

Healthcare RFID In Germany: An Integrated Pharmaceutical Supply Chain Perspective

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ABSTRACT

Today's healthcare environments are characterized by a variety of products, services, and associated data and information that are transferred across many healthcare sector participants. Pharmaceutical supply chains in particular are one example of fragmented information flows among supply chain participants. Pharmaceutical supply chain processes have a crucial influence on medication quality and ultimate patient outcomes. When manufacturing problems arise, temperature control cannot be maintained throughout the supply chain, counterfeit medications enter the supply chain, containers are damaged or sensitive medication is improperly transported and stored, the drugs' effectiveness can be affected and this can result in serious consequences, including patient sickness or even death. In this paper, we analyze Radio Frequency Identification Technology (RFID), a technology that can improve communication of data and information, reduce counterfeiting, and enable monitoring of drug quality in pharmaceutical supply chains. The study is conducted in the context of an RFID platform implemented in Germany. The paper extends and complements previous studies by analyzing the RFID implementation and business value in an end-to-end supply chain process across multiple stakeholders in the pharmaceutical supply chain, from the manufacturer via the wholesaler to pharmacies and hospitals. The results confirm that RFID benefits are realized when supply chain processes are changed with the help of technology, but that different supply chain participants have different benefit realization perceptions. The analysis further reveals specific types of process changes for each supply chain participant and their corresponding benefits.

Keywords: Healthcare RFID; Pharmaceutical Supply Chain; Germany

INTRODUCTION

Today's healthcare environments are characterized by a variety of products, services, and associated data and information that are transferred across many healthcare sector participants. In many cases, the existing healthcare information technology (IT) infrastructure is fragmented, leading to errors and decreased responsiveness. Pharmaceutical supply chains are one particular area of the healthcare system sensitive to these issues. Pharmaceutical supply chain processes have a crucial influence on medication quality and ultimate patient outcomes. If manufacturing problems arise, if cold chains are interrupted, containers are damaged or sensitive medication is shaken during storage or transport, the use of the affected drugs can have serious consequences, including patient sickness or even death. For example, low quality manufacturing in a U.S. compounding pharmacy yielded contaminated products, resulting in over 300 illnesses and 23 deaths until the illness could be traced back to the source (Cohen & Bonifield, 2012). Counterfeit drugs are another increasing problem worldwide, with over 1,700 incidents reported in 2011, costing the pharmaceutical industry approximately 10 percent of total revenue, and contributing to numerous patient deaths (Chaterjee, 2010; Peronne, 2012). About 70% of fraudulent drugs appear in developing countries (Schweim, 2007), but an increasing number of counterfeit medications are now entering developing country supply chains with tens of millions of counterfeit tablets being

seized yearly in European Union member countries alone (Schiltz, 2009; Perrone, 2012). Few counterfeit drugs have a comparable quality and quantity of ingredients to their legitimate counterparts (Schweim, 2007). In the U.S., drugs affected include Avastin, Viagra, Lipitor, and Alli, while in Germany incidents involve Viramune and Combivir (Klemperer, 2010; Perrone, 2012). Last, but not least, as drugs are transferred across supply chain partners, data accompanying the drugs (name, dose, expiration date, etc.) is captured repeatedly by non-integrated systems, increasing the chance of errors that will adversely affect patients.

In this paper, we analyze Radio Frequency Identification Technology (RFID), a technology that can improve communication of data and information, reduce counterfeiting, and enable monitoring of drug quality in supply chains. Such capabilities are essential in a world of global, distributed supply chain processes, where tracking and tracing of products becomes a necessity for ensuring efficiency and effectiveness (Diessner, 2007; Narsing, 2005). RFID is a communication technology based on radio waves. RFID tags storing identification numbers and other information can be affixed to objects, and RFID readers can query and read the tags automatically and communicate the information to other systems for further processing. Passive RFID tags can store the information and send it back when queried by a reader (up to 4 meters away), while active tags have a power source (battery) and can transmit information independently and at longer distances (up to 100 meters). RFID tags can operate at different radio waves frequencies, and this influences their range (from centimeters to meters to hundreds of meters) and price as well (Asif & Mandviwalla, 2005; Narsing, 2005; RFID Journal, 2012; Zhu et al., 2012).

Major applications of RFID include retail, food services, logistics, travel, library services as well as healthcare. The technology has been implemented in many countries, including the U.S., Taiwan, and other parts of the world, in both the private and public sector (Chong & Chan, 2012; Liao et al., 2011; Narsing, 2005; Zhu et al., 2012). In particular, because of its real-world awareness capabilities (Heinrich, 2005, 2006), RFID is predicted to support the next wave of disruptive innovation for healthcare (Wamba & Ngai, 2012).

This paper focuses on an RFID implementation case study in the healthcare sector: a real-world solution supporting pharmaceutical supply chains in Germany, from the manufacturer via the wholesaler to pharmacies and hospitals. The paper complements previous studies of technology initiatives in the healthcare sector by evaluating the post-implementation benefits in an end-to-end supply chains process, across multiple stakeholders. The paper investigates how the RFID technology proven in other industry settings can be successfully applied to healthcare. The case study uncovers what benefits accrue to supply chain participants, and how. We believe that documenting and communicating the value of the RFID implementation in the German healthcare context should ultimately drive successful adoption by other supply chain participants in other countries as well.

The paper is organized as follows. We review relevant studies on RFID applications, and highlight gaps in the literature. We describe our case methodology and the collected data. We present the industry context and the technology studied, including a general description of RFID technology applications to healthcare, as well as specific details about the RFID solution studied. Finally, we discuss our findings and conclude by presenting contributions and limitations.

THEORETICAL BACKGROUND: RFID APPLICATIONS, ADOPTION, AND DIFFUSION

A recent literature review of almost 100 articles published in journals indexed by SCI or SSCI reveals a significant number of papers describe applications of RFID to logistics and supply chain management, followed by retail application descriptions and implementation descriptions (Liao et al., 2008). These studies reveal that many companies adopting RFID are betting the technology will provide significant benefits. RFID can help prevent inventory shrinkage (due to product theft, misplacement, or damage), improve accuracy of inventory records, and increase information visibility (Zhu et al., 2012). RFID experts agree that RFID has many advantages over barcoding when used for asset management: improve traceability, achieve operational efficiency, provide real-time information access, improve external and internal coordination of material flows, increase visibility, as well as reduce errors and labor costs and increase collaboration and decision, among others (Wamba & Ngai, 2012). RFID technology can help supply chains become more efficient and effective (Narsing, 2005) and support supply chain resilience capabilities such as visibility, collaboration, and agility which are essential for competing in today's complex global business environment (Ponis & Koronis, 2012).

