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Strategies to Implement a Material Management Information System for Medical Device Recalls

Paul Leo LaFrance
Walden University

Walden University

College of Management and Technology

This is to certify that the doctoral study by

Paul L. LaFrance

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Dr. Franz Gottleib, Committee Chairperson, Doctor of Business Administration Faculty

Dr. Alexandre Lazo, Committee Member, Doctor of Business Administration Faculty

Dr. Judith Blando, University Reviewer, Doctor of Business Administration Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
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Abstract

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MBA, Strayer University, 2008

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Abstract

Health care business executives lack strategies to implement material management information systems (MMIS) related to medical device recalls. Lacking sufficient MMIS, health care business executives face insufficient product tracking related to medical devices affecting operational efficiency. Grounded in the conceptual frameworks of the technology acceptance model and diffusion of innovation, the purpose of this qualitative single case study was to explore health care business executives' strategies for implementing an MMIS related to medical device recalls. The participants were 6 health care executives who implemented an MMIS in an urban hospital in the northeast region of the United States. Data were collected through semistructured interviews and a review of company documents. Using thematic analysis, 3 themes emerged: communication and planning, instrumental knowledge and research, and implementation preparation. A key recommendation is that health care leaders implement an MMIS to avoid high costs and inefficiencies of outdated IT systems. The implication for positive social change is that health care executives can increase patient safety by implementing an MMIS to support tracking patients' implanted medical devices.

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Dedication

First, I dedicate this doctoral study to my wife, Kimberly and my two daughters, Elaine and Michelle. Second, I dedicate my doctoral work to my parents who passed away during the writing of the literature review. They both have been an inspiration to me and taught me dedication in support of my educational goals. My loving parents were always there for me when I obtained my bachelor's and master's degrees. Both provide the spiritual uplift needed, as I made my doctoral journey a dream come true.

Acknowledgments

I acknowledge that without the feedback, encouragement, and support of my chair, Dr. Franz "Mike" Gottleib completing my doctoral study would not have been possible. Dr. Gottleib was always available to offer his keen sense of wisdom and required direction so I would not stray too far off course. I would also like to acknowledge my committee members, Dr. Christos Makrigeoris and Dr. Judith Blando. Thank you for your wisdom and guidance. I sincerely appreciate the support I received from my leadership at work who were always providing extra time for me to complete my doctoral study. I also acknowledge the hospital executives I met during my data collection. I was extremely impressed with their knowledge and experience, which in turn added rich data to my study. Their commitment to the health care profession was evident during my interviews. Finally, I thank my colleagues at work for providing their encouragement and feedback when I needed it most to complete my doctoral study.

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Section 1: Foundation of the Study

Hospitals lack operational efficiency processing medical device recalls because their legacy information technology (IT) may not support new unique device identification (UDI) requirements, which may lead to increased costs (Dhruva, Ross, Schultz, & Krumholz, 2018). IT adoption remains a barrier among health care business executives because they lack strategies to implement new IT associated with medical device recalls (Bianchini, Francesconi, Testa, Tanase, & Gemignani, 2019). Measuring the benefits of new IT about using UDI to improve medical device recall processing may help manage costs (Wilson et al., 2020).

Background of the Problem

The acquisition of new health care information technology (HIT) that supports UDI requirements may improve a hospital's operational efficiency and productivity. Deficient IT in supporting UDI systems complicates efficiency in processing medical device recalls for health care business executives (Reed et al., 2017). Researchers addressed the role of IT in the *Efficient Health Care Consumer Response* (EHCR) report (1996) initiative as one of the leading components to support a UDI system that can improve medical device recalls (Drozda et al., 2018). Even though the EHCR report (1996) supported adoption of an IT system such as a material management information system (MMIS), hospital business executives had limited knowledge of the financial benefits of new IT (Huang, Chen, Lin, & Sun, 2016). However, many health care business executives retained their legacy systems and elected not to invest in an MMIS (Kalong & Yusof, 2017; Tang & Hu, 2014). Given the lack of implementation strategies and the importance of hospital operational efficiency, the use of UDI systems related to medical

device recalls might increase awareness of the financial benefits to influence hospital business executives' decision to invest in new IT.

Problem Statement

Hospital providers have outdated information systems, which result in insufficient product tracking related to medical devices affecting operational efficiency (Zhang, Masci, Jones, & Thimbleby, 2019). Approximately 40% of hospital leaders have not invested in IT systems, such as an MMIS, to support the use of UDI within their organizations (Karas, 2016). Failure of one hospital not investing in such a system could result in lost revenue more than $2.7 million (Singh, Mindel, & Mathiassen, 2017). The general business problem is outdated hospital IT requires labor-intensive procedures for medical device recalls. The specific business problem is that some health care business executives lack strategies to implement an MMIS related to medical device recalls.

Purpose Statement

The purpose of this qualitative exploratory case study was to explore health care business executives' strategies for implementing an MMIS related to medical device recalls. The population for this study was a census sample of health care business executives located in an urban hospital in the northeast region of the United States who implemented MMIS strategies to support medical product recalls. The implication for positive social change is the potential to influence health care by increasing patient safety through improved medical device tracking (Ronquillo & Zuckerman, 2017).

Nature of the Study

The three research methods I considered were qualitative, quantitative, and mixed methods. Quantitative and mixed-method research typically include a scientific approach to test hypotheses and to operationalize relationships between variables (Wisdom, Cavaleri, Onwuegbuzie, & Green, 2012). I did not select quantitative or mixed-method research for this qualitative study because I did not intend to test a theory using operational variables. Qualitative research promotes a deeper understanding of a phenomenon (Daher, Carré, Jaramillo, Olivares, & Tomicic, 2017). The qualitative method encourages creativity that may lead to a discovery about the research phenomenon (Katz, 2015). The qualitative method is the best approach for this study because the exploratory and creative capabilities can lead to a deeper understanding of health care business executives' strategies to implement an MMIS related to medical device recalls.

I considered four research designs for this proposed qualitative study: (a) ethnography, (b) phenomenology, (c) narrative, and (d) case study. The ethnographer explores a specific social phenomenon to observe the day-to-day activities of a cultural group (Cruz & Higginbottom, 2013). An ethnographic approach was not appropriate for this study because data collection did not involve observing culture groups. A phenomenological design provides a deeper understanding of issues, claims, and concerns from participants' lived experiences and perceptions regarding a phenomenon (Englander, 2012). The phenomenological design was not appropriate because the intention of this study was not to explore participants lived experiences. The significance of narrative research deals with analyzing and comprehending the meaning of stories in multiple ways (Salawu, 2016). The narrative approach was not appropriate because the

intent was not to explore the experiences of the participants and then retell a story. A case study design allows the researcher to gather research data using multiple data sources to explore a program, event, activity, process, or individual(s) in depth within a specified boundary to address a research question (McRae, 2017; Cronin, 2014). Therefore, a case study design was appropriate because I used multiple data sources such as face-to-face interviews and archival document analysis toward answering the research question.

Research Question

I explored hospital business executives' strategies to implement an MMIS related to medical device recalls. The research question that guided this case study was: What strategies do health care business executives use to successfully implement MMIS systems for medical device recalls?

Interview Questions

The following are open-ended interview questions to help address the research question:

1. What was your involvement in the implementation of an MMIS?

2. What were the most significant challenges you faced in implementing an MMIS?

3. What strategies were considered successful when implementing an MMIS related to medical device recalls?

4. What strategies were considered unsuccessful when implementing an MMIS related to medical device recalls?

5. What have been the key challenges to implementing the MMIS related to medical device recalls?

6. What are some of the system functionalities related to medical product recalls that would influence your strategies to adopt an MMIS?

7. How do attitudes and perceptions of other hospital business leaders influence your decision-making strategies toward implementing or rejecting an MMIS?

8. What strategies are influenced by your perception of the usefulness of MMIS technology associated with medical device recalls?

9. What strategies are influenced by your perception of the ease of use of MMIS technology associated with medical device recalls?

10. What other issues associated with an MMIS and medical device recalls would you like to add to this discussion?

Conceptual Framework

The technology acceptance model (TAM), introduced by Davis in 1989 showed that users' intrinsic behavior might influence acceptance and use of new technology. Davis applied TAM to business leaders and presented two variables perceived usefulness (PU) and perceived ease of use (PEOU) that may influence their behavior toward adoption of IT (Davis, 1989). Davis defined PEOU, as a person's belief using IT would be easy to use and PU as a person's perception that using a system would enhance job performance to reduce cost. To apply TAM in health care, researchers have examined health care business executives' PU and PEOU as a predictor of adoption and behavioral intentions toward system use (Andayani, Hidayanto, Pinem, Sandhyaduhita, & Budi, 2018). TAM is a useful theory in determining the influential factors of hospital business executives' attitude and behavior toward adoption of IT.

Rodgers (2003) introduced the diffusion of innovations (DOI) theory, a process in which peer groups discuss the perceived attributes of IT over time within their social system (Rogers, 2003). When executives communicate about innovation among their peer groups, the five key users' perceived characteristics that can develop are: (a) relative advantage, (b) compatibility, (c) complexity, (d) trialability, and (e) observability (Fu, Lima, & Rocha, 2018; Gonzalo, Graaf, Ahluwalia, Wolpaw, & Thompson, 2018). Gonzalo et al. (2018) examined the social communicative processes and perceived innovation characteristics as part of the DOI theory that could influence a business executive's decision to adopt new IT.

The research objective of this study was to explore hospital business executives' strategies with implementing an MMIS associated with medical device recalls. Elements of the DOI and TAM theories may explain the intrinsic and social system factors to understand decisions toward adopting a computer system such as an MMIS (Lemos de Almeida, Farias, & Carvalho, 2017). TAM and DOI form the framework for this study because these theories provide evidence toward understanding the behavioral and cultural influences of hospital business executives' decisions to invest in IT.

Operational Definitions

Global location number: A 13 digit number assigned to a medical device that uniquely identifies the location of the device to either a health care provider, distributor, or manufacturer (Sayle, 2016).

Global trade identification number: A 14 digit number that uniquely identifies each medical device currently in use at a hospital (Jayaraman, Taha, & Collazos, 2015).

Material management information system (MMIS): An information system that can handle complex supply chain and business-related functions for an organization to include tracking medical devices because of product recalls (Huang et al., 2016).

Medical device recall classifications: An FDA system to categorize medical recalls according to relative severity of health hazard presented by the product (Ronquillo & Zuckerman, 2017).

Tag cloud: A visual representation of text data used to depict keywords on websites or to visualize free form text (Latham & Tello, 2016).

Treemapping: A method of displaying hierarchical data using nested figures usually rectangles (Latham & Tello, 2016).

Trialability: A term used when a business leader evaluates new IT without total commitment and with minimal investment before adoption (Fu et al., 2018).

Unique device identifier (UDI): A numeric or alphanumeric code comprised of a device identifier (DI), and a product identifier (PI) that distinguishes each medical device manufactured (Avgar, Tambe, & Hitt, 2018).

UDI system: A catalogue for medical devices containing a unique device identifier and a global database called the global unique device identification database (Avgar et al., 2018).

Assumptions, Limitations, and Delimitations

Assumptions

Assumptions are realistic expectations that researchers believe to be true but not yet verified (Lips-Wiersma & Mills, 2014). Disclosing assumptions in qualitative research can contribute to the study's credibility and quality (Leedy & Ormrod, 2010). Assumptions that

contributed to the credibility and quality of this study are: (a) the participants answered the interview questions truthfully and honestly from their experiences with an MMIS; (b) the interviewees had the professional knowledge in IT, financial management, and managing medical devices related to medical device recalls; (c) the audio recordings and transcripts created from the interview sessions were an accurate representation of the participants' responses to each open-ended interview question.

Limitations

Limitations are potential weaknesses that can affect the research findings because the researcher has no control over them (Dean, 2014). The importance of disclosing limitations is to maintain transparency and seek out trustworthiness through credibility (Madsen, 2013). A potential limitation was the small research population of this case study. Studies with small research population sizes might limit the research findings and affect generalization to a larger population (Guercini, 2014). Another limitation may have been restricted data from archival documentation because of company representatives' interests in protecting proprietary material, which could have limited the fullness of the data to answer the research question.

Delimitations

Delimitations are restrictions or boundaries intentionally placed by the researcher to limit the scope of the study (Andrade et al., 2019). In general, delimitations are limits the researcher can control, which may include sample population and sample size (Pomare, Churruca, Long, Ellis, & Braithwaite, 2019).

A delimitation of this case study was the narrow focus of the research objective on implementation strategies of an MMIS for medical device recalls. I did not consider other

strategies in processing medical device recalls. Another delimitation of this study was the census sample of six health care executives at one urban hospital located in the northeastern United States. Strategies created by competitors or other health care facilities are beyond the scope of this study.

Significance of the Study

Contribution to Business Practice

This case study may provide insights into medical device recalls leading to improved operational performance. Implementation strategies for an MMIS can lead to several benefits for hospital business operations such as (a) efficient traceability of medical devices, (b) less time spent on manual documentation, (c) cost reduction through improved processing, and (d) medical device inventory accuracy (Singh, Mindel, & Mathiassen, 2017). The future of the health care industry requires integration of an information system such as an MMIS to enhance medical device recall processing Pinsonneault, Addas, Qian, Dakshinamoorthy, & Tamblyn, 2017). This study may contribute to health care business executives' understanding of an MMIS perceived usefulness contributing to operational efficiency.

Implications for Social Change

Patient safety is a primary concern in health care. Medical device industry executives and health care administrators are concerned about implanted medical device failure (Horvath, 2017). Implementing MMIS technology can increase tracking of patient medical devices leading to greater confidence in identifying potentially malfunctioning devices (Palojoki, Saranto, & Lehtonen, 2019). The results from this study might contribute to positive social change by

increasing patient safety through implementation of IT to support tracking of implanted patient medical devices.

A Review of the Professional and Academic Literature

The purpose of this qualitative exploratory case study was to explore health care business executives' strategies for implementing an MMIS related to medical device recalls. The focus of the academic literature review is how researchers evaluated the usefulness of an MMIS toward technology adoption. I used the TAM and DOI theories to provide an understanding of the research phenomenon. To achieve the proposed objective, I reviewed the following key elements: (a) history and overview of medical devices and medical device recall, (b) legal aspects, (c) conceptual frameworks, and (d) health care information technology. An analysis of the academic literature led to a better understanding of hospital business executives' knowledge of the financial benefits of an MMIS associated with medical product recalls.

To identify materials for this review, I searched the following databases: (a) Association for Healthcare Resource and Material Management, (b) Business Source Complete, (c) EBSCO host, (d) ProQuest, and (e) PubMed. I also searched the FDA website. I used the following keywords in my searches: *diffusion of innovation, enterprise resource planning, FDA Amendment Act and medical device recalls, health care information technology, health care and enterprise resource planning, health care information systems, health care informatics, medical devices, medical device recalls, MMIS, MMIS and health care*, *technology acceptance model*, and *unique device identification*. The research also included various health care agencies for reports on medical device recalls and the use of MMIS in the health care industry. Health care agency research included such agencies as the Agency for Healthcare Research and Quality, Association for

Healthcare Resource and Materials Management, American Hospital Association, Healthcare Information and Management Systems Society, and Alliance for Healthcare Reform for information on UDI, medical device recalls, and MMIS. I checked academic resources using the Ulrich website to confirm whether a journal was peer-reviewed. The literature review included 107 academic journals and articles, of which 85% were peer-reviewed and published from 2016 to 2020. References published before 2016 were cited for historical purposes comprising 15% of the total references. The searches produced hundreds of peer-reviewed articles (see Table 1) from 1986 to 2020 that were referenced for this study.

History and Overview of Medical Devices and Medical Device Recalls

History of medical devices. Technological advancements led to the need to pass quality tests on medical devices. The materials used to make medical devices in the early 17th century included stone, wood, metal, and plastic, which were not a safety concern (Lewelling, 2017). Science and technological advancements led to safety evaluations of materials that constitute medical devices (Kuder, Gelman, & Zenilman, 2018). Plastics became a popular substance for medical devices, and later in the 18th century, manufacturers had to pass stringent performance tests (Dolbow, 2018). The evolution and safety of medical devices through the 17th century was slow.

In the early 1800s, no regulatory control over medical devices existed. Manufacturers of the first medical devices were physicians or small companies that sold medical devices directly to the public without adhering to any regulatory standard (White & Walters, 2018). Scientific advancement of medical devices made regulating medical devices imminent (Dolbow, 2018). In 1879, Squibb proposed the first statute to standardize food and drugs (Lewelling, 2017).

Table 1

Academic Literature Search Results

Search terms	Searches	Articles	Date range
Medical device recalls	275	13	2012-2020
FDA	50	8	2013-2019
Health care information technology	509	14	2011-2019
TAM	625	20	1988-2019
Diffusion of innovation theory	141	7	1986-2019
Unique device identification	121	10	2011-2020
MMIS	50	12	2000-2019
Enterprise resource planning	375	14	2013-2019
Medical devices	170	9	2012-2019
Total	2,741	107	

Ongoing medical device improvements continued through the 20th century.

Congress approved the Food and Drug Act in 1906, which was the beginning of regulating medical devices (Ghobadi et al., 2019). The U.S. Bureau of Chemistry had jurisdiction over the manufacture and distribution of medical devices (Kuder et al., 2018). The lack of regulatory requirements meant an increase in the ratio of defective medical devices purchased by hospitals (White & Walters, 2018). The purpose of regulatory control was to minimize the number of defective medical instruments and increase patient safety.

Processing early medical device recalls was difficult because staff at the U.S. Bureau of Chemistry could not identify a defective device before it caused harm to patients (Lewelling, 2017). Poor records-keeping from the executives at the U.S. Bureau of Chemistry made sending out notification of a defective medical device a challenge (Ghobadi et al., 2019). The U.S. Bureau of Chemistry executives prosecuted a small number of manufacturers for the sale of

substandard medical devices (Kuder et al., 2018). In most situations, the government was unable to establish a case against medical device manufacturers; therefore, defective medical devices remained in the system.

In 1927, the U.S. Bureau of Chemistry became the Food and Drug Administration (FDA; White & Walters, 2018). Business leaders at the FDA established premarket quality standards for medical devices to ensure safety and effectiveness (Morrison et al., 2015). These standards constituted the beginning of the FDA's regulation of medical devices (Pinsonneault et al., 2017). Medical device manufacturers followed the established FDA standards, which eliminated the need to recreate and invent their test requirements for medical devices (Dooms, 2016). One purpose of the FDA was to ensure the safety and quality of all medical devices used by patients.

