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# Strategies for Reducing Adverse Medical Events from Implanted Medical Devices

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Abstract

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MS, Wilkes University, 2014

BS, Drexel University, 1984

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## Abstract

Managing medical device monitoring processes is challenging and lacks a realtime, life cycle tracking strategy to reduce adverse medical events and revision costs for hospital administrators, physicians, and patients. Understanding the malfunctions of medical devices for cardiac and orthopedic patients could save lives and reduce hospital liability. Grounded in the business process reengineering conceptual framework, the purpose of this single qualitative case study was to explore strategies hospital managers used to redesign the implant recall surveillance process at one hospital in Pennsylvania. The 5 participants selected successfully implemented a medical device surveillance process that reduced adverse medical events and revision costs. Data were collected using semistructured interviews and a review of relevant medical device surveillance workflow documents. The 4 themes that emerged from a thematic analysis were effective data communication process, central data repository integration, continuous process improvement, and end-to-end surveillance process. A key recommendation for hospital administrators, physicians, and managers is to use blockchain distributed ledger technology to assess device identification challenges as part of the surveillance process to reduce health risks. The implication for positive social change includes the potential to improve the quality of life for medical device recipients who may spend less on healthcare services.

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# Dedication

I dedicate this doctoral study to my best friend and love of my life, Adeline, for enduring my long days and nights of research and writing, and her unconditional love, and support. Adeline, you are my rock. I also dedicate this study to my children (Gary, Aaron, and Luke), grandchild (Levi), and grandchildren to be, as a reminder and example of using your God given gifts to achieve the impossible and to make a difference to make this world a better place.

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# Section 1: Foundation of the Study

As advances in medical device technology improve the treatment of disease, health care managers must implement innovative strategies to redesign the device surveillance process continuously. Implantable medical devices have the potential to lengthen life span and improve the quality of life (Guerra-Bretana & Florez-Rendon, 2018). Although medical device implants have significant benefits, there are potential risks that make implant products unsafe or do not contribute to improving health outcomes (Chen et al., 2018; Guerra-Bretana & Florez-Rendon, 2018). Protecting medical device recipients from harm requires supportive regulatory conditions and a surveillance process that sustains an acceptable level of safety and cost for patients. According to Wagner and Schanze (2018), understanding the existing medical device regulatory framework is necessary to improve device monitoring and safety. Optimizing the medical device surveillance process can have a positive impact on implant safety (Wagner & Schanze, 2018). The need for a real-time medical device surveillance process can potentially solve the challenges of medical device lifecycle surveillance to improve care and reduce costs. The focus of this study was to explore potential strategies health care managers use to redesign the medical device surveillance process to reduce adverse medical events and revision costs.

## Background of the Problem

The problem is that managing current medical device monitoring processes is challenging and lacks a real-time life cycle tracking strategy to reduce adverse medical events and revision costs. Medical device implants are instruments that contribute to improving health outcomes, yet device failures raise concerns regarding postmarket surveillance for performance and revision notification after implantation. In 2013, leaders of the Food and Drug Administration (FDA) issued a unique device identification (UDI) rule to track medical device lifecycles, permitting device data transparency throughout the supply chain process (Dhruva, Ross, Schulz, & Krumholz, 2018). In 2018, based on UDI results from the Department of Health and Human Services data, UDI systems have not been effective in transmitting device recall notifications, resulting in fewer incident reportings, increased delays, and higher revision costs (Dhruva et al., 2018). The need for better UDI monitoring transparency continues to expand as more medical devices enter the market.

The use of medical devices has potential recall risks. Recalls of medical devices affect thousands of patients with severe injury or death and create a financial burden on the health care system (Lee, Berstock, Whitehouse, & Blom, 2017). The estimation of all medical device incident reporting is 0.5% and cost Medicare 1.5 billion dollars in excess medical fees in 2018 (Craig, O'Meley, & Carter, 2019; Dhruva et al., 2018). Hospital managers must adopt management solutions to enable a redesign of the medical device

recall process and minimize UDI data fragmentation to enhance recall notifications (Lee et al., 2017). A medical device recall is an action taken to address device problems that violate FDA law (FDA, n.d.c). A medical device recall is a removal, revision, or correction of a product that the FDA considers violating the law and can initiate legal proceedings. Recall notification delays can increase the risk of poor medical outcomes due to revision time sensitivity. Managers who support medical device processes must collaborate to improve policy compliance and standardize processes to avoid adverse medical event complications and revision costs.

## Problem Statement

Implant devices in the medical industry malfunction at alarming rates. Twelve percent of implant devices in the medical industry fail within the first year, and approximately 40% fail after 3-years (Cadossi et al., 2017; Gagliardi et al., 2018). The general business problem was that postmarket implant surveillance is in decline because of inadequate tracking systems, which result in lower recall notifications and potentially increases health risks and revision costs. The specific business problem was that some hospital managers in health care organizations in the United States lack strategies to redesign the implant recall surveillance process that reduced adverse medical events and revision costs.

## Purpose Statement

The purpose of this qualitative single case study was to explore strategies that managers in hospital health care organizations use to redesign the implant recall surveillance processes that reduced adverse medical events and revision costs. The targeted population comprised of five managers in one hospital facility in the northeast region of the United States who successfully redesigned the implant surveillance recall process. Although medical device usage is worldwide, I focused on the successful strategies that health care managers in the United States use for medical device surveillance to reduce adverse medical events and unnecessary costs. Hospital managers commonly use multiple unambiguous labeling strategies for successfully conducting postmarket medical device surveillance to confirm compliance and to control recall costs. Exploring the medical device lifecycle process may provide insights that avoid future medical complications and revision costs. The implication for positive social change includes healthier local communities for all individuals. People in society can prosper economically when health care providers produce better outcomes, leading to further business expansion that enhances employment opportunities for individuals in local communities.

## Nature of the Study

Researchers can choose among three standard research design methods: qualitative, quantitative, and mixed. Qualitative research is valuable for researchers to

guide the development of new products, services, and to gain an understanding of not only human behavior, but on the strategies and processes that may lead to positive outcomes (House, 2018). Qualitative research pertains to gathering data through real-time engagement with knowledgeable participants (Clark & Thompson, 2016). For qualitative analysis, researchers use an inductive discovery approach by which new insights develop through face-to-face interviews using open-ended questions to explore and analyze the strategies, experiences, and perceptions of the individuals experiencing the phenomena (Park & Park, 2016). A quantitative research method was not appropriate for my study because exploring the research problem does not require the testing of hypotheses to understand the relationships between variables through a random choice of participants and collecting to measure statistical significance (House, 2018). Some researchers combine quantitative and qualitative methods to conduct a mixed-method study to expand the understanding phenomena. A mixed-method approach was not appropriate for my study because the exploration of the research problem did not require testing the significance of variables' relationships. My doctoral study involved understanding manager strategies for postmarket medical device monitoring to avoid medical complications and high revision costs. I used a qualitative method for this study to explore strategies to redesign the process of medical-device implant recall notifications.

The potential qualitative designs I considered for this study included a single case study, ethnography, and phenomenology. Using a single case study design entails using

interviews, observations of normal process operations, and enables the researcher to collect data from various participants and sources (Yazan, 2015). Ethnographic research is about exploring and observing the cultural characteristics and behavior of individuals for a specific circumstance and necessitates a relatively long-term data collection process to study participants (Hammersley, 2018). Researchers use a phenomenological design for interviewing, observing, and deriving meaning from a participant's personal experiences with the research phenomenon (Alase, 2017). In this study, the focus was not on culture, behaviors, or individual meanings of experiences, but on understanding successful postmarket medical device surveillance strategies and processes. I used a single case study to explore a unique, critical, and complex business problem within one organization through an in-depth description of an existing process. Researchers can use a single case study as a suitable method to collect quality information about management strategies from participating managers (Yazan, 2015). A multiple case study design typically requires more time to complete than a single case study and can include the use of several organizations and systems that are unnecessary in a single case study (Yin, 2018). I selected a single case study design to explore strategies within specific circumstances and conditions to analyze the phenomenon using multiple sources of data.

## Research Question

What strategies do hospital managers use to redesign implant recall surveillance processes that reduced adverse medical events and revision costs?

## Interview Questions

1. How would you describe the existing surveillance process for medical device recalls?
2. What are your hospital's strategies to redesign the medical device surveillance process to reduce adverse medical events and revision costs?
3. What strategies were the most and least effective?
4. What situations influenced a change in strategy leading to redesigning the medical device surveillance process?
5. What were the barriers you encountered while implementing the strategies to redesign the medical device surveillance process?
6. What strategies did you use to overcome the critical process redesign challenges to mitigate medical device recall surveillance errors?
7. How does your organization redesign medical device surveillance processes for tracking consistency in a failsafe manner?
8. How did you measure the effectiveness of the redesigned medical device surveillance process to reduce adverse medical events?
9. What else can you share with me about your organization's strategies to redesign medical device recall surveillance processes to reduce adverse medical events and possible revision costs?

## Conceptual Framework

Business process reengineering (BPR) was the conceptual framework for this study. Michael Hammer introduced the BPR concept in 1990, and the concept is relevant to the research study for exploring the strategies and processes for mitigating medical device recall and postmarket tracking errors. The BPR is about redesigning processes that change and enhance current service for better performance (Lawrence, Forbat, & Zufferey, 2019; Mohapatra & Choudhury, 2016). By using BPR as the conceptual framework, I had an opportunity to identify strategies that hospital managers use to redesign implant recall notifications to reduce adverse medical events and revision costs. The purpose of using BPR was to identify, develop, and implement process strategies to redesign medical-implant device recall procedures to enhance current service speed, reduce adverse medical events, revision costs, and to improve safety.

Researchers use BPR to understand existing processes and explore how to improve outcomes and reduce costs by enhancing service, product quality, and increasing the speed of performance (Hammer, 1990). The BPR approach helps facilitate using a continuous and sequential cycle that involves: (a) developing business vision and objectives, (b) identifying, scrutinizing, measuring, and prioritizing processes for reengineering, and (c) building a prototype of the new process to improve process performance (Hammer, 1990). Researchers can use BPR to understand existing processes to explore how redesigning an organizational process can improve outcomes and reduce

costs while enhancing service, product quality, and increasing the speed of performance (Hammer, 1990).

The critical factor for my selection of BPR was its history for enabling workflow value creation in the health care discipline to produce better outcomes. I used the BPR model to understand how hospital managers achieve success by understanding successful existing medical device surveillance strategies. The BPR model assisted me in identifying and understanding how the managers successfully addressed my specific business problem.

## Operational Definitions

*Adverse medical event:* An adverse medical event is a random, undesirable patient outcome consequence that may require intervention to prevent harmful results (U.S. Food and Drug Administration [FDA], 2016).

*Agnostic Tracking:* Agnostic tracking is a ubiquitous static and dynamic data detection accessibility technique that is scalable by leveraging broadband telecommunication services and cloud technology to increase monitoring transparency (Brissaud, Franccis, Chrisment, Cholez, & Bettan, 2019; Grubesic, Helderop, & Alizadeh, 2018;).

*Medical Device:* A medical device is an instrument intended for use in the diagnosis of a disease independent of body metabolism and affects the structure or function of the human body without chemical reaction (FDA, n.d.b).

*Medical Device Recall*: A FDA notification of a medical device problem is either a correction or automatic revision, removal of device use, or device replacement (FDA, n.d.a; FDA, n.d.c).

*Postmarket Surveillance:* Postmarket surveillance is the practice of monitoring the medical device performance lifecycle for safety issues after the device is FDA approved, marketed, and implanted (Wagner & Schanze, 2018).

*Unique Device Identification (UDI):* A UDI is a unique numeric or alphanumeric code that consists of two parts: a device identifier and a production serial number identifier (FDA, 2019).

## Assumptions, Limitations, and Delimitations

### Assumptions

Assumptions potentially include expectations that the researcher presumes to be true without accurate verification. According to Helmich, Boerebach, Arah, and Lingard (2015), the definition of assumptions is accounting for risk aspects that may not be controllable by the researcher and can affect study outcomes. The researcher must verify assumptions to separate untruths from facts to reduce belief bias and increase study validity and rigor (Marshall & Rossman, 2016; Smith & McGannon, 2018). I assumed that hospital managers would participate in a 45-minute interview and that all participants possess knowledge about strategies for redesigning the medical device surveillance process to reduce adverse events and costs. Other assumptions I made included gaining

access to relevant organization documents that are current, complete, and can support interview findings. I also anticipated that all participants would answer honestly. Understanding the assumption risk factors are essential to communicate the inferences of the emerging study knowledge.

**Limitations**

Limitations exist in all research studies and cover a wide range of variables. Limitations are constraints beyond the control of the researcher that can potentially impact the study's outcome (Marshall & Rossman, 2016). Limitations signify the potential weaknesses of the research that diminish the control of the researcher, require interpretation, and can impact accurate evaluation (Podsakoff & Podsakoff, 2018). Completing an assessment of all instruments used to collect study data is a strategy for researchers to analyze study strengths and to mitigate limitations (Podsakoff & Podsakoff, 2018). The most common limitations to overcome include a lack of literature, conceptual framework application, and rigid participant perceptions (Gregory, 2019). A potential limitation to this study is the geographic location, which could constrain application of the findings to hospital systems within the study area rather than throughout the United States.