Particularly in healthcare settings, the value of RFID stems from significantly improved process enabled by tracking and monitoring of patients, assets, and medication (Çakici et al., 2011; Tzeng et al., 2008; Zhu et al., 2012). For example, RFID patient tracking is especially valuable in the case of disease outbreaks such as SARS (Tzeng et al., 2008) and for materials and medication management for complex procedures (Çakici et al., 2011). The manual processes that ensure correct use of medication is time consuming and error prone, and can result in mismatches and adverse events for the patient, as well as losses through discarding of mismatched medication and stock and billing errors (Çakici et al., 2011). By eliminating manual processes and solving inventory problems, RFID can become very profitable. It is important to note that RFID technology alone will not lead to improvements unless the processes it supports and the corresponding human resources allocation are also appropriately changed (Tzeng et al., 2008).

Formal models of RFID adoption and implementation can also shed light on the benefits of this technology. Zhou and Piramuthu (2010) build an analytical model showing RFID use for real-time tracking and coordination. They find that RFID leads to more effective processes and better labor allocation. Goebel and Gunther (2011) analyze a store model for item-level RFID tagging for inventory management; their simulation indicates that RFID has a better return on investment for certain types of products (those with low volume, high cost, and subject to shrinkage). Shapanow et al. (2011) build a formal model describing the flow of data in a pharmaceutical supply chain, with a focus on counterfeiting prevention. The results indicate that, using the U.S. supply chain as an example, an RFID solution will need an infrastructure capable of storing 15 billion drug movements per year (or the equivalent of ~ 250 TB of storage).

Several papers investigate other factors, apart from benefits, that influence RFID adoption, implementation and management. For example, Zhu et al. (2012) identify and review existing literature on management issues (deployment and return expectations, cost allocation along supply chain, business value, mandated adoption, and institutional response) and risks and limitations (technology problems and limitations, as well as privacy concerns). Matta and Feger (2011) survey over 200 supply chain managers regarding their cost-benefit perceptions about RFID use. Managers in all parts of a supply chain - manufacturer, distributor, wholesaler, retailer, transportation, and 3rd party logistics are surveyed about RFID costs for adoption, training, and maintenance. The results indicate that on average, maintenance costs are the highest, training costs the lowest, and adoption cost are somewhere in the middle. While maintenance and training costs are similar across managers in all sectors, adoption costs are the highest for manufactures (because they usually have to bear the cost of affixing tags to products, cases, or pallets). In general, manufactures and retailers have more negative perceptions about adoption and overall cost, while hybrid supply chain players (those providing both manufacturing and logistics services) perceive the lowest cost of RFID.

Chong and Chan (2012) test a model for RFID diffusion in healthcare that considers three diffusion stages – evaluation, adoption, and routinization – affected by technological factors (relative advantage, compatibility, complexity, cost, security), organizational factors (top management support, organization size, financial resources, technological knowledge), and environmental factors (competitive pressure, expectation of market trends). Structural equation modeling analysis of 183 survey responses from managers of health care companies and hospitals in Malaysia reveals that all diffusion stages are positively affected by complexity, cost, security, and top management support. RFID relative advantage is significantly impacting the evaluation stage only, expectations of market trends impacts evaluation and adoption only, and the other factors' impact differs by adoption stage.

While RFID has been gaining increasing attention from researchers from around the world, recent literature reviews indicate gaps in the literature exist as well. Most of the studies identified by one review paper fall into two major categories: either industry or practitioner-based reports that describe working RFID systems but do not provide detailed analysis or empirically-validated benefits, or academic papers focused on analytical models that are removed from practice (Zhu et al., 2012). Similarly, most studies identified by Liao et al. (2008) include reviews, models, and prototype descriptions, with very few case studies of implementation, business value or impacts on inter-organizational relationships. This paper is an attempt to fill in the gaps through a rigorous case study of a working, real-world RFID implementation, as described in the next sections.

METHODOLOGY

The study employs a revelatory case analysis methodology (Yin, 1994), which is appropriate for the study of this nascent phenomenon. Indeed, according to recent surveys, RFID is used in only 3% of EU companies (Zhu et al., 2012) and 8% of companies in Taiwan (Tzeng et al., 2008). The study is also focused on important but less researched questions related to process change and business value in the context of the entire supply chain.

The study was conducted in the context of the German pharmaceutical supply chain, which is described in detail in the following section. The analysis focuses on a successful RFID implementation by German firm XQS GmbH. Launched in 2006, XQS has several customers using the RFID solution, including one major German distributor (Max Pharma) and several pharmacies and R&D companies focused on oncology (cancer) and stem cells medication. This particular implementation of RFID technology was chosen for the revelatory case study because of its documented track record in trials for tracking medication in the entire pharmaceutical supply chain over the last several years. We also note that the oncology drugs supply chain is subject to both counterfeiting (with adverse consequences for patients) and quality problems (if manufacturing, transportation, and storage are not properly performed), and can therefore provide useful insights regarding the application of RFID in these situations. A detailed description of the technology architecture is provided in the next section.

The goal of our study is to analyze how RFID supports end-to-end supply chain processes from the perspective of the supply chain participants. To this end, we contacted one organization in each stage of the chain; this included a manufacturer, wholesaler, pharmacy, and a hospital/clinic which have all participated in RFID trials using the XQS solution. In each organization, semi-structured interviews were conducted with a knowledgeable respondent (senior manager, product manager, or quality assurance manager). The interviews contained generic questions about the organization and respondent, as well as about the adoption, implementation issues, and benefits of the RFID solution. Pictures documenting the process changes were also taken at the interview sites.