Manufacturers of medical devices follow procedures to determine whether their product is useful, safe, and practical. Prior to considering a medical device for sale, manufacturers follow these steps: (a) they place medical devices into one of three categories Class I, Class II, or Class III; (b) they test medical devices for usefulness; and (c) they enter medical devices into the FDA's quality management system (QMS) to identify patient safety issues (Gupta, 2016). After business executives within the FDA consider a medical device safe and effective, manufacturers begin marketing medical devices for sale to hospitals (Grantcharov, Shushmita, Wac, & Rivas, 2019). Even though a medical device meets all regulatory requirements, FDA executives can still declare the medical device deficient for safety reasons or if a manufacturer fails to provide proof of quality and safety during an inspection (Dolbow, 2018). The FDA QMS is in place to ensure the safety of medical devices, and tracking a medical device after its sale to a hospital provider is a critical part of the process.

Overview of medical device recalls. As the sales volume of medical devices increased, so did the need for FDA business executives to reevaluate the health industry's medical device recall process. From 2004 to 2009, sales of medical devices rose 56% to $9 billion, which increased the number of recalls from manufacturers (Sarkissian, 2018). In 2013, approximately 43.8% of all medical devices purchased annually failed (Palojoki et al., 2019). The number of recalls submitted by hospital providers precipitated the administration of the FDA to evaluate the quality and effectiveness of processing recalls.

Medical device recalls have steadily increased with no identification system implemented to create a track-and-trace system for processing recalls (Schonberger & Vasiljeva, 2019). In 2007, manufacturers released more than 66,000 medical device recall reports that did not have product identification or lot numbers, which made identifying and processing medical device recalls problematic (Bayrak & Copur, 2017). As the number of medical device recall reports increased by 97%, processing the recalls continued under a manual system (Mukherjee & Sinha, 2018). Health care business executives oversee the processing of medical device recalls (see Appendix A), and many admit to manually processing recalls with only two-thirds processed and one-third lost or never properly identified (Fu et al., 2017). To improve the efficiency of the medical device recall process, the FDA established a UDI system, which includes a barcode on all medical devices, and the global unique device identification database GUDID (Horvath, 2017). Establishment of a UDI system brought medical device recall processing closer to automation rather than manual processing.

The objective for establishing a UDI was to create a method by which manufacturers could refer to the UDI of a medical device during the recall process, and business leaders in

hospitals could identify failed medical devices more easily. Leaders in health care organizations realized an immediate benefit from UDI barcoded devices was keeping an effective inventory (Dhruva et al., 2018). Hospital business leaders who have applied best business practices to the UDI system have established an information system to manage their medical device inventory and track recalls (Maresova, Hajek, Krejcar, Storek, & Kuca, 2020). An information system such as an MMIS can assist by providing information about a recall more quickly and effectively than a manual system.

The adoption of new IT to support UDI systems significantly improved medical device recall processing. Implementing an IT system such as an MMIS to support medical device recalls, enhanced the transaction accuracy rate approximately 73% (Karas, 2016). The implementation of IT together with a UDI system would provide hospital business executives the necessary tools to locate medical devices during product recalls (Ronquillo & Zuckerman, 2017). A UDI system includes two components to improve the medical device recall process: (a) an alphanumeric code that uniquely distinguishes each medical device and (b) a global database called the global unique device identification database that serves as a catalog for every medical device with a UDI barcode (Flores, Oppenheimer Velez, Thompson, Windebank, & Greenberg, 2018). An IT system can support UDI systems and provide hospital business executives with a comprehensive way to manage medical device recalls (Sanders & Ganeshan, 2018). Hospital business executives should substantiate the financial benefit of IT through improved medical device recall processing.

Legal Aspects

Before 1976, government officials were reluctant to impose their authority on lifesaving medical devices to ensure each device passed a quality test for safety (Fox & Zuckerman, 2014). However, the U.S. government needed more oversight through regulation to guarantee medical devices were safe and effective. In 1976, the FDA received regulatory control and safety of all medical devices (Schonberger & Vasiljeva, 2019). Business leaders within the FDA approved improvements to the manufacturing of medical devices by establishing a premarket authorization process (Schonberger & Vasiljeva, 2019). The FDA executive steering committee established medical device recalls into three classifications: (a) Class I devices are general use products requiring little to no regulatory oversight, (b) Class II medical devices are more sophisticated and must pass a review process, and (c) Class III are high-risk medical devices that sustain human life and must pass a premarket authorization (Walker, 2018). The FDA improved the manufacture of medical devices through the regulatory control process.

Published reports alerted hospital business executives regarding the importance of establishing IT to assist in processing medical device recalls. The 1996 EHCR report was a key initiative that led to improving processing medical device recalls (Sayle, 2016). Processing medical device recalls in hospitals continued to be labor intensive. In 2005, the FDA began developing the details of a new tracking system (Bayrak & Copur, 2017). The FDA completed a comprehensive plan to track and monitor medical devices, and in 2012, the FDA Safety and Innovation Act established a track- and - trace system (Rubenfire & Conn, 2016). The EHCR initiative made hospital business executives aware of the labor intensity of processing medical device recalls, which led to the signing of the Amendment Act of 2007 as well as the Safety and

Innovation Act to permit a more accurate and timely reporting of medical device recalls (Resnic et al., 2017). Because of the 1996 EHCR report, some hospital business executives recognized the need for new IT to establish a tracking system to improve medical device recall processing.

The objective within the FDA was to ensure all manufacturers provide a UDI that included a global location number and a global trade identification number on all medical devices and with the right IT systems, improves medical device recall processing (Mukherjee & Sinha, 2018). The Amendment Act of 2007 and the Safety and Innovation Act of 2012 established straightforward guidelines to begin requiring UDI barcodes on all medical devices (Sayle, 2016). In 2013, the FDA mandated that all medical devices manufactured within the United States carry a UDI that included a global location number and global trade identification number (FDA, 2013). Some health care business executives realized the requirement for a UDI barcode on medical devices could assist in tracking and processing recalled medical devices (Drozda, Dudley, Helmering, Roach, & Hutchison, 2016). Unique device identification systems can provide an opportunity for hospital business executives to explore the functionalities of new IT such as an MMIS to improve medical device recall processing.

Unique device identification barcodes can lead to increased patient safety by enabling enhanced implant medical device tracking. Hospital business executives purchase approximately 25% of their implanted medical devices from other countries (Sayle, 2016). Of the imported medical devices, 43% relate to device failure, which raises a patient safety concern because business leaders may not be able to locate their medical devices during a recall (Palojoki et al., 2019). The advantage of a UDI barcode is that hospital business executives can track critical medical devices from electronic medical records to locate implants in patients (Dhruva et al.,

2018). The FDA requirement for UDIs on medical devices does not specify how business executives of health care organizations manage implant medical devices but warn of patient safety by not locating one during a recall (Sachs, 2018). However, with an IT system such as an MMIS, business leaders have a tool to scan the UDI barcode from the implanted medical device directly to a patient's electronic medical records.

Some hospital business executives had reservations about the Amendment Act of 2013 because the implementation of the FDA policy in this act would have had a detrimental monetary impact on their operations. The act was a cost burden for manufacturers that adversely affected business relationships with hospital organizations (Sarkissian, 2018). Business executives within the medical device industry paid over $350 million in one-time costs and over $55 million in annual recurring costs because of the passing of the act (Dhruva et al., 2018). Recognizable benefits of a UDI system increased hospital business executives' awareness of its usefulness. Executives found that a UDI system: (a) allows more accurate reporting, (b) provides a standardized identifier that will enable manufacturers and hospital providers to manage medical devices, (c) produces a global location number, and (d) establishes a global medical device identification system. Some hospital business executives who leaned toward adoption observed that the cost of a UDI system was worth the financial investment for an increase in patient safety (Drozda et al., 2018). Executives who held reservations about adopting IT to support a UDI system withdrew those reservations after understanding the usefulness of the system for operational performance and patient safety (Sayle, 2016).

Conceptual Frameworks

Technology acceptance model. The TAM introduced by Davis (1989) explained behavioral intentions toward computer acceptance regarding a person's attitudes that can affect PU and PEOU. The TAM is a popular theory among researchers working to determine what causes business executives to adopt or reject new IT for professional use (Hsiao & Chen, 2016; Teo & Noyes, 2011). Davis defined PU as a contributing factor that can influence behavior in which a person believes the new information system will enhance his or her professional performance. Davis (1989) further described PEOU as a variable that represents the degree to which a person's perception of using new IT would be effortless. TAM is useful for understanding health care business leader's PU and PEOU that can influence their behavior toward IT acceptance (Abdullah, Ward, & Ahmed, 2016). The behavior variables, PU and PEOU, as defined by Davis, form the basis of a user's willingness to adopt new technologies.

Some researchers have extended the TAM to include behavioral outlook toward determining a person's willingness to adopt new IT. The TAM can help to define the relationships between information system, PU, PEOU, attitude, and behavioral intent (Ko, Wagner, & Spetz, 2018). Studies have shown a correlation between PU and a person's attitude toward system use (Liberati et al., 2017). The TAM is influential in presenting two behavioral variables PU and PEOU that researchers illustrated to determine a health care business executive's acceptance and use toward health care information systems such as an MMIS (Hsiao & Chen, 2016). Researchers in health care illustrated the possibility of determining that the variables PU and PEOU can influence hospital business leaders' decision to use IT (Ko et al., 2018). Understanding the TAM regarding the relationship between the two variables PU and

PEOU and a person's attitude toward system use is important to determine the factors that may influence a hospital executive's decision-making toward adopting IT.

Researchers applying the TAM in hospital settings have indicated that PU is more influential among hospital business leaders (Andayani et al., 2018). Researchers have also found that PEOU had little effect on hospital business executives' attitudes toward IT use and that PEOU primarily relates to the complexity of new IT (Handayani et al., 2017). Further examination of PU confirmed that hospital business executive's decisions to adopt new IT would increase if a system could demonstrate usefulness through some form of financial gain (Askari, Tam, Aarnoutse, & Meulendijk, 2019). Perceived usefulness was more influential than PEOU in executives' intent to adopt or reject innovation because hospital business leaders can assess PU by examining the financial benefits of new IT over time (Abdullah et al., 2016). An evaluation of TAM by Hsiao and Chen, (2016) indicated that when hospital executives contemplate new technology; PU is dominant in their decision to adopt and use the technology (see Figure 1).

The TAM has received criticism as a tool to predict the behavior of an individual toward adopting or rejecting technology because it does not attend to cultural influences. The main objective of earlier TAM research was on the individual and technology use but not the social factors that may influence IT adoption (Brandsma, Stoffers, & Schrijver, 2020). Critics of TAM have noted that TAM excludes the social environment as a set of cognitive factors that influence an individual's attitude and behavior (Abdekhoda, Dehnad, & Zarei, 2019). Researchers have

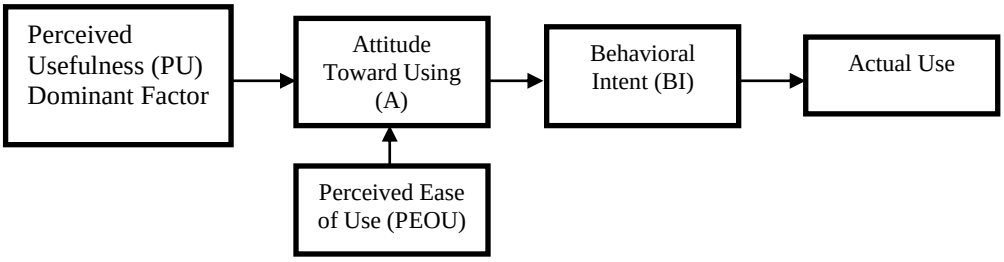

Figure 1. Technology acceptance model (TAM) with PU as dominant factor. Adapted from "Theory Development in Nursing and Healthcare Informatics: A Model Explaining and Predicting Information and Communication Technology Acceptance by Healthcare Consumers," by J. Y. An, L. I. Hayman, T. Panniers, and B. Carty, 2007, *Advances in Nursing Science*, *30, E37-E49.* Copyright 2007 by Wolters Kluwer Health/Lippincott Williams & Wilkins. Reprinted with permission (see Appendix B).

also shown TAM to be incomplete because the theory does not cover social influences within an organization, which may compel the adoption or use of new IT (Lemos de Almeida, Farias, & Carvalho, 2017). Despite these criticisms, the TAM provides useful information for explaining an executive's decision-making process regarding IT adoption.

When researching a health care organization, researchers should assess the stress levels of health care business leaders in addition to PU, PEOU, and behavioral intent, to ensure a more predictive model. Executive's stress levels may negatively influence their decision-making regarding the adoption of new IT (Garavand et al., 2016; Lemos de Almeida et al., 2017). Garavand et al. (2016) found that stress level, as a cognitive factor, could not substantiate hospital business executives' decision to adopt new IT. Researchers who have used the TAM to predict behavioral intent toward IT adoption have contended that stress levels were too unpredictable in explaining hospital business executives' decision to invest in IT (Garavand et al., 2016).

Researchers using the TAM have evaluated psychological attachment in an attempt to determine another cognitive factor that might influence a business leader's behavior toward IT

adoption. Researchers have found that if TAM could determine an individual's comfort level with new IT, the psychological attachment would increase PEOU (Abdekhoda et al., 2019; Venkatesh & Bala, 2008). Some researchers have disagreed whether the extent to which psychological attachment to a system is a factor in determining PEOU (Fu et al., 2018). Askari et al. (2019) agreed psychological attachment would be a factor in increasing an executive's comfort level of new IT only if the IT system evaluated could perform IT-related job tasks in meeting work goals and reducing labor costs. Social influences, not perceptions, or behavioral intent would increase PEOU and contribute to an executive's psychological attachment toward new IT (Sun & Qu, 2015). Without applying the psychological attachment factor, researchers can use TAM as a model to explain hospital business executives' behaviors related to the adoption and use of innovation (Alipour, Mehdipour, & Karimi, 2019); however, a psychological attachment may not be a factor that influences behavioral intent toward IT acceptance.

Ussahawanitchakit (2012) showed PU and PEOU did not effectively predict behavior toward the acceptance of IT when applying TAM theory to business leaders. In a case study conducted in the business industry, Ussahawanitchakit concluded that a business leader's knowledge of IT gained through tasks, resources, and people does not positively affect PU and PEOU. However, the same study showed that an increase in knowledge and understanding of IT increased a business leader's strategies that may influence financial performance and help achieve a competitive advantage (Ussahawanitchakit, 2012). Using studies of business leaders outside the hospital industry may not be practical to determine IT acceptance within the health care domain.

An extension of TAM beyond PU and PEOU determined extrinsic factors that could also influence behavioral intent toward the adoption of innovation. Researchers have re-evaluated TAM and determined that external factors of job relevance, output quality, and computer self-efficacy may have an influence on hospital business executives' decisions regarding adopting new IT (Rajković, Janković, Milenković, & Kocić, 2018). When researchers used TAM to evaluate the relevance of extrinsic factors on behavior, the results were not always favorable (Avgar, Tambe, & Hitt, 2018). However, when who used TAM to combine PU, PEOU, and extrinsic factors relating to job relevance, output quality, and computer self-efficacy, the results influenced business executives' PU toward the adoption and use of new technology (Alipour et al., 2019; Abdekhoda et al., 2019). Revaluating TAM produced a better understanding that intrinsic and extrinsic determinants may affect hospital business executives' decision to adopt new IT.

Diffusion of innovation theory. The DOI theory shows that the diffusion process occurs when individuals communicate innovation within a social network environment. This communication leads to rejection or adoption and use (Rogers, 2003). The diffusion process is the result of social factors, in which researchers can use the DOI theory to explain how and why a person adopts new technology in organizational culture (Ko et al., 2018). Four elements that can determine the success of the diffusion process are: (a) communication channels, (b) perceived characteristics of innovation, (c) characteristics of adopters, and (d) social environment (Fu et al., 2018). The diffusion process will occur when clear communication about the innovation flows from person to person as illustrated in Figure 2.

Communication within a social network plays a role in affecting hospital business

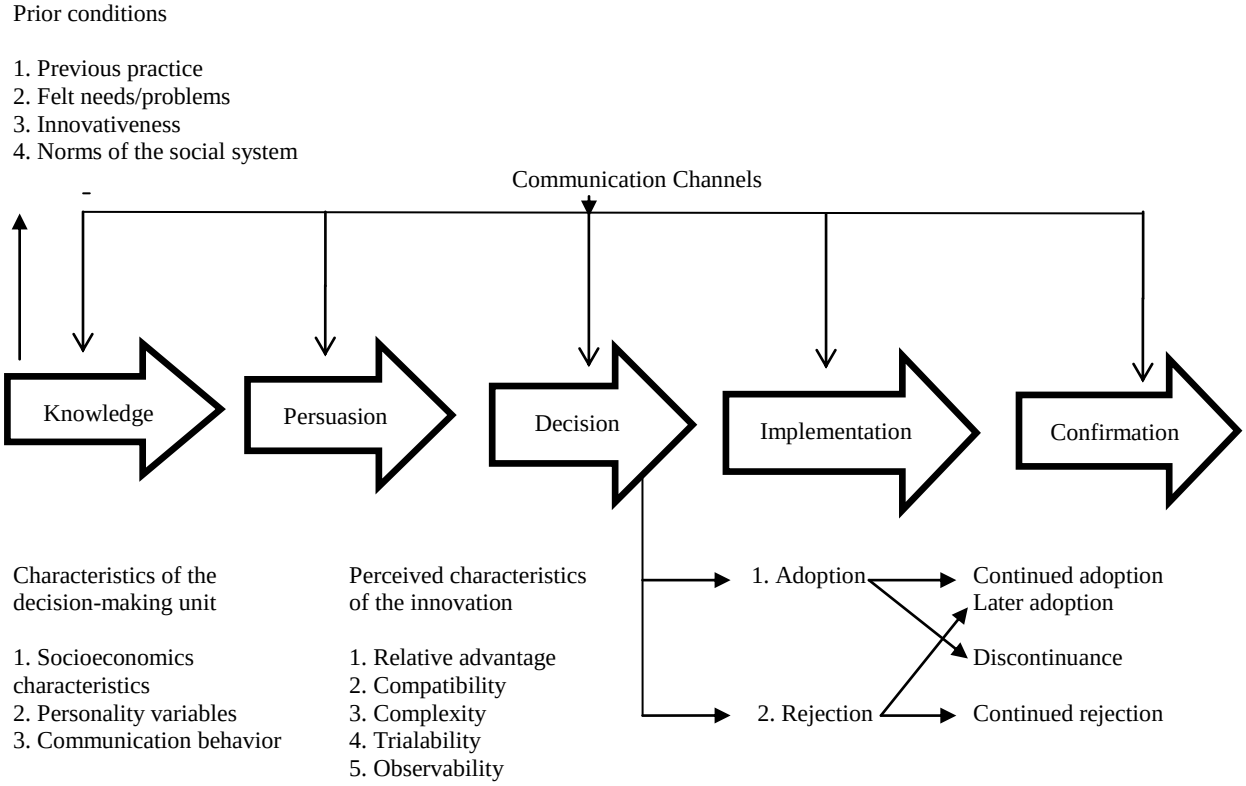

Figure 2. Diffusion process communicated through a social network channel leading to decision, implementation, and confirmation. Adapted from *Diffusion of Innovations,* 5th ed by E. M. Rogers 2003, p.170 Copyright 1995, 2003 by Everett M. Rogers. Copyright 1962, 1971, and 1983 by Free Press, a division of Simon & Schuster, Inc. Reprinted with permission (see Appendix C).

executives' behavior regarding the adoption of IT. The focus of the DOI theory is on the influences of a social system concerning the characteristics of innovation that affect an individual's behavior to adopt new technology (Ko et al., 2018). In a hospital organization, DOI depends on how clearly information flows through communication channels within hospital business executives' social networks (Lemos de Almeida et al., 2017; Fu et al., 2018). Social norms involved in hospital business leaders' decision-making regarding innovation are those processes in which an individual communicates information to other members of the social system (Rogers, 2003). Communication within a business social network about innovation from

one member to another can effectively influence a colleague's decision regarding the adoption of IT.

