, decreasing replacement costs.¹⁵ Limitations of RFID technology may include liquid or compounded dosage forms, where tags may not work well, and the fact that there are multiple frequencies in use with RFID.

Read times of less than 100 milliseconds allow large numbers of RFID tags to be scanned at once.¹⁶ Barcodes are programmed for specific products and cannot be altered, whereas RFID tags are rewritable and reusable up to thousands of times. They have been successfully used by pharmacy automation companies and warehouses in supply chain applications with well-documented return on investment

(ROI). In addition, many components of RFID have advantages over bar coding technology that can improve the effectiveness and security of the supply chain industry.¹⁷

Automatic data collection is necessary in the pharmaceutical industry to ensure patient safety and decrease expenses.¹⁸ The cutting-edge technology of RFID has the potential to decrease the immense costs in the pharmaceutical industry by augmenting patient safety, ensuring visibility of products, and simplifying management of inventory.¹⁹ In addition, it has become a much more affordable option as the technology has matured, with a passive tag cost of \$0.10 to \$0.50 per tag.²⁰

The purpose of this research study was to analyze the benefits to the pharmaceutical industry and healthcare system of the adoption of RFID technology as a result of newly implemented supply chain regulations.

Methodology

The research approach of this review followed the steps and research framework utilized by Yao, Chu, and Li (2010).²¹ Figure 1 displays the process of RFID adoption in healthcare. To research how RFID systems can help improve the pharmaceutical process, the first requirement is to identify the existing benefits of its adoption in the US pharmaceutical supply chain and problems with RFID adoption. Solutions can then be identified to resolve or partially resolve these challenges. The use of the conceptual framework of this study was appropriate because it addressed the process of adopting and utilizing any health information technology (HIT) system. The technology adoption process works much like any project development system in that it is circular; it starts with problems and issues, and needs are determined before a solution is created and initialized. In this case, the solution is the utilization of an RFID system. After the RFID system has been adopted, the process includes an assessment of the benefits of and barriers to the use of RFID, and the process starts over so that the barriers can be addressed and the benefits assessed (see Figure 1). The use of this conceptual framework in the present study is applicable because the focus is to show how new technologies can be applied in healthcare settings. In addition, this approach has been successfully replicated in previous studies, supporting its internal validity.^{22,23}

The methodology for the examination of the benefits of and barriers to RFID adoption followed the basic principles of a systematic review. The study was conducted in three stages: (1) identifying the literature and collecting the data, (2) analyzing and evaluating the literature found, and (3) categorizing the literature.

Step 1: Literature Identification and Collection

The methodology used for this review consisted of a literature review and research of case studies following the basic principles of a systematic search. The electronic databases EBSCOhost, Academic Search Premier, CINAHL, Business Source Premier, Iowa Drug Information Service (IDIS), and MEDLINE were searched for the terms *RFID* AND *pharmaceutical industry* OR *pharmacy management* OR *pharmacy* OR *medicine* OR *pharmaceutical*. Reputable websites including Kaiser Permanente, RFID Incorporated, RFID Journal, and other reliable healthcare and technology websites were also used.

Step 2: Literature Analysis

Literature was selected for review on the basis of benefits of and barriers to RFID implementation. Inclusion and exclusion criteria were as follows: Only articles published from 2006 to 2015 were utilized to keep this review current. The search was restricted to sources attainable as full texts and written in the English language. Only primary and secondary data from articles, reports, reviews, and research studies written in the United States were included in this research study.