**Delimitations**

Delimitations refer to the scope and boundaries of a study. In contrast to limitations, delimitations are intentional study biases controlled by a researcher. The

delimitations add study restrictions and narrow the research scope, allowing researchers to choose which characteristics define the boundaries of their study (He, Yang, & Song, 2016). The common delimitations for this study included open-ended interview questions, a specific number of interview questions, participant selection, and time restraints in answering the interview questions. The participant selection criteria for this study included hospital managers with a minimum of 2 years of experience monitoring medical devices. In addition, I did not collect data from clinical hospital personnel regarding strategies for reducing adverse medical events and revision costs. I also chose the geographic location of a specific hospital to explore the postmarket medical device surveillance process. Other non-surveillance health care management issues that may affect implant recall, adverse medical events, and revision costs were not part of the study. The focus of my research was to explore medical device surveillance strategies to reduce implant adverse medical events and revision costs.

## Significance of the Study

### Contribution to Business Practice

Reducing postmarket medical device surveillance errors is a pragmatic approach to proactive care and reducing adverse medical events and health care costs. Health care managers are making incremental process changes to track the medical device lifecycle from product design to postmarket monitoring to ensure acceptable device performance (Chen et al., 2018). A strategic process reconfiguration approach can reduce health care

costs by tracking revision updates in real-time from regulatory changes to assessing claims on poorly or non-functioning devices (Chen et al., 2018). The results of the study have the potential to inform health care managers of strategies and processes for augmenting existing postmarket medical device surveillance practices to reduce adverse medical events, risk, and the costs of patient care.

## Implications for Social Change

An appropriate level of health care affects everyone. Regardless of social class, income, age, education, ethnicity, or geography, all individuals should receive effective health care (Manulik, Karniej, & Rosinczuk, 2018). Fewer disruptions in the postmarket medical device surveillance process directly benefit individuals in the community by improving health outcomes for all individuals and increasing social cohesion across diverse groups (Trujillo & Plough, 2016). In addition, the effectiveness of postmarket medical device surveillance results in higher quality products, improved services, and higher standards of living for community members. Healthier individuals lead to healthier communities; therefore, contributing more to local economies through tax revenues and spending less on health care, can enable improved lifestyles.

# A Review of the Professional and Academic Literature

The purpose of this single case study was to explore strategies that hospital managers use to redesign implant surveillance processes that reduced adverse medical events and revision costs. In this in-depth review of the professional and academic

literature, I established the most significant facets of the research that served as the foundation of the study. According to Onwuegbuzie and Weinbaum (2017), the literature review is the standard way to gain knowledge and establish a study's direction. The literature review is an opportunity to identify different study gaps, patterns, and themes that expand research and engage a researcher deeper into scholarly learning (Inouye & McAlpine, 2019). Gaining an understanding of previous medical device surveillance processes enhances understanding of the topic with the goal of producing new knowledge.

The literature review discussion topics include an overview of BPR application to the current medical device surveillance strategy managers use in the health care field. I focally explored the strategies that supply chain logistic managers use to redesign medical device recall processes to reduce adverse medical events. In the following sections, I addressed BPR, complementary and other conceptual frameworks, the medical device surveillance process, BPR process challenges, and innovative technology strategies to gain a better understanding of the strategy managers use to mitigate risks in the medical device recall notification process. The approach that I used to conduct research encompassed an extensive search of the literature from several sources and disciplines. The study problem is prevalent and the literature is replete with publications regarding implant device monitoring. Device usage and adverse medical events are increasing as the population ages globally and is creating attention for better monitoring

solutions (Claridge et al., 2018). As the population and implants age, physician treatment of disease takes an innovative medical device strategy approach to improve quality of life.

The literature review consists of relevant documentation on strategies in the postmarket medical device surveillance life cycle phase, including peer-reviewed articles, seminal books, government, and journal sources that provide other researchers with descriptive problem information and findings. Keywords and phrases such as *health care business process reengineering, medical devices, implants, supply chain unique device identifiers, postmarket surveillance, monitoring medical devices,* and *medical device insurance claim* were used to search for peer-reviewed journal articles to conduct the literature review. Using the Walden University library, I explored database resources including ProQuest, EBSCOhost, ScienceDirect, MIS Quarterly, Sage Direct, Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), government publications, Google Scholar, and a collection of peer-reviewed journal articles.

The search result scope included references published in English, and that focused on two main topics associated with the theme of this work: medical devices and process monitoring. A combination of research keywords included, “medical device” OR “recall,” OR “surveillance” and “monitoring” OR” “patient safety reporting,” OR “incident reporting system,” OR “regulation” OR “oversight” OR “vigilance,” AND

“business process reengineering.” Moreover, I conducted an additional search by combining previous results with keywords such as “adverse medical events’’ and “technology-induced error” and “medical device surveillance innovation.” The sources I used in this study were (a) 194 peer-reviewed scholarly articles, (b) seven seminal books, (c) six government sources, and (d) one dissertation. Of the 205 sources used, 94% were peer-reviewed, and 194 had publication dates from 2016-2019. I did not have any difficulty retrieving a substantial number of useful resources, many of which are not part of this study.

Synthesizing various study topic literature sources is a way to compare previous findings to understand inconsistencies and regularities with other research approaches, designs, methodologies, and variables (Onwuegbuzie & Weinbaum, 2017). An extensive literature review provides the researcher with a basis to identify and support the conceptual framework, being mindful of evidence of preconceived bias (Buhn et al., 2017). Analyzing and interpreting recent topic literature for similarities and distinctiveness is critical for developing new knowledge. Researchers use business process reengineering as guides for deeply exploring redesign process strategies.

## Conceptual Framework

### Business Process Reengineering

The purpose of using BPR was to explore, identify, develop, and potentially suggest redesign process strategies that improve medical-implant device recall

procedures. BPR is commonly used in health systems to understand and redesign ongoing process models to enhance service quality by improving process speed, safety, and reducing costs (Grocott, Plumb, Edwards, Fecher-Jones, & Levett, 2017; Yeuk, 2017). The resolution of medical device lifecycle surveillance can be beneficial to health care managers who lack strategies to combine regulatory and practical health care demands to reduce revision costs.

**Applying business process reengineering.** The purpose of this qualitative single case study was to explore strategies that managers in hospital health care organizations use to redesign the implant recall surveillance process that reduced adverse medical events and revision costs. Business process reengineering applies to this study, given the need for connection with innovative technology applications that can promote new core business processes to improve product safety, quality, and reduce costs. The BPR process is about analyzing existing process workflows that are underperforming and redesigning processes to increase efficiencies. The BPR conceptual framework is an approach that managers can use in the health care sector to identify the nature of the medical device surveillance problem and to redesign process solutions. Business process reengineering allows managers to take the first step to explore the medical device surveillance problem from an organization and business environment perspective. Integrating processes is an achievable use of BPR via a conceptual, shared information ledger that facilitates tracking medical device information (Chang, Chen, & Lu, 2019). According to Chang et

al. (2019), redesigning the ledgering process not only enables the sharing of tracking information but also promotes a network for multilateral collaboration among supply chain members and meets customer demands for product transparency. Sharing information can improve synergistic collaboration among managers.

Several health care processes depend on software applications to improve efficiencies. Business IT processes and software are vital elements for daily operations. Health care organizations have adopted IT as a core organizational process, and software has become an integral component in business operations (Musa & Othman, 2016). Health care managers can apply BPR to understand how business processes and software applications can lead to identifying strategic opportunities that potentially reduce process weaknesses, inconsistencies, contradictions, and provide process improvement opportunities. Business process reengineering software success factors include technology functionality, organizational acceptance, and social employee involvement impact (Omidi & Khoshtinat, 2016). In contrast, inadequate software application and process design can contribute to adverse medical events and inappropriate care. The lack of integration between software applications and human workflow procedures can impede the improvement of efficiency and safety of any process (Sebok, & Walters, 2016). Software applications, workflows, and surveillance processes are critical for device monitoring systems to adequately alert managers to administer prompt device remediation or recall when the need arises.

Identifying existing processes is essential before redesigning business procedures. Hammer (1990) applied BPR to identify existing business processes and strategies to redesign and transform business procedures. According to Khoshlafz, Mohsen, and Hekmati (2016), managers can use BPR to change longstanding processes for new processes that significantly improve business performance. Managers use BPR to improve outcomes and reduce cost by enhancing product quality through better service performance (Hammer, 1990). Specifically, the aim of BPR regarding medical device recalls is to understand critical procedural aspects in the management process to improve care quality and safety. Managers can use BPR to build on event-driven, end-to-end process chains that can explore device status and lead to problem-solving processes redesign for better outcomes. The benefits of using BPR is understanding the combination of complex medical procedures that culminate in a single event instance to incrementally implement a process redesign for lasting success (Hammer, 1990). The benefit of using BPR methods can improve process effectiveness.

The business process concept is common in the research literature. The BPR conceptual framework first gained attention when used by Hammer in 1990 and later expanded in use with Champy in 1993 (Musa & Othman, 2016). The current literature supports the application of BPR for the assessment of postmarket medical device surveillance processes to track device recalls and to consider possible revision. Leaders may use the BPR conceptual framework when planning a change initiative. The BPR

framework allows managers to rethink and make radical process changes across business workflows to improve process effectiveness and to reduce costs (Hammer, 1990). The aim of individuals using BPR is process redesign and may involve managers adopting new innovative technologies that enhance social change by decreasing patient treatment cycle time and health care costs.

However, managers must make some assumptions before applying BPR. The BPR conceptual framework depends on the assumption that the medical device surveillance process is technical, non-linear, complex, and dynamic; but still adaptive to process change to improve performance (Omidi & Khoshtinat, 2016). The BPR model allows health care managers to develop and provision new processes that will enhance medical device surveillance and reduce medical costs by lowering non-action and unproductive activities that can increase adverse medical events. Managers who implement the complete business logic of BPR to the device tracking ecosystem is an applicable but challenging approach to obtaining maximum process benefit (Chang et al., 2019). Managers that only apply specific components of the BPR conceptual framework potentially limit results to a partial solution.

Managers face a variety of challenges adopting BPR. The challenges that managers may experience when selecting BPR include adopting new technology, developing accessible big data networks, and applying business intelligence feedback applications (Zheng, Xie, Dai, Chen, & Wang, 2018). A study conducted by Hashem

(2019) indicated that factors such as management commitment, IT infrastructure, resource management, change readiness, data decentralization, and data analytics contribute to successful BPR implementation. Fasna and Gunatilake (2019) further supported the importance of understanding the characteristics of existing processes, the type of process to be reengineered, the form of reengineering needed, and the approach for implementing BPR to determine the success of changing the process.

**Supporting Conceptual Frameworks**

Other innovative conceptual frameworks that hospital managers can use to understand complex problems and adopt new processes include diffusion of innovation (DOI), the technology acceptance model (TAM), the sociotechnical model, complex adoption system (CAS) model, and the Deming plan-do-study-act (PDSA) model. The list of conceptual frameworks above align with BPR and are potential conceptual frameworks that can increase the understanding of my study topic. For instance, the DOI and TAM conceptual frameworks complement each other and concern the role technology plays to create social change through the implementation and adoption of new technology. Combining these two models can make understanding the study phenomena robust because each model supports the application of innovative information system technology for process improvement (Al-Rahmi et al., 2019; Sujatha, & Sekkizhar, 2019). Rogers (2003) described the DOI as having the following phases:(a) awareness, (b) innovation knowledge, (c) persuasion, (d) decision making, (e) implementation, and

(f) confirmation. According to Davis, Bagozzi, and Warshaw (1989), the DOI depends on the TAM concepts of ease of use and usefulness. The dynamic use of these two models can provide researchers with a method for accessing business processes.

Exploring business processes further using a sociotechnical lens can potentially improve the understanding of operational business processes that are human-centric. The application of the sociotechnical model is an alternative framework for understanding business process design and procedure practice (Crick & Chew, 2017). Advances in technology provide managers with process agility that enables the rapid transfer of accurate process information to provide better services (Van der Merwe, Biggs, & Preiser, 2018). Technology can influence the system design that connects the medical device user holistically and sociotechnically. Technology functionality, from an Information Technology (IT) perspective, can potentially improve medical device lifecycle surveillance for tracking the plethora of devices, their performance, and the need to issue a revision recall. The sociotechnical framework is an approach to analyze technical process issues that potentially lead to technology improvisation as part of operational business processes to deliver new useful capabilities.