The decision process from the DOI theory indicates that knowledge of innovation is the most important element of the innovation decision process. The innovation decision model for diffusion within a social network happens in a five-stage process of (a) knowledge, (b) persuasion, (c) decision, (d) implementation, and (e) confirmation that leads members of the decision-making unit toward adoption or rejection and possibly implementation (Rogers, 2003). The five-stage model for diffusion depends mostly on an individual's willingness and ability to adopt innovation and adoption depends on hospital business executives' awareness, interest, evaluation, and trial of innovation (Lemos de Almeida et al., 2017). The key element in Rogers' model is knowledge of innovation and depends on the level of understanding a business executive possesses regarding the existence and functionalities of the system (Lemos de Almeida et al., 2017; Fu et al., 2018). In Rogers' model, a hospital business executive's innovation decision process begins with preconceived knowledge and gains an understanding of how the innovation functions (Fu et al., 2018). Through exposure to innovation, a hospital business executive can gain a better understanding and increase knowledge of the system's functions.

The speed of diffusion process depends on the characteristics of hospital business leaders. Hospital business executives constitute the decision-making units as described in Rogers' innovation decision process, and categorized by socioeconomics, personality variables, and communication behavior; and represent the knowledge element of the innovation process (Gonzalo, Graaf, Ahluwalia, Wolpaw, & Thompson, 2018; Rogers, 2003). The decision-making unit, or hospital business executives, falls into one of five distinct groups: (a) innovators, (b)

early adopters, (c) earlier majority, (d) later majority, and (e) laggards. In a hospital environment, 16% of social systems are laggards, which relates to executives who lack knowledge of IT; the other adopter categories are 2.5% innovators, 13.5% early adopters, 34% early majority, and 34% are late majority (Ko et al., 2018; Fu et al., 2018). Understanding the characteristics of hospital business executives in each adopter category and increasing their knowledge of IT could accelerate the innovation diffusion process.

Innovation characteristics, as part of the persuasion stage of the decision process, can influence hospital business leaders' PEOU. Characteristics about innovation that influences a hospital business executive's decision to adopt or reject technology include factors as relative advantage, compatibility, complexity, trialability, and observability (Rogers, 2003; Fu et al., 2018). Perceived characteristics of innovation can influence a hospital business leader's PU and PEOU. However, 60% of the characteristics directly influence PEOU during the innovation decision-making process toward end-user adoption (Desveaux, Soobiah, Bhatia, & Shaw, 2019); Fu et al., 2018). Gonzalo et al. (2018) posited that if a business leader's perceived efficiencies gained by the innovation relative to its complexity or degree of difficulty to learn, its trialability toward its intended use, and the innovation's observed functionality for ease of use can increase his or her decision-making toward adoption (see Figure 3). These innovation factors add dimension to the construct that the more complex the IT system is to understand and use, the less likely those characteristics will influence users' behavioral intention to adopt (Desveaux et al., 2019; Fu et al., 2018). Innovation characteristics can accelerate hospital business executives' decision to adopt new IT by gaining an understanding of how less complex the innovation is.

TAM and DOI. Examination of the TAM and DOI theories separately may not reveal

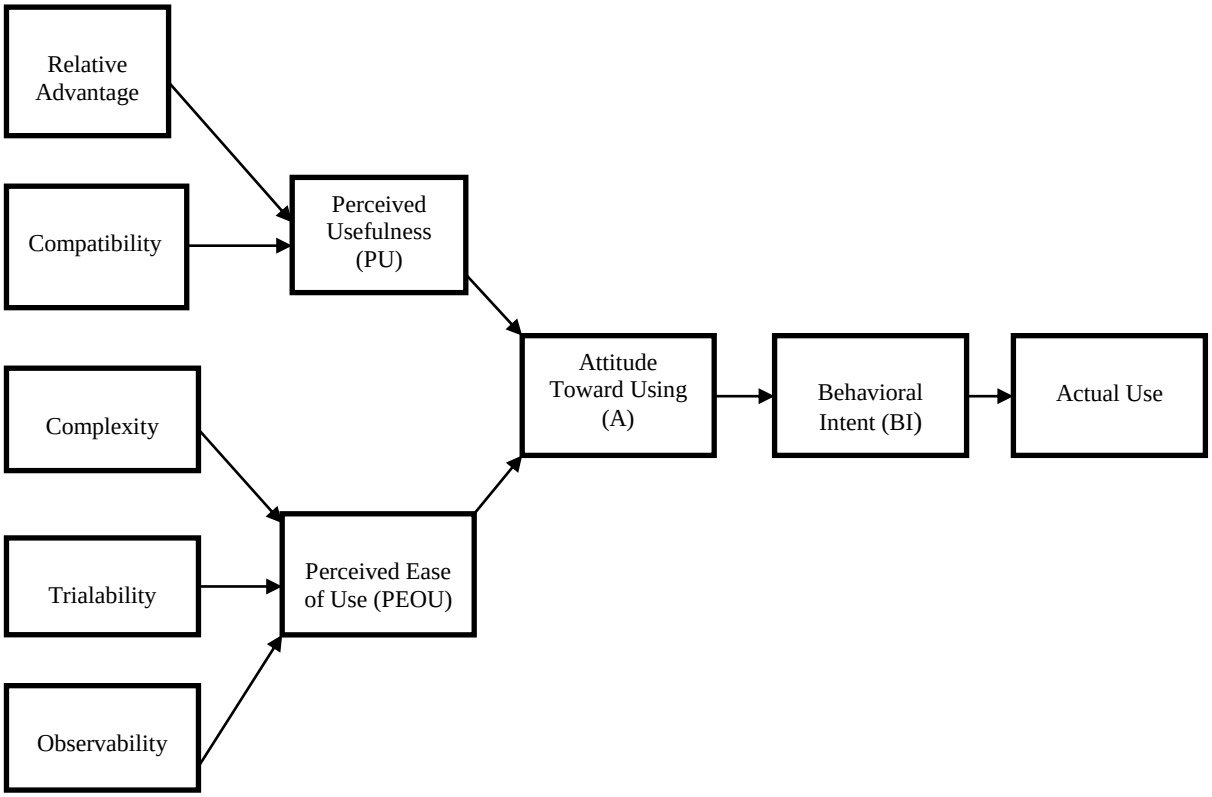

Figure 3. Technology acceptance model (TAM) and diffusion of innovation (DOI) together. Adapted from "Theory Development in Healthcare Informatics: Information and Communication Technology Acceptance Model (ICTAM) Improves the Explanatory and Predictive Power of Technology Acceptance Models," by J. Y. An, 2006, *Studies in Health Technology & Informatics*, *122*, 63-67. Copyright 2006 by IOS Press. Reprinted with permission (see Appendix D).

any relationship between TAM and DOI; however, together they helped form key concepts in an individual's willingness to adopt technology (Desveaux et al., 2019). Business leaders may form their views about new IT adoption or rejection through system usefulness and their social network (Sieck, Pearl, Bright, & Yen, 2020). Amiri, Rahimi, and Khalkhali, (2018) examined the adoption of new technology and revealed that the TAM only helped explain one dimension of an individual's process to and behavioral action toward adoption of new technology. TAM focuses on the concept of how a person perceives the usefulness of the innovation, DOI

concentrates on the social processes of communicating IT characteristics, and both theories elucidate the behavioral influences toward adoption (Sieck et al., 2020).

Convincing health care business executives to adopt new technology can be challenging. The health care industry consists of highly educated business leaders who operate in a unique environment, which makes acceptance of new technology problematic among hospital organizations (Hsiao & Chen, 2016). Because of the complex system of a health care organization, explaining behavioral intent toward new technology can be difficult using the theory of technology acceptance (Mussi, do Valle Pereira, de Oliveira Lacerda, & dos Santos, 2018). Integrating TAM and DOI theories together serves to combine the cognitive factors PU and PEOU, as well as an individual's social system on behavioral intent, to determine users' acceptance and use of technology (Claude, Hansson, & Ben, 2019). Researchers of business executives' behavior toward adoption of new IT should discuss both TAM and DOI. Researching the influences of hospital business executives' behavior can be challenging; TAM and DOI can explain individuals' PU, PEOU, and the communication of perceived characteristics of innovation to enhance his or her decision to adopt or reject new IT.

I established the conceptual framework of this study from the TAM theory developed by Davis (1989) by focusing on two cognitive variables: PU and PEOU to understand one's behavior intent toward technology adoption (Davis, 1989). I also included the DOI theory as part of the conceptual framework, which comprised such perceived characteristics of innovation as relative advantage, compatibility, complexity, trialability, and observability that, when discussed among business executives, enhances the decision-making process toward adoption (Hadorn, Comte, Foucault, Morin, & Hugli, 2016). Also, the DOI theory relies on the idea that

potential users make decisions to adopt an innovation based on characteristics they form through communicating about innovation to gain a better understanding of its functions (Rogers, 2003; Desveaux et al., 2019; Fu et al., 2018). Because of the complex environment in which health care business executives work, TAM and DOI are essential to explaining the behavioral, intent and social influences affecting decision-making ability toward technology acceptance.

The TAM and DOI revealed that analyzing the perceptions of someone who uses IT (Davis, 1989) and innovation characteristics, as also theorized by Rogers (2003), could determine what influences business leaders toward adoption of IT. An examination of both theories revealed that the more useful and less complex IT is, the more likely a person is going to adopt and use the information system (Al-Rahmi et al., 2019). Handayani et al., (2017) argued that PU exists when a business executive can perceive the information system, as improving job performance and demonstrating a positive financial gain to increase the chances for adoption to occur. Another explanation of the influential factors of a person's behavior toward adoption of innovation relates to the belief that using a particular IT system must be free from effort (Ducey & Coovert, 2016). The TAM and DOI can assist business leaders to understand that positive financial benefits and perceived characteristics of technology are helpful influential factors toward adopting new IT.

Despite the limitations of the TAM and DOI, the models include useful information and offer the social-technical factors necessary to assist a hospital business executive's decision-making to adopt an information system. The social-technical issues in health care led to a focus on the PU of hospital business executives' rather than PEOU as the dominant behavioral trait to influence executives' decision toward adoption. An individual's attitude and culture within a

hospital organization are significant in both initial acceptance and subsequent diffusion of the innovation. The TAM and DOI failed to illustrate a universal solution to which factors are more significant in a hospital executive's adoption of innovation for specific health care organizations. The TAM and DOI do provide clarity on the external variables that might influence behavior to predict user acceptance of technology.

Researchers should try to refine and test the adoption models and the importance of the different components of an organization's social system. Researchers should also address the phenomenon of which intrinsic and external social factors are more significant for a particular organization. Davis (1989) and Rogers (2003) lacked clarity explaining where TAM and DOI may exhibit common ground and how the two theories can enlighten communication of various professional groups within a health care organization.

Competing theories. Many theories exist that researchers rely upon to explain technology adoption. In contrast, the information visualization theory combines PU and PEOU from TAM, and social influence derived from DOI theory to develop a third element perceived authority, toward technology acceptance (Bresciani & Eppler, 2015). Kucher, Schamp-Bjerede, Kerren, Paradis, and Sahlgren (2016) described perceived authority as the variable in the technology adoption process that integrates with social networking, image, observability, branding, and visualization effects toward technology acceptance. The framework surrounding information visualization benefits the adoption process by employing such illustrative factors as treemaps and tag clouds (Latham & Tello, 2016). Researchers have shown that the information visualization theory is problematic for attempting to determine which influential factors have the most prevalent impact on the behavior of hospital business executives toward adoption because

all three factors must coexist for the theory to be useful (Crnovrsanin, Mueler, Faris, Felmlee, & Liu Ma, 2014). Applicability of the information visualization theory within the health care industry is not significant, and researchers use the theory more frequently in other areas of business because of its visual image influence (Nilsen, Dugstad, Eide, Gullslett, & Eide, 2016).

The unified theory of acceptance and use of technology (UTAUT) differs from TAM and DOI because the theory incorporates various factors such as performance expectancy (PE), effort expectancy (EE), social influence (SI), and facilitating conditions (FC) that influence behavioral intention toward adoption and use (Venugopala, Jinkab, & Priyac, 2016). Because UTAUT relies on cognitive models of PE and SI, researchers have used the theory within hospital organizations to determine hospital business executive's intention to use new IT (Sharifan, Askarian, Nematolahi, & Farhadi, 2014). Research findings showed PE and SI could determine approximately 60% of hospital business leaders' behavioral intention toward adoption of new IT (Kim, Lee, Hwang, & Yoo, 2016; Sharifan et al., 2014). However, EE and FC only influenced behavior toward technology use and not intention to adopt (Venugopala et al., 2016). The UTAUT demonstrated PE and SI influenced hospital business executives' attitude and behavior intention toward adoption and use, but could not find relevancy of EE and FC when determining influential behavioral factors.

Health Care Information Technology

HIT has an important role in large health care organizations by automating existing processes, increasing efficiencies, and reducing costs (O'Keefe, 2017). The development and use of health care IT in hospitals have led to improvements in health care processes such as medical device recalls (Ko et al., 2018). HIT can be an important asset for health care facilities

by increasing efficiency through eliminating manual processing, which can lead to reduced labor costs.

Health care IT is a major component of a health care executive's financial plan. Forty-six percent of an average hospital's operational budget is for information systems and logistical costs (Moatari-Kazerouni & Bendavid, 2017). The distribution of these costs includes 27% for medical supplies and inventory, 4% for labor performing miscellaneous IT tasks, and 15% for employees assigned to perform material management functions such as medical device recalls (Moatari-Kazerouni & Bendavid, 2017). Health care executives can reduce their operating budgets by implementing automation solutions that can eliminate inefficiencies such as those resulting from processing medical device recalls (Mackey et al., 2019). Some hospital executives may not realize the financial benefits of adopting HIT.

Health care business executives do not adopt innovation for many reasons. Some executives decide to secure their existing information systems to conserve costs (O'Keefe, 2017). Health care IT might not fit into upper management's organizational plan, and many leaders decide not to invest in a new IT system, but the decision may be obvious if the financial benefits are transparent (Haggstrom et al., 2019; Heart, Ben-Assuli, & Shabtai, 2017). Health care business executives might decide not to invest in an MMIS if the business leaders of a government entity such as the FDA implement a policy that does not allow enough time for hospital business leaders to ensure compatibility of the new IT systems (Agote et al., 2016). Lack of knowledge regarding the financial benefits of IT may correlate to health care business executives' decisions not to invest in an MMIS (Heart et al., 2017). Many hospital business executives find HIT performance benchmarks too complicated to measure monetary benefits

related to their hospital processes (Zipfel et al., 2019). The functionalities of HIT is such that hospital business leaders require a better understanding of the economic value an IT system can provide before adoption can occur (Haggstrom et al., 2019).

Hospital business executives require HIT to demonstrate usefulness through efficient workflow processes and increased productivity. To help understand the factors influencing health care business executives' decisions to invest in new IT, researchers proposed that the benefits from HIT systems equal the product of technical efficiency multiplied by allocative efficiency (Menon, Lee, & Eldenburg, 2000). In relation to TAM, technical efficiency corresponds to PU, and allocative efficiency resembles one's PEOU, both of which have a positive effect on business executives' attitude toward adoption (Feng & Shanthikumar, 2018). For hospital business leaders to perceive a new IT system as useful, the IT system must demonstrate an increase in technical and allocative efficiency (Sarihan & Marsap, 2019; Wilson et al., 2020). From the perspective of health care executives, IT investment centers on improvements to current business workflow processes that will increase productivity and produce a profit.

Regulations on the health care industry have caused hospital business executives to rethink their IT systems. When deciding to adopt new IT, health care business leaders consider the investment cost, compatibility, and current IT infrastructure (Ivarsson, Wiinberg, & Svensson, 2016). Health care business executives consider their current IT infrastructure and the degree of interoperability against the various regulations before any investment in new IT (Heart et al., 2017). Also, health care business leaders will not discard old IT infrastructure without first examining all FDA requirements against their current IT system's capability (Tsai, Cheng, Tsai,

WanHung, & Chen, 2019). Health care business leaders considering new IT should measure the technological innovation for compatibility within an organization's knowledge, skills, and interoperability resources (Wilson et al., 2020). The challenge for health care business executives is to consider all FDA requirements against their organization's current IT infrastructure before investing in any new IT system.