Step 3: Literature Categorization

Abstracts of the articles were reviewed first to determine the relevancy of the data to the study. Citations and abstracts identified by the search were also assessed in order to identify relevant references. If academic articles and studies were found to be appropriate from the abstract reviews, the full articles were analyzed and categories were generated on the basis of the findings. The literature review generated 96 sources that were assessed for information pertaining to this research project, and 62 were used in the

Results section. The literature search was conducted by M.N and C.K., MT and was validated by A.C., who acted as a second reader and also double-checked that the references met the inclusion criteria of the research study. The results were organized following the conceptual framework, which employed subcategories including the cost of counterfeit drugs to the pharmaceutical industry and RFID as a solution (20 references), implications of RFID for patient safety in pharmaceuticals (20 references), and RFID and improvement of efficiency in pharmaceuticals and the supply chain (22 references)

Results

The Cost of Counterfeit Drugs to the Pharmaceutical Industry and RFID as a Solution

Counterfeit drugs are a growing problem in the pharmaceutical supply chain worldwide (see Table 1). The World Health Organization (WHO) has stated that about 10 percent of the pharmaceutical trade globally has been confirmed counterfeit.²⁴ The global market is expected to see a 90 percent rise in the amount of counterfeit drugs from 2014 to 2019, and it has been reported that about \$75 billion annually will be spent on purchasing and dealing with counterfeit products.²⁵ In addition, legitimate manufacturers lose \$32 billion yearly in revenue because of fraudulent drug activity.²⁶

Because of the complexity of the pharmaceutical distribution infrastructure, less than 1 percent of the four million pharmaceuticals shipped via the US mail system are screened by the Food and Drug Administration (FDA).²⁷ This lack of screening has resulted in up to an estimated 10 percent of pharmaceutical packages containing unauthorized drugs.²⁸ It is also widely believed that RFID implementation is the most promising technology to quickly combat counterfeit drugs and ensure compliance with new track-and-trace regulations, especially because the information can be governed by the future. ²⁹ (See Table 1.) Other technologies under development could replace this technology in the future. However, technologies beyond RFID systems are not ready for full-scale implementation across the pharmaceutical supply chain.

According to Bacheldor (2007),³⁰ only 12 percent of pharmaceutical companies were adopting RFID, 16 percent were evaluating the benefits, 10 percent were unaware of the technology, and 40 percent were aware but not evaluating it when the Wal-Mart program gained momentum. For varied reasons, the pharmaceutical industry has been slow to adopt RFID technology. One of the biggest barriers to full scale RFID in the Pharma supply chain has been the pharmaceutical companies' perception that the ROI is not achieved in the short term. Perception has been that RFID is an expensive long-term investment with only partial adoption with achievement of ROI only being achieved over time. There has historically been a significant expense to complete software and hardware implementation with a significant ongoing cost tag post implementation.³¹ Attaran (2012)32reported that the implementation of a complete RFID system, in a large manufacturing company, can cost \$10 to \$25 million. Some companies may see the investment as a financial risk, but some studies have shown that the ROI may be tenfold, and this knowledge may influence healthcare institutions' decision to implement RFID.³³ For example, after RFID was implemented at RiteCare Pharmacy, the cost of warehouse inventory was reduced by 60 percent, order fulfillment time was cut in half, and salary expenses were decreased. Accuracy, scalability, productivity, and customer satisfaction increased, proving the potential for a positive ROI with RFID implementation.³⁴

Another challenge of RFID is that the technology is scalable across the US pharmaceutical supply chain but has yet to be fully implemented and prior to the DSCSA was covered under individual state regulations. That chain is composed of multiple segments, each of which would have to have the technology implemented to fully utilize RFID to its potential.³⁵ These segments include manufacturers and their affiliates, drug wholesale distributors, secondary or gray-market suppliers or intermediaries, retail pharmacies, hospital pharmacies, specialty pharmacies, physician offices and clinics, dental offices, and companies that handle pharmaceutical returns.³⁶ The complexity of the healthcare distribution system and its many different processes and systems has complicated the full utilization of RFID.