Most interviews were conducted in German, transcribed and translated by one author. A follow-up interview was conducted in English by two of the authors with several informants to clarify any remaining issues. The transcripts, together with the pictures as well as publicly-available information about the solution implementation (news and practitioner articles, press releases, and company reports) were collected into a case database. The case database materials were analyzed by a second author who compared the resulting insights with theoretical themes derived from an extensive literature review of recent papers on RFID and business value of technology, iteratively, until no new insights could be derived from the data (Eisenhardt, 1989). The results of the analysis were then verified for face validity by the primary interviewer, and any inconsistencies were discussed until consensus was reached. Last, but not least, the results of the analysis were reviewed by a high-level senior executive of the RFID solution provider (who was not involved in the analysis). Thus, the study achieves triangulation by presenting multiple points of view from different supply chain participants and researchers (Yin, 1994).

CONTEXT

Pharmaceutical Industry Supply Chain: Description and Challenges

The modern supply chains of pharmaceutical industry have undergone major transformation in recent years due to declining profits, safety concerns, and increasing costs of bringing new medicines to market. Some of the transformations that have increased the complexity of these supply chains are:

- (a) Globalization of regulation— due to the health care reforms implemented in the U.S. and many European Union countries, the structure of regulations of pharmaceutical products and the requirements of compliance have become more strict and diversified. This requires more advanced supply chains with better governance structures and advanced technology to manage the technical and business processes of pharmaceutical companies.
- (b) Channel redesign – the drug distribution channels have become complex networks of physicians, traditional pharmacies, internet pharmacies, hospitals, wholesalers, and government organizations. Advanced technological and systems capabilities are required to manage these chains for effective delivery of medicines from the developers and producers to the end users.

- (c) Declining patent protection – due to the expiration of patents for many block buster medicines and de-recognition of some patents in large consumer countries, pharmaceutical companies have to compete against generic drugs often produced more cheaply in less developed countries with growing pharmaceutical capabilities such as India and China.
- (d) Medicine safety and security – increased requirements of drug safety and security against counterfeiting is forcing companies to assimilate technologies for traceability of their medicines in the supply chain.

Before these transformations, it was sufficient for a pharmaceutical company to discover appropriate molecules, produce drugs rapidly, and supply them to wholesalers and retailers with limited regulatory, safety, and competitive concerns. The changing reality has made the global supply chains of pharmaceutical companies very complex, and has brought about a need to consider the impact other players in the company’s value chain have. Figure 1 contains a generic pharmaceutical supply chain model that captures the essence of the forces that heavily influence the supply and value chains in three widely recognized distinct phases – drug discovery and development, drug production, and drug delivery and dispensing (see Figure 1).

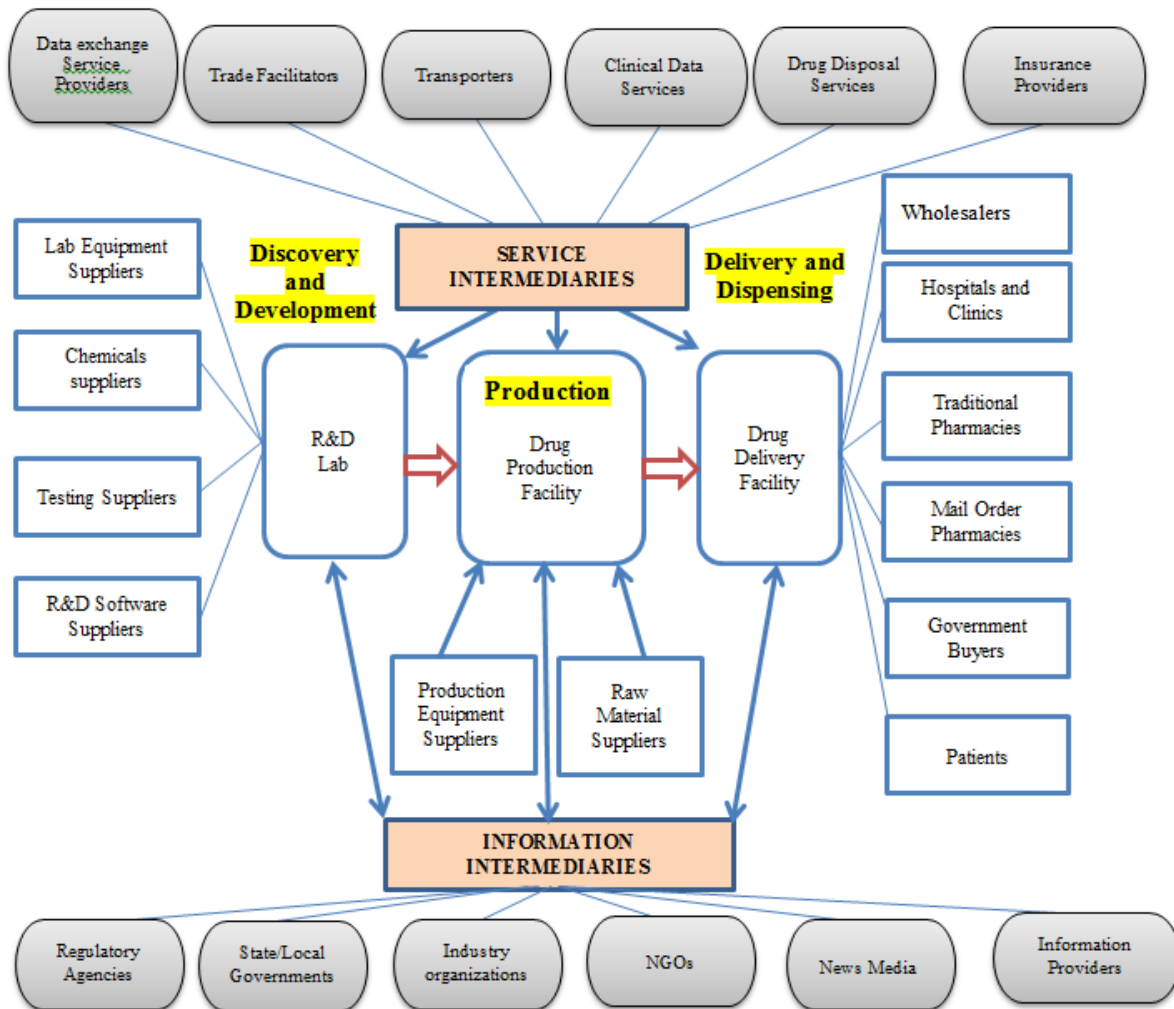


Figure 1: A Generic Global Pharmaceutical Industry Supply Chain

The major players in the discovery and development phase are R&D labs, laboratory equipment suppliers, suppliers of chemicals and biological specimen for initial testing of molecules, and the suppliers of R&D software,