During the adoption process, health care business executives consider such factors as interoperability and the ways new technologies will improve business processes such as tracking medical devices using UDI. Some executives have already invested in an information system for tracking and managing their own medical devices with a UDI barcode (Ryan, Doster, Daily, & Lewis, 2016). Upper management will consider the adoption of HIT if an automated system can support UDI barcoding and be compatible with the organization's electronic health care records (EHRs), and the automated information and data capture (AIDC) equipment it uses to manage medical device recalls (Schaffer, Booton, Halleck, Studeny, & Coustasse, 2017). However, hospital business executives are still reluctant to invest in new IT to improve internal business processes such as medical device recalls (Ramsey, Lord, Torrey, Marsch, & Lardiere, 2016). The cost of investing in new IT and leader's lack of understanding of its financial benefits impedes decisions regarding adoption.

Enterprise resource planning. Hospitals can benefit from a central information system with the capacity to manage daily business workflow procedures. Given the changes promulgated by the FDA, hospital executives must focus on how their information system can manage their organization's processes, manage their medical devices, and bring together the various departments feasibly and efficiently (Tang & Hu, 2014). An enterprise resource

planning system is a viable resource if organizational leaders can reduce costs and provide a better workflow process (Dyerson, Spinelli, & Harindranath 2016). An ERP system that can realize a financial benefit would be useful to health care business executives.

Hospital business executives require evidence of performance benchmarks to define if an ERP system is feasible. Hospital business leaders determine the performance of an ERP system from improvements in workflow processes such as medical device recalls to medical device asset management (Dyerson et al., 2016). Empirical studies have shown that ERP systems do not hold a competitive advantage as business leaders of other organizations can acquire the same ERP package from any vendor; however, adopters of ERP customize their system to conform to organizational processes (Spinelli, Dyerson, & Harindranath, 2013). Hospital executives are not seeking a competitive advantage as much as they want to integrate their health care information across the entire organization (Sheffer et al., 2017). Hospital business leaders can realize a financial benefit from an ERP system when they benchmark performance and manage costs.

Enterprise resource planning systems must meet hospital business leaders' objectives both financially and operationally. Health care business managers must focus on efficiency and combine all functionalities from every department to find an ERP system suitable (Haggstrom et al., 2019). The average capital investment of an ERP system is approximately $13 million to $300 million (Elmuti & Topaloglu, 2013). With approximately 75% of upper management in health care organizations using and operating outdated legacy systems, integrating an ERP system involves an extensive and costly training program because of the lack of knowledge of the workforce and business executives (Merlo, 2016). Hospital business executives must consider costs such as implementation, training, repair, and all other costs in addition to initial

capital outlay (Escobar-Rodriguez & Bartual -Sopena, 2015). Enterprise resource planning systems can make hospital organizations more operationally efficient and cost-effective.

Hospital business executives manage the operation of complex business environments but lack knowledge of how ERP systems can functionally manage their inventory, material assets, and medical device recall processes (Sheffer et al., 2017). Some health care business leaders believe ERP systems are for financial purposes and may not fully understand the interoperability of the ERP into their operation (Abukhader, 2015). Hospital business executives consider ERP systems to involve many risks about not being able to integrate all business functions within their organization and about being a key contributor to a lack of understanding and PU of IT such as an MMIS (Escobar-Rodriguez & Bartual-Sopena (2015). However, with an ERP system, integrating and streamlining information through an organization can increase the accuracy of business functions such as purchasing, medical device recalls, and inventory of medical devices, thus eliminating the guesswork of on-hand quantities and what medical devices to purchase (Heart et al., 2017). Hospital business executives have a general understanding of how an ERP system can manage business environments but lack knowledge of how ERP can manage inventory, medical device recall processes, and other business processes.

Health care business leaders must close the knowledge gap of how to integrate an ERP into a hospital organization and achieve positive financial returns. Enterprise resource planning systems will be an integral part of health care organizations, although business executives lack knowledge on the operational functionalities of an ERP (Merlo, 2016). Alignment of current business processes with the ERP system is a critical decision-making step toward adoption (Heart et al., 2017). Health care business executives' motivation to make a change and adopt

innovation comes from knowledge of ERP to streamline information and integrate business functions throughout the organization (Abukhader, 2015). Enterprise resource planning systems can exhibit advantages to hospital business leaders by integrating all functions of the organization while increasing efficiency and demonstrating a financial benefit.

Material management information system. An MMIS is an information system that can handle complex supply chain and business-related functions, but early MMISs did not have the sophisticated software applications to integrate and automate to manage a health care organization's medical devices and processing medical device recalls (Huang, Chen, Lin, & Sun, 2016). Health care business executives for organizations such as the Association for Health care Resource and Materials Management, and the Health care Information and Management System Society found MMIS systems needed to integrate into hospitals' business workflow processes for systems to be useful (Kim & Kwon, 2016). Integration became a major task for health care facilities with an MMIS (Karahanna, Chen, Liu, & Serrano 2019). For example, early implementation of MMIS systems did not recognize universal product number barcodes into their software application ("How you'll modernize," 2016). The FDA amendment of 2013 required all medical devices to have a UDI and health care business executives engaged software vendors to develop MMIS software applications to meet the mandated barcoding requirements (Karahanna et al., 2019). Upper management negatively viewed the PU of MMIS because software applications could not maintain the current health care requirements to integrate workflow processes (Huang et al., 2016). Health care business executives continued to view MMIS negatively until software manufacturers developed more sophisticated software applications.

Establishing a successful MMIS in a health care environment first requires health care business-executive-level support. To gain essential upper management support, an MMIS must prove itself as an integral component and produce automated processes such as asset management, barcoding, purchasing, and medical device recalls (Tsai et al., 2019; Jones, & Van de Ven, 2016). Because of a lack of an IT system, asset management of medical devices remained inaccurate, which led to a problematic medical device recall system (DeGraff, 2013). Automating medical device recall processes through an MMIS saves hours of labor, which can demonstrate cost savings and eventually adoption (Tsai et al., 2019). If hospital business leaders can substantiate the financial benefit of an MMIS through improved workflow efficiencies, the decision to adopt should be positive.

Sophisticated software is necessary for an MMIS to be useful. Some hospital business executives decided not to adopt an MMIS system because of the large capital investment required for hardware and software applications (Karahanna et al., 2019). After the implementation of an MMIS in some health care organizations, the system failed to provide the automation necessary to increase productivity and efficiency essentially because of inferior software (DeGraff, 2013). Approximately 75% of health care business executives kept their organization's legacy system for fear of a lack of information integration with the MMIS (Volland, Fugener, Schoenfelder, & Brunner, 2016). The lack of software applications with the MMIS gave health care business leaders a reason to spend excessive amounts of money on manual, labor-intensive tasks such as processing medical device recalls (Huang et al., 2016). Health care executives opposed to MMISs indicated that software applications for MMISs were not worth the investment.

An MMIS that has the required software scripts, business leaders in hospital organizations can automate workflow processes, which can lead to a reduction in manual labor (DeGraff, 2013). Software vendors developed sophisticated software scripts so leaders of health care facilities did not have to spend millions of dollars to replace MMIS hardware (Tsai et al., 2019). Software scripts were attractive and worth the investment. When implemented into MMISs, health care business leaders recognized significant results in reducing labor-intensive work managing medical devices and processing medical device recalls (Tracol, 2016). MMISs have demonstrated a reduction in manual labor to nearly 40% however; health care business leaders have not made the financial investment toward adopting such a system to manage medical device recalls (Karas, 2016). Software scripts are a necessary element to enable MMISs to automate such processes as medical device recalls.

Influential decision-making aspect that may be able to seem more plausible to persuade hospital business executives not to adopt an MMIS is an ERP system. MMISs have been in existence for 20 years while ERP systems are new to the hospital industry (Schaeffer et al., 2017). Health care business leaders are looking for one information system that can offer more than medical device asset management such as interoperability with automated medical records (Kim & Kwon, 2016). Enterprise resource planning systems do not have as much functionality as the MMIS, which would inhibit an ERP system from automating medical device recall workflow processes (Huang et al., 2016). Expensive software applications that exist with an MMIS persuade business leaders to adopt ERP systems (Kalong & Yusof, 2017; Elmuti & Topaloglu, 2013). However, understanding detailed workflow processes such as medical device recalls can facilitate the decision-making process for health care business executives relating to

the adoption of an ERP or MMIS (Schaeffer, 2017). MMIS has demonstrated more technological functionalities over an ERP system to handle processing medical device recalls and making an MMIS more desirable.

Material management information systems should demonstrate interoperability with other systems to establish an increased financial benefit for health care business leaders. MMISs can integrate with other automated systems such as EHRs, and AIDC equipment to read and transfer UDI information (Karahanna et al., 2019). Material management information systems have demonstrated their functionality to integrate with other systems that have resulted in the successful transfer of UDI information from the medical device to a patient's EHR (Singh et al., 2017). A material management information system can reduce manual labor through interoperability that is a tangible financial benchmark for hospital business leaders (Tsai et al., 2019; Volland et al., 2016). Processes such as barcoding are a necessary function of MMISs to reduce manual labor in tracking medical devices from a patient's EHR (Yoon, Lee, & Schniederjans, 2016). Integrating MMIS with other automated information systems such as AIDC or EHR has revealed a 40% reduction in labor hours making an MMIS desirable for hospital business executives (Kim & Kwon, 2016).

Hospital business executives may not be aware of how an MMIS can use UDI information to process medical device recalls. The UDI barcode imposed by the FDA has led to a lack of clarity among hospital business leaders regarding what to do and how an MMIS can capture and make good use of the UDI information (Sayle, 2016). With the assistance of experienced personnel, the transfer of UDI information from the MMIS to patient's EHR will enhance medical device recall processing (Alsohime et al., 2019). The disadvantage of not

implementing an MMIS to process UDI information may not be apparent until a recall occurs and identifying the specific model and lot numbers affected by the recall becomes difficult (Tracol, 2016). The published research on UDI systems revealed approximately 11% of health care business leaders had implemented an MMIS to support UDI information and medical device recalls, whereas 40% of health care business executives lack knowledge of the financial benefits of adopting an MMIS (Karas, 2016). Hospital business executives may not fully understand the financial benefits of an MMIS from a UDI system that can create an efficient track-and-trace medical device recall process.

Hospital business executives may not have the fundamental understanding of the intricacies of an MMIS to understand the financial benefits the system can deliver (Palojoki, Saranto, & Lehtonen 2019). The administrators at the FDA directed manufacturers to have a UDI barcode on all medical devices, and the challenge is for hospital business executives to make good use of the UDI information (Sayle, 2016). Some health care business executives have considered investing in an MMIS and incorporating UDI information for processing medical device recalls, while others have chosen not to adopt and to keep their current legacy IT or to purchase an ERP system (Agote et al., 2016). Health care business executives may not have the fundamental understanding of the functionalities of an MMIS, so they must benchmark job performance toward establishing their perceived usefulness in an MMIS (Tsai et al., 2019). An MMIS can create automated medical device recall workflow using UDI information and demonstrate a financial benefit by reducing labor-intensive manual processing (DeGraff, 2013). However, hospital business executives' insufficient understanding of the financial benefits of an MMIS results in their reluctance to execute business strategies to implement new IT (Huang et

al., 2016). This lack of knowledge may be attributable to the absence of understanding the functionalities of an MMIS (i.e., capturing UDI information and facilitating medical device recalls).

Summary

Researchers who focus on the TAM have examined intrinsic factors such as PU and PEOU to explain behavioral intent and attitude toward adoption or rejection of technology, but excluded the social environment as a cognitive factor that influences behavior (e.g., Fu et al., 2018). Merlo (2016) presented findings that revealed PU as the dominant behavioral trait to influence hospital business executives' decision toward the adoption of IT. The DOI theory complements the TAM by adding the dimension of the diffusion process, which occurs within a hospital business executive's social network (Claude et al., 2019). Researchers Desveaux et al. (2019) and Fu et al. (2018) have used DOI to formulate discussions on user-perceived innovation characteristics, which can influence the behavior of hospital business executives toward the adoption of new IT. The internal and external variables introduced through TAM and DOI theories are factors that influence hospital business executives' behavior to predict the acceptance of new technology.

An MMIS can demonstrate efficiency through job performance, which can convey a financial benefit to gain executive management's support toward adoption. Health care business executives require high MMIS performance traits toward establishing PU and eventually the adoption of IT (Tsai et al., 2019). Interoperability with AIDC equipment and UDI systems to deliver automated medical device recall processes that can reduce manual labor are good performance objectives that can demonstrate the financial benefits of an MMIS (Sayle, 2016).

However, despite literature illustrating the financial benefits of an MMIS, less than 20% of hospital business executives have IT to support UDI systems and medical device recalls, and approximately 40% lack strategies to implement an MMIS preventing adoption (Huang et al., 2016; Karas, 2016). The lack of strategies to implement an MMIS may lie within hospital business executives not understanding the financial benefits or the functionalities of how an MMIS can capture UDI information to facilitate medical device recalls.

Transition

In Section 1, I presented the objective of this qualitative exploratory case study, which is to explore hospital business executives' strategies associated with implementing MMISs associated with medical device recalls. I discussed the underlying problem for this study and presented a central research question, interview questions, conceptual framework, assumptions, limitations, and delimitations, as well as the research approach, which includes a qualitative methodology with an exploratory case study design. Section 1 also included a thorough review of the literature on the TAM and DOI theories as they relate to factors that influence health care business leaders' attitude and behavioral intent toward adopting new IT. In the literature review, I described how HIT, such as an MMIS, leads to an enumeration of possible contributing factors that provide an understanding regarding why 40% of hospital executives lack strategies to implement an MMIS associated with medical device recalls. In section 2, I will focus on the overview of the research project.

Section 2: The Project

The research methodology I cover in Section 2 includes a discussion of the data collection process and an explanation of the steps taken to assure the reliability and validity of the study. Content in Section 2 includes a description of (a) the purpose, (b) the role of the researcher, (c) research participants, (d) the research design and methodology, (e) population and sampling, (f) data collection techniques, (g) data analysis, and (h) the ethical components of the research. This section sets the tone for the collection and analysis of data. In Section 3, I present an overview of the study and the findings from the data analysis.

Purpose Statement

The purpose of this qualitative exploratory case study was to explore health care business executives' strategies for implementing an MMIS related to medical device recalls. The population for this study was a census sample of health care business executives located in an urban hospital in the northeast region of the United States who implemented MMIS strategies to support medical product recalls. The implication for positive social change is the potential to influence health care by increasing patient safety through improved medical device tracking (Ronquillo & Zuckerman, 2017).

Role of the Researcher

The role of the researcher in qualitative research is to form a working relationship to establish trust with participants during data collection and to eliminate internal biases to interpret and understand what was said (Xu & Storr, 2012). Disclosing personal expertise in the subject area can add trustworthiness with participants (Onwuegbuzie & Hwang, 2014). Establishing trust with the participants allows for an uninhibited understanding of the phenomenon (Cronin,

2014; Snyder, 2012). To meet that goal, I worked through two challenges: (a) I ensured that no personal opinions, feelings, or biases interfered in carrying out the interviews; and (b) I established trust with all participants, so they felt at ease, which allowed natural (yet unpredictable) themes to emerge.

My relationship with the topic culminates my 30 years' of experience working as a business leader in supply chain management combined with over 5 years working in health care logistics. Indecision can be a threat to any implementation plan, and I have witnessed hospital executives' hesitancy to adopt new IT such as an MMIS. From this, I learned health care executives' indecisiveness stems from their perception of IT systems to demonstrate process improvement. The overarching question I tried to answer was what strategies would affect successful implementation of an MMIS? Motivated by management's decision paralysis whether to adopt or reject IT, I designed this case study to explore successful implementation strategies of an MMIS related to medical device recalls.

Researchers of qualitative studies conducting interviews must ensure the data are credible and trustworthy from the participants' perspectives (Resnik, Miller, Kwok, Engel, & Sandler, 2015). To avoid personal bias, researchers should not ask leading questions (Onwuegbuzie & Hwang, 2014). I mitigated personal bias by refraining from asking leading questions, using an interview protocol, and performing member checking with the interview data. An interview protocol is a tool that can provide a list of the interview questions as well as a guide directing the researcher through the interview process (Atchan, Davis, & Foureur, 2016; see Appendix E). The rationale for using the interview protocol was to keep each interview session focused. Member checking provides an opportunity for participants to verify, confirm, and clarify the

researcher's interpretation and summary of the interview responses (Culver, Gilbert, & Sparkes, 2012; Harvey 2015). I used member checking to mitigate personal bias and to ensure the data collected conformed to each participant's experiences and not my own.

The researcher's responsibility is for the protection of participants in a study. In addition to building trust and removing bias, it is the researcher's due diligence to guarantee all ethical principles are adhered to (Samaranayake, 2012). The Belmont Report provides guidelines for the researcher to ensure research integrity by assuring three ethical tenets be adhered to when researching human subjects (a) respect for persons, (b) beneficence, and (c) justice (U.S. Department of Health & Human Services, 1979). I ensured the protection of all participants by following the ethical standards as identified in the Belmont Report.

Participants

The participants for this study were a census sample of six health care business executives from an urban hospital in the northeastern United States who developed strategies to successfully implement an MMIS related to medical device recalls. Study participants should be a group of individuals who can share their knowledge, experience, and information toward the unknown (Harland, 2014). Knowledgeable participants can provide substantive data for answering the research question (Sangestani & Khatiban, 2013; Smith, Colombi, & Wirthlin, 2013).

I established access to the participants by creating a working relationship with one of the health care business executives in the hospital organization. Establishing contact with a business leader facilitated trust among the remaining research participants. Researchers should establish business relationships with those who provide access to research participants (Holloway &

Wheeler, 2013). I assured my trust and mutual relationship through a data collection request in which I outlined the assistance required, terms, and conditions as delineated by the health care executive. A copy of the data collection request is included in Appendix F. I maintained communication via e-mail with the participants up until the time of the interview to continue my working relationship. I communicated with all participants and ensured each felt comfortable to contact me via e-mail or phone if they wished to withdraw from the study.