RFID has allowed the creation of electronic drug pedigrees (e-pedigrees) instead of the current manual ones. E-pedigrees are auditable electronic documents that provide the distribution history of a drug, including the dates of sales, purchases, or trades as well as the parties associated with each

transaction.³⁷ E-pedigrees help to ensure authenticity of the medication through the supply chain. Also, this feature seems to be one of the most promising areas of use for the RFID technology, and the new rules seem to have generated additional interest in the implementation of RFID. Pharmaceutical pedigrees have historically been and continue to be recorded on paper, allowing room for gaps, forgery, and drug counterfeiting and creating storage and retrieval challenges.³⁸ Unlike paper pedigrees, e-pedigrees contain technology to prevent tampering, thereby reducing the amount of drugs counterfeited and the revenue losses experienced by pharmaceutical companies.³⁹

One barrier that has slowed implementation of RFID has been the multiple regulatory processes in a complex system. Previously there were no federal or global standards that guided the pharmaceutical industry on standardization of drug pedigrees. In addition, the worldwide pharmaceutical supply chain offers multiple opportunities for a product to become contaminated, diverted, or adulterated. At the state level, numerous attempts have been made to tighten licensing and regulations of the pharmaceutical supply chain. These attempts include, but are not limited to, track-and-trace legislation put into place in California several years ago. Even with tight state regulations, counterfeiting and product alteration remains at an all-time high worldwide. Newly passed federal regulations attempt to streamline and standardize a very complex system and to provide guidance on this issue.

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA), which became law, amending the Federal Food, Drug, and Cosmetic Act.^{40,41} Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), sets forth new definitions and requirements related to product tracking and tracing of prescription drugs, including the work of drug wholesale distributors and third-party logistics providers.⁴¹ These rules replace the previous differing state rules and regulations concerning the pharmaceutical supply chain and standardize the US market's track-and-trace rules. The DSCSA outlines critical steps to build an interoperable electronic system by November 27, 2023, which will identify and trace certain prescription drugs as they are distributed in the United States, facilitating the exchange of information at the individual package level about where the drug has been in the supply chain.⁴² This new system will enhance the FDA's ability to help protect US consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain.

New supply chain regulations will require several key items in the future. Both manufacturers and repackagers will need to put a unique product identifier on prescription drug products, starting with the lot level and eventually at the package level, including either an electronically readable barcode, RFID tag, or other method of identification. Systems to identify products must be implemented and standardized. Regulations also require a process to quarantine or segregate inventory that is suspected to be counterfeit.⁴³ Products must also have product tracing throughout the drug supply chain identifying each time a product is handled. New track-and-trace rules for manufacturers and repackagers went into effect on January 1, 2015. Beginning July 1, 2015, the drug supply chain began providing information about each time a product is handled or sold in the US market, including lot number, transaction history, and a transaction statement. As key elements are phased in over the next several years, the opportunity to maximize the use of RFID to meet these guidelines becomes more affordable and more appealing to pharmaceutical manufacturers. With new regulations in place, there now seems to be momentum to make the change from paper pedigrees to e-pedigrees, and RFID can help accomplish this task.

Implications of RFID for Patient Safety in Pharmaceuticals

A medication error is an avoidable event that leads to inappropriate medication use or patient harm. An estimated 1.5 million medication errors occur annually in the United States.⁴⁴ Medication errors cause up to 200,000 injuries or deaths in the United States annually.⁴⁵ These errors can occur during prescription writing or filling, order communication, product labeling, packaging, compounding, dispensing, distribution, and administration.⁴⁶ RFID technology, through automatic identification, can detect and avert errors during medication administration and has penetrated through the healthcare system.⁴⁷ Use of RFID has been estimated to decrease this risk across the healthcare continuum in a variety of ways.⁴⁸

In 2008, it was estimated that the cost of medical errors equaled \$17.1 billion. This amount was also 72 percent of the \$2.391 trillion that was spent on healthcare in 2008.⁴⁹ To prevent medication errors, five "Rs" have historically been assessed prior to administration of medications, including right medication, right patient, right time, right dosage, and right route. Implementation of RFID decreases the risk of a medication error by ensuring four of these five items.⁵⁰ RFID tags on medication bins, the patient's wristband, and the provider's identification badge serve to reduce medication errors. RFID technology has also led to more accurate assessment of patient allergies and drug interactions, further decreasing the risk of adverse events.⁵¹

RFID tags in the pharmaceutical industry have helped to reduce the adverse effects associated with patient noncompliance.⁵² With increased demands, physicians spend an average of only six to eight minutes with each patient, leaving limited time to explain the medication regimen, purpose, and detrimental effects of noncompliance.⁵³