which is being increasingly used by drug research laboratories. In the drug production phase, the major players are the raw material suppliers and production equipment suppliers for the manufacturing facilities. In the delivery and dispensing phase, the important participants are wholesalers, hospitals and clinics, traditional pharmacies, mail order and Internet pharmacies, government buyers such as the Veterans' Administration in the U.S., and finally the patients who ultimately consume the pharmaceutical products. In this dynamic environment, two types of intermediaries have evolved who facilitate the supply chains - service intermediaries and information intermediaries. While service intermediaries expedite the supply chain logistics for pharmaceutical companies, information intermediaries exchange data with these companies related to R&D, marketing, and regulatory compliance pertaining to drug counterfeiting and public safety. The service intermediaries include value-added network service providers for document interchange, trade facilitators for obtaining customs documents, transporters for shipping and delivering medicines, clinical data services for critical trials, drug disposal services for unused and spent drugs, and insurance providers for reducing the liabilities of the supply chain participants. The examples of information intermediaries are governments at various levels – including regulatory agencies, non-governmental organizations, news media, industry organizations, and information providers.

The pharmaceutical industry is faced with several emerging supply-chain management challenges related to counterfeiting and medication quality. The delivery and dispensing phase of the supply chain model in Figure 1 is currently presenting the greatest management challenge due to the emerging drug counterfeiting and provenance authentication concerns in the increasingly globalized pharmaceutical markets. A report from the National Association of Boards of Pharmacy in the U.S. indicates that drug counterfeiting is a \$75 billion worldwide industry and growing at 13% per year. The board found that in 2011, more than 8,400 websites selling medicines were out of compliance of the U.S. laws and could supply fake drugs to customers. Fake medicines from just one company, Pfizer, were found to be present in more than 75 countries (NABP, 2012). Medication quality is another issue affecting pharmaceutical supply chains. If manufacturing problems arise, cold chains are interrupted, containers are damaged or sensitive medication is shaken during transport, drug quality is affected and serious consequences, including patient sickness and even death, can occur (Sultanow et al., 2011; Cohen & Bonifield, 2012).

In order to protect their products and profits and maintain the integrity of their supply chain, pharmaceutical companies around the world are implementing new technologies and processes. Since counterfeiting of drugs is a public safety issue, governments at various levels are enacting laws and regulations to guaranty the safety of drugs dispensed to patients. As an example, the Prescription Drug Marketing Act of 1992 imposes requirements for all drug suppliers in the U.S. In addition, the State of California has enacted a new law in 2008 that requires pharmaceutical companies to implement systems for serialization of drug packages and determining electronic pedigree (e-pedigree) of drugs (Thomas, 2011) for transaction integrity in delivering, repackaging, and return of drugs. These systems must be based on technologies that provide interoperability among different participants in the supply chain. This law is expected to be fully implemented in 2015-16 (CA.gov, 2009).

RFID Technology for the Pharmaceutical Supply Chain

Drug labeling and serialization are two central components for counterfeit security and drug quality assurance. Around the world, regulatory bodies have recommended the improvement of existing labeling practices (Thomas, 2011), moving from text-only information and bar codes identifying the type of drug to advanced processes that assign a unique serial number to each drug container (a procedure called serialization). Two technologies available for affixing these numbers to containers so they can be tracked throughout the supply chain show great promise for the pharmaceutical industry: optical recognition of 2-D barcodes and RFID. Barcodes are inexpensive (costing 0.1-1 U.S. cents per label) and have support from both U.S. and European regulatory agencies, but are chemically and mechanically unstable, do not allow bulk reading of multiple labels, and cannot accommodate additional sensors for movement or temperatures. In contrast, RFID labels are more expensive (costing 7-15 U.S. cents for simpler labels, or 35 U.S. cents or even dollars more for more advanced labels), have support only from the U.S. regulatory agency, and affixing them to products is more complex, requiring changes in the manufacturer's processes and systems. However, RFID labels are tamper-proof and chemically and mechanically stable, have fault-tolerant bulk reading ability, and can accommodate additional sensors for real-time data collection (Asif & Mandviwalla, 2005; RFID Journal, 2012; Sultanow & Kretzer, 2012). RFID technology is especially useful when other labeling and serialization technologies such as 2-D barcodes fall short of requirements,

for example when there is contamination (i.e., by oil, paint, or dust), the line of sight to the object is impeded (i.e., by multiple layers of packaging), information changes (i.e., changing product status must be recorded in real-time), labeling must last for several years and may require frequent updates, or many items need to be processed simultaneously (Clemens, 2009).

Thus, despite its higher cost, RFID has clear advantages, especially in the pharmaceutical environment, where counterfeiting or lower quality can lead to significant adverse events for patients, and, as described in a previous section, to significant financial impacts for organizations that cannot control these problems. In addition, because the optical 2-D barcode technologies require that each individual pack be held in front of a reader, the shipping and receiving processes, where each item needs to be recorded, are likely to be much slower than with RFID, which can enable reading of item information in bulk.

Because of these advantages, RFID is being explored by most large companies to comply with regulatory requirements. For example, Abbott Laboratories had begun a pilot program to use RFID for identifying every bottle with a unique serial number to trace its products and prevent counterfeiting even before the California e-pedigree law was enacted (Abbott Laboratories, 2004). Purdue Pharma, the manufacturer of OxyContin, inserts RFID tags in each bottle of the painkiller to track its progress through the supply chain. Distributors of the drug can determine the e-pedigree and provenance of the bottles with these RFID tags, which prevents counterfeiting of the medicine (Scaler, 2007). However, the success of these pilot initiatives will require a centralized database to authenticate the information available in the supply chain. Pfizer was the first company to use RFID tags with a central authentication server to protect counterfeiting of its most famous drug Viagra. However, Pfizer discovered that metals and liquids in proximity to RFID tags can create interference, especially at high frequencies, which diminishes the reading efficiency of these tags. Pfizer also found that the use of similar tags and hardware by all players in the supply chain is essential to make the deployment of RFID effective (Thomas, 2006).