Qualitative researchers should establish ethical working relationships with all participants by respecting their opinions, perceptions, and experiences while maintaining open lines of communication (Gallagher, 2019). After I established my relationship with the supporting health care executive, and after I executed a community partnership agreement, I requested a roster of the executive leadership team. Once I obtained a list of interviewees, I sent e-mail letters to the respective health care executives and requested their participation in the study (see Appendix G). The e-mailed letter served three purposes for this study: (a) a special invitation for each candidate to contribute toward the research, (b) a summary of the purpose and goals of the research, and (c) the primary means for screening each candidate. I established ethical relationships and ensured all participants had an opportunity to express their knowledge toward supporting implementation strategies of an MMIS.

Research Method and Design

Research Method

I chose the qualitative research method for this study. Qualitative research is a methodical approach to collecting, organizing, and interpreting empirical data used in the exploration of a research phenomenon as experienced by the participants (Wahyuni, 2012). The

purpose of qualitative research is to understand the complexity of a phenomenon through a series of systematic and interpretive techniques (Katz, 2015). Researchers choose qualitative research methodology because of their need to address complicated issues through a well-documented data collection and analysis process (Andrews, 2017).

In quantitative research, researchers rely on quantification of operational variables and statistical analysis (Goertz & Mahoney, 2013). Quantitative research is typically a scientific approach where the focus is (a) testing a hypothesis, (b) performing analysis, and (c) developing meanings of concepts and variables (Allwood, 2012). Quantitative research does not afford the researcher the ability to use open-ended questions for exploring and understanding a business phenomenon (Vance, Talley, Azuero, Pearce, & Christian, 2013). I did not select the quantitative research method because the phenomenon I am researching is difficult to quantify. I am not testing a hypothesis, and quantitative research does not afford the use of open-ended questions.

The mixed method approach combines both qualitative and quantitative methodologies. The mixed method is appropriate when conducting research requiring a larger, transformative purpose of a social cause (Ponterotto, Mathew, & Raughley, 2013). Mixed methods offer researchers the ability to use participants' experiences and operational variables to test a hypothesis and answer a central research question (Guise, Hansen, Lambert, & O'Brien, 2017). I chose not to use the mixed methods research for this study because I am not testing a hypothesis. The qualitative approach is appropriate for this study because the methodology allows for a deep exploration of the complexities of business executives' strategies and decisions.

Research Design

I considered the following designs: (a) phenomenology, (b) narrative, (c) ethnography, and (c) case study. Researchers select a phenomenological design to study participants' lived experiences with the phenomenon to reach a better understanding of the research problem (Daher et al., 2017). A phenomenological design involves extensive researcher-participant engagement, such as interviews, to develop rich data, patterns, and themes (Annansingh & Howell, 2016). I did not need extensive researcher-participant engagement because my research was narrowly focused on implementation strategies of an MMIS for medical device recalls. The phenomenology design was inappropriate because the design is limited to experiences and I intended to employ multiple data sources (face-to-face interviews and archival documents) toward developing a rich understanding of the research phenomenon.

A narrative research design is an exploration of the individual experiences presented as a story in chronological order or by the meaning of the experience (Thomas, 2013). Narrative studies explore the biographical life experiences of individuals on an event (Petty, Thompson, & Stew, 2012). The narrative approach was inappropriate for this study because I was not searching for a story, but rather my intent was to discover the implementation strategies of adopting an MMIS for medical device recalls using methodological triangulation.

Ethnographic research is a qualitative research design where the researcher studies the social interaction, behavior, or perceptions of a population within their environment to gain an understanding of a research phenomenon (Cruz & Higginbottom, 2013). The research objective of an ethnographic study is to provide detailed insights of a population within a specific culture and document from an inside view an understanding of a social phenomenon (Williamson,

Twelvetree, Thompson, & Beaver, 2012). An ethnographic design was inappropriate for this study because I intended to explore the implementation strategies of a small group of health care business executives as opposed to a larger population within a specific culture.

I chose a case study design for this study. Case studies must be a systematic investigation conducted over a period where researchers can explore, describe, and collect data using multiple data collection techniques to obtain in-depth data on the research phenomenon (Cronin, 2014). Case study designs afford opportunities to collect data within the environment of the research phenomenon using a variety of data collection techniques (Petty et al., 2012). A case study design was appropriate because I relied on multiple data collection techniques (i.e., face-to-face interviews and document analysis) where I explored the real-life context of health care business executives' MMIS implementation strategies.

The qualitative researcher can achieve data saturation when the information from the study begins to replicate, and no new data emerges (Fusch & Ness, 2015). Researchers should focus on rich, thick data when collecting data from interviews, documentation, observations, or focus groups that will provide the best opportunity for data saturation (Higginbottom, Rivers, & Story, 2014). Qualitative researchers should cease interviewing additional participants when no new knowledge or understanding of the research phenomenon surfaces (Robinson, 2014). I achieved data saturation through face-to-face semistructured interviews and asked open-ended interview questions to all respondents and by the sixth participant, no new information emerged from the interviews and crosschecked with data from the archival documents came forth.

Population and Sampling

The target population for this qualitative case study was a census sample of health care business executives with knowledge of implementation strategies of an MMIS located in an urban hospital in the northeastern United States. The eligibility criteria that was used to select the study participants was that the executives had to have experience successfully applying strategies to implement an MMIS related to medical device recalls. I ensured all participants met the eligibility criteria through the signed consent form.

I chose census sampling for this study. Census sampling is collecting data from all participants within a universe leading to more accuracy than purposeful or convenience sampling methods might provide (Dani, Idrus, Nimran, & Sudiro, 2013; Mouhamadou, Jeanie, & Rosa, 2017). Swanier (2016) used census sampling in an exploratory case study to collect data from five participants who shared their implementation strategies of an ERP system. I used census method to perform data collection from all six executives of the leadership team from the chosen research site who know implementation strategies of an MMIS. The advantages of census sampling are that this method provides an opportunity to gather rich, thick data and as a result, the researcher can achieve more accuracy Mouhamadou et al., 2017). Disadvantages of census sampling are (a) this method requires dedicated time collecting data, (b) sampling can be very expensive, and (c) data collected through a census method is more susceptible to statistical errors (Dani et al., 2013). Determining the correct sample size is crucial because a large sample size can cause ethical issues and likewise too small of sample size may not lead to a better understanding of the research problem (Onwuegbuzie & Byers, 2014). Interviewing all participants through census sampling allows the researcher to gain accurate information, which

increases credibility (Mouhamadou et al., 2017). I used census sampling because of the convenience to interview members of the same management team who had a role in MMIS decisions.

I scheduled in-person face-to-face interviews onsite for convenience of the participants. I ensured the setting was appropriate and the participants chose either their office or a secure conference room. I also made sure, when we were ready to conduct the interviews, I scheduled the interviews at a date and time they chose and were comfortable. Conducting interviews in predesignated places with no interruptions, allows for an open exchange of communication, leading to rich responses to the interview questions (Jacob & Ferguson, 2012).

Qualitative researchers should choose a sufficient sample size that will align the research study in a manner to attain data saturation (Gibbins, Bhatia, Forbes, & Reid, 2014). The sample for this proposed case study is a census sample of six subject matter experts that have successfully implemented an MMIS related to medical device recalls. Achieving data saturation, a researcher continues to collect data until no new data emerges and there is enough information to replicate the study (Fusch & Ness, 2015). A researcher is concerned with information that is rich in depth to produce enough data to reach data saturation (Higginbottom et al., 2014).

Researchers should not be concerned with the size of the population but rather the method that will get to data saturation (Morse, Lowery, & Steury, 2014). I selected methodological triangulation as my data collection strategy where I conducted face-to-face interviews and selected various company documents for analysis. Face-to-face interviews with open-ended questions were my primary data collection technique. Interviews are a method for

researchers to achieve saturation (Denzin, 2012). To achieve saturation, I conducted face-to-face interviews with all participants within my census sample until no new data emerged.

Ethical Research

Ethical research starts with the researcher taking responsibility to understand the guiding principles that govern ethical research and following those principles and standards throughout the development and conclusion of the research study. A researcher must be responsible, make ethical choices from the beginning of the study to the end, and consider the appropriate treatment of the participants (Phelan & Kinsella, 2013). According to the American Counseling Association (ACA, 2005), ethical research is the behavior that is conducive and consistent with guiding ethical principles while conforming to federal and state laws governing research with human participants. After completing the required ethical training, the National Institute of Health Office of Extramural Research acknowledged my general understanding of the protection of human subjects and awarded me certificate number 686035. I treated all respondents with respect, honesty, and courtesy and ensured transparency throughout the research process.

The informed consent process provides an opportunity for the researcher to explain to the participants their right to speak freely, think for themselves, and the freedom to make an un-coerced decision about their participation in the study. During the informed consent process, the researcher explains the research phenomenon, the purpose of the study, and the central research question (Chiumento, Khan, Rahman, & Frith, 2015). Each participant received an informed consent agreement to review and sign. For this study, I explained to all participants they may withdraw from the study without prejudice by indicating their intent through e-mail or other

means of communication. There was no compensation or incentives provided to the participants for their participation in this study.

To ensure autonomy, I established a working relationship that was honest and trustworthy with the selected participants and discussed the research topic, research problem, the purpose, and objectives achieved by conducting this study. By establishing an open relationship with the participants, their willingness to contribute and provide in-depth responses to the interview questions increases (Samaranayake, 2012). Transparency was necessary for the ethical value of this research.

I established confidentiality of all participants' identity by preassigning an alphanumeric code. Assigning a code to the participants assisted in identifying each participant as I completed the Section 3 of this study. I also protected the research site by not referring to the health care organization by name. Confidentiality is a necessary ingredient to protect the privacy of the participants (Killawi et al., 2014).

This study passed the requirements of the Institutional Review Board (IRB) process and Walden University assigned approval number #08-13-18-0273577 on August 13, 2018. The IRB approval number indicates I have met all ethical requirements for my research. In addition, I stored all research data on an external hard drive and all paper copies from the data collection are in a locked safe. All data collection findings will remain locked in a safe for 5 years per Walden University IRB regulations. After the 5-year period, I will destroy all data.

Data Collection Instruments

I acted as the primary data collection instrument. I chose methodological triangulation to include interviews and historical document analysis as the data collection instruments for this

qualitative case study. I received archived documents for review such as medical device recall standard operating procedures (SOP), MMIS training documentation, medical device recall and inventory reports, strategic planning documentation, and implementation lesson learned reports from May 2011 to June 2013, which informed how the TAM theory may influence hospital business executives' decision toward adopting an MMIS. Triangulation included a comparison of interview data with company documents to show hospital business executives' perceived usefulness of the system. This provided an understanding of how members of a social system can influence behavior toward adoption of an MMIS. Using multiple forms of data provided converging lines of inquiry in the process of understanding a research phenomenon (Heale & Forbes, 2013). Research that applies multiple sources for data collection can produce evidence toward meeting the rigor of case study research (Singh, 2014). Controls should be in place to mitigate for inconsistent data collection procedures, which may jeopardize credibility (Atchan et al., 2016). Asking the same interview questions to all participants allows for a diverse range and depth of answers that can enhance the credibility of the study (Kyvik, 2013). In addition, an interview protocol (see Appendix E) lists procedures necessary to ensure consistency from collecting data from the interviews. For this case study, interviews and document analysis assisted in providing the necessary research data toward understanding health care business executives' implementation strategies of an MMIS.

Company archived documents provided additional research data toward a better understanding of the research phenomenon. Documentation assisted in corroborating the data collected from interviewing the participants (Cronin, 2014). Qualitative researchers who perform document analysis can provide history in defining background information that cannot

be determined through interviews or observations (Wilson, 2014). I requested to review documents such as medical device recall reports, medical device recall SOP, MMIS training documentation, medical device inventory reports, strategic planning documentation, and lesson learned reports from May 2011 to June 2013 as support documentation to collaborate with the interview responses by the participants. The use of multiple data collection sources increases the quality and credibility of the study (Dasgupta, 2015). I examined the medical device recall and inventory reports together with written operating procedures to compare the collected data with the recall process. Next, I inspected the detailed inventory reports and determined the organization's sustained inventory accuracy and downward trends in inventory losses of medical devices. Finally, I examined the strategic planning documentation against the lesson-learned reports to substantiate past failures into implementation strategies that are successful. Corroboration of company documents with the interview questions lead to a successful implementation strategy such as understanding MMIS functions that provided positive influence on health care executives toward adoption. Social communication of an MMIS resulted in an implementation strategy that the system has the infrastructure elements to be compatible with existing systems. The triangulation of the interview questions and the company's artifacts provided the necessary indicators of the system's usefulness in answering the research question.

Semistructured interviews allowed flexibility to adjust the interview questions based on the responses to gain a deep understanding and thick description of a research phenomenon (Gallagher, 2019). For the initial interviews, I interviewed all participants face-to-face at a predetermined time and place selected by the participants where they felt comfortable to answer the interview questions without interruption. I used e-mail for any follow-on communication

with the participants, which I kept those discussions during normal working hours. I asked open-ended questions about the research problem and probing questions as necessary to add to the responses and assisted the participants with developing rich information to the interview questions. In addition, I used a research log during the interview to assist in focusing on the participant's point of view relevant to the research question. In my research log, I illustrated important quotes made by the participant that served as a reminder to follow up later for further discussion. The semistructured interview with open-ended questions was the main approach for this study because this type of interview allowed for greater interaction with the participants to share his or her experiences, thoughts, and ideas.

I established credibility, the qualitative term for validity, through member checking, which is a process of having participants review my interpretation and summary of the interview questions to ensure I captured their responses accurately. Member checking goes beyond the mere content of the data and provides an opportunity for participants to verify, confirm, and clarify the researcher's interpretation and summary of the interview responses for accuracy, thus assuring credibility (Culver et al., 2012; Harvey, 2015). Through member checking, I increased reliability and validity of the data collected.

Data Collection Technique

Data collection commenced after the participants reviewed their invitation letters (see Appendix G), the informed consent agreement and agreed to participate. Once I received consent via e-mail, I arranged a convenient date and time based on the needs of the participants for the interview sessions. Before the start of each interview session, I attached a copy of the interview questions in an e-mail and submitted to each participant.

I conducted face-to-face interviews with open-ended questions as the primary data collection technique. Semistructured interviews allow for flexibility from the responses of the participants, which may elicit an in-depth understanding of the research phenomenon (Jamshed, 2014). The advantage of semistructured interviews, in case study research, is this data collection technique allows participants freedom in their responses thus leading to new themes about the research phenomenon (Hermanowicz, 2014; Jamshed, 2014). The prevalent disadvantage of conducting interviews is there is no fortification against researchers leading the participant to a particular answer thus increasing the risk of biasing the interview (Onwuegbuzie & Hwang, 2014). I conducted face-to-face semistructured interviews with pre-defined open-ended questions in which I captured the thoughts, ideas, and the experiences of each participant.

I obtained permission to record the interview sessions through the informed consent agreement. The interviews were audiotaped using an Echo Smartpen. Recordings of the interview sessions assist the researcher in validating responses and assists in identifying additional thoughts (Lampropoulou & Myers, 2013). Qualitative researchers should review the research data from each interview session and ensure the credibility of the data (Houghton, Casey, Shaw, & Murphy, 2013). After the interview session, I transcribed the recordings using the software tool Livescribe and created a summary of responses to the interview questions onto to a Microsoft Word document. Transcribing the interview session is an essential step toward data analysis (Nelson, Onwuegbuzie, Wines, & Frels, 2013).

I explained to each participant all personal information in the informed consent form was safeguarded before such information was obtained during data collection (see Appendix H). I e-mailed each research participant a copy of the interpretation of my summarization of their

transcribed interview data, requested two days to review the written summary of the interview responses for accuracy, and provided adjustments where necessary. I conducted a follow-up interview with each participant via e-mail, communicated any changes that were necessary to ensure all information was accurate, and represented the responses of each participant. After the follow-up interviews, I made all appropriate editorial corrections to my summaries as suggested by the participants.

I used an interview protocol and member checking to ensure credibility. The interview protocol for this study (see Appendix E) outlined the steps necessary to collect data from each respondent. The interview protocol served as a guide as I greeted the participants, reviewed the purpose of the research, explained the member checking process, and reviewed the informed consent criteria before beginning each interview. Inconsistent data collection procedures may jeopardize research credibility (Atchan et al., 2016). I performed member checking by having each participant review my summary of his or her responses to the interview questions. Member checking is a tool in qualitative research used to confirm, clarify, and assure the accuracy of the data collected during the interviews (Harper & Cole, 2012). Researchers can use member checking to test and fit their interpretation of participants' responses (Green, 2013). I summarized each participant's interview response and allowed each participant to clarify my interpretation if necessary.

I used methodological triangulation in this study to corroborate interview data with document analysis. Methodological triangulation in case study research involves using multiple sources of data (Bhatta, 2018). Before I received any company artifacts for review, I requested permission through the informed consent agreement. I reviewed such company documents as

strategic planning document, medical device recall SOP; MMIS training documentation, medical device recall reports, medical device detailed inventory reports, and lesson learned reports May 2011 to June 2013. An advantage of document analysis is the researcher can acquire unexpected clues to fill interview data gaps about the case (Stake, 1995). A disadvantage of archival document analysis is that the researcher is subject to bias in interpreting the data contained within the documents (Andrews, 2017). Multiple sources of data such as interviews and company documents are beneficial in providing comprehensive data, increased validity, and enhance understanding of the phenomenon (Heale & Forbes, 2013). The strengths of triangulation are completeness and confirmation of the data (Cronin, 2014). The combination of documents generated from an MMIS and participants' interview response provided the detailed information necessary and contributed toward answering the research question.

Data Organization Technique

I created an electronic research log in Microsoft Word, which I considered my case study database that contains all research data collected from this study. The research log created was stored on a password-protected portable electronic storage device that included all interview transcripts, notes documented during the interviews, weekly reflections, decisions made, methods adopted, personal feelings, biases, and insights from the research process. Qualitative case study researchers should create a database to accommodate all data from the research (Yin, 2012). Researchers should begin to organize all case study data after the first interview to prepare for analysis and thematic coding (Onwuegbuzie & Byers, 2014). I maintained all data in a research database that ensured an audit trail that can provide a methodological reference for when, why, and what changes took place during the research.

I used letters and numbers to identify the participants from my interview summaries. The letter P and a number represented each participant (e.g., *P01* will represent the first participant). Keeping the data coded protected the confidentiality and anonymity of the participants (Yin, 2013). Qualitative researchers should protect personally identifiable information by organizing and safeguarding the research data (Cairney & St. Denny, 2015). I ensured and protected all personal information of the participants in this case study by coding all participants' names and their respective audio tapes as P01, audio tape P01, P02, audio tape P02, P03, audio tape P03, etc. I kept each audiotape file of the interviews and an electronic Microsoft Word file of all interview interpretations and summaries locked in a safe and secured at all times.