Patient safety has improved as a result of pharmacies' ability to efficiently manage expired and recalled drugs. ⁵⁴ Recalls have been a growing concern, increasing 309 percent from 2008 to 2009 and continuing to grow as medication suppliers become more global in nature.⁵⁵ RFID can track the location of recalled medication within the supply chain.⁵⁶ RFID tags combined with "smart shelves," automated cabinet or robotic dispensing, and other inventory management tools help to identify drugs that have been recalled by reading lot numbers.⁵⁷ The patient or pharmacy can then be contacted and informed of the recall.⁵⁷

A growing threat to international health is counterfeit drugs, which have been associated with approximately 1 to 10 percent of the drug supply in developed nations, 10 to 30 percent of the drug supply in developing nations, and more than 50 percent of the drug supply in certain Asian and African markets.⁵⁸⁻⁶¹ This threat has created an urgent need for tracking of medications from the manufacturer to the patient.⁶² The World Health Organization (WHO) has estimated that 30 percent of the drugs in Asia, Africa, and Latin America are counterfeit. This has a direct effect on the United States because 40 percent of drugs are from overseas, and 80 percent of the ingredients are imported.⁶³ E-pedigrees protect consumers from contaminated and counterfeit drugs by verifying the authenticity of the drug before it reaches the consumer.⁶⁴

Medication errors have created an added financial burden on the healthcare system because they are classified as "never events" and are not reimbursed by the Centers for Medicare and Medicaid Services (CMS).⁶⁵ The malpractice claims that partially stem from these errors cost \$55.6 billion in 2010.⁶⁶ Using RFID technologies to improve patient safety and satisfaction can help to decrease malpractice claims, reduce the number of dispensing errors, and help to control the rising costs of healthcare.⁶⁷

Another major concern that has arisen among pharmaceutical companies and patients alike is the fear of invasion of patient privacy.⁶⁸ RFID tags are reusable and can be read from a distance through various materials. The obtainment of private information by unauthorized users raises the question of whether tags should be capable of authenticating the reader. It is also important to determine if the tags should be decommissioned to protect patient privacy.⁶⁹ The process of protecting patient privacy has been called "privacy by design" or "Architected IT." and has shown that privacy concerns are valid, but it has been noted that RFID helps to protect patient privacy because of the special devices necessary to read the tags.⁷⁰

RFID and Improvement of Efficiency in Pharmaceuticals and Supply Chain

Approximately \$11 billion healthcare dollars were wasted in 2008 because of the lack of supply management structure.⁷¹ Many of the inefficiencies in the pharmaceutical industry originate from the inventory management of recalled, expired, overstocked, and out-of-stock drugs. RFID uses precise automated inventory management to help overcome these inefficiencies.⁷²

Drug companies lost more than \$2.7 billion in 2010 because of product recall logistics and returns from drug expiring and overstocking.⁷³ In 2006, Barua, Mani, and Whinston⁷⁴ estimated that pharmaceutical stock-outs cost an estimated \$3.14 billion. RFID makes pharmaceutical ordering more

precise by providing real-time current inventory, allowing maintenance of smaller stocks and thereby reducing the amount of drugs that expire and are wasted.⁷⁵ With the use of RFID, pharmaceutical companies can manage as much as 40 percent of their inventory more efficiently, potentially saving large manufacturers \$17 million to \$55 million annually.⁷⁶ The decrease in pharmaceutical costs and overall healthcare savings is beneficial to all US healthcare consumers.⁷⁷

The time and funds spent tracking and replacing expensive equipment are a source of significant costs for pharmacies.⁷⁸ Historically, pharmacies have used manual processes to manage their assets, resulting in high labor costs, opportunities for diversion, lost time, and the possibility of human error. RFID tracking can increase efficiency and reduce costs related to asset management.⁷⁹ RFID access points set up throughout facilities provide the exact location of mobile RFID-tagged items.⁸⁰ RFID has also helped pharmacies improve asset utilization by reducing expenses related to lost and stolen equipment.⁸¹