The surveillance and communication of evidence-based care are critical in the health care industry. Although current monitoring technology plays a significant role in medical device surveillance and delivery, between 30 to 50% of all care lacks available evidence and standard communication protocols (Sturmberg, 2018). The complex,

unpredictable, and stochastic aspects of health care require knowledge translation and communication that is unambiguous (Sturmberg, 2018). Complex adoption systems (CAS) offer the potential for managers to explore and understand the uncontrollable non-linear process aspects of health care and provide for the transition to more accurately follow procedures to facilitate the adoption of change for better care (Bucknall & Hitch, 2018). Business process reengineering is compatible with CAS because both foci on helping the researcher understand existing systems, discover patterns, and combine different system elements by redesigning core processes to improve procedures. Aligning and adopting care transitions with the complexity of process operations is a condition that is critical to better health outcomes (Penney et al., 2018). Although the translation of complex systems is essential, health care policy models must adapt to new system alignments that sustain process improvements (Kitson et al., 2018). The BPR concept provides managers with a framework to redesign complex systems into a functionally operating system (Hammer, 1990). Business process reengineering relates to the CAS approach to improve process efficiencies that extend beyond internal operations and can share system information across organizations for sustainable medical device surveillance that may reduce adverse medical effects. The Deming plan-do-study-act (PDSA) model is an approach extending beyond manufacturing practices. The Deming PDSA model relates to the BPR conceptual framework because both models concern medical practice performance improvements (Baum, 2019). Business process reengineering is compatible

with PDSA as both conceptual frameworks provide an approach that can increase the effectiveness of modern health care through making continuous improvements. Like the BPR, the application of the PDSA model allows managers to redesign processes to remove barriers that can improve training, service quality, increase productivity, and decrease cycle time, which results in minimizing the total cost of processes (Baum, 2019). The PDSA method supports change by guiding the rethinking process to produce better outcomes.

In summary, the alternative conceptual models discussed align with the BPR model from an innovative and continuous improvement perspective. Medical device surveillance is a process of quality control that will evolve with new recall notification technology. Conceptual models such as DOI, TAM, the sociotechnical approach, CAS, and PDSA apply to this study because the exploration of the approaches allows managers to understand the variation in the existing process before making a change decision (Ahmed, Ahmad, & Othman, 2019). Although the other models are useful in this study, the BPR conceptual model is the most salient approach because present business technology creates excessive process variation and requires radical legacy system redesign to maximize standard outcomes, decrease process times, and to reduce costs (Vanwersch et al., 2016). Processes are a critical business asset and applying the correct process management model allows managers to continually improve business processes to increase customer value for sustainable business and social outcomes.

The BPR model applies to organization processes that involve redesigning business operations into practical and sustainable behaviors by employees. Managers use the BPR model for guidance by empowering employees to engage in responsible actions that dramatically improve quality, productivity, and cycle time (Hammer, 1990). Giving managers a new starting point through end to end process accountability will help achieve the organization's values of meeting patients' needs concerning reducing recall revision cycle time and health care costs. Health care managers can use the BPR to improve process performance that affects patients through providing sustainable and accurate medical device lifecycles. Other conceptual frameworks, such as DOI, CAS, and sociotechnical conceptual frameworks, support the adoption and use of innovative process technologies by enhancing the BPR framework.

The general purpose of using the BPR is to identify, develop, and implement process strategies to redesign medical implant device recall procedures to enhance current service speed, reduce adverse medical events and revision costs, and to improve safety. The objective of applying BPR is for managers to learn how to identify process limitations and to redesign the core business processes to dramatically improve quality, productivity, and cycle time (Hammer, 1990). The construct is about improving activities that add to medical device lifecycle surveillance value and eliminating activities that do not add value. Managers can innovate and adopt a new medical device surveillance system that emphasizes the needs of the patient by establishing communication between

database processing, which increases data transparency leading to better proactive decision making (Hammer, 1990). The BPR conceptual framework encourages hospital managers to rethink traditional processes and initiate new procedures that reduce adverse medical events, fees and delivers beneficial patient value.

The BPR conceptual framework provides researchers with an exploration model to take an in-depth overview of the concepts of tracking the medical device lifecycle from creation to disposal. An assessment of adverse medical device events by Palojoki, Borycki, Kushniruk, and Saranto (2017) indicated that the current problem is inadequate postmarket medical device surveillance. Specialization and technological advances in the medical field set the stage for deciphering and understanding complex processes, and the BPR is a management tool that applies in modern health care settings (Grocott et al., 2017). Process improvement and reengineering methods reduce complexity (Szmelter, 2017). Researchers can use the BPR framework to simplify and reduce process complexity in the surveillance process of medical devices.

Health care managers have an opportunity to promote better health and business sustainability by applying new approaches to improve the postmarket medical device surveillance process. According to Grocott et al. (2017), monitoring constraint factors before an adverse medical event occurs is an approach a manager can use to rethink the process design. Rethinking and redesigning the postmarket medical device surveillance

process serves managers as well as product developers, physicians, payors, policymakers, and patients.

**Current Medical Device Surveillance Processes**

Medical devices fill a critical role in the lives and health of millions of individuals globally. Every day, individual patients rely on medical device manufacturers to provide safe and practical functionality. Medical device recalls potentially affect thousands of patients with severe injury or death and creates a financial burden on the health care system (Lee et al., 2017). A component of the general business problem is the degree of inconsistent data repository connectivity and transparency to support medical device identifier data tracking from multiple platform sources (Lee et al., 2017; Sheffer et al., 2017; Whitacre, Wheeler, & Landgraf, 2017). Elements of the tracking system include the need for transparency, accurate data, notification promptness, and compliance with the recent federal unique device identification (UDI) law mandated to improve device safety through proactive notification (Sheffer et al., 2017). Managers have the responsibility to enhance data management techniques to produce better outcomes by reducing medical device repair time and lessening financial health system pressures and expenditures (Sheffer et al., 2017). Managers are in a needed position to close the medical device surveillance gap by improving the transparency of monitoring and transferring data.

Postmarket surveillance of medical device implants is an FDA mandate that requires a unique device identification (UDI) labeling system, which facilitates providers' abilities to capture adverse medical event data for prompt revisions (Bayrak & Ozdiler-Çopur, 2017). The labeling of medical devices adds item intelligence and provides a clear line of sight to increase the speed of product identification in the case a device creates an adverse medical event (Fernandez-Carames & Fraga-Lamas, 2018). The UDI is a standard alphanumeric label identification system having two parts that are machine and human-readable. The first labeling component concerns the device identifier (DI), which identifies the device manufacturer and the model, or version, of a specific device. The second UDI component is the product or production identifier (PI). The PI identifies the manufacturer lot, batch, serial number, expiration date, and date of manufacture. The Global Standards One (GS1) organization is responsible for managing the assignment of various identification numbering schemes that are unique to each product. Table 1 below depicts the standard GS1 UDI labeling parameter format.

Table 1.

*FDA UDI Label Format*

| Issuing Agency | Data Delimiters | Identifier | Data Type | Human-readable Field Size | Database Field Size |
|---|---|---|---|---|---|
| GS1 | 1 | Device Identifier | Numeric | 16 | 14 |
| GS1 | 11 | Manufacturing/ Production Date | Numeric [YYMMDD] | 8 | 6 |
| GS1 | 17 | Expiration Date | Numeric [YYMMDD] | 8 | 6 |
| GS1 | 10 | Batch/Lot Number | alphanumeric | 22 | 20 |
| GS1 | 21 | Serial Number | alphanumeric | 22 | 20 |
| GS1 | NA | Maximum Base UDI | alphanumeric | 76 | 66 |

*Note*. Example of GS1 human-readable plain-text UDI: (01)26187652541982(11)180923(17)200704(10)A313B1(21)9876
*Retrieved from* https://www.gs1.org

The numbering format is commonly known as a universal product code (UPC) or barcode. Barcoding can provide managers with a secure method to collect real-time UDI data quickly, reliably monitor medical device information, and monitor a variety of other measurement items such as inventory and cost (Welch & Samios, 2017). The barcode data collection process involves a portable barcode scanner and software that allows managers to collect and assemble data by scanning machine codes from the product UDI labels (Welch & Samios, 2017). A study by Welch and Samios (2017) confirmed that

barcoding supports other aspects beyond surveillance services such as monitoring device inventory data and the standardization of device categories to streamline recall notification. Therefore, barcoding is a technological component that improves medical device surveillance services by enhancing product lifecycle data collection for timely information gathering when a need for further revision research exists.

UPC labeling also complies with the standard of identifying commerce products on a global scale. The FDA UDI mandate either requires affixing the UDI label directly on the device for repetitive use; otherwise, the device packaging must display the UDI label. Figure 1 below depicts a generic example of the present standard FDA UDI identification elements needed on a generic medical device label. It is important to note that the UDI number is a barcode that is both human and machine-readable and contains information about the item.

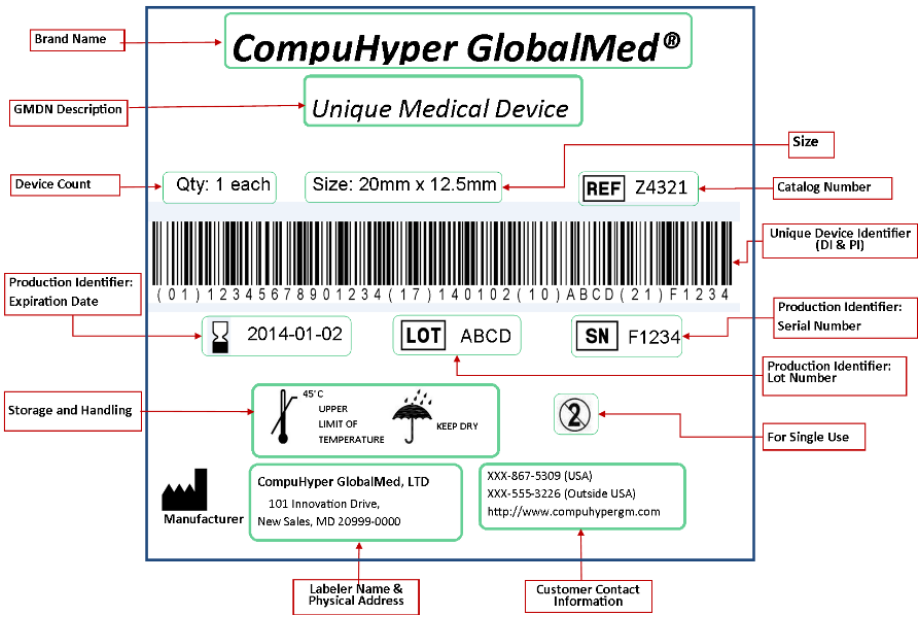


*Figure 1*. Generic fictitious UDI medical device label design. Adapted from U.S. Food and Drug Administration. (n.d.a). *Medical devices - Unique device identification system (UDI system.* Silver Spring, MD. Retrieved from https://www.fda.gov/medicaldevices

Another type of barcode that is gaining popularity for medical device labeling is the quick response (QR) code. The QR code is a type of two-dimensional image encryption barcode that is a mix of pixel blocks that form a quick response, human-readable code during decryption (Kumar & Nishchal, 2019). The QR code is immutable and serves as a source of item authentication (Kumar & Nishchal, 2019). Figure 2 depicts a generic example of a QR code for product identification.

*Figure 2*. Generic fictitious QR UDI medical device label design.

The final UDI rule published on September 24, 2013, established a unique device identifier (UDI) system to facilitate the identification of medical devices throughout the supply chain distribution and a patient's lifetime use. The final six-phase rule went into effect on September 24, 2014. Table 2 illustrates the regulation compliance phases.

Table 2.

*FDA UDI Compliance Phases*

| Device | Compliance Publish Date | Regulation Format Date |
|---|---|---|
| Class III including life support or life-sustaining (LS) function | September 24, 2014 | Class III LS devices, permanent UDI label by September 24, 2015 |
| Implantable Class I, Class II, and Unclassified | September 24, 2015 | NA |
| LS (Class I, Class II, and Unclassified) | September 24, 2015 | September 24, 2015 |
| Medical devices licensed under the Public Health Service (PHS) Act. | NA | All other Class III devices, permanent UDI label by September 24, 2016 |
| Class II or unclassified other than LS or implantable device. | September 24, 2016 | September 24, 2018 |
| Class I or unclassified other than LS or implantable device. | September 24, 2018 | September 24, 2020 |

Note: Adapted from. *Medical devices - Premarket approval (PMA)*, by U.S. Food and Drug Administration. (2019). Retrieved from https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm

The FDA supports the use of the UDI system because of the potential to improve patient health care quality by adding real-time item location functionality within the supply chain and while in use with a patient (Brown, Kaushiva, & Chi, 2015; Resnic et al., 2017). Resnic et al. (2017) analyzed data from 73,124 medical device patients and confirmed that active surveillance rapidly identifies potential implantable device safety issues for prompt revision. The objective of the UDI is to link the device data to other databases from the manufacturer to the patient. Linking device data helps managers reduce medical device errors, improve adverse medical events reporting, provide rapid resolution of recalls, and reduce revision costs (Brown et al., 2015; Resnic et al., 2017; Lau, 2017). However, the existing process is inefficient for tracking adverse medical events and could be made more functional to monitor implant devices (Ibrahim & Dimick, 2017). The most significant process inefficiencies include lack of UDI data interoperability and transparency between the manufacturer, the point of care, electronic health records, and claims. Ibrahim and Dimick (2017) confirmed that medical device data is available. Nevertheless, monitoring processes lack adequate connectivity to issue timely safety warnings since the existing system relies mainly on voluntarily reporting, which increases adverse medical event detection, malpractice risk, and revision cost.