The data generated from company documentation about the research topic formed the final electronic data file for the study. All research material contained in the external storage device will remain in a locked safe for a minimum of 5 years that will be accessible only by me. After the 5-year period, I will dispose of the research material in a manner that will render all information unusable.

Data Analysis

In this case study, I used the data from interviews and archival documents as methodological triangulation to code identify themes and interpret the data. Data analysis in qualitative research involves exploring themes and analyzing the findings through interview transcripts, research log, documents for analysis or other data collection techniques (Guion, Diehl, & McDonald, 2013). Case study researchers use methodological triangulation for flexibility in finding trends during data analysis (Dasgupta, 2015). The interview questions were the main data collection source to facilitate the exploration of the main research question. The

overall process of data analysis consists of data coding development, compressing the data into themes, and then interpreting the data toward a better understanding of the research phenomenon (Gallagher, 2019).

I used NVivo Version 10 software during the coding process that facilitated the sorting, arranging, and storing of the data collected for quick accessibility of the information. NVivo is useful because the software can detect common patterns and relationships from interview transcripts thus simplifying the coding process (Oliveira, Bitencourt, Santos, & Teixeira, 2015). NVivo was a timesaving software tool that assisted in identifying commonalities within the data and therefore easier to establish themes.

The coding process started with the data associated with the participant identified as P01 and continued through participant P06. Data analysis began after I have reviewed all the data from the interview responses and archived documents. The coding process involves exploring key data points for common categories, themes, and ideas that enabled analysis, organization, and comparison to extract meaningful data (Onwuegbuzie & Byers, 2014). I determined the creation of categories from recurrent words that best represented the research phenomenon. Then, I reread and selectively coded any data that related to the main category I identified. Selective coding is determining the core variables that represent the main idea from the data collected (Gale, Heath, Cameron, Rashid, & Redwood, 2013). There were three themes related to the TAM and DOI theories, which underpinned the conceptual framework for this case study. The three themes included: (a), communication/planning, (b) instrumental knowledge/ research, and (c) implementation preparation. The results from the analysis of the themes should align with the study's theory (Vaismoradi, Turunen, & Bondas, 2013). I completed my analysis by

performing a comprehensive examination of the themes and applied those concepts to the TAM and DOI theories.

Reliability and Validity

The term *reliability* has no relevance and can be misleading in qualitative research based on the term's use for evaluating quantitative studies (Parameaswari, 2013). One key difference between qualitative and quantitative studies is that the quantitative researcher defines and measures variables then tests hypotheses (Brown, Strickland-Munro, Kobryn, & Moore, 2017). Because the qualitative researcher does not measure variables to test a hypothesis, the criterions that strengthen the quality of the research regarding reliability and validity are different. The applicable terms are: (a) dependability, (b) credibility, and (c) confirmability (Houghton et al., 2013). These criterions are not measurable and need to be established using qualitative methods.

Reliability

Reliability in qualitative research is dependent on the accuracy, and the quality of the data the researcher gathers and analyzes (Yilmaz, 2013). Qualitative data analysis is constantly changing, and the researcher can achieve reliability through dependability and consistency by verifying the data and research processes (Street & Ward, 2012). The description of the researcher's process, outlining the decisions made during the process, enhances dependability of the findings (Elo et al., 2014). Qualitative researchers can also achieve dependability through triangulation, a detailed interview protocol, and member checking (Jacob & Ferguson, 2012).

A research log was used to examine my decisions during interviewing, summarizing participants' responses, and data analysis. The advantage of using a research log is the data contained in the log provides an audit trail to ensure reliability (Cypress, 2017). I used

methodological triangulation to identify themes across two data sources: interviews and archival documents. Triangulation in this case study assisted in assessing, interpreting, and making conclusions from the data and reinforced dependability. Another way to achieve dependability is through an interview protocol (Traynor, Galanouli, Roberts, Leonard, & Gale, 2016). I used an interview protocol that served as a secondary instrument throughout the interviews. To enhance dependability, I applied member checking and verified whether my interpretation of the interview was accurate.

Validity

Data validation is a process that ensures the data presented is meaningful and trustworthy. In qualitative research, data validation refers to the process whereby the study findings portray the findings as intended (Grossoehme, 2014). Personal bias and inconsistent processes may undermine the internal validity by reducing the confirmability and credibility of the study (Cope, 2015). In this case study, I ensured validity through credibility, confirmability, and transferability of the data.

Triangulation and member checking where participants accurately assess and validate data can achieve credibility (Yates, & Leggett, 2016). Ensuring data accuracy enhances credibility and promotes trustworthiness from the participant's point of view (Mori, Norman, Brooks, Herold, & Beaton, 2016). Through member checking, I ensured the accuracy of my interpretations thus ensuring the data were credible.

Confirmability is the ability of the researcher to eliminate bias through maintaining transparency during and after the research (White, Oelke, & Friesen, 2012). To ensure confirmability, I used a research log to document weekly reflections, decisions made, methods

adopted, personal feelings, biases, and insights from the research process. Research journals are a means to eliminate bias because documenting the misperceptions, mistakes, and obstacles discovered during the investigation process demonstrates openness and enhances transparency (Cypress, 2017). In addition, I took notes and recorded the various interview sessions into the research log to confirm the findings were a result of the experiences and ideas of the participants rather than my own bias and preferences.

Transferability is the degree to which the researcher can use or apply the findings to other settings (Burchett, Mayhew, Lavis, & Dobrow, 2013). Transferability is dependent on the study's credibility through member checking and triangulation (Yates & Leggett, 2016). A researcher can address transferability by providing thick descriptions of the study's framework, which may allow readers to judge if the data applies to another study in a different setting with a different population (Yilmaz, 2013). I achieved transferability using my research log that now contains documented descriptions and results from the interview sessions.

The best opportunity to reach saturation is from the depth of the data (Finfgeld-Connett, 2014). Methodological triangulation is the recommended approach using multiple data collection techniques to obtain rich, thick data to achieve data saturation (Denzin, 2012). In this case study, I used methodological triangulation by directing face-to-face interviews and analyzing archival company documents. I achieved data saturation by conducting interviews and reviewing archival document data until no new information came forth.

Transition and Summary

Section 2 included a discussion of the purpose, research design, population, sample, and data collection and analysis methods. In Section 3, I provided an overview of the study and a

presentation of the findings. The discussion included my interpretations, analysis, and presentation of key themes. I related my findings to the TAM and DOI theories that conceptually framed the study and to current literature to provide (a) study conclusions, (b) applications to professional practice, (c) implications for social change, and (d) personal recommendations.

Section 3: Application to Professional Practice and Implications for Change

In Section 3, I provide an analysis of the transcripts and archival documents to arrive at the findings for this study. In the following sections, I discuss in depth the three themes identified from the findings and correlate each theme to the conceptual framework. The participants were health care business executives located in an urban hospital in the northeastern United States. Section 3 includes (a) an introduction, (b) the presentation of findings, (c) applications to professional practice, (c) implications for social change, (d) recommendations for further study, and (e) reflections. I conclude Section 3 with a summary of the study.

Introduction

The purpose of this qualitative exploratory case study was to explore health care business executives' strategies for implementing an MMIS related to medical device recalls. The data for this study came from interviews with six health care executives and an analysis of organizational archival documents at a hospital in the Northeastern United States. After analyzing the data, I identified three themes: (a) communication/planning, (b) instrumental knowledge/research, and (c) implementation preparation. The findings may assist health care executives in developing strategies to implement an MMIS related to medical device recalls.

Presentation of the Findings

The overarching research question from this qualitative case study was: What strategies do health care business executives use to successfully implement an MMIS for medical device recalls? The findings revealed three themes: executive leaders should (a) develop a plan and communicate within an executive social network (communication/planning), (b) share their knowledge to determine the cost benefits and direct relationship to medical device recalls

(instrumental knowledge/research) and (c) prepare for implementing an MMIS through interoperability and training (implementation preparation). I used transcripts and organizational documents as my source of data that provided strategies to implement an MMIS.

Theme 1: Communication/Planning

The interviews revealed the majority of the executive leadership team discussed planning to include objectives and action steps for successfully implementing an MMIS. P01 posited, "From the executive leadership team's perspective, the purpose of the planning document was to be prepared for implementing an MMIS." The findings revealed two key components of planning, which were executive leadership buy-in and declarations of personal knowledge. All participants indicated that planning was necessary for leadership to implement a successful MMIS. P01 also stated, "In my experience, as a member of the executive leadership team, having a plan in place and communicating the plan among executive leadership was essential when considering implementing an MMIS." P05 added, "As long as I have been a member of the executive leadership team, a successful plan should include executive buy-in and declarations of personal knowledge before considering implementing an MMIS." Having a plan in place allowed executive leadership to concentrate on how the application of an MMIS could improve business performance.

Mutual support (buy-in) and commitment. Executive leadership buy-in emerged as a critical aspect of planning. The participants identified three actions in achieving executive leadership buy-in (a) early commitment to the plan; (b) a shared vision, goals, and objectives; and (c) communication. According to the participants, the first step was making themselves available at the start of the MMIS planning process. Achieving executive buy-in to any

implementation plan may involve many open discussions such as whether an MMIS can integrate with the organization's current IT system (Mennemeyer, Menachemi, Rahurkar, & Ford, 2016). Beglaryan, Petrosyan, and Bunker (2017) revealed that health care executives must engage in high-level discussions in order to facilitate ownership and commitment to any implementation plan. P05 added,

> As one of the senior members, I have noticed over the years that executives on our leadership team needed to address all issues that would otherwise prevent the MMIS implementation project from completing on time. We then took those issues and discussed them with everyone on our team to ensure involvement and commitment toward implementing our MMIS.

P03 and P04 both agreed that having shared vision, goals, and objectives secured commitment toward implementing the MMIS. P03 felt strongly that they should be committed to a plan "Since I have been a member of the executive leadership team, executives that commit to the plan up front demonstrate their willingness to work together to support shared goals and objectives from adoption to implementation." Shared visions, goals, and objectives are important steps and must resonate from all stakeholders on the executive leadership team (Bullard, 2016). P04 stated,

> One of our successes was executive leadership exhibited their willingness to be transparent, proactive, and working together toward being committed to support the realization of the goals and objectives of our team's plan. This strategy was crucial because the cost of making a bad capital investment may result in serious financial implications.

P06 provided a summary statement about executive engagement. He affirmed the importance of executive involvement by stating, "Executives searching for strategies to implement an MMIS should take note because the leadership team must form and maintain close relationships with one another." Active involvement from all executives is necessary for shared vision, goals, and objectives toward tracking pre-implementation activity (Arsoniadis & Melton, 2016; Bullard, 2016). Health care executives' involvement during the pre-implementation planning activity of a new MMIS is critical for success (Nilsen et al., 2016). All participants felt strongly that the strategy to form strong executive relationships would increase buy-in and commitment toward employing a successful MMIS implementation plan.

The participants agreed on the need to form close relationships to support implementing an MMIS. However, they noted at times forming relationships was difficult and became problematic, as some executives did not agree with all the goals, visions, and objectives during the initial planning stages. Lemos de Almeida et al. (2017) forecasted the difficulty of achieving mutual concurrence on conceptualization and implementation of new IT short and long-range objectives. P03 stated, "Some executives from the leadership team found it difficult to support the goals and objectives on implementation. These differences must be worked on to achieve buy-in/commitment otherwise you are looking at long delays." P02 elaborated,

> I cannot stress enough how important executive leadership agreement is to reach buy-in commitment and move forward with the adoption process and implementation. Not all executives on the leadership team reach an agreement. We need to achieve at least 50% agreement from the leadership team to move forward else implementing an MMIS is off the table.

The participants emphasized how critical communication was and that poor communication could be detrimental toward any plans to adopt and implement. P04 elucidated, "Avoiding communication would cause delays and possibly put the implementation plan on hold." P06 believed communicating within a social network was a strategy executives should use to provide additional understanding of the functionalities and benefits. P06 commented,

> I highly suggest for anyone deciding to implement an MMIS to have discussions with executives outside the organization. Going outside the organization increases your knowledge and provides varying perceptions of an MMIS, which will assist leadership in deciding to implement.

The participants agreed that communication was necessary for determining the relevance of the MMIS. Communication of new IT through social networks influences executives who are deciding IT adoption (Beglaryan et al., 2017). P04 emphasized communicating within one's own social network inside the organization was effective and all that is required. P04 stated, "I firmly believe if executives are struggling to decide whether to implement an MMIS, communicating within their own social network inside the organization is all that is necessary." The participants agreed executives one way or another communicate within their social network to increase their understanding of the various functionalities of an MMIS.

When executives discuss new IT within a social network invariably, innovation characteristics emerge (Akan et al., 2016). P02 and P03 provided commentary about what they felt were the important MMIS characteristics in discussion within their social network. P02

noted, “Most executives want to know about how the system will improve current operations and the extent of the complexity of the system.” P02 summarized:

> Organizations need to know if the IT system they are considering to purchase is going to improve operations and the extent of learning the new system. We watch what other organizations are doing versus what we are doing and spending. Communicating with other executives is vital on how we make decisions about whether to adopt or reject new IT systems. We are accountable for our decisions and want to have a feeling those decisions about new IT systems are right.

P03 added,

> When I discussed the MMIS with other executives, I was interested in system functions, how the MMIS will improve operational efficiency such as medical device recall processing, and complexity of the system. I found confiding in other executives was essential and increased my understanding of the MMIS, which helped me decide to adopt the MMIS we are currently using.

Communicating within an executive’s social network is essential to gain knowledge and understanding of an MMIS. Most participants agreed including external assistance within their social network was beneficial. However, P04 indicated communication within the organization was all that was necessary. In both cases, obtaining additional knowledge assisted in making a strategic decision to implement. Exploring technology by communicating the system’s value from other executive’s perspective influences technology acceptance (Nilsen et al., 2016). Communication about innovation from one executive to another can effectively influence one’s decision regarding the adoption of IT.

Declarations of personal knowledge about IT. Participants referred to the baseline knowledge as the minimum amount of IT knowledge to begin open discussions and determine how much assistance maybe required from outside firms. Health care executives form their views about new IT through their knowledge, in which adoption and implementation occur through system usefulness and their internal and external networks (Sieck et al., 2020). P03 indicated, "As a leadership team we realized that evaluating our combined IT knowledge was a good strategy in determining how much assistance would be needed for MMIS training and initial set up from an outside consulting firm." The participants determined that knowing the level of IT knowledge of the leadership team could be an effective financial tactic if the organization wants to be economically sensible toward budgeting for contracting an outside consulting firm.

The participants discussed knowledge in relation to software selection and spoke of the importance of carefully selecting an MMIS software suite, which must allow the MMIS to integrate with the existing IT infrastructure to improve organizational efficiencies. P02 briefly discussed the decision process whereby each executive selects a software suite and presents his or her case regarding why the leadership team should select that software. The participants promoted the idea that 50% of the leadership team was required for buy in/commitment in order to move forward, however, during the MMIS software selection process all executives must agree on one software suite that is best for the organization. P02 commented, "We as a leadership team determined the software selection process should continue until all executives agree on one software package for the MMIS." P01 noted, "Whenever we sit down to discuss software selection, I remind everyone that our software decision affects the entire organization,

therefore, this makes the necessity of knowledge declaration from all executives a central strategy for the MMIS implementation project." P05 discussed his concern about planning for enough time to make a decision. P05 commented, "The leadership team should apportion enough time for selection of the MMIS software - additional research and time may be required - should not be rushed." The participants referred to having the right software for the MMIS, as essential in terms of usability and performance.

I reviewed the organization's plan and lessons-learned reports from May 2011 to June 2013, which revealed the need to have an open exchange to discuss the various functionalities of the MMIS. The lessons-learned reports revealed the importance of all executives learning from each other to understand how the MMIS may improve medical device recall processing. I concluded from the participants' transcripts that, after the executives accomplished their goal of understanding the MMIS, the next step was to hold a meeting to discuss adoption and implementation toward improving medical device recall processing.

Theme 2: Instrumental Knowledge and Research

Participants referred to instrumental knowledge as the knowledge base to have in order to understand the functional usefulness of an MMIS when weighed against cost and the relevant relationship of an MMIS to medical device recalls. Strategies referenced by the participants for implementing an MMIS included examining the functional benefits of an MMIS, improving medical device recall processing to include patient safety, support FDA requirements, and increasing executive's functional understanding of an MMIS. The participants mentioned both cost benefit and relationship to medical device recalls are dynamics that may influence an executive's PU of an MMIS.

Cost benefits analysis. Not all participants agreed on the cost versus the benefits of an MMIS but most were able to understand the system can justify implementation costs if an improvement within the business operations such as medical device recalls processing can be made. Cohen (2017) agreed that the challenge of IT acceptance by executives lies within operational improvements. P05 who was skeptical commented, "My fear during our discussions of adopting a new MMIS was always that the financial obligation might not justify proceeding with adoption and implementation." P01 had a more positive outlook and commented,

> Our discussions of the functional benefits of an MMIS proved later to be fiscally justified. However, my colleagues would caution that implementation costs of an MMIS may be too high and not worth the risk. Understanding the associated costs involved, the strategy for us was to examine the different functionalities of the MMIS such as improved patient bedside scanning, faster medical device recall processing, and meeting FDA UDI requirements then weigh those benefits against costs. I believe there will always be a risk by the uncertainty of success of a new system. The costs of a new MMIS are very important, which is why I compared costs against those benefits and in the end discovered implementing an MMIS was worth the investment.

P03 stated the costs could be justified through the functional usefulness of the MMIS provided the system can demonstrate improvements to the overall operational efficiency. P03 added, "I wanted to know how the system was going to improve our business operations." The cost benefits of an MMIS considered for adoption must provide tangible system effectiveness and contribute to overall organizational productivity to receive executive support (Collum,

Menachemi, & Sen, 2016). P03 presented a strategy to determine the benefits necessary to improve the overall business operation. P03 stated,

> I believe the best strategy is to provide a thorough mapping of existing organizational processes and identify existing problems areas in need of improvement. For example, an area in need of improvement was medical device recall processing and our MMIS needed to provide the necessary functionality to improve those processes. My recommended process should continue to ensure the MMIS could address and improve other problem areas.