Standardization, however, is not an easy task to accomplish. According to the EPC-Global initiative of the GS1 organization, which develops standards for world trade, 75 countries have agreed to a global regulatory scheme for implementing electronic product code (EPC) identification with RFID for pharmaceutical and other products. EPC-Global has identified five critical areas to address in the supply chain: Pedigree Management, Air Interface Standard for item level tagging, EPC tags for item serialization, Decommissioning of tags, and Network Security. At this time, however, there is no industry-wide standard although regulatory requirements are being implemented in different ways. Companies can choose from a unique 96-bit EPIC ID serialization number similar to a Global Trade Identification Number (GTIN) or an XML transaction number based on EPC-Global's Information Services standard. Companies are also free to choose any desirable method of capturing data such as standard linear barcodes, 2-D barcodes, RFID transactions, or manual data entry.

The Healthcare Sector and the Pharmaceutical Supply Chain in Germany

Our study investigates the deployment of RFID in the German supply chain because of the importance of German pharmaceutical industry in the global markets. Germany is the largest country in Europe (with 82 million people) and one of the top pharmaceutical markets in the world, with EUR 41.5 billion in sales in 2008. The German pharmaceutical industry is the second largest in the world with 900 companies listed with the German Pharmaceutical Association in 2012. These companies export \$50B worth of pharmaceutical products worldwide (Germany Trade & Invest, 2011; Salama, 2013). The quintessential German pharmaceutical company Bayer AG was the first company to implement RFID-based system called VistaTrak in 2007 to automate radiology related pharmaceutical processes. RFID was used for capturing product utilization data by tagging and tracing bottles of medicines to reduce human error in the supply chain. The importance of German pharmaceutical industry can be further underscored by the fact that two companies, Celesio and Phoenix, with Alliance UniChem of the United Kingdom, control more than 60 percent of the distribution market in the European Union countries, with combined sales of more than 50 billion euros (Behner & Bunte, 2007).

The importance of the pharmaceutical industry in Germany is increasing. A rise in life expectancy coupled with health awareness and high income levels are resulting in an older population that demands high quality medication. Germany spends 11% of its national GDP on healthcare and about 18% healthcare spending covers

medications (Germany Trade & Invest, 2011). At the same time, changes in the German health system intended to improve its efficiency and effectiveness are under way. These include the closure of health insurance companies and increases in required insurance premiums. Many recognize that the German health system is one of the best in Europe, as it covers all of its citizens, even those who are too poor to pay for medication or treatments. However, the German government has established guidelines for health insurance intended to ensure the viability of the system.

First, insured persons and their employers as well as the retirees and the federal government pay premiums into a health fund (reaching about 161 billion euros in 2008) that covers approximately 90% of the German population (with the remaining percentage being covered by private health plans) (Germany Trade & Invest, 2011). The money is then distributed to public health insurance companies based on their membership levels, and additional money is available for people who are chronically ill and require more expensive care. Because the health fund eliminates premium competition between insurance companies, it encourages these companies to compete on service variety and quality, including medication safety and quality.

Second, specific legislation has been enacted in order to ensure safety and quality of medications distributed in Germany. Since 2006, the pharmaceutical supply chain stakeholders need to follow specific guidelines for storage and transport of medication or risk criminal prosecution for fraud (Krüger, 2007). Following a 2010 amendment of the law, pharmaceutical companies which (due to data complexity and diversity) cannot trace their product distribution pathways need to agree to significant mandatory fines/discounts/charges, resulting in millions of dollars in financial damage (Sultanow et al., 2011).

Thus, tracking products and their condition through the pharmaceutical supply chain becomes of utmost importance for pharmaceutical companies in Germany. Processes throughout the supply chain have a crucial influence on quality. The tracking requirements have been prompted by several factors that can decrease medication quality, including drug counterfeiting and transportation and storage issues. As in other parts of the world, professional counterfeiting operations have also been discovered in Germany (Klemperer, 2010; Perrone, 2012). In addition, around 250 drugs requiring cold chain distribution are currently used in Germany; these drugs must be refrigerated at specific temperatures throughout the entire transport chain, from production to dispensing, in order to maintain quality. Temperature fluctuations outside the permissible range or violent shaking during transport lead to irreversible changes to the active ingredients, putting patient safety at risk. In addition, the number of such drugs is steadily increasing as more sophisticated treatments are developed (Sultanow et al., 2011).

AN RFID TECHNOLOGY ARCHITECTURE: THE XQS MODEL

The XQS model of counterfeit security and drug quality assurance was developed by XQS Service GmbH and introduced in the oncology market. The XQS model uses RFID passive tags as well as temperature and motion sensors, coupled with a central infrastructure that enables the tracking and tracing of items. The pilot was initially launched by the wholesaler Max-Pharma in cooperation with its manufacturing partner Sun Pharmaceuticals Germany (Swedberg, 2011). In the interim, various other manufacturers as well as oncology pharmacies and clinics have adopted the XQS solution. Next, we describe the technology infrastructure and the new processes supported by this RFID solution for the pharmaceutical supply chain.

In a pharmaceutical supply chain, original products from a manufacturer are shipped in bulk to wholesalers. Wholesalers combine items from multiple manufactures to fulfill pharmacy orders. Pharmacies receive and disassemble orders, then dispense specific items directly to patients or to hospitals and clinics where patients are treated for more serious conditions.

A graphical description of this process, together with the RFID infrastructure that enables drug tracking and tracing, is presented in Figure 2. A central component of the RFID solution presented in this paper is the Pharmaceutical Trust Center. The center provides the technology infrastructure of the solution through servers and databases, and acts as a trusted verifier of the products. At any stage in the supply chain – from manufacturer, wholesaler, pharmacy, or hospital – communication with the trust center can take place in order to verify drug information or provide information on new drugs (such as infusion bags prepared by the pharmacy).