**Background of Medical Device Regulation**

In 1976, FDA officials entered the medical device arena after patient deaths and harm claims involving 200,000 women using the Dalkon Shield intrauterine device (IUD)

for contraception (Faris & Shuren, 2017). Adverse effects of pelvic inflammatory disease, uterine rupture, and septic pregnancies prompted Congress to pass the Medical Device Amendment bill to the Food, Drug, and Cosmetic Act in 1976 (Faris & Shuren, 2017). The amendment gave FDA officials a framework to evaluate medical device risk using three regulatory classes to match various devices to specific requirement levels of safety and effectiveness. Manufacturers of medical devices must lawfully meet the risk classification of a product before the item sells on the market by completing the FDA assessment or premarket approval (PMA) process for Class III devices for safety and effectiveness. The PMA evaluation is the most rigorous FDA device approval application before marketing an item (FDA, 2019). The objective is to ensure that potential device harm to users is minimal.

Some implants receive more attention from FDA officials than others, depending on the intention of use and associated risk of the device, which determines device classification. In the case of class I, II, and III medical devices, defining each type are necessary. The FDA classifies medical devices according to an acceptable risk evaluation that relates to the device and then applies regulation in the form of a specification to give a reasonable assurance of safety and effectiveness (FDA, 2019). Medical devices classify into one of three regulatory classes: Class I, Class II, or Class III. Class I medical devices have the least amount of supervisory because the device presents minimal potential harm to the user. Class I devices have a simple design, easy to manufacture, and have a history

of safe use. Examples of Class I devices include tongue depressors, arm slings, and hand-held surgical instruments. Most Class I devices are exempt from the premarket notification and may be exempt from compliance with the proper manufacturing practices regulation (Maisel, 2004). Classifying medical devices is necessary to provide end-users reasonable assurance of safety.

Both Class II and III medical devices can have medium to high risks. Class II medical devices are those devices that can have a moderate to high risk to the patient or user. For example, FDA officials reported that approximately 43% of medical devices are in the Class II category (FDA, n.d.b). Most medical devices are considered Class II devices. Examples of Class II devices include dental implants, defibrillators, hearing aids, and pregnancy test kits. Class III medical devices are devices that have a high risk to the patient. These devices include life support systems, implants, or any medical device that has a high risk of causing potential illness or injury. Class III represents 10% of medical devices regulated by the FDA. Examples of Class III devices include implantable bone joints, pacemakers, coronary stents, cardiac catheters, prosthetic heart valves, implantable cardioverter defibrillators, and breast implants (Maisel, 2004). Implants are in the class III medical devices. However, recent literature illustrates that implants may also fall under class I or II, depending on risk. An implant class recall is severe if a reasonable probability exists that use or exposure to a medical device will cause serious adverse

health consequences or death (Wu & Eagles, 2016). Although medical devices benefit millions of people, risks that can cause adverse medical events are probable.

In 2013, the FDA officials issued a unique device identification (UDI) final rule to track medical device lifecycles for permitting device data transparency throughout the supply chain process (Dhruva et al., 2018). The FDA UDI identification system only applies to medical devices sold in the United States from manufacturing through distribution to the patient. The intent of the UDI process is to enhance medical device safety through device flaw notification of a specific device lot and for cost-effective recall revisions (Sayle, 2016). However, current UDI monitoring data results from the Department of Health and Human Services indicate that present device UDI monitoring systems are ineffective and increases in device recall delays are increasing Medicare costs (Dhruva et al., 2018). Using a clinical application alone is not improving medical device traceability and visibility. An agnostic tracking approach may increase device tracking transparency and have a positive impact on many health care circumstances across multiple health systems. Agnostic tracking is a ubiquitous data mining technique that is scalable by leveraging broadband telecommunication services that allow providers to persistently monitor devices digitally (Grubesic, Helderop, & Alizadeh, 2018). The medical device tracking process evaluation by the Department of Health and Human Services suggests that using different technology tools in a symbiotic agnostic manner potentially improves the device monitoring process.

For medical devices that do not require a PMA, manufacturers must submit a 510(k) premarket notification checklist form. The 510(k) process is specifically for new medical devices or revisions that are equivalent to previous legal instruments on the market (FDA, 2019). The three types of 510(k) checklists include traditional, unique, and abbreviated. Each 510(k) process is to ensure product quality, safety, and effectiveness. The idea of the 510(k) approval notification process is to foster medical device innovation through approval process flexibility.

One recall can affect thousands of patients and therefore, requires regulation and oversight. A medical device recall is like a vehicle recall. For example, a single vehicle recall can impact thousands of vehicle owners, and likewise, a single medical device recall can affect thousands of individuals. A product recall is a postmarket process that ensures failure prevention through manager remediation activities such as prompt notification (Allard, 2017). The purpose of the postmarket process is to track the medical implant device effectively to quickly notify the manufacturer, FDA, physician, and patient that the equipment is faulty and may need revision. Increasing the speed of the postmarket medical device surveillance notification process can reduce patient harm and the frequency of medical lawsuits significantly (Bernon, Bastl, Wenqian-Zhang, & Johnson, 2018). A study by Ball, Shah, and Donohue (2018) identified factors such as competence and the ability to understand the root causes of manager behavior in reporting a recall from Fortune 500 medical device organizations. Although the decision

to report a device problem triggering a recall is voluntary, the decision to publish a potential recall can substantially affect several aspects of an organization (Bernon et al., 2018). Some of these aspects include the career of a manager, medical device manufacture credibility, financial performance, and patient safety.

**Postmarket Medical Device Surveillance Processes**

Manufacturers continuously enhance medical device design to improve usefulness. Implanted medical devices have become the most significant and useful health care advances over the past 50 years (Drozda, Dudley, Helmering, Roach, & Hutchison, 2016). Medical devices provide diagnosis options to treat disease, but the benefit can also lead to adverse medical events if the device use exceeds capability and malfunctions. According to Zippel and Bohnet-Joschko (2017), the current state of the postmarket medical device surveillance process lacks a reliable tracking system to collect critical device empirical data. An analysis of the data provides the researcher with the potential to sort out equipment defects, rare problems, outcomes, or complications through the device lifecycle. The implementation of such a system is given as a directive by the FDA as a condition for active implantable medical devices (AIMDs) but lacks system connectivity to share data. The process of sharing AIMD data is a way for manufacturers, regulatory agencies, physicians, and patients to receive device function and adverse medical events information in real-time (Zippel & Bohnet-Joschko, 2017). Zippel and Bohnet-Joschko (2017) indicated that only 6% to 14% of manufacturers report

using the postmarket surveillance model for monitoring the lifecycle of medical devices. One reason for the non-compliance is surveillance cost justification. Still, as the number of medical devices increases each year, manager surveillance strategies have the potential to reduce adverse medical events risks and costs.

**Passive and Real-Time Postmarket Medical Device Surveillance Processes**

Postmarket medical device surveillance data is health care data that is currently passive and not accessible to all medical device surveillance participants with an internet connection (Dagher, Mohler, Milojkovic, & Marella, 2018). According to Dagher et al. (2018), any health care data is accessible electronically in real-time using an internet connection but requires the right connectivity technology using the right interoperable platform. The primary need is to first to collect valuable patient medical device data and process the data into insightful patterns. The value proposition is about speed, scale, and convenience, and sharing the medical device life cycle on a generalizable global scale is desirable and involves designing and building a platform to collect device data (Sayle, 2016). Dagher et al. (2018) posited that a connectivity platform using blockchain or distributed ledger technology (DLT) as a mechanism to address the health care data accessibility, integrity, and security is a process solution to data collection. Data collected in this manner is important for processing and sharing by addressing the speed, scale, and convenience concerns. According to Dagher et al. (2018), the comparative performance study of on and off-block or data chain process indicated that device data interoperability

meets all health IT for the Economic and Clinical Health Act (HITECH) and the Health Insurance Portability and Accountability Act (HIPAA).

For data-sharing, the concept is a paradigm shift from traditional organizational data ownership and business and can produce effective outcomes. Dagher et al. (2018) argued that redesigning the electronic communication framework gives data ownership at the point of application. The right communication network design is the best place to start medical device identification and data-sharing (Sayle, 2016). A scalable and accessible network provides device connectivity, location, probing, and monitoring capability to issue recalls. The UDI serves as a fingerprint to authenticate a single device out of the many medical devices in use (Sayle, 2016). Without the use of a UDI, the authentication requires a person to confirm and determine the device validity using several manual resources (Yang & Zhang, 2018). Combining all sources of medical device data increases the reliability of the device's identification and reduces device surveillance costs (Sayle, 2016). Capturing UDI data is a valid and reliable procedure to track the medical device lifecycle to maintain effective care that improves device surveillance to reduce adverse medical events and to control revision costs.

Establishing a medical device surveillance system using UDI labeling within a digital environment is challenging because of the needed investment in modern analytical tools and the lack of legislation and oversight. According to Bayrak and Ozdiler-Çopur (2017), the implementation of a UDI surveillance process for each medical device lacks

legislation guidance and consistent labeling procedures across the medical manufacturing industry, which consist of thousands of manufacturers globally. Bianchini, Francesconi, Testa, Tanase, and Gemignani (2019) also confirmed that medical device surveillance lacks UDI labeling transparency, causing problems within the medical device industry to enhance safety and quality effectiveness. The current UDI registry process is ineffective to track medical devices and to share data at all levels of care (Bayrak & Ozdiler-Copur, 2017). Bayrak and Ozdiler-Copur posited that the current model of tracking medical devices using UDI labeling is deficient and requires better development across all manufacturers, and throughout the supply chain to the end-user. Improving UDI labeling can potentially augment the medical device tracking process.

Tracking medical devices is critical for many business applications. Health care managers have the responsibility to improve device tracking surveillance vigilance to increase patient safety, reduce counterfeits, and decrease costs (Bianchini et al., 2019). Bayrak and Ozdiler-Copur (2017) proposed a surveillance method consisting of continuous device data monitoring, managing the data, and transmitting the data. According to Bayrak and Ozdiler-Copur, the challenge is to provide standard global surveillance to approximately 22,000 and 6500 medical device manufacturers in Europe and the United States, respectively. However, the United States is the lead manufacturer and consumer of medical devices and generated 148 billion dollars or 43% in total global medical device revenue in 2016 (Bayrak & Ozdiler-Copur, 2017). The United States

continues to be the surveillance leader for domestic medical device tracking, but concern remains regarding device traceability in the United States and on a global scale.

Surveillance is a critical part of maintaining the safety and integrity of medical devices, and regulations serve as a significant component to modernize the device tracking system. Melvin and Torre (2019) argued that the current medical device surveillance systems only require legislative framework revisions rather than a process redesign as the regulatory system is the linchpin that can either strengthen or weaken the current device tracking system. According to Horvath (2017), the fear of timely access to new device technologies caused the Congress representatives to mandate a less burdensome medical device evaluation. The combination of Congress representatives relaxing medical device evaluations and approval and current regulations are not sufficient to control the quality and safety of marketed medical devices.

Implementing a medical device surveillance system is critical to close the device safety risk gap. Drozda et al. (2016) argued that the FDA recognizes the need to improve medical device performance tracking using UDI and electronic medical record data to mitigate safety risk. The first step is to strengthen the implant device identification system by using a UDI and a patient information implant card for routine medical data. The UDI can ensure that medical device performance and revisions are traceable and that the card matches the patient implant to the medical history registries for adverse effects and safety analysis. Drozda et al. (2016) asserted that adding an implant device UDI into

the patient electronic health record by using barcode scanning improves real-time device safety surveillance and quality through longitudinal monitoring research. Transferring UDI data into electronic health records will allow hospital managers to quickly enter medical device identification data (Drozda et al., 2016). Having immediate access to UDI data can improve device surveillance transparency, safety standards, and inventory management.

Studies conducted concerning the link between medical devices and UDIs are prominent. The Drozda et al. (2016) prototype coronary stent study confirmed that linking UDIs with GS1, global trade identification numbers GTINs, the FDA UDI database, and with clinical attributes could improve implant device tracking. Deploying UDI surveillance content and extracting and interpreting meaningful knowledge must include external data collection systems to increase device surveillance transparency to prevent process delays, lower costs, and potentially increases revenue (Boisier, 2016). Linking electronic medical data systems with manufacturer UDI barcodes extends the device surveillance lifecycle for all implant medical devices, generalizes any immediate revision needs, and assesses longitudinal performance for patients and hospitals (Ghobadi et al., 2019). Although the UDI data contains critical informatics for identifying implant devices in patients, redesigning the medical device surveillance process to include data from hospital electronic information systems closes the reporting gap to improve quality and safety.

Due to the abundance of medical devices, they are moving into the remote Internet of Things (IoT) technology pool that requires continuous tracking identification and communication. The objective of medical device surveillance is for hospital managers to improve implant inventory management to prevent procedure delays and enhance device revisions proactively to lower costs, increase revenue, and prohibit injury to the patient (Drozda et al., 2016). The challenge is for managers to establish a balance between the right combination of technology tools to minimize device surveillance vulnerabilities and to maximize connectivity monitoring functionality (Alexander, Haseeb, & Baranchuk, 2018). The goal for health care managers and physicians should be to provide accurate postmarket medical device data through reliable, interoperable network platforms.