The many methods of improved efficiency have served to reduce labor costs for pharmaceutical companies.⁸² Also the benefits of RFID in terms of cost reduction can be seen in hospitals, as in the example of Mission Hospital in California. After the hospital's implementation of RFID asset-tracking technology, the rate of lost and stolen devices decreased from 13.8 percent to none, resulting in annual cost savings of \$150,000 to \$200,000.⁸³

Inventory visibility is vital when it comes to supply chain management because companies can receive information about their inventory that will improve the management of their assets.⁸⁴ Some hospital administrators are also recognizing this fact, and this low-cost system is improving the quality of care in patients. In 2014 the Texas Health Alliance saved more than \$65,000 every month by using RFID at the Texas Health Harris Methodist Hospital Alliance in Fort Worth.⁸⁵

After the fall of 2012, when 750 individuals were sickened and the deaths of 60 people were caused by contaminated drugs, both houses of Congress decided to strengthen the FDA's ability to support the regulation of large drug companies. This regulation was implemented with the DQSA, which focused on issues of drug compounding and the drug supply chain.⁸⁶ In order to make the drug supply chain more secure, the DSCSA was passed to ensure safety with product identification, tracing, and verification, as well as detection of and response to problems.⁸⁷

Discussion

The purpose of this research study was to analyze the benefits to the pharmaceutical industry and healthcare system of the adoption of RFID technology as a result of newly implemented supply chain regulations. The findings of this study suggest that implementation of RFID technology could help reduce pharmaceutical costs related to counterfeiting, patient safety, and inefficiencies, and result in greater compliance with new track-and-trace regulations.

It has been established that RFID can help to decrease counterfeiting, improve patient safety, and increase pharmaceutical management efficiency, all of which have the potential to decrease pharmaceutical costs. In addition, medication errors can be significantly be reduced. However, implementation of RFID alone is not sufficient. The RFID technology must be integrated into the company's existing workflow and information technology infrastructure. In addition, the RFID technology implemented by a company must be interoperable with the RFID systems of partner companies, and manufacturers want a standard across the world, not multiple systems and varying or inconsistent regulations and standards.

The findings of this study suggest that adoption and use of RFID technology in the pharmaceutical industry can lead to decreased costs and increased supply chain security, resulting in improved patient safety, efficient supply chain management, and reduction in counterfeiting. With the implementation of the new regulations through the DQSA, full RFID implementation across the pharmaceutical supply chain will help reduce the number of medication errors, reduce the number of counterfeit drugs making it into the supply chain, and increase supply chain security by increasing compliance with the federal requirements.

A challenge with RFID implementation is that the type of RFID tag that can be used often depends on the item that is labeled. Errors have been noted in reading RFID tags on liquid items due to attenuation of RFID signals passing through liquids.^{88,89} This fact can require a line of sight to the RFID tag, largely eliminating the advantage of RFID in these circumstances.

A lack of updated quantitative research on the financial benefits of RFID implementation for the pharmaceutical industry was one limitation of the study. There is also limited research on the extent of pharmaceutical companies' implementation of this technology. Of the research found, many of the websites and blogs were not peer-reviewed and could contain biased or inaccurate data. Minimal research was found on how RFID can improve patient safety and pharmaceutical supply chain management; therefore, more research is needed in these areas. Also, further research, such as a rigorous systematic review and/or a meta-analysis, should be conducted to assess future outcomes of RFID implementation in the pharmaceutical industry.

The practical implication of this study is that pharmaceutical companies have the potential to increase the cost effectiveness of supply chain and asset management through implementation of RFID technology. However, to obtain the maximum results, the implementation must include a well-devised plan that is adequately executed to ensure interoperability with the manufacturer's information technology (IT) infrastructure and customers' and partners' current HIT infrastructure.

Conclusion

New regulations on the pharmaceutical supply chain, healthcare reform, and changes in payment to a performance-based system will demand that the pharmaceutical industry provide pharmaceuticals in an efficient, secure, and cost-effective manner, which can be aided by the utilization of RFID.