Executives leveraging an MMIS for operational efficiency look toward decreasing labor hours through improved business processes (Arsoniadis & Melton, 2016).

Participant P02 noted the importance of researching additional MMIS benefits implemented in another organization and stated, "Comparing other organization's MMIS was a strategy I used that contributed toward my decision to adopt." P02 also commented,

> As part of my analysis of an MMIS from other health care organizations I particularly look at the speed from an overall system functionality perspective because our leadership team would negatively view any initiative that slows down key clinical tasks such as medical device recall processing. Visiting other organizations proved very helpful.

When considering costs, the participants concluded that a thorough evaluation of the system's benefits was necessary. Understanding the functional usefulness of an MMIS may require visiting neighboring organizations that have implemented an MMIS and evaluate their system for

effectiveness. Executives should receive various professional viewpoints to evaluate key system requirements for an MMIS (Bullard, 2016).

A review of the organizational lessons-learned reports of May 2011, June 2012, and July 2012 revealed several instances in which health care executives suggested that communication with each other was essential for implementation. I concluded from the reports that the discussion should focus on the relative benefits of the MMIS to improve medical device recall processing. The reports align with the contention of Fu et al., (2018) that once the need for an IT system has been established, executives must commit to understanding the ethos and value the system will bring and lead executives toward adoption and implementation. The respondents emphasized that during the cost benefit phase, executives should determine whether an MMIS could meet the needs of the organization to be an investment for the organization.

Direct relationship to medical device recalls. Participants' knowledge of the expected outcome from the MMIS was common and all were in an agreement that the system should provide (a) improve medical device recall processing to include patient safety and (b) support all FDA requirements concerning UDI labeling. Most participants felt strongly about the functional relationship of the MMIS to medical device recalls, which increased executive leadership's PU and improved the investment possibility. P03 and P04 emphasized the problem areas of their medical device recall processing procedures and how the MMIS could improve their procedures. P03 commented, "In my experience, improved medical device recall processing starts with inventory management and should have a database that can serve as a catalog for every medical device." P04 indicated, "The number one reason for prolonged medical device recall processing times was not being able to locate the recalled asset when needed." Health care executives are

reluctant to invest in new IT unless the system can demonstrate improved internal business processes such as medical device recalls (Ramsey et al., 2016). The participants felt that in order for the MMIS to appear useful depends on how well the MMIS can improve the overall process of medical device recalls.

Uncovering the functional usefulness of the MMIS to medical device recall processing, patient safety rose to prominence. An examination of executive support for implementation must include improvements to patient safety (Bushelle-Edghill, Lee Brown, & Dong, 2017). P05 shared the relevance of patient safety in recalls and commented,

> Patient safety should be at the forefront of any executive contemplating investing in an MMIS. With that said, the MMIS must be able to identify the patient when a recall occurs. Investment of an MMIS should be reconsidered, if the MMIS cannot perform all the functions necessary to identify the device and the patient involved within a reasonable time.

P06 had previously worked for the FDA and was cognizant of FDA's requirements concerning UDI labeling that a new MMIS must be able to read and produce UDI barcodes. P06 elaborated:

> In the case of our MMIS, the system was able to support the FDA requirements for UDI labeling systems and provided leadership with a comprehensive way to manage medical device recalls, which eventually resulted in implementation of the MMIS.

P03 who had prior work experience with medical device recall processing and considerable knowledge of the FDA UDI requirements added,

> In my experience, the most overlooked functionality of any MMIS related to medical device recalls is the ability of the system to integrate with [AIDC] equipment to identify, record, store, and scan three-dimensional UDI labels affixed to each medical device. My recommendation to any executive: do not invest in an MMIS unless the system can integrate with AIDC equipment and perform all the functions of UDI labeling as required by the FDA.

The participants agreed that in order for the MMIS to appear useful depends on how well the MMIS can improve the process of medical device recalls, increase patient safety, and manage the FDA requirements for UDI labeling.

A thorough review of organizational documents such as inventory detail reports from January 2013 to July 2018 of medical devices and the medical device recall SOP revealed the participants' comments aligned with the archival documentation. The inventory detail reports revealed a high level of inventory accuracy, which listed all medical devices and other material. The medical device recall SOP revealed the MMIS has a workflow system and procedures documenting the process of the recall from start to finish. The organization's MMIS was consistent with all FDA requirements for medical device recall processing. Because of P03's experience with medical device recall processing, she voiced the following concluding statement,

> When I began working here over 10 years ago, the processing time for one medical device recall was somewhere like 24 to 48 hours and sometimes longer. The current MMIS system has dramatically improved medical device recall reporting to

just 1 to 2 hours. The labor savings from processing medical device recalls was well worth the implementation costs of our MMIS.

Theme 3: Implementation Preparation

The participants referenced interoperability as one aspect of implementation preparation, and described the MMIS function as the capability to interface with current operating systems and improve operational efficiency. The participants identified the strategy behind interoperability was to increase executive's PU toward the MMIS. Interoperability according to the respondents was not limited to one aspect of the IT infrastructure (ERP) additionally, most participants felt that interoperability should also include EHRs or any AIDC equipment to meet FDA UDI requirements. Implementation preparation also applied to training as a strategy to increase executives' knowledge and comfort level PEOU to influence adoption. Nilsen et al. (2016) posited that executives considering adopting new IT systems should explore those qualities that will improve operational efficiency and training to familiarize themselves with new system capabilities. The participants felt that interoperability should be a MMIS characteristic and make hands-on training a requirement.

Interoperability. Participants referred to interoperability as a valued characteristic to boost operational efficiency and agreed the MMIS must be able to integrate with the organization's current IT system(s) to include EHRs. P05 noted the importance of interoperability because if the MMIS can provide the information necessary about patients, then accurate decisions can be made about treatment. P05 commented,

We are in the medical business so exactness of our data is critical and our MMIS was able to improve our current system already in place. For example, the MMIS was

> able to enhance EHRs and increase patient care by improving accuracy in our medical documentation.

P02 presented his concerned about the cost of integrating an MMIS with the organization's current IT system. Because of the added financial burden, P02 contemplated not approving the MMIS for adoption.

> I am making a point here about cost because the interoperability of our new MMIS with the existing ERP and EHR systems was important but proved to be costly in the short term. However, I reconsidered my decision and approved the adoption of our MMIS along with my colleagues. I realized the benefits of interoperability such as more accurate health data reduced errors and this in itself increased productivity, which actually reduced costs in the long term.

Similarly, Bullard (2016) posited that health care executives should understand fully the importance of integrating a new MMIS into the organization's existing ERP system in terms of improving business processes while weighing in on costs.

P01 was interested in tracking patient medical devices and improving operational efficiency and stated,

> Our MMIS fully integrates with patient's EHRs, which improves business effectiveness because each transaction that involves a patient medical device is recorded in the inventory module of the MMIS. Allowing the integration of the two systems increased the overall tracking of those medical devices assigned to the patient.

Cohen (2017) commented if a health care organization wishes to achieve success in process improvement, then the decision to integrate with EHRs is pivotal for the MMIS. P03 had

personal experience in processing medical device recalls and discussed that she was able to increase her PU toward their MMIS because the system was able to meet the FDA's requirements for medical device recall and UDI processing. P03 further commented,

> You have to increase your internal cognizance toward the MMIS in order to make adoption easier. For me, the adoption and ultimately implementation of our MMIS required that the system demonstrate function(s) that the current system does not provide. What influenced me to agree and proceed with adoption of our MMIS was the system's ability to integrate with current ERP system and AIDC equipment to support all the FDA's medical device recall processing and UDI requirements.

Respondents agreed interoperability is a valued characteristic that can increase an executive's PU toward adoption of an MMIS. The participants noted three benefits of interoperability that can bring about improvement to operational efficiency: (a) increase patient safety, (b) provide accurate data, and (c) increase productivity. The discussions of system integration brought about a consistent change in all executive's PU, which led to adoption and implementation of their MMIS.

P05 had emphasized and cautioned executives implementing an MMIS not to compromise system performance. Operational managers not involved in the implementation at times make budgetary decisions that may or may not be the best decision. Failures in implementation occur and executives should note not to undermine system performance to satisfy the budget (Arsoniadis & Melton, 2016). P05 noted failures within the implementation process typically occur with team members outside the leadership team. P05 stated,

> Executives within Operations Management were aware that an upgrade was required for the MMIS to integrate with our AIDC equipment. Management decided to wait a year before placing the required part on the budget plan and in the meantime purchased a sub-par substitute. However, the substitute failed to deliver the proper system performance and medical device recall processing was taking twice as long to process recalls. Leadership immediately reversed decisions and authorized operation management to purchase the required upgrade. Several months elapsed to get the part then a couple of months to implement. Never-the-less patient care was substantially degraded while waiting for the proper upgrade for our MMIS.

P05 expressed his concern never to compromise operational performance for budgetary constraints because patient care might also be affected. Upgrading the organization's IT infrastructure requires a flexible budget to handle unforeseen circumstances.

There was no organizational documentation to confirm the participants' comments concerning interoperability. However, comments from the participants concerning usefulness of the MMIS to provide a function the current system does not provide revealed alignment with the literature. The cost of investing in new IT will not overcome upper management's decision to adopt unless a fundamental usefulness such as interoperability with existing IT system can demonstrate improved operational efficiency (Schaffer, Booton, Halleck, Studeny, & Coustasse, 2017).

Not mentioned in the literature were the participants' comments concerning integrating an MMIS with current ERP systems. The literature illustrated the difference between MMIS and

ERP systems. However, there was a gap in the literature about the interoperability of an MMIS, ERP, and EHR system.

Training. The participants expressed their support for MMIS hands-on training tailored to specific requirements for each individual's job for understanding the various functionalities of an MMIS. Executive compulsory IT training should focus on the detailed requirements of the individual's job (Nilsen et al., 2016). P03 valued the training in particular because she just wanted to know and understand the new functionalities of their MMIS. P03 stated, "I have been using computers at work when I was just a young business woman and considered myself very well proficient in the use and understanding of computers therefore, do not require basic training other than just training on the upgrade or improvements the MMIS will bring." The respondents supported the contention that MMIS hands on training unique to the individual needs of the executives are all that is required.

The participants recognized that hospital organizations that are engaged in fostering a workplace that supports learning and adjusting to a new IT system might increase executives' comfort level associated with PEOU or PU toward an MMIS, which ultimately may influence adoption. Participant P06 believed adequate training increased his understanding of the MMIS therefore increased his PEOU and referred to the training as a precursor to adoption and commitment toward their MMIS. P06 commented, "My commitment and interest in an MMIS was co-related to the learning component of the training I received, which led to my interest and adoption of our MMIS." Health care executives that have received adequate training may increase their PEOU toward an MMIS (Bushelle-Edgehill, Brown, & Dong, 2017). Cohen (2017) commented that executives who receive training on new IT systems tend to be more

satisfied than those who do not. P05 commented a deep interest in the simulated work training increased his comfort level or PEOU toward the MMIS. P05 stated, "Everybody does not have to have the same sentiment on training as I do. However, my commitment and interest in our MMIS was definitely influenced through the training I received." Arsoniadis and Melton (2016) revealed executives that received hands-on training with new IT are more satisfied and more likely to adopt. P05 emphasized, "The more everyone learns the ins and outs of our MMIS, the more positively influenced their desire will be toward adoption."

P04 discussed the timing to receive the training should be close to when the decision of adoption is near. Participant P04 commented,

> I have always recommended that our leadership receive 'hands-on' work environment simulation training to ensure realization of the benefits or usefulness of an MMIS... our strategy was to ensure leadership received their training and became familiar with the MMIS before our decision was to be made toward adoption.

Akan, Ulker, and Unsar (2016) posited that the timing of executive training on a new IT system should coincide when the decision to adopt is near else executives may forget key functions. The feelings of the participants were consistent that work environment training provided an increased appreciation for the various functions of the MMIS, which influenced their PEOU and PU toward adoption.

Respondents discussed the importance of the timing receiving hands-on training close to the point before deciding to adopt their MMIS. However, P02 shared that implementation failures or delays may occur because of the lack of synchronization from when executives received training to the timing employees actually uses the system. Participants acknowledged

employee MMIS training as a valued success indicator because employees play a critical role toward improved operational performance. P02 commented,

> The time lapse a new MMIS was taking to put to actual use was critical. Leadership was completely unaware of the length of time before clinical users could begin performing their work on the new MMIS. At one point, clinical employees using the old system were purposely taking twice as long to process medical device recalls resulting in unacceptable processing times. Leadership eventually recognized the situation needed attention and made appropriate changes.

Tracking employees' emotional health is important to leadership if they want to have a successful system implementation (Akan et al., 2016). Some of the participants offered employee training as a possible fix to preventing users from being frustrated over the time lapse from implementation to use. P03 suggested employee training, as a successful tool to assist employees in being understanding and committed to the same implementation goals and strategies as the leadership team.

Correlation to Conceptual Framework

The participants' responses paralleled both TAM and DOI theories. The TAM and DOI theories are essential to understanding the behavioral and cultural influences of health care business executives' decisions to invest in IT (Sieck et al., 2020). P05 illustrated the correlation between PU and PEOU, "A successful plan should increase the executive leadership's perception of ease of use and overall usefulness of the MMIS before considering adoption." Razmak and Belanger (2018) identified PU and PEOU as the two main variables of TAM and as influencing factors that lead executives to use technology. Similarly, Brandon-Jones and Kauppi (2018)

found innovation, ideas, and perceptions of innovation spread through social networks guiding adoption decisions. Executive leadership buy-in is associated with the DOI theory because the executives relied on their communication channels, which ultimately led to acceptance.

The DOI theory relates directly to executives communicating MMIS system characteristics within their social network. The influences of an executive's social system concerning the characteristics of innovation can affect an individual's behavior to adopt new technology (Volland et al., 2016). Given the concept of DOI, executive leadership buy-in occurred after executives sought further knowledge of the MMIS characteristics and functions. P03 agreed executives reached buy-in after communicating MMIS functionality characteristics within their social network. "We discussed MMIS characteristics with executives within and outside our organization that included system functions, how the new system will improve operational efficiency, and complexity of the system." DOI is dependent on the communication of information within a social network (Lemos de Almeida et al., 2017). Reaching IT agreement also increases executive decisions toward adoption and possible implementation (Dyerson et al., 2016). The participants' comments correlate to the DOI theory as buy-in occurred after communicating the various functionalities within their social network.

Literature on TAM indicated both PU and PEOU are behavioral variables used to determine acceptance and use toward IT systems such as an MMIS (Razmak & Belanger, 2018). Perceived usefulness is a major factor influencing behavioral intention (Handayani et al., 2017). Most participants shared similar viewpoints that increasing their understanding of the MMIS translated to the decision toward adoption. P03 stated, "The executive leadership team must reveal how the new medical device recall procedures will maximize business performance and

productivity." The participant interviews illustrated that understanding system functionalities underscored perceived usefulness.

Researchers of the TAM theory related PEOU to the complexity of new IT (Abdullah et al., 2016). Interview transcripts illustrated that training must be an investment in IT in order to achieve ease of use. Supporting documentation from MMIS (SOP) and training records revealed executive training was instrumental. P03 commented, "As an executive, I support the importance of training because without training executive leadership up front leads to system unfamiliarity and therefore put adoption of an MMIS at risk." P04 commented that a commitment to fostering learning could provide the perceived ease of use necessary toward adjusting to a new IT system. Training can increase executives' knowledge and understanding of new IT, making adoption a rational decision. Perceived efficiencies gained by learning the innovation's complexity toward its intended use and observed functionality can increase decision-making toward adoption (Fu et al., 2018). Comments from the participants affirmed the conceptual framework that increasing ease of use had a positive influence toward adoption.

Applications to Professional Practice

The findings from this study applied mainly toward health care organizations but the application of an MMIS may also increase the level of operational efficiency for any business organization contemplating adopting new IT. Health care business executives should assess their own IT landscape and apply the strategies identified from the findings to integrate an MMIS into their current system. Leaders may benefit from understanding strategies for implementing and integrating MMIS with current ERP systems and EHRs (Collum et al., 2016). Executives must be cognizant of the applications of an MMIS to decide if the MMIS they are considering for

adoption can meet the goals and objectives within their organization's business practices (Bushelle-Edghill et al., 2017). The findings presented from this study illustrated three major applications to professional practice: (a) improve medical device recalls, (b) fulfill FDA requirements for UDI labeling, and (c) insure interoperability of MMIS with other IT systems such as ERP and EHRs.

Applying the findings from this study, health care executives can achieve higher business performance by improving medical device recall processing through implementing successful strategies of an MMIS. Forty percent of health care organizations lack MMIS systems to manage medical device recalls and increase their operational performance (Mennemeyer et al., 2016). Therefore, applying implementation strategies from the findings may prevent the need for executives to pay the high cost to maintain the operation of outdated IT systems that do not manage medical device recalls effectively (Singh et al., 2017). Applying these strategies presents an opportunity for health care business executives to (a) invest in efficient medical device recall processing, (b) spend less time on manual documentation, and (c) reduce costs through improved processing (Bayrak & Copur, 2017). Thus, health care business executives can achieve internal business process improvement by following the implementation strategies illustrated in this study.

Implementing MMIS systems requires attention to detail to meet FDA compliance concerns for UDI labeling within health care organizations. The application of an MMIS to business practice can meet material vigilance by ensuring medical device recalls are processed expeditiously to increase patient safety, incident reporting to FDA, circulation of information, and inventory reporting (Tracol, 2016). Health care executives should also consider the

application of integrating an MMIS with AIDC support equipment to identify, record, store, and scan three-dimensional UDI labels affixed to each medical device. Similarly, executives should strive to improve their medical device recall processes to sustain the organization's performance and to achieve FDA compliance with implementing a successful MMIS.

Another application from this study is the integration of an MMIS to an organization's existing IT infrastructure. The application of interoperability emerged from the findings as an MMIS quality whereby executives must be able to assess the valued outcome of integrating an MMIS with the organization's current IT system(s). The interoperability of a new MMIS with the existing ERP and EHR system satisfies both the business as well as the medical side for value improvement. Health care executives must ensure measurable statistics on clinical and business integration from an MMIS to achieve improved operational performance (Volland et al., 2016). In order for executives to adopt an MMIS, the system must integrate with the organization's ERP and EHRs already in place (Bano, Zowghi, & da Rimini, 2017). Executive leadership's focal areas to measure operational improvement should result from current business ERP and clinical EHR integration.