Although medical device surveillance requires a network monitoring system that includes UDI identifiers, barcodes, insurance claims, and historical data repository connections, reporting adverse medical event outcomes continues to be a voluntary and subjective postmarket human intervention process. Medical devices cover a broad spectrum of diagnosis, and surveillance input relies on manufacturers, physicians, health care managers, and consumers to identify and report adverse medical events (Aslani et al., 2018). The ability to provide an early warning system before a needed device revision or recall becomes life-threatening is critical.

Inadequate awareness and manual reporting efforts of adverse medical events limit health care managers to intervene proactively to prevent impairment or serious bodily injury. Automation of reporting processes potentially resolves some of these reporting issues. According to Desveaux and Gagliardi (2018), automating medical device surveillance data collection and notification functionality is a challenge that requires redesigning the monitoring process to reduce information fragmentation and discrepancies. The medical device tracking system should provide a transparent chain of data. Keeping current with evolving medical device surveillance technology to ensure postmarket regulatory compliance, safety, and proactive recall intervention can alleviate excess revision cost, management stress, and patient risk.

Medical devices that sustain human life must comply with an expeditious FDA premarket approval (PMA), but quick processing has the potential to increase recall risk. According to Rathi, Krumholz, Masoudi, and Ross (2015), 36% of life-sustaining medical devices are recall candidates, of which 4% are life-threatening. The high-volume processing of medical devices impacts quality, which places more pressure on postmarket surveillance (Rathi et al., 2015). Aligning the FDA PMA with medical device risk, device class, and functional benefit is a strategy to improve safety and process effectiveness. One way to redesign the postmarket surveillance process is to standardize UDIs across all medical devices to close the knowledge gap between manufacturers, clinicians, patients, and researchers (Brown et al., 2015; Jones, Mi, & Webster, 2019). Although UDI has

fallen under legislation ruling, only 14% of manufacturers use a postmarket surveillance process such as UDI labeling to track and monitor medical implant devices (Zippel & Bohnet-Joschko, 2017). As more medical devices enter the market as optional treatment mechanisms, enforcing FDA compliance guidelines across a broad spectrum of device classes becomes a challenge.

Medical devices are part of care processes that provide several treatment options that can improve the health of an individual. According to Lee and Bae (2017), levels of medical device use, and benefit of that use, depends on (a) disease severity, (b) substitute availability, (c) procedure improvement, (d) outcome improvement, (e) survival increase, (f) quality of life improvement, and (g) cost. In terms of cost, the rapid growth of unique medical devices accelerates expenditures that can limit economic value (Lee & Bae, 2017). Currently, any medical device that completes the FDA approval process is reimbursable by health plans. However, the willingness to pay for the mechanism relates to each benefit and corresponding cost and is not standardized (Lee & Bae, 2017). Standardizing FDA reimbursement criteria for implantable medical devices can potentially improve revenue for health care practices by reducing financial expenses.

An evaluation of medical device cost-effectiveness by McLaren et al. (2017) indicated that combining internal and external procedures is necessary to inform physicians how to standardize evidence-based medicine, which influences policymakers. The increasing application of medical devices is evolving into an evidence-based need

approach that providers can use as an informing mechanism to make better medical, resource, cost, and reimbursement decisions. Recent studies support the idea that clinician monitoring of medical device health outcomes using lifecycle surveillance evidence enhances the FDA approval process through performance feedback to the manufacturer (McLaren et al. 2017; Melvin, & Torre, 2019). The result is potentially better device quality, treatment diagnosis, and reimbursement procedures.

In reporting adverse medical device events, manufacturers and users of medical devices have access to the FDA manufacturer and user facility device experience (MAUDE) and alternative summary reporting (ASR) databases to report device adverse medical events voluntarily. The purpose of MAUDE and ASR is to proactively prevent adverse medical events for the patient (Yao, Kang, Wang, Zhou, & Gong, 2018). The manufacturer and user facility device experience and ASR data are not available to the public but contain mandatory and voluntary reports of medical device events since 1993 (Yao et al., 2018). However, on June 21, 2019, the FDA formally ended the ASR program and is now making all report exemptions available from 1999 to 2019. Over 6 million previously hidden medical device incidents from 1999 to 2019 are now available in the public domain (FDA, 2019). Although greater awareness may not increase voluntary device malfunctions and recalls, monitoring as a service through a third party may provide un-bias reporting and consistent lifecycle device surveillance.

**Adverse Medical Events and Medical Device Revisions**

The frequency of medical device revisions may be the result of novel device use and learning curve influences that influence use outcomes. Although new device performance monitoring is critical to track procedural issues, Federici, Armeni, Costa, and Tarricone (2017) posited that specific types of medical device technology require a learning curve to evaluate the initial performance for reliability. A study conducted by Kohani and Pecht (2016) found that exposing the medical device to various applications and environmental conditions may cause the medical device to fail. One common reason for medical device failure may be inherent to the device design because many device ratings are for specific extremes rather than the norm (Ghobadi et al., 2019). Additional revisions may involve a replacement, which potentially increases the risk to the patient and incurs greater costs. However, according to Matharu, Eskelinen, Judge, Pandit, and Murray (2018), implant revision surgery is improving by implementing medical device surveillance processes in patients that lower the threshold for performance revisions. Applying a medical device revision before an adverse medical event threshold occurs is optimal and warrants further discussion.

Robust reporting is necessary to track medical devices beyond traditional reporting from individuals, which include manufacturers, hospitals, and providers. Jang, Choi, and Kim (2017) used a qualitative study to explain how UDI reporting systems provide managers with a flexible tool to monitor adverse medical events from the

manufacturer to the patient independently. Managers who use thorough UDI reporting can manage devices and patient outcomes more effectively (Jang et al., 2017). If managers have the opportunity to bridge the evidence gap between data registries across the total medical device lifecycle using the UDI as the critical element of the surveillance process, patient safety, and cost savings will increase (Zeitler et al., 2016). In this way, medical device surveillance participants should include a broad range of connecting groups that include device manufacturers, regulators, supply chains, physicians, professional societies, academicians, providers, payers, and patients. Zeitler et al.'s (2016) study highlighted the importance of improving medical device information transparency by creating a reusable infrastructure for real-time lifecycle data collection and analytics.

The need for an effective data collection process that serves patients by admitting them as soon as a monitored device begins to show signs of malfunction can save lives and be economically proactive. In a study by Zerhouni et al. (2018), the authors illustrated that adding the UDI to a patient claim serves as a supplemental backstop data collection process that enhances patient safety by admitting patients sooner before critical conditions develop. Combining the UDI with the insurance claim and electronic health records from different health care systems can provide a comprehensive medical device data capture platform to better care for patients. In the event that a patient receives treatment through a different health care system, the first electronic record entry will not

capture the most current health information to determine what is causing the adverse medical event (Zerhouni et al., 2018). Connecting different health care data platforms, including the insurance claim processing component, may serve as a better platform to collect, search, and access device data for efficient medical treatment.

A second significant gap to fill regarding medical device implant safety is device-identification data on insurance claims. Comprehensively tracking the frequency of failure by specific brands and models can provide needed information on specific devices (Andrew & Justin, 2017). For example, if a medical device fails, managers can learn about the event or problems quickly from various hospitals or offices because the insurance claim can link data from multiple hospitals. Integrating the UDI on an insurance claim closes the device surveillance gap by connecting data systems upstream (purchase order to manufacture) and downstream (inventory, patient, claims) to substantiate the need for further action (Andrew & Justin, 2017). Insurance claim data that includes the medical device UDI enriches medical device lifecycle surveillance transparency and can help reveal more widespread problems or trends. Managers can use insurance claims to coordinate care by determining device longitudinal performance patterns and avoid placing patients' safety at risk. Bowers and Cohen (2018) found that physicians or surgeons implanting medical devices are not fully aware of all the evidence behind the functioning or success of implanting many medical devices. Periodic screening or testing to check if the medical devices are functioning according to a set of

standards that are not currently part of the workflow process. Postmarket reporting of medical device information and failures are potentially significant in improving health IT safety and learning in-depth about the pros and cons of implanting a device (Bowers & Cohen, 2018). Having a set of standards that spans multiple systems could save lives, cost, and expand evidence-based knowledge of health information and technology use safety.

Rugera et al. (2014) found through qualitative methods that regulatory authorities do not have the resources to regulate and track medical devices manually. Despite medical device regulation laws that govern product performance, lack of resources and internet data source limits create a negligent surveillance system (Jung, Uejio, Duclos, & Jordan, 2019). Data gathering constraints delay monitoring systems in collecting rich data that can improve the current device tracking system (Rugera et al., 2014; Jung et al., 2019). The potential surveillance barriers to overcome are complex processes and regulations. The challenge is to redesign the surveillance process for the timely detection of medical device issues to reduce adverse medical events and costs.

**Innovative Medical Device Surveillance Process Strategies**

Implementing a variety of innovative strategies to penetrate existing data silos, sources of fixed data uniquely controlled by one entity can enhance medical device surveillance to optimize device lifecycle monitoring. Different types of medical device surveillance strategies include IT and non-IT solutions such as (a) using radio frequency

identification technology (RFID), (b) IoT technology, (c) integrative data architecture for big data analytics, (d) social media technology, and (e) rethink and redesign traditional processes (Haddud, DeSouza, Khare, & Lee, 2017). Monitoring the medical device information lifecycle entails closing data gaps by activity looping raw device data from manufactured items to potential recalls and patient recovery (Govindan, Jha, & Garg, 2016). Tracking the entire medical device lifecycle using technology and non-technology methods from raw material to recovery is ideal for patient safety and cost reduction.

Innovative process advancements in IT provide health care managers with solutions that can enhance data management and synthesize knowledge by using (RFID) data collection technology (Haddud et al., 2017). Managers use existing RFID electronic item tag system technology and the internet as a data distribution hub to transmit product information electronically using wireless communication. The wireless RFID technology is a tool that managers can use to continuously monitor medical devices from manufacture to the patient using mobile cellular connectivity applications.

The purpose of RFID technology is the growing need to track items, validate medical device identity data, prevent inferior products from reaching the market, and from adhering to FDA regulatory policy (Basole & Nowak, 2016). The Haddud et al. (2017) study confirmed that the practical benefit of any item with an RFID tag system is a reliable real-time data collection system that is compliance auditable and provides storage automation that is accessible, traceable, scalable, flexible, and adaptable.

Three essential components of RFID technology to identify and capture device data automatically include: (a) a unique electronic transponder or tag, (b) a handheld scanning device or reader, and (c) a database to process and store device information (Basole & Nowak, 2016). The challenge of deploying RFID is the integration platform for a variety of item sensor tags that stochastically communicate and transmit data securely without human intervention (Alaba, Othman, Hashem, & Alotaibi, 2017). Although RFID provides managers with technology to collect and link various devices to measure performance, recall analysis requires continuous collaboration with all members of the monitoring system, from the manufacturer to the patient, to minimize technical and social barriers (Haddud et al., 2017). Managers can use a new technology approach to link and combine data collection sources to establish device monitoring networks.

Developing new networks to improve medical device surveillance is an innovative approach. According to Alaba et al. (2017), IoT is an innovative technology approach to establish a continuous integrative network that incorporates interoperable communication software protocols between all surveillance members. The approach serves to collect physical and other mobile device data that may influence device performance (Alaba et al., 2017). Innovative medical device surveillance designers should consider adopting a combination of monitoring strategies that track and exchange information flow (Tyndall & Tyndall, 2018). In addition to information flow, monitoring strategies could serve to improve device performance and reduce adverse medical events.

Managers must consider redesigning innovative surveillance strategies that use IT to enhance data-sharing because the recent development of integration platforms ease the resource burden of linking a device to a data collection network, including electronic health records. According to Powell and Alexander (2019), the barriers to overcome redesigning innovative surveillance processes are vendor database products that limit interoperability to exchange data. Software database vendors knowingly block health information and are perceive the exchange of health information as an opportunity to gain revenue (Adler-Milstein & Pfeifer, 2017). However, newer integration tools such as application program interfaces and fast health care interoperability resources allow managers to make inquiries and share database information beyond data ecosystem silos without compromising vendor database functionality (Tyndall & Tyndall, 2018). Nevertheless, automating data collection generates a large volume of data from several sources that may be humanly impossible to manage.

One challenge for managers is to sort and monitor device data to evaluate emerging performance patterns. The evaluation of performance patterns can help interpret disease trends with easy access to the system for proactive device recall management (Basole & Nowak, 2016). Despite the value of integrating, monitoring, collecting, filtering, and analyzing data using technology from open sources, non-technology process solutions such as collaboration and agreements between organizations are critical to realizing the full benefit of device surveillance (Witkowski, 2017).

Collaboration between all medical device business partners is essential to implement a complete medical device surveillance technology system that can become part of standard practice (Basole & Nowak, 2016). Surveillance data accessibility is critical, and recent developments in IT to monitor medical devices for safety issues make patients more aware of the risk and expect better device management (Yang & Zhang, 2018). Device manufacturers, the FDA, hospital systems, providers, and patients must all work together to form ecosystems to collect and share medical device monitoring data transparently with complete accessibility.