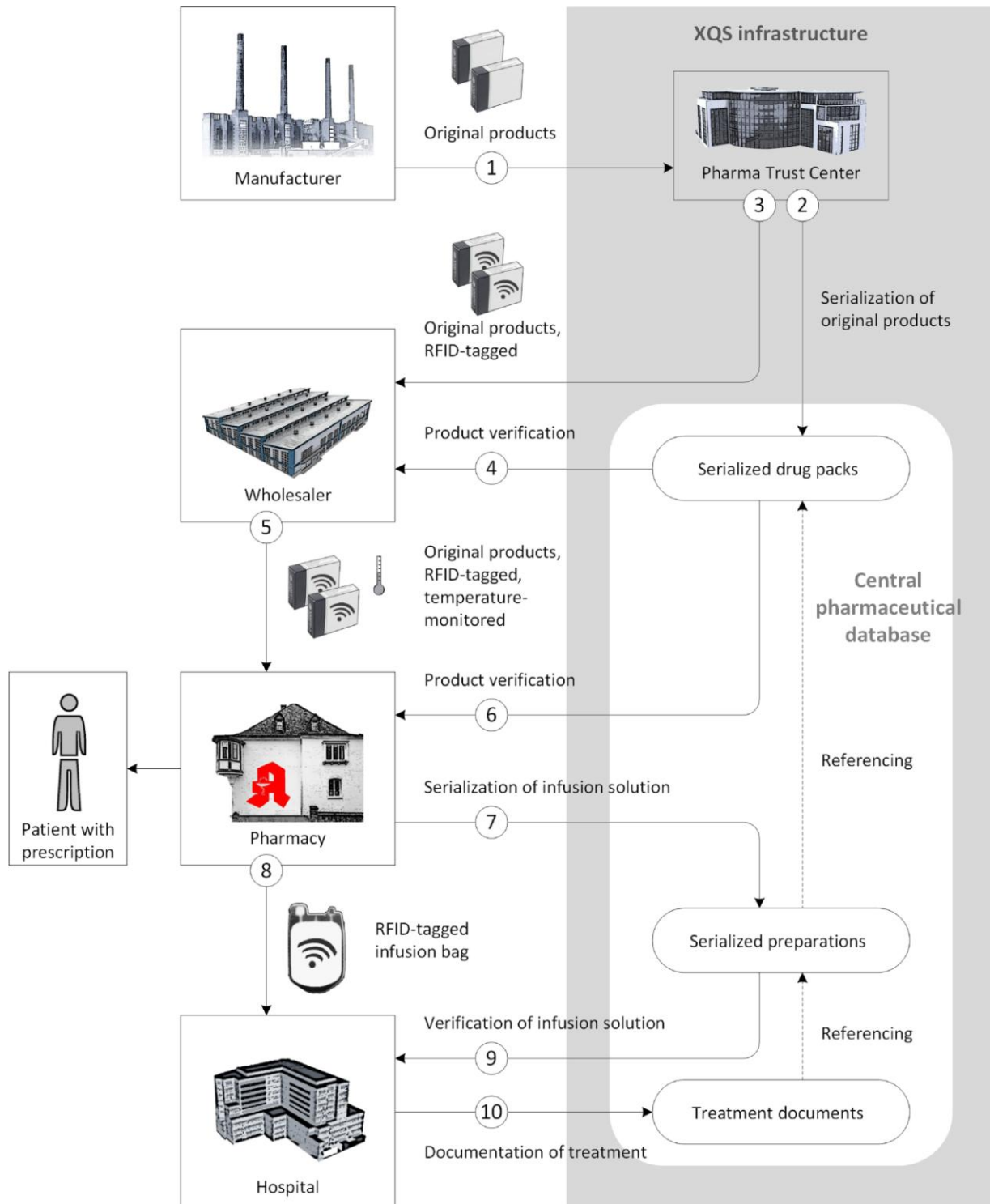


Figure 2: The XQS RFID-Supported Supply Chain Processes (Based on Sultanow and Kretzer, 2012)

RFID labeling and serialization of items can be carried out by the manufacturer, or they can be performed by the trust center. In each case, RFID labels are attached to the products, with unique identification numbers coded into the RFID tags. Then a bulk reader (tunnel) is used to read hundreds of RFID-tagged packs simultaneously. The bulk reader transmits the unique ID number from the RFID tag, including the relevant product data, to the Trust

Center, where it is stored persistently in a database. Packages which are serialized in the Trust Center are termed “RFID-secured” (“RFID-tagged”). Once this process is complete, the packages are ready for shipping to the wholesaler.

The wholesaler verifies the RFID-tagged products and activates the temperature monitoring feature using a QS terminal, a specialized terminal with a computer and RFID (as well as 2-D barcode) read-write capabilities). The RFID-tagged and temperature-monitored drugs are then dispatched to the pharmacy, which also has a QS terminal. The pharmacist then verifies each tagged package and checks the temperatures which have been monitored during transport. The terminal transmits the temperature monitoring data to the central database. The pharmacist and wholesaler can access these data anytime, anywhere via an Internet portal.

The preparation of cytostatic drugs (infusion bags) in the pharmacy for future dispensing to hospitals is also software-based. The preparation software imports the data from the RFID-tagged packs received by the pharmacy, so all the drugs used in each preparation can be tracked and traced in full. The infusion bag is also RFID-tagged and serialized. The preparation software sends the preparation’s ID number to the central database, together with details of the substances used in the preparation, the quantities used and their origin (ID number from the packaging). The oncologist verifies each infusion solution at his terminal in the hospital and documents the treatment. The treatment documents also reference the preparation data, which in turn are referenced to the serialized drugs.

The flow of information and the technical infrastructure required to support the entire pharmaceutical supply chain is presented in Figure 3 (See Figure 3). We note this solution supports timely, valid, complete, and accurate collection of supply chain data, as well as continuous cross-referencing of all data. Apart from providing real-time process support, this infrastructure also allows analyses to be carried out for the purpose of counterfeit security and quality assurance as the basis for optimizing value chains, as well as for health care research.