Alberto Coustasse, DrPH, MD, MBA, MPH, is a professor of healthcare administration at Marshall University in South Charleston, WV.

Craig A. Kimble, PharmD, MBA, MS, BCACP, is an assistant professor of pharmacy practice at Marshall University School of Pharmacy in Huntington, WV.

Robert B. Stanton, MBA, PharmD, is assistant dean of experiential learning at Marshall University School of Pharmacy in Huntington, WV.

Mariah N. Naylor MS, is a graduate student in the healthcare administration program at Marshall University in South Charleston, WV.

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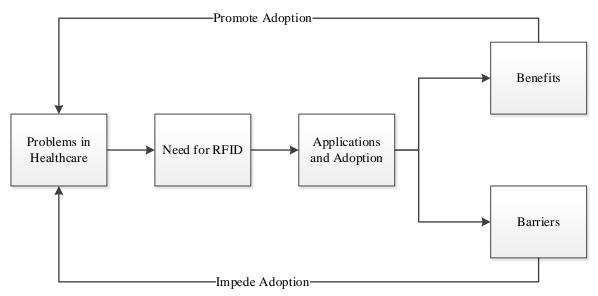
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Figure 1

Research Framework



Source: Adapted from Yao, W., C. H. Chu, and Z. Li. "The Use of RFID in Healthcare: Benefits and Barriers." *Proceedings of the 2010 IEEE International Conference on RFID Technology and Applications (RFID-TA)* (2010): 128–34.

Table 1

Examples of Counterfeit Drug Issues Threatening Health and Safety Worldwide That Are Potentially Preventable with Radio-Frequency Identification (RFID) and Widespread Implementation of e-Pedigree Technology

Drug Name	Issue
Procrit (epoetin alpha) ⁹⁰	Procrit is a drug used in to treat anemia in HIV, kidney failure, and cancer treatments. Counterfeit product that made it into the US market was actually bacteria- contaminated water or diluted product.
Cardiovascular medications like heparin ^{90,91}	Heparin is an anticoagulant also known as a "blood
	thinner." Product was contaminated with oversulfated chrondroitin sulfate somewhere in the supply chain in China. Responsible for 152 adverse events in 113 patients in 13 states.
Biaxin (clarithromycin) and other antibiotics ^{90,91}	Product with no active ingredients (placebos) made its way into the US supply chain. These products could make patients sicker by not treating an infection. Products may also be tainted by heavy metals or other dangerous ingredients.
Lipitor (atorvastatin) ⁹⁰	Large quantity of counterfeit product made its way into the US pharmaceutical supply chain, resulting in a large recall with more than 200,000 units recalled.
Zerit (stavudine) ^{90,91}	HIV medication that had counterfeit and misbranded products (e.g., 40 mg labeled as 30 mg) made its way into the US market. Problems with HIV drugs subject patients to dangers such as lack of treatment and exposure to toxic compounds.
Multiple drugs in Africa including drugs to	WHO reports that many counterfeit items have been
treat HIV, cardiovascular drugs, and drugs	used in Africa, and some nations may have up to 40
used to treat tuberculosis ^{91,92}	percent of their drug supply consisting of counterfeits.
Cialis (tadalafil), Viagra (sildenafil), Levitra (vardenafil) ^{91,93}	Counterfeit versions of erectile dysfunction drugs have been found in the mail on the way to US consumers. Products have been noted to contain any number of hidden poisons such as road paint, antifreeze, or an undeclared and unapproved medication such as Sibutramine.
Botox (Onabotulinumtoxin A) ^{94.96}	Product used for cosmetic purposes and to treat migraines. With one batch, four victims were hospitalized with severe botulism poisoning. The paralysis was temporary as a result of being injected with potent, unapproved botulinum toxin.
Antineoplastic drugs ^{91,95}	Fake cancer drugs have been found in Israel, China, and the United States. Multiple products were affected, including Avastin vials containing no real drug.

Abbreviations: HIV, human immunodeficiency virus; WHO, World Health Organization.