Another BPR strategy for medical device surveillance is developing a robust integrative infrastructure having a multiple-layer architecture to perform big data analytics. Goncalves, Pereira Barbosa, Freire de Castro Silva, Fernandes Martins, and Cheng (2018) explored data mining and big data analytics to reveal hidden relationships between patient data, treatments, and disease surveillance. The function of big data analytics is to process data using algorithms to interpret the data from multiple device data exchanges simultaneously (Farahani et al., 2018). Goncalves et al. (2018) found that big data analytics is useful for predicting outcomes because data volume, variety, veracity, and velocity add value to the monitoring process for decision making. Farahani et al. (2018) posited that the enhancement of big data analytics is possible by making medical devices smart using the internet of medical things (IoMT) technology to enable automatic big data collection selectively.

Furthermore, IoMT provides managers with a strategy to connect people and devices for continuous monitoring of therapeutic applications and establishes a self-sustainable ecosystem to reduce adverse medical events concerning devices (Watts-Schacter & Kral, 2019). The device communication ecosystem is made up of a combination of participating organizations, hardware, software, and connective services (Farahani et al., 2018). The participants include the manufacturer, hospitals, physicians, and patients who connect devices and cloud computing for seamless connectivity, accessibility, transparency, and usability to detect early warnings.

Creating a ubiquitous and smart communicative monitoring platform requires coordinating multiple devices, manufacturers, service providers, patients, and numerous protocols virtually through the exploitation of the UDI (Basatneh, Najafi, & Armstrong, 2018). Basatneh et al. (2018) posited that a smart device platform simplifies device communication variation and allows the adoption of standard protocols to enable device connection that eliminates the burden of configuration away from the consumer of care. Smart device statistics can serve as a big data analysis filter to normalize the volume of incoming data to improve decision making and device performance (Basatneh et al., 2018). Despite the benefits of high-speed data collection through automation, managers struggle to recognize the value of analytical applications to filter data for trends over time as a method for finding decision-making patterns (Goncalves et al., 2018). Data filtering

potentially allows managers to simplify analysis to support everyday application decisions.

Innovative medical device surveillance technology gives managers a toolset to democratize device monitoring rather than being confined to unique cases. A mobile social media platform may serve as the transformative pioneering tool that increases control and access to health information at the next level. A quantitative study conducted by Al-Gayar and Shubber (2019) illustrated how e-learning, mobile health, and mobile applications increase and improve health care. A second study by Liu and Young (2018) explored the use of social media as a technology platform and illustrated how applications such as Twitter and other big data research analytics provide real-time health monitoring for making predictions. Both authors found that modeling social media data with other datasets can lead to novel surveillance approaches to monitor and identify changes in behavior to potentially determine if proactive medical device health intervention is necessary (Al-Gayar & Shubber, 2019; Liu & Young, 2018). Social media analysis may provide a rich source of data that can link several venues of care to study the dynamics of the medical device lifecycle to avert adverse medical events before they have an opportunity to occur.

The challenge to re-engineering the business process for medical device surveillance may be to overcome the lack of application normalization and to obtain a personnel skillset to deploy a new type of platform to ease usability complexity. The data

surveillance platform infrastructure must match medical information needs but be sharable and understandable for the medical public. Al-Gayar and Shubber (2019) concluded that a social media medical system brings high medical monitoring by combining social networking systems, e-learning, mobile health, and health software applications for interaction empowerment. The outcomes can have a positive impact on how medical device manufacturers design devices, monitor the device lifecycle, and issue recalls reducing adverse medical events and costs. User acceptance testing (UAT) gives managers a method to evaluate the usability of a process (Zavar & Keshavjee, 2017). A UAT prototype will allow managers to measure user competency, effort, influences, and support expectations through consistent observations and feedback. The purpose of UAT is to establish self-efficacy measures to ensure that users accept the new technology process to achieve solutions and to match functional competency levels to perform the process tasks.

## Transition

The purpose of this qualitative single case study was to explore strategies that managers in hospital health care organizations use to redesign the implant recall surveillance processes that reduced adverse medical events and revision costs. Section 1 served as a guide to present the study, analyze the literature, and to outline the following sections of the study. In Section 1, I presented the background of the problem, problem statement, and the purpose statement. The study literature review consisted of current

knowledge, substantive findings, and the BPR conceptual framework. In the professional literature review subsection, I discussed the current medical device surveillance strategies, regulations, the application of BPR, and supporting conceptual frameworks. The review of literature exposed management opportunities to improve and support the medical device UDI postmarket surveillance process for FDA compliance.

Research that relates to UDI postmarket surveillance processes exists, and the need for a more efficient and effective method is evident by the high medical device recall rates. Inconsistent medical device surveillance processes continue to produce adverse medical events that potentially increase revision costs. Published qualitative studies of BPR factors that adhere to pre- and post-approval quality measures for medical devices support the need for this study.

In Section 2, I discuss the details of the research project. The critical elements include the role of the researcher, justification of the sample size, the criteria for participant selection, and the research method and design. I outline details of ethical research execution procedures to ensure the respect, rights, and privacy of study participants. In Section 2, I describe data collection instruments and technique procedures to ensure consistency and effective use of time. I discuss the details of the data organization and analysis using software tools. Lastly, I discuss aspects of reliability and validity to establish study trustworthiness and to ensure that the findings are dependable, credible, transferable, and confirmable.

In Section 3, I present and discuss the results and implications of the study. The discussion includes a comparison of the findings to existing literature and application of the findings to current business processes. Section 3 also contains implications for social change, recommendations for further research, and reflections on my experience of conducting the study. I end Section 3 with evidence supporting study findings.

# Section 2: The Project

Section 2 contains a discussion concerning the study design and the research project completion to explore the specific problem of implant recall notification processes that cause adverse medical events and revision costs and the need for hospital managers to engage in a more efficient and effective process. Two critical components of Section 2 are data collection and synthesis. In Section 2, I present a discussion on (a) the role of the researcher, (b) participant criteria and recruitment strategy, (c) research method and design, (d) ethical considerations, and (e) sample size justification. I also include details about (a) data collection, (b) organization, and (c) analysis. Finally, I conclude with a description of dependability, credibility, transferability, and confirmability methods to ensure the study's reliability and validity.

## Purpose Statement

The purpose of this qualitative single case study was to explore strategies that managers in hospital health care organizations use to redesign implant recall notification processes that reduced adverse medical events and revision costs. The targeted population comprised of five managers in one hospital facility in the northeast region of the United States who successfully redesigned the implant surveillance recall process. Hospital managers commonly use multiple unambiguous labeling strategies for successfully conducting postmarket medical device surveillance to confirm compliance and to control recall costs. Exploring the medical device lifecycle process provided insights that avoid

future medical complications and revision costs. The implications for positive social change include healthier local communities for all individuals. People in society can prosper economically when health care providers produce better outcomes, leading to further business expansion that enhances employment opportunities for individuals in local communities.

## Role of the Researcher

My role as a researcher was to serve as an instrument to conduct this qualitative case study in an unbiased and ethical manner. Many qualitative researchers serve as the primary investigator by collecting and interpreting data (Yin, 2018). Therefore, I abided by the Institutional Review Board (IRB) guidelines to protect the study's participants. The researcher also determines the number of additional participants potentially needed for reaching data saturation (Tran, Porcher, Tran, & Ravaud, 2017). My specific tasks included interviewing a minimum of four participants from a single hospital organization, managing the interview process, collecting and analyzing data, mitigating personal bias, and making recommendations for future research while following the IRB guidelines (Yin, 2018). Institutional Review Board policies apply to academic, community, government, and investigative medical research protocols (Liberale & Kovach, 2017). Following IRB guidelines ensure the ethical protection of participants.

The purpose of the IRB is to protect the welfare of human research subjects. Such protection is the principal concern for any research involving human subjects (Friesen,

Kearns, Redman, & Caplan, 2017; U.S. Department of Health and Human Services [HHS], 1979). I used the principles of the Belmont Report as an ethical guideline to protect participants in my study from harm, thereby ensuring the validity of the research. The three critical elements of the Belmont report that enhance the research experience for the researcher and participants are (a) respect, (b) beneficence, and (c) justice (Adashi, Walters, & Menikoff, 2018; HHS, 1979). By showing respect, researchers provide subjects autonomy, confidentiality, and the ability to withdraw or decline participation at any time without question (Adashi et al., 2018; HHS, 1979). Applying the beneficence rule allows researchers to maximize study benefits and minimize participant harm (Adashi et al., 2018; HHS, 1979). The justice guideline is for the researcher to address the fair and equal distribution of the study benefits and risks to participants to ensure equal treatment of all parties (Adashi et al., 2018; HHS, 1979). I followed the principals of the Belmont report throughout the research process.

To demonstrate IRB understanding, I completed the Walden University (ID 2906) Collaborative Institutional Training Initiative (CITI) Program IRB coursework requirements for student researchers. The training consisted of completing seven research ethics and compliance course modules. The training focused on the protection of human participants. My training and certification identification numbers are 8107976 and 31600874, respectively.

I served as the primary research instrument to collect and interpret data to complete the study. In the context of qualitative research, investigators are the main research instrument because the primary focus of interest is to understand the phenomenon under study from the participants' perspective, often best completed by gathering thick and rich interview data directly from the participants (Peredaryenko & Krauss, 2013). The relationship between participants and the researcher was significant when using a qualitative methodology because the research material was co-produced (Raheim et al., 2016). Building trusting relationships with participants reduces participant vulnerability, thereby gaining a deeper understanding of the participants' knowledge about the phenomena with their increased willingness to share (Raheim et al., 2016). Similarly, the experiences, knowledge, and ideas of the researcher, and the participant can enhance the quality of the data collected during the interview process (Kaliber, 2019). The challenge is keeping a minimal relationship distance between the researcher and participant to establish a neutral professional rapport to mitigate personal prejudice, bias, and to assure confidentially.

Privacy and confidentiality are critical elements of research. Organization managers need assurances of privacy and confidentiality during and after the research process (Omidoyin, Opeke, & Osagbemi, 2016). As a technical director in a health care organization, I am familiar with interview techniques and aware of bias sources that may stem from managers using postmarket medical device surveillance processes. Following

the recommended interview process concepts by Kaliber (2019), Korstjens, and Moser (2018), I reduced qualitative study bias by separating my knowledge and experience from the participants by using a standard interview protocol and member checking throughout the data gathering process.

The rationale for using an interview protocol is to control the interview process by following a consistent interview plan that aligns with answering the research question. An interview protocol is a valid method to measure an individual's thoughts by limiting oversights and inconsistencies during the interview process (Culbert, Ristic, Ovington, Saliba, & Wilkinson, 2017; Horeni, Arentze, Benedict, Dellaert, & Timmermans, 2014). A researcher uses an interview protocol to determine the essential information to obtain and define what to ask objectively (Cypress l., 2017). Using an interview protocol (see Appendix A) improves interview efficiency and reduces bias by providing the researcher with a consistent process to follow for each participant interview (Rosenthal, 2016). The interview protocol also serves as a method to replicate the process without bias.

Biases and preexisting assumptions can skew the interpretation of the study's results. Incorrect interpretation of the findings may diminish the transferability and generalization of the study (Toews et al., 2017). The researcher may encounter dissemination, confirmation, and interview biases. Toews et al. (2017) argued that although dissemination bias in qualitative research is uncommon, deciphering known causes of dissemination bias can provide insightful non-bias guidance. Confirmation bias,

however, is more common because of the human resistance to change beliefs or opinions (Miller & Jangula, 2019). According to Miller and Jangula (2019), confirmation bias can influence data collection and analysis through subjective data filtering. Researchers can mitigate bias and increase participant engagement by maintaining a flexible, professional mindset approach to reduce participant interview stress and to enhance cooperation (Antes et al., 2016). I mitigated bias by adjusting to the participant's level of engagement, according to the interview questions, in a professional manner to enhance a collaborative rapport.

To avoid personal views and bias, I remained impartial by separating my conscious experience and emotions from participant data interpretation. Personality differences, personal characteristics, and an unstructured question process can potentially create a bias (Hilgert, Kroh, & Richter, 2016; Kaliber, 2019). According to Levashina, Hartwell, Morgeson, and Campion (2014), adding interview structure and standardizing the interview process for all participants can minimize off subject variation and bias. I assessed my potential biases by being aware of preexisting assumptions. I remained objective and maintain impartiality by using a semistructured interview protocol approved by Walden University's IRB, and by conducting member checking to validate the participants are sharing what they intend to share and that my interpretation is correct. I also acknowledged that my professional experience might cause research bias and did not interview participants with which I have any professional or personal relationship.

Throughout the interviews, I remained professional, follow the interview protocol with consistency, and use active listening skills to normalize the participant interview process and to mitigate bias in my research.

## Participants

Selecting study participants with relevant experience is critical to authentic research. Defining participant eligibility criteria ensures that the participants' expertise and characteristics align with the research topic to eliminate the potential for fraudulent responses (Chandler & Paolacci, 2017). The participant criterion for this qualitative single case study included hospital managers with at least two years of postmarket medical device surveillance process experience, at least two years of business process redesign decision authority, and hospital managers who were successful in implementing process redesign.