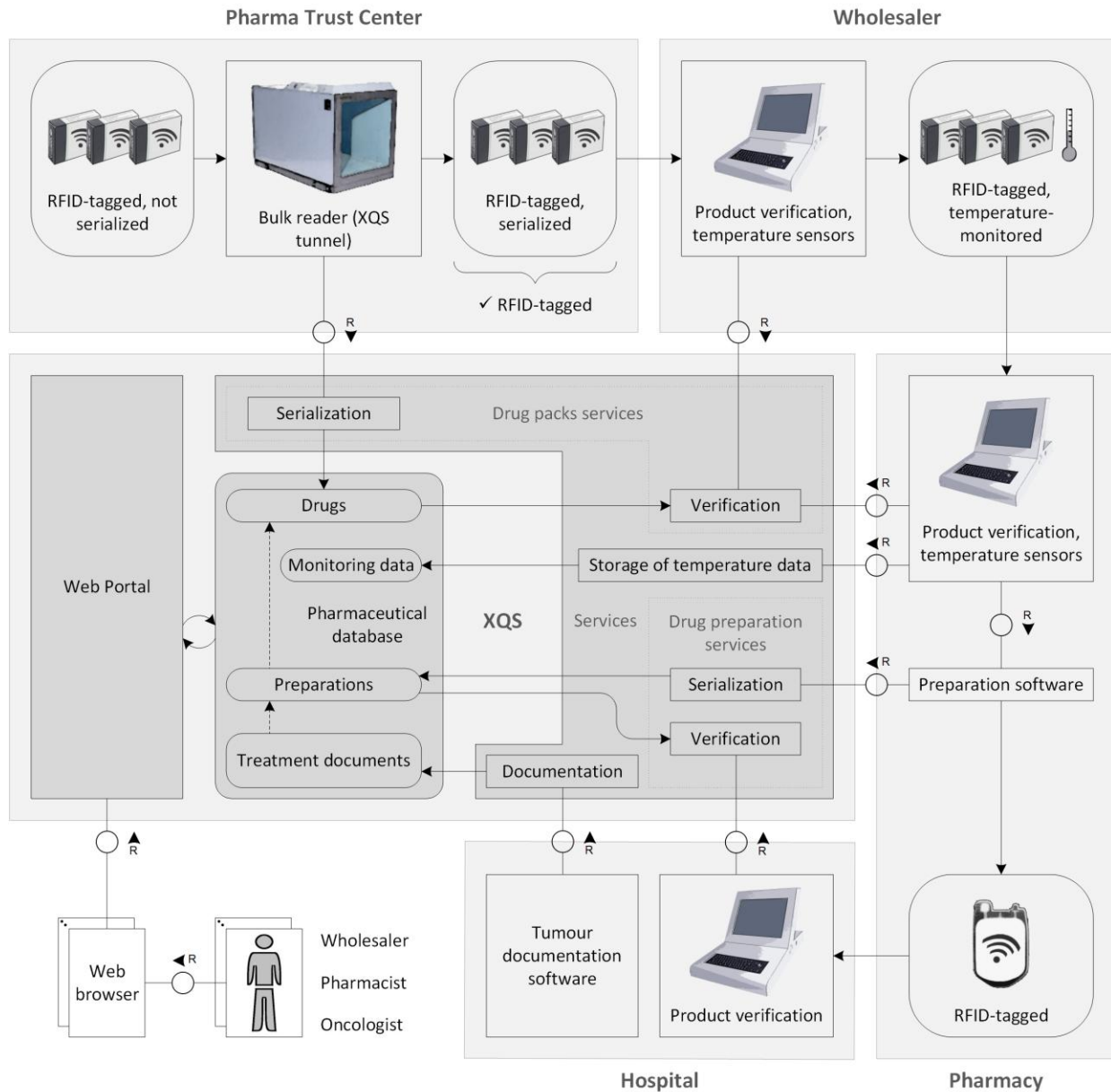


Figure 3: Technical Infrastructure (Based on Sultanow and Kretzer, 2012)

ANALYSIS AND FINDINGS

Our interview analysis reveals that the XQS solution for RFID implementation in the supply chain has been positively received at all levels of the supply chain, with significant benefits being cited by all supply chain participants. The RFID solution “can save time and earn more money for our company because of the marketing effect. Moreover, we can win the trust of the doctors and patients, because the safety of the medication is now ensured,” according to the manufacturer. The wholesaler agrees that trust and quality are increased because of RFID, and therefore “the relationships to suppliers/manufacturers and loyal customers have been strengthened and new customers have joined our network.” At the pharmacy level, the RFID solution provides “better and [more] comprehensible documentation,” as well as efficiency improvements. And at the hospital level, the solution has provided “amazingly detailed and visually efficient information,” to enable tracking and tracing of drugs, in a “very pleasant and user-friendly way.”

Interviewees were acutely aware that, although track and trace capabilities for medications are not mandated at the moment, the EU-Directive 2001/83/EC and the Regulation EC 726/2004 specify these must be implemented in just a few short years, by 2017. Thus, the pressure of future regulatory requirements and the respondent's own concern for patient safety were major drivers of adopting a track-and-trace solution. We note that several supply chain participants mentioned they will also consider 2-D barcodes as a complement to the RFID solution when possible (a complete solution using optical technology is not available at the moment and it is not expected to be available until 2017). However, as previously discussed in this paper, RFID presents a superior process improvement solution when compared to 2D barcodes. Consistent with this, the interviews reveal that a major contributor of the technology success is the value realized through beneficial process changes supported by RFID technology.

From the manufacturer's perspective, the pre-RFID processes did not provide unique product numbers or visibility into the supply chain. Even if well designed at first, these old processes "became less efficient, less effective, and harder for controlling and transportation," especially in terms of ensuring the safety of the medications: "The interests of the pharmaceutical companies were infringed. The medicaments could be miss-sent. There were even counterfeit drug in the market." The new processes supported by the RFID solution are "more efficient, more effective, and easier for controlling and transportation of the medication" as sending the wrong product or quantity can be now prevented and costs can be kept down.