Employing an MMIS following the application of strategies outlined from the findings of this study may result in business process improvement. It is important for health care organizations to maintain up-to-date technological proficient information systems to meet the demands required by the FDA (Kalong & Yusof, 2017). Adopting and implementing an MMIS can provide the necessary operational efficiency for EHRs, medical device recall records, material, and inventory management. Garavand et al., (2016) noted executives who elected to adopt and implement an MMIS realized the next level of performance in their business

operations. Health care executives who advance their operations with new technology may benefit from applying the lessons and implementation strategies from this study.

Implications for Social Change

Adoption and implementation of new IT may have a positive effect on medical device recall management concerning patients. A business management approach to improving health care process capabilities may ultimately lead to increased patient safety (Ryan, Daily, & Lewis, 2016). The discussions from the respondents illustrated the various capabilities and functionalities of the MMIS. IT enhancements and health care executive involvement influence workflow processes, inventory, and ultimately best practices in patient medical device tracking (Drozda et al., 2018).

Organizations that have implemented MMIS technology can provide efficient tracking of implanted medical devices (Lemos de Almeida, Farias & Carvalho, 2017). With the assistance of IT, health care executives can achieve 100% traceability for implanted medical devices, which will satisfy the FDA requirement for patient medical device recalls (Horvath, 2017). Improving patient safety requires expeditious processing of any patient medical device recall and tracing the medical device back to the patient with 100% accuracy (Tracol, 2016). The results from this study might contribute to positive social change by increasing patient safety through the implementation of an MMIS to support the tracking of patient implanted medical devices.

Recommendations for Action

Findings and recommendations from this study may be useful for any health care or business executive contemplating the implementation of an MMIS. Adopting the study strategies may guide executives to implement an MMIS and increase operational efficiency. The

findings of this study revealed the following recommended actions to achieve greater operational performance:

1. Start at the ground level to achieve executive buy-in/commitment.

To ensure commitment, open communication is essential with all leadership team executives to discover their knowledge of the MMIS and to increase their PEOU that would assist adoption.

2. Once an MMIS has been identified, offer product support training to increase executive comfort level toward the new technology.

3. Make a determination to insure the MMIS can support the current business and clinical operations, improve medical device recall processing and interoperability with ERP and EHR systems.

4. Address the cost/benefits of the MMIS to avoid an impulsive rush to acquisition.

5. Assist other health care leaders to identify, assess, and evaluate strategies needed for an MMIS.

A range of health care professional organizations are available for disseminating the study results, such as the Association for Health Care Resource and Materials Management, supply chain conferences, and scholarly and professional business journals. Additionally, the findings from the study may be appropriate for health source educational seminars regarding MMIS implementation strategies that health care executives need to implement a successful MMIS to support medical device recalls.

Recommendations for Further Study

I used a census sample of health care business executives from an urban hospital located in the Northeastern United States to gather data from six participants using semistructured

interviews and archival documents made available by participants as the foundation for the data collection. I acknowledged key dynamics and facts through the analysis of the data relating to MMIS implementation strategies necessary for executing a successful medical device recall system. The findings from this study warrant additional research and exploration of MMIS implementation strategies for health care executives. Health care executives should adopt new IT implementation strategies to improve and integrate business processes (Marciniak et al., 2016).

A recommendation for further study is to explore IT employees' responses to MMIS implementation. IT staff are integral to MMIS system implementation but may have variant opinions, reactions, and responses to the process. As FDA requirements for medical device recalls are mandated, awareness of others' in the implementation chain may add value to achieve compliance. Therefore, researchers are encouraged to pursue further exploration of the topic.

Researchers could conduct a quantitative investigation of the relationship between the return on investment from implementing an MMIS system. Alternatively, future researchers could use the findings from this study to develop a phenomenological study to explore the lived experiences of health care executives in addressing system integration problems with EHRs. Finally, future researchers could conduct studies to compare MMIS implementation strategies in the health care industry to those in the private business sector. A comparison could reveal which industry implementation strategies are amendable for avoiding cost overruns, delays, or failure.

Reflections

The Doctor of Business Administration program at Walden University is a comprehensive program meant for students who want to embrace the business world with in-

depth knowledge representing the highest academic qualification. When I embarked on my journey in pursuit of this degree, I gained an understanding of the level of detail required for original doctoral-level research. The level of attention to detail required for scholarly research was at times overwhelming. During my doctoral journey, I met many faculty members and students who offered immeasurable support and had a genuine interest in ensuring my success.

The data collection process was formidable and a challenge I accepted early on to complete my doctoral study. My engagement with the participants was invaluable. The insight and knowledge I learned from their candid responses added immeasurable value towards writing this study. I felt good about contributing to the knowledge of this topic. The informed respondents benefited from the content of this study, and my role during the research validated not only their experience but justified my own expenditure of time, money, and effort to capture and share their expertise. I am proud to be part of scholarship as an active player connecting practitioners to a wider audience.

As a business professional, I have prior knowledge related to implementing new IT within the U.S. Department of the Navy, and the findings of this study paralleled experiences I encountered while attempting to implement a new system. Although the participants demonstrated some differences in their perspectives, there were also many similarities and challenge that, all health care business executives face as leaders when implementing a successful MMIS. During this study, I presented new implementation strategies that could be useful to health care executives. The goal in conducting this qualitative single-case study was to share awareness relating to areas of concern that health care executives might encounter in

implementing MMIS systems related to medical device recalls and to enhance my own ability to conduct qualitative research.

Summary and Study Conclusions

Requirements of the FDA within the health care industry related to medical device recalls make implementing an MMIS necessary for health care organizations. The findings from this study illustrated executives who implemented an MMIS increased operational efficiency by (a) streamlining medical device recall processing, (b) ensuring interoperability with patient EHRs and existing IT systems (i.e., ERP), and (c) meeting FDA compliance through UDI labeling. Amiri et al., (2018) noted that the cost to implement MMIS systems continues to increase, but the performance of an MMIS outweighs the cost. Health care executives require effective strategic planning guidance to define the critical success factors necessary to adopt and successfully implement an MMIS while maximizing operational efficiency.

The purpose of this qualitative single-case study was to explore successful MMIS implementation strategies used by health care executives related to medical device recalls in an urban hospital located in the Northeastern United States. The specific business problem for this study was some health care business executives lack strategies to implement an MMIS related to medical device recalls. The qualitative exploratory single-case study involved the in-depth study of an urban hospital in which executives have successfully employed MMIS implementation strategies. I used the TAM and DOI theories for the conceptual framework.

Six health care executives participated in semistructured interviews, and thorough research of archival documentation supported the interview data. After conducting interviews and analyzing data, three themes emerged: (a) communication/planning, (b) instrumental

knowledge/research, and (c) implementation preparation. The findings revealed health care executives require implementation strategies such as executive buy-in, ensure MMIS can measurably improve medical device recall processing, training, cost benefits, and provide interoperability into current ERP and EHR systems. Health care executives should actively participate in the implementation process, learn, and understand the complexities of an IT system toward successfully implementing an MMIS.

In conclusion, the findings indicated that health care executives would benefit by following the effective MMIS implementation action steps from this study and address critical factors such as executive leadership noninvolvement that would prevent the successful implementation of an MMIS. Implementation of new technology could fail if executive non-involvement exists, which would end or delay the implementation process (Beglaryan et al., 2017). According to the TAM and DOI theories, health care executives communicate the characteristics of innovation within their peer group, which may lead to understanding system functionalities increasing the chances of executive adoption and implementation of new IT (Razmak & Bélanger, 2018). The findings from this study also illustrated implementation strategic actions that when applied can assist executive leadership to successfully implement an MMIS that can measurably improve medical device recall processing. Health care executives should take into account the implementation strategies discussed in this study but most importantly consider the implementation strategies that are most suitable for their organization.

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Appendix A: Sample Class I Medical Device Recall

Microport Orthopedics Inc., PROFEMUR Neck Varus/Valgus CoCr 8 Degree, Part number PHAC1254

Recall Class: Class I
Date Recall Initiated: August 7, 2015
Product: PROFEMUR Long Cobalt Chrome 8 Degree Varus/Valgus Modular Neck, Part# 1254

All lots are affected
Manufactured from: June 15 2009 to July 22, 2015
Distributed from: June 15, 2009 to July 31, 2015
Devices Recalled in the United States 10, 825

Use: MicroPort Orthopedics has a variety of hip joint replacement systems that allow the surgeon to fit the implant specifically to the patient. During total hip replacement surgery, the damaged portions of the hip joint are removed and replaced with prosthetic parts including a femoral head, femoral stem, and modular neck. The PROGEMUR Neck Varus/Valgus CoCR, part number PHAC1254 is the modular neck recalled.

Recall Firm:
MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN 38002

Reason for Recall: MicroPort Orthopedics Inc. has received reports of an unexpected rate of fractures after surgery related to this specific modular neck. If the modular neck fractures, the patient may experience sudden pain, instability, and difficulty walking and performing common tasks. An acute fracture will require revision surgery to remove and replace the neck and stem components. Acute fracture and emergency revision surgery is a serious adverse health consequence and could lead to neurovascular damage, hematoma, hemorrhage, and even death.

Public Contact: Questions should be directed to MicroPort Orthopedics Inc.'s Customer Experience Department at 1-866-872-0211, Monday through Friday, between the hours of 7:30 a.m. and 7:30 p.m. Central Standard Time.

FDA District: New Orleans District Office

More Information about this Recall:
On August 7, 2015, MicroPort Orthopedics, Inc. informed distributors and hospital staff of a voluntary device product recall.
Instructions for distributors and hospital staff including risk managers and surgeons: the following instructions were provided:

1. Review the notification and ensure affected personnel are aware of the recall.
2. Locate all affected product identified in the recall letter.

3. Stop using and distributing the affected product.
4. Return the recalled product to MicroPort Orthopedics, Inc. Distribution Center at 11481 Gulf Stream, Arlington, TN 38002. mark all return shipping boxes with "RECALL" on several sides for better identification and processing.
5. Regardless of whether you have the affected product, complete and return the Verification Form/Effectiveness Check by Fax to 901-451-6032 or by e-mail to cathy.park@ortho.microport.com.

Instructions for Patients:
1. Patients should continue to follow up with their health care provider at regular intervals as prescribed by their surgeon.
2. There is currently no evidence that modular neck fractures can be anticipated by patient history, physical exam, and visual inspection or by using any imaging modality including X-Ray, MRI, or CT scans.
3. Patients not experiencing symptoms should not take any further action.
4. Patients should seek immediate medical treatment if they experience any sudden onset of severe pain in their post-operative hip, difficulty or inability walking, significant trauma to their hip or leg (e.g. falling) or tingling sensation or loss of feeling in their leg.

About Class I Recalls:
Class I recalls are the most severe type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.
Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by Fax.

Appendix B: Copyrighted Permissions

Title: Theory Development in Nursing and Healthcare Informatics: A Model Explaining and Predicting Information and Communication Technology Acceptance by Healthcare Consumers

Author: Ji-Young An, Laura Hayman, Teresa Panniers, et al

Publication: Advances in Nursing Science

Publisher: Wolters Kluwer Health, Inc.

Date: Jul 1, 2007

License Number	4135670032070
License date	Jun 24, 2017
Licensed Content Publisher	Wolters Kluwer Health, Inc.
Licensed Content Publication	Advances in Nursing Science
Licensed Content Title	Theory Development in Nursing and Healthcare Informatics: A Model Explaining and Predicting Information and Communication Technology Acceptance by Healthcare Consumers
Licensed Content Author	Ji-Young An, Laura Hayman, Teresa Panniers, et al
Licensed Content Date	Jul 1, 2007
Licensed Content Volume	30
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Type of Use	Dissertation/Thesis
Requestor type	Individual
Portion	Figures/table/illustration
Number of figures/tables/illustrations	2
Figures/tables/illustrations used	figure 1, p. E39 and figure 3, p. E42
Author of this Wolters Kluwer article	No
Title of your thesis / dissertation	Strategies to Implement a Material Management Information System for Medical Device Recalls
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Appendix C: Copyrighted Permissions

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Christine J. Lee
Permissions Supervisor

1230 Ave of the Americas, 14th Fl
New York, NY 10020
Christine.Lee@simonandschuster.com

VIA EMAIL

July 6, 2017

Paul LaFrance
Walden University
Paul.Lafrance@waldenu.edu

Dear Paul LaFrance:

You have our permission to include Figure 5-1: "A Model of Five Stages in the Innovation-Decision Process" from p. 170 of our book, DIFFUSION OF INNOVATIONS, 5E by Everett M. Rogers, in your doctoral dissertation entitled "Strategies to Implement a Material Management Information System for Medical Device Recalls."

The following acknowledgment is to be reprinted in all copies of your dissertation:

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Sincerely,

Christine J. Lee

Christine J. Lee

AGREED TO AND ACCEPTED

Paul LaFrance

From: Paul Lafrance [mailto:paul.lafrance@waldenu.edu]
Sent: Monday, June 19, 2017 10:52 PM
To: Copyright Representative; Simon & Schuster
Subject: Request Permission to use Figure in Doc Study

I am a doctoral student at Walden University and I would like permission to use figure 5-1 on page 170 in my doctoral study. The figure can be found from the book Diffusion of Innovations, 5th edition by Everett M. Rogers. Thank you in advance.

Sincerely,

Paul L. LaFrance
College of Management & Technology
Doctor of Business Administration
Phone: 757-620-1326

Appendix D: Copyrighted Permissions

Paul LaFrance
Date:
9/06/2015

E-mail

paul.lafrance@waldenu.edu

Question

I am a doctoral candidate at Walden University and I would like to ask your permission to use figure 1 "Proposed Research Model for the Study" on page 64 in my case study. The aforementioned figure can be found in the below article. In advance thank you for your consideration.

An, J.Y., 2006. Theory development in health care informatics: Information and communication technology acceptance model (ICTAM) improves the explanatory and predictive power of technology acceptance models. *Studies in Health Technology & Informatics*, *122*, 63-67.

respectfully,

Paul LaFrance

Dear Paul LaFrance,

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Not in the office on Wednesdays

IOS Press BV
Nieuwe Hemweg 6B
1013 BG Amsterdam
The Netherlands
Tel.: +31 (0)20 687 0022
Fax: +31 (0)20 687 0019
Email: c.koolbergen@iospress.nl / publisher@iospress.nl

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Appendix E: Interview Protocol

Name: _____ Interviewer: _____ Date: _____

Title: Strategies to Implement a Material Management Information System

Purpose: The purpose of this qualitative exploratory case study is to explore health care executives strategies associated with implementing an MMIS related to medical device recalls.

1. Prior to the start of the interview sessions, the study participants will have previously read the informed consent form, provided their consent with a digital signature, and submitted via e-mail. I will have provided the interview questions for their review, information regarding the member checking process, the voluntary nature of the participation, the withdrawal policy that allows a participant to withdraw from the study at any time, and the assurance of confidentiality.

2. I will schedule the date, time, and location for the interview with the participants who have provided their consent to participate, via e-mail.

3. I will start the interview sessions with greetings, and introduce myself. I will thank the participants for their willingness to participate in the research study. After the salutations, I will provide a hard copy print out of the signed informed consent letter for their records.

4. To help to establish rapport, I will provide a brief explanation of the purpose of the research. I will ask the participants if they have any questions before I begin the interview. I will ensure each participant understands there are no time restrictions to answer the interview questions in full, including any additional follow-up or probing questions.

5. I will turn on the audio recorder and I will note the date, time, and location.

6. I will indicate the coded sequential representation of the participant's name (e.g.,

‘participant 01 (P01)’) on the text document of the audio recording, and documented on my copy of the consent form.

7. The interview will begin.

8. The last interview question will be an invitation for the participants to add anything they consider important to the discussion of what strategies do hospital business executives have that relate to implementing an MMIS associated with medical device recalls.

9. At the close of the interview, I will thank all research participants for their time and participation in the study, and will schedule time with the participants for member checking procedures to assist with accuracy and ensuring the reliability of the data.

10. I will analyze the data after each interviewing process (i.e., interview, and member checking), to help establish when saturation occurs.

Appendix F: Data Collection Coordination Request

Date:

Dear

I have contacted the Head of the Business Department and requested support to collect data for my research project entitled Strategies to Implement a Material Management Information System for Medical Device Recalls.

I am requesting your cooperation in the data collection process. I propose to collect data on xxx. I will coordinate the exact times of data collection with you to minimize disruption to your work schedule. I will select six participants for this study and each interview session will last approximately 30-45 minutes.

If you agree to be part of this research project, I would ask that you (a) provide a list of candidates to be interviewed, (b) assist with locating a secure place to conduct the interview sessions, (c) provide a location of the various rooms and facilities as I will need assistance traversing through your hospital facility.

If you prefer not to be involved in this study, there will be no consequences.

If circumstances change, please contact me via phone: 401-385-9116 or e-mail: paul.lafrance@waldenu.edu.

Thank you for your consideration. I would be pleased to share the results of this study with you if you are interested.

I am requesting your signature to document that I have cleared this data collection request with you.

Sincerely,

Paul L. LaFrance

Printed Name

Date

Written or Electronic Signature

Appendix G: Invitation Letter to Participants

Date:

Dear [potential participant's name]

I am requesting your participation in my research study. I will be conducting interviews as part of the data collection process for my research project entitled Strategies to Implement a Material Management Information System for Medical Device Recalls. As a hospital business executive, you are an ideal candidate to be a participant because of your prior experience successfully applying strategies to implement a MMIS related to medical device recalls.

Each interview session will last approximately 30-45 minutes. Your responses to the interview questions will be kept confidential. I will not reveal your name or any other identifying information. Each participant will be assigned the letter "P" and a number (i.e. P01) to ensure confidentiality.

Participation is strictly voluntary. You may withdraw from the study at any time. If you are willing to participate, I will coordinate the exact date and time of the interview session with you to minimize disruption to your work schedule. Prior to the interview, I will disseminate the interview questions and information regarding the member checking process to you for review. If you have any questions please do not hesitate to call me at 401-385-9116 or send me an e-mail. Thank you in advance.

Sincerely,

Paul L. LaFrance