Researchers depend on accessing appropriate participants within the business to provide pertinent and relevant data that improves the understanding of the current real-world issue and to align participant knowledge with the research question (Palmatier, 2017). In addition, recruiting participants with experience eliminates barriers such as lack of knowledge and inability to articulate opinions in a reflective manner (Duncan & Hagglund, 2018; Ledford, 2018; Palinkas et al., 2015). Eligible participants provide a rich source of relevant knowledge that improves single case study validity (Duncan & Hagglund, 2018; Ledford, 2018). Failure to recruit knowledgeable participants can

reduce the efficacy and potential value of the study (Juurlink, Bavera, Sclafani, Petrov, & Reid, 2018). Recruiting participants who are knowledgeable about the study issue ensures a better understanding of the research problem and question. Gaining access to potential participants is critical. According to Cridland, Jones, Caputi, and Magee (2015), researchers can gain participant access through directories, Internet searches, and in-person recruitment meetings. I gained access to participants using the organization's directory list and followed up with an email to contact potential participants (see Appendix D).

I gained access to participants by completing the hospital research IRB requirements at the site and complied with the organization's IRB criteria to obtain the correct organization authority for access (Dichter et al., 2019). Once I met the hospital and Walden University IRB requirements, I proceeded to contact potential participants relevant to the study. I obtained permission from Walden University's IRB and from the hospital organization's IRB (see Appendix E) before contacting potential participants by any form of communication.

I established a relationship with the participants by sending a formal invitation via email (see Appendix D), sharing the purpose of my study, and presenting each manager with an opportunity to participate in the doctoral research voluntarily, and without any consequences, if there is a decision made to withdraw from the study at any point and for any reason. The email invitation included detailed information regarding interview time

expectations, ethical protection, participant confidentiality, response anonymity, and data storage security during and following the research study. Establishing a symbiotic working relationship breaks down role conflict between researcher and participant, engages participants to present their views, and helps co-interpret the phenomena (Raheim et al., 2016). I established a working relationship with the participants by engaging them through consistent and purposeful communication using an initial email and further email and telephone discussions to confirm participant eligibility, recognize and acknowledge their expertise, and to form a professional rapport. I developed trustful relationships by meeting potential participants in private office rooms, assuring confidentiality, explained the consent form (see Appendix C) in accordance with the stringent academic code of ethics, and asked them to reply to the informed consent form email with the words *I consent* before beginning the interview.

## Research Method and Design

I used a qualitative single case study and purposeful sampling, methodological triangulation, participant interviews, member checking, and the review of relevant process documents to explore strategies to address the specific business problem. A qualitative single case study is a flexible method researchers can use to gain understanding and insight into individual business problems through participant perspectives by exploring how and why a process operates in a real-life setting (Gaikward, 2017; Rolfe, Ramsden, Banner, & Graham, 2018; Rosenthal, 2016). A

qualitative case study is applicable for exploring issues by understanding the context of a phenomenon through an exhaustive investigation of a bounded system (Creswell & Poth, 2018; Kegler et al., 2019). I focused on the rich context of participant real-life business activity, experience, and knowledge to gain an insightful understanding of the phenomena under study.

**Research Method**

Researchers select one of three methodology approaches to conduct research. The three methods are qualitative, quantitative, or mixed methods (Creswell & Poth, 2018). Qualitative and quantitative methodologies are the dominant approaches to addressing the research question and hypothesis, the latter being a component of quantitative studies. A researcher uses a qualitative research method to gain a deeper understanding and rich insight from the participant's perspective (Hamilton & Finley, 2019). Qualitative research is valuable for researchers to guide the development of new products, processes, services, and to gain an understanding of strategies that lead to specific outcomes (House, 2018). According to Rolfe et al. (2018), qualitative research is more relevant in the health care field because the co-partnering relationship established between participants and the researcher helps address the problem by establishing which priorities to explore in a somewhat relaxed interview setting. Bansal, Smith, and Vaara (2018) posited that the breadth and variety of qualitative research offer more significant insights into understanding complex problems. The scope of a qualitative methodology has the

advantage of being broad enough to capture new meaning for a more in-depth understanding of a complex phenomenon.

In contrast, some scholars argued that quantitative research is more objective. According to Rendle-Short (2019), a quantitative methodology relies on numerical data that represents a narrow consensus of perception, and instead focuses primarily on statistically analyzing variables. Hammarberg, Kirkman, and de Lacey (2016) stated that quantitative research represents a broader sample of a population and is objective. However, researchers can manipulate the collected data by sample size and make statistical assumptions that do not identify and quantify the in-depth meaning of the phenomena through engaging directly with study participants (Taguchi, 2018). Some scholars argued that a mixed-method approach provides a balance of data collection by using both qualitative and quantitative methodologies to enhance the trustworthiness of research claims (Cohen, Manion, & Morrison, 2018). According to Taguchi (2018), the combination of methods may dilute researcher rigor by adding multiple statistical factors that skew qualitative outcomes.

I selected a qualitative approach to explore manager strategies regarding postmarket medical device surveillance processes to reduce adverse medical events and revision costs. Using a case study, researchers collect unstructured data from participants and observe processes (Gaikwad, 2017). Qualitative research pertains to the analysis of unstructured data to answer *how* and *why* questions within a real-world context (Yin,

2018), and is the primary reason why I selected a qualitative approach. My intention in this study was not to quantify different numerical values and is not a preliminary method that leads to quantitative or mixed-method research. Since structured statistical analysis is not required, quantitative and mixed-method approaches were not appropriate for this study. Instead, in using the qualitative approach, I was able to easily obtain the breadth of knowledge I was seeking in working directly with hospital managers.

**Research Design**

There are several research designs to choose from in conducting a qualitative study. As choosing a research design is a process that directs the manner in which information will be gathered, it is essential to select the design most appropriate for gathering information-rich insights that align with the research question (Benoot, Hannes, & Bilsen, 2016; Knapp, 2017; Yin, 2018). I considered three qualitative research methods: case study, ethnographic, and phenomenological, before selecting a case study design with interviews to address the research question.

A case study is a research method that is commonly used as a strategy to investigate a phenomenon. According to Yin (2018), a single case study research design is used to generate insights from in-depth inquiry to study complex phenomena within a real-life context. According to Saunders, Lewis, and Thornhill (2016), the case study design can include a person, change process, activity, program, or event and is the primary vehicle for generalizing a study's findings (Creswell & Poth, 2018; Yin, 2018).

Researchers use case study designs to conduct an exhaustive exploration of either a single case or multiple cases to understand a concept from different angles and by using diverse sources (Netland, 2016). A single case study method is appropriate for this study because the emphasis is to understand strategies unique managers use to successfully monitor the medical device lifecycle process to reduce adverse medical events and revision costs. The ethnographic design is a common qualitative synthesis approach (Benoot et al., 2016) and appropriate to explore shared values, beliefs, and behaviors of a culture or group (Saunders et al., 2016; Creswell & Poth, 2018). Because the objective of this study was to explore process redesign strategies, it did not require the analysis regarding shared cultural values, and I did not choose the ethnographic design. A phenomenological design is not appropriate for this study because the intent is not to explore the lived experiences of individuals (Creswell & Poth, 2018). Rather, I used a single case study design to obtain rich data from individual participants to answer the research question.

Data saturation occurs when participants repeat the same information, and no new information in the data leads to new emergent themes. Achieving data saturation is when a researcher determines that the data collection and analysis process produce minimal or no response change (Tran, Porcher, Falissard, & Ravaud, 2016; Tran et al., 2017). Researchers achieve data saturation by collecting all data relevant to the case study until nothing new emerges (Tran, & Ravaud, 2017). I conducted semistructured interviews and review process documents to obtain data saturation, and considered the data set complete

when the same information from participants was redundant, and no new knowledge from the data produced additional themes. I asked open and probing interview questions to all study participants until the responses did not generate new information, ideas, or themes indicating data saturation.

## Population and Sampling

The population for this qualitative single case study consisted of medical device hospital managers from one hospital in the state of Pennsylvania. The study hospital organization population consisted of 8 hospital managers who monitor medical device surveillance processes. Researchers use a purposeful sampling strategy to select population participants who can identify and contribute rich, comprehensive knowledge to address a study's research question and can bring insight to a specific problem (Lavallee et al., 2017; Marshall & Rossman, 2016; Setia, 2016). Purposeful sampling is a standard, nonrandom selection method used to confirm that participants who have the experience, knowledge, and capability are in the final sample used to address the research question (Benoot et al., 2016; Setia, 2016; Yin, 2018). Purposeful sampling requires critical planning, such as defining criteria to serve as a guideline to recruit potential participants who can provide rich information about the topic (Benoot et al., 2016; Rosenthal, 2016). I used purposeful sampling in this single case study to identify five managers from the study hospital population who have specific knowledge of the study topic to reduce interferences and who provided rich data.

The participant sample included hospital managers with 2 years of postmarket medical device surveillance process experience, possess decision support making authority, and who have successfully implemented strategies to redesign implant recall notification processes that reduced adverse medical events and revision costs in their organization. I used purposeful sampling to ensure that the sample for the research included hospital managers who have experience and decision-making authority implementing strategies to enhance medical device lifecycle surveillance. Through purposeful sampling, I identified five potential participants who had the appropriate level of experience and were able to contribute to the study topic knowledgeably and provide data that helped answer the research question.

Determining sample size is critical and recruiting more than four participants depended on whether four participants is sufficient to achieve data saturation. Firm guidelines to determine the sample size for qualitative research are sparse because size determination varies and is partially dependent on the phenomena under study, the research question, and the richness of the data provided (Boddy, 2016; Elo et al., 2014; Hennink, Kaiser, & Marconi, 2017). However, previous studies are useful for estimating sample size and reaching data saturation and can provide researchers with a parameter for justifying sample size (Boddy, 2016). Yin (2018) suggested a minimum sample size between three to five for a case study. A qualitative research study in a health care setting conducted by Cronin (2014), concerning the implementation of new process strategies,

revealed the researcher was able to reach data saturation by interviewing five participants. In another qualitative study regarding strategies to mitigate process risk, Bowman (2015) reached data saturation by interviewing four participants. Because my study was a single case study about process strategies such as in the previous case studies mentioned, I used five participants as the sample size from one hospital organization located in Pennsylvania. I reached data saturation using five interview participants.

Although I identified five potential participants for data collection, I reached greater data saturation by combining multiple data sources. Data saturation is not only about the volume of information gathered, but rather the ability to conduct the research until there is no new information shared (Weller et al., 2018). Researchers employ data triangulation to add credibility to a study's findings by collecting and verifying data using multiple data sources to analyze the same event, concept, or variable (Kern, 2018; Saunders et al., 2016). I performed semistructured interviews with business managers; used organization documents, including process documents, policies, and metric reports; and conducted a thorough review of the literature to support the collected data to ensure data saturation.

I explored two additional qualitative sampling approaches for this exploratory study: (a) snowball and (b) quota sampling methods. Snowball or network sampling is a nonprobability research method for identifying additional hard to find participant or informant sources (Heckathorn & Cameron, 2017; Saunders et al., 2016; Suri, 2011).

According to Marcus, Weigelt, Hergert, Gurt, and Gelleri (2017), the snowball sampling technique is a disadvantage because the method potentially adds bias due to participants recruiting close associates to participate in the study. I did not use snowball sampling for this study because participants are not difficult to find, and there is no need to recommend other associates. Quota sampling is a nonprobability, nonrandom sampling method that is appropriate for studies involving more than one sample population or subgroups based on participant criteria, accessibility, and availability (Saunders et al., 2016; Setia, 2016). According to Ochoa and Porcar (2018), the reason researchers implement quota sampling is to select participants to ensure the final sample aligns with the target population, subgroups, and any study variations that enhance data collection. I did not use the quota sampling method because only one sample population was necessary for data collection in the study.

## Ethical Research

Researchers must consider ethical components during data collection. Ethical research execution concerns respecting and protecting the privacy and rights of study participants. The IRB guidelines are intended for researchers to protect participants ethically and are mandated in the United States by the Code of Federal Regulations (Miracle, 2016). The IRB process first began in the United States in 1974 in response to the Belmont Report to protect study participants. The Belmont Report is a guide and includes the three core principles of respect, benefice, and justice. The three core

principles ensure research is conducted ethically (Brothers et al., 2019). Researchers use the respect principle to protect the participant's autonomy and the right to participate or withdraw from the study without reason and at any time (Miracle, 2016). The beneficence principle relates to the need for researchers to protect the participant from harm by minimizing risks and maximizing study benefit (Miracle, 2016). Researchers use the justice principle to focus on safeguarding the participant from any exploitative procedures (Miracle, 2016). Federal regulations provide ethical guidance for research projects that involve human subjects and require IRB approval before any research activity commences (Liberale & Kovach, 2017). To ensure my research processes are appropriate and will do no harm to participants, I completed the Collaborative Institutional Training Initiative (CITI) (ID 2906) training for student researchers. My training and certification identification numbers are 8107976 and 31600874, respectively (See Appendix B).