From the wholesaler perspective, the pre-RFID processes were "classical, old-style processes." Our interviewees point out that they "just sent the product out, followed by a delivery note," and had to deal with the "cost of human error due to delivery of the working quantity or sometimes the wrong substance." The data entry was manual: "[Information about] drugs - even those which are expensive, was captured by using the barcode and the lot number (charge). Delivery notes were paper based and manually entered into third-party systems by our customers." In case of problems, the patients were significantly impacted – since the wrong medication meant the patients "could not be treated, which is a huge problem in the critical area of cancer treatment, which has [strict] timelines when to get each [drug] preparation." There were also significant costs as the "very expensive medicine" was "very sensitive to temperature," and had a "very high risk of being destroyed during transportation." Because of this, "logistics costs were huge" as the company had to use "more expensive, more qualified specialized transport companies." After implementation, these issues were resolved by serialization and the storing of unique ID numbers in the trust center databases, which "prompted an increase of trust of customers and suppliers." The RFID solution now enables the wholesaler to "analyze the compliance of regulations on temperature, transport conditions and stability" and adjust its packing and shipping processes accordingly and maintain product quality.

At the pharmacy, a manual tracking solution for medication, from the moment it was received from the wholesaler until it reached the patient, has been in place for more than a decade; however, this resulted in "high costs for employees, computer hardware, and software," which were hard to recoup from limited insurance funds. To ensure errors were detected and corrected, multiple employees had to verify data entry into the systems – resulting in increased administrative and personnel cost. After the RFID implementation, the manual data entry costs were reduced, allowing pharmacists to focus on value-added tasks.

At the hospital level, the pre-RFID processes were plagued by errors: "The infusion solutions were checked by their label. You could not see the details (source, batch, expiry dates, pictures, etc.) of the drugs used. [...] The performance was bad, because we have to read the small printed label on the infusion bag without any visual feedback." After the RFID implementation, the medication information is read by an RFID reader and clearly displayed on a computer screen. Doctors and nurses thus can check the original item label for the drug, the drug's name and manufacturer, dose, unique ID number of the particular package, as well as additional information.

In order to facilitate these improvements, the organizations we interviewed also had to make additional changes in interacting processes and systems. These were sometimes unexpected, but generally well managed. The manufacturer had to now apply the RFID-label to the product, code it, and enter the related information into the common system database. According to the manufacturer, "the process of implementation was not as fast as we have thought before, for instance, there must be a database for the information of all products. [...] Of course, due to the new technology there must be some changes, for instance, we need qualified technicians; new system and process

are introduced.” The wholesaler, pharmacy and hospital all had to change their processes so that they could receive the products automatically by reading the RFID labels, compare the information from the RFID label with the information in the database, and enter status change information (i.e., shipping to the next player in the supply chain, etc.) into the database. The wholesaler, building on a close relationship with the RFID provider, was able to customize the technology to fit its processes, and keep changes to a minimum: “Only few steps had to be added such as serialization and verification.” For the pharmacy, the main additional process change was related to ensuring regulatory compliance during the implementation phase and the training of personnel during the six-week implementation period, when the productivity of employees was affected; but “after this time mistakes appeared rarely, the daily routine had been normalized.” And from the hospital perspective, the additional changes were minimal as the installation and upgrades to the existing systems were outsourced.

Several important insights regarding all these process changes were captured in our interviews with the wholesaler key informants. First, “the technology orients on processes and not vice versa.” Second, “the main problem [...] is that all actors must have buy-in: the pharmaceutical manufacturer, the wholesaler, the clinic,” and many discussions were needed to ensure their buy-in for a technology pilot implementation. Third, the pilot helped demonstrate benefits for each supply chain participant, since “you can only realize benefits after implementation.” As they started using the system, the participants started to “see how easy it is to import data [...] and to book their delivery” and these “real benefits [started to] make their life easier.” Thus, adoption was ensured by tailoring the technology to support existing processes from each stakeholder perspective, getting early buy-in for a pilot, and then demonstrating benefits to each stakeholder as the pilot was under way.

CONCLUSIONS, LIMITATIONS, AND IMPLICATIONS

This paper confirms that, as suggested by previous studies, RFID benefits are realized when supply chain processes are changed with the help of technology. The analysis reveals specific types of process changes and their corresponding benefits. The results further suggest that different supply chain participants have different benefit perceptions. Intangible benefits such as trust and increasing the size of partner networks are most important for manufacturers and wholesalers. Pharmacies focus on tangible benefits such as labor savings. And patient-facing units, such as clinics, focus on intangible benefits such as patient safety.

This paper advances the current literature on RFID implementation and benefits by providing an evidence-based evaluation of an integrated, supply chain, end-to-end process that is largely missing from current RFID research (Liao et al., 2008; Zhu et al., 2012). This paper is similar to a study by Mauro et al. (2008), which describes the implementation of smart cards for healthcare provision in Germany, in that we evaluate the impact of technology on healthcare process changes. In addition, this study goes one step further by evaluating the technology using case study data, rather than the authors’ subjective evaluation.

Previous studies have presented case study analyses from a single point of view – focusing on one healthcare organization (such as a hospital or hospital unit) or on a single patient record (across different sources of patient data), while also emphasized the importance of adopting an end-to-end view when analyzing healthcare processes, since flawed data, information and judgments can enter the care process at multiple points and propagate, sometimes with fatal results, unless adequate controls are in place (Bradley et al., 2012; Çakici et al., 2011; Chircu et al., 2013; Kataria et al., 2011). This paper extends and complements previous studies by analyzing an end-to-end supply chains process across multiple stakeholders, from the manufacturer to distributor, pharmacist, and hospital.

For practice, this paper can provide insights regarding the benefits realized by early adopters, which can be demonstrated to other supply chain participants in order to support a full roll-out of the solution. The paper can also provide suggestions to technology providers for the design of RFID solutions for the pharmaceutical supply chain.

Because we wanted to provide a rich picture of both the technology architecture and the implementation benefits, our analysis is limited to a single RFID platform (XQS) and one country (Germany). Future research can explore alternative RFID implementation models in the context of other countries as well. Future studies can also compare the technology architecture requirements and resulting benefits for RFID and other technology platforms, such as optical 2-D bar codes, that are currently being still under development. The impact of regulation on pharmaceutical supply chain deployments is another interesting research avenue.

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