Based on the Belmont Report and Walden University IRB guidelines, I obtained IRB approval before contacting the participants and collecting data. After receiving Walden University IRB approval, I notified the organization by email of Walden University's IRB approval to collect data using semistructured face-to-face interviews. I contacted leaders at the organization via email to present the purpose of my study and to request names of potential participants that meet the inclusion criteria of having specific experience and knowledge with the medical device surveillance process. I emailed

potential participants a recruitment letter (see Appendix D) and the informed consent form (see Appendix C). In the email, I included instructions for the potential participant to reply via email if they are willing to take part in the study. If the participant had understanding of the study well enough to make a conscious decision to participate in the study, I asked the participant to respond by replying to the email with the words *I consent* to my original email thread and attach the informed consent. The recruitment letter contained contact information for potential participants to contact me directly to address any concerns or questions.

When interviewing participants in any study, obtaining written consent is necessary. Obtaining informed consent is a mandatory element to conduct ethical research involving human subjects (Gaikwad, 2017; Liberale, & Kovach, 2017). The informed consent form ensures that potential participants engaged in the research have relevant yet comprehensible information about the study to decide about participating in the research (Karbwang et al., 2018). According to Karbwang et al. (2018), the informed consent form is a detailed study explanation of the purpose, procedures, participants' rights, welfare, safety, risks, benefits, withdrawing methods, disclosure about participation without incentives, and confidentiality. I emailed the informed consent form, included in Appendix C, to each potential study participant and gave the potential participant the opportunity to ask questions, review their rights as outlined in the consent form, and to obtain their consent via email without coercion pressure. Researchers use

informed consent to provide the potential participant with a clear understanding of their rights and impact (Saunders et al. 2016). I ensured that the potential participants had a clear understanding of the informed consent form, and I followed up with a telephone call for further explanation, if requested, before the participant replied *I consent* with an email. I will email each participant an informed consent form and ask voluntary participants to reply *I consent* to my original email thread and attach the informed consent form to their reply email as part of the ethical research process.

Through the informed consent process, I explained to participants that they have the right and freedom to withdraw from the study at any time without reason or consequences by notifying me via email or telephone. The consent form allows the participant to voluntarily withdraw from the study without cause (Angelos et al., 2018). I made the participants aware that participation is entirely voluntary without compensation or incentives for their participation. I stored the information on a removable external hard drive with encryption and dual password authentication. The hard drive will be stored in a safe with a combination lock for a minimum of five years before deleting the files permanently. I will be the sole person to have access to all stored study files in the safe. I included the Walden University IRB approval number 02-28-20-0614432 on the final document manuscript.

Respecting and protecting the privacy and rights of study participants is critical. Researchers commonly use pseudonyms to protect the identity of research participants to

ensure data confidentiality and privacy (Surmiak, 2018). According to Leibenger, Mollers, Petrlic, Petrlic, and Sorge (2016), the use of pseudonyms sustains participant confidentiality and provides research privacy for new knowledge development and ensures legal protection. Allen and Wiles (2016) concurred that assigning aliases to research participants confirms data confidentiality, privacy, identity protection, and adds the psychological benefit of participants feeling comfortable to offer rich study content liberally. I used participant pseudonyms such as Par 1 through Par 5 to reference the five research interview participants for the study. I will securely hold and protect the original names of the study participants from any revealing documentation or circumstance that could identify any participant or the organization at which I am conducting the study. I will be the only one to know the true participants' identities, and I will be solely responsible for keeping identities confidential. All data obtained from the participants during and after the study will be confidential. The participating organization and participants' privacy will always be protected.

## Data Collection Instruments

There are several ways in which to collect data. In qualitative research, a researcher becomes the primary instrument for data collection (Clark & Veale, 2018; Marshall & Rossman, 2016; Yin, 2018). According to Marshal and Rossman (2016), a researcher's data collection objective is to gain access to participants to collect and record the data for future analysis and interpretation. I served as the primary instrument for data

collection for this qualitative single case study using face-to-face semistructured interviews. Researchers can use semistructured interviews as a method to collect data about a specific phenomenon from a participant's perspective and experience with a phenomenon without constraints (Heath, Williamson, Williams, & Harcourt, 2018). I asked the participants nine open-ended interview questions that have no restrictions, constraints, or the need to choose one out of several possible responses.

Although procedures exist to conduct a qualitative semistructured interview, an interview protocol can guide the researcher to ask the same questions consistently to each participant to avoid skewing the data in any way. A researcher may gain in-depth information and uncover new knowledge from a participant's subjective responses when answering open-ended questions (Clark & Veale, 2018). According to Weller et al. (2018), open-ended and follow up probing questions allow study participants sometimes to offer unexpected information when answering interview questions. I followed an interview protocol to ask questions consistently (see Appendix A).

I ensured capturing the accurate and intended responses from the participants by using member checking. Member checking is a technique for exploring the credibility of response results by doublechecking with participants that a researcher's analysis of the interview data is the correct interpretation (Birt, Scott, Cavers, Campbell & Walter, 2016). According to Baillie (2015), member checking is the technique of choice to confirm researcher understanding and to affirm credibility. I conducted follow-up

sessions after the initial data collection interview. During this session, I shared a brief, written interpretation of what I believe they have shared to assess my accuracy in understanding their intended meaning. Member checking in this manner serves to decrease incorrect interpretation and enhance the trustworthiness of the study.

## Data Collection Technique

Researchers can use a variety of primary and secondary data collection techniques to gather information from multiple sources to gain insight relevant to the study. Conducting interviews and reviewing relevant documents are the most common data collection techniques for case study research. According to Rosenthal (2016) and Yin (2018), researchers must complete many data collection activities such as (a) develop an interview protocol, (b) conduct the interview and collect data, (c) audio record the interview, (d) transcribe the audio recordings, (e) conduct member checking to confirm data interpretation, and (f) review existing relevant documents. Interview protocols and reviewing documents are strategies that a researcher can use to collect data (Rosenthal, 2016). The techniques that I used to collect data included semistructured face-to-face interviews and document review.

The location and time of the interview can potentially influence the data collection process. Researchers should conduct interviews in a setting that is convenient and comfortable for the interview participant, and that can occur using several communication mediums (Rosenthal, 2016; Saunders et al., 2016). Current and valid

interview communication mediums include face-to-face interviews, telephone conferences, or using an electronic application such as Skype video chat (Rosenthal, 2016). In the study being conducted, I used the communication medium of face-to-face interviews and choose a location for the in-person interviews. I scheduled an interview place and time that was secure, private, and convenient for the participant to speak freely and without interruptions.

I initiated data collection after IRB approval, beginning with emailing potential participants the informed consent form and the recruitment letter. Participants provided consent by replying *I consent* to my original email thread. I then completed the data collection process below:

1. I obtained site authorization from executive leadership to conduct the study.
2. I performed a trial run with an expert participant to field test the interview protocol and the interview questions.
3. I identified and recruited participants. I emailed the informed consent form to potential participants. The participant email contained instructions to respond via email with the words *I Consent* if they are willing to take part in the study.
4. I scheduled and conducted face-to-face semistructured interviews and agreed to a place, date, and time. I reserved a private location to conduct the 45-minute interviews using an interview protocol.

5. When I met the participant, I introduced myself, reviewed the informed consent, and answered any questions. I collected study data using a nine-question interview protocol (see Appendix A) to conduct the semistructured face-to-face interviews using opened-ended questions.
6. I audio recorded each interview and transcribed the responses into a Microsoft Excel workbook folder for each participant.
7. I completed a preliminary participant response summary of the transcript.
8. I scheduled and conducted member checking to share a brief, written interpretation of what I believed they have shared with the participants within 48 hours for further data interpretation and inform the participants that they can add any information if necessary.
9. I collected secondary data during the interview and member checking sessions. I asked for permission from participants to share relevant documents to support the interview responses. Relevant documents included charts, graphs, spreadsheets illustrating strategy performance metrics, and other internal documents that the participant determined essential and supported the participant's point of view. Specifically, I asked to share non-confidential documentation regarding postmarket medical device surveillance process workflow activities including device manufacturing, FDA recall notification letters, internal recall notification time logs, internal notification emails,

device removal, revision, correction completion logs, aging notification recall logs, unique device identification data, and business process workflow mapping that illustrate the end-to-end surveillance recall notification process.

10. I stored data on a password-protected external flash drive. I secured the external hard drive in a home office locked safe for five years before permanently deleting electronic data files.

**Interview Protocol and Interviews**

Using an appropriate interview protocol and set of interview questions to obtain the most salient information from participants can be challenging. Field testing is a common way to assure the interview questions, and the protocol used to guide the study is effective (Kallio et al. 2016). According to Kallio, Pietila, Johnson, and Kangasniemi (2016), a semistructured interview protocol is a strategic approach that allows the researcher to focus on specific study details to increase consistency in the data gathered and aid in affirming the reliability of the study. The field test helped me to supply the correct information on the interview protocol while allowing for a free flow of information that sometimes goes beyond the bounds of the protocol.

Potential disadvantages of using an interview protocol include poor quality of data, sample size, lack of researcher experience, and participants giving verbose responses. However, following a semistructured interview protocol can lend to data accuracy and consistency. A study by Kallio et al. (2016) indicated that a rigorous

interview protocol gives a researcher the advantage of asking specific questions to the aim of the study that contributes to quality findings. Researchers use semistructured interview protocols to focus on specific content and to probe for in-depth answers to increase data quality and reliability (Gaikwad, 2017; Saunders et al., 2016). Another advantage is potentially gaining opinions and perspectives directly from the participants' experience (Rosenthal, 2016).

Researchers use semistructured interviews to explore participant thoughts, perceptions, and experiences. Using a combination of open-ended and probing questions can encourage participants to explain responses in greater depth are common and useful in qualitative research (Rosenthal, 2016; Saunders et al., 2016). I used semistructured interviews, asked open-ended questions (see Appendix A), and used probing questions to obtain rich qualitative data. Researchers also use field-testing to ensure the appropriateness and accuracy of the interview questions. Field-tests are appropriate for small sample sizes using a single case study design to match the interview questions with the research question (Kaae et al., 2016; Kallio et al. 2016; Purswell & Ray, 2014). Conducting the field test with an expert allowed me to feel confident that the interview questions were appropriate to gather the most comprehensive and salient responses from the participants.

Achieving accuracy and rich data from the interviewing process include several factors. According to Chandler and Paolacci (2017), the quality of data depends on

participant eligibility, experience, and integrity in answering the interview questions to ensure trustworthiness. According to Morse and Coulehan (2014), the participants' relationship with the researcher can have a response impact. In this study, I aimed to remain objective and established a rapport with the participant to gain the most accurate information without overtly contributing to any opinion shared by the participants. A lack of researcher experience can influence the interview data (Raheim et al., 2016). Levit, Huang, Chang, and Gong (2017) posited that transcribing participant responses can be difficult due to the potential to create interpretation error out of both researcher inexperience and the nature of conducting semistructured interviews. Reviewing interview audio recordings and using the member checking process are techniques the researcher can use to clarify and interpret ambiguous responses for accuracy (Levit et al., 2017). I used the interview protocol, audio recorded the interviews, and used member checking to minimize inconsistencies and enhance the data collection technique process.

**Documentation**

The advantage for researchers reviewing relevant documents is to compare the interview information with historical organization operation data of the organization under study. Marshall and Rossman (2016) posited that organization documents could serve as a data source that supports and reassures the study's findings. According to Yin (2018), the advantages of using document review are that the data are a source of background information, collecting the data is unobtrusive, and the data may include

other important themes. Collecting data from relevant documents is an approach to add rigor to a study (Cardno, 2018). I used document data as an additional resource to support the study findings.

Using both document and interview data can enhance the study findings to answer the research question. Combining document reviews with interviews is a triangulation method that contributes to study reliability and validity (Fusch, Fusch, & Ness, 2018). Validating one set of data with the second set of data minimizes inconsistencies (Yin, 2018). Reviewing relevant documents is an approach researchers use to crosscheck to ensure a consistent, accurate representation of the phenomena in relation to the data shared by the participants during the interview and member checking processes (Clark & Veale, 2018; Korstjens & Moser, 2018). Comparing operation documents to the actual interview data is a way to ensure data integrity and address the research question most effectively. I reviewed relevant organizational documents such as medical device surveillance process procedures, device notification policies, and recall measuring metrics to increase my understanding of the medical device surveillance processes and compared the document data with the interview information to accurately understand the existing strategy process that related to addressing the research question.

While reviewing relevant documents is often valuable, there are disadvantages. Reviewing relevant documents is potentially time-consuming; the information may lack detail, version control, or have an organizational policy and proprietary limits that restrict

the researcher from selecting specific data (Cardno, 2018). Cardno (2018) posited that because documents are not produced for research purposes, they may contain insufficient detail as an accurate research data source. I reviewed relevant documents that were appropriate and salient to crosscheck the interview data and provide plentiful information.

My data collection technique activities included member checking. Member checking is a common technique that researchers use to provide participants with an opportunity to review a segment of the transcript material and summary to ensure that the researcher's interpretation of what the participant shared was interpreted correctly by the researcher (Birt, Scott, Cavers, Campbell, & Walter, 2016; Drisko, 2016). According to Birt et al. (2016), member checking is a critical, time-consuming and rigorous process that actively involves confirmation of the researcher's interpretation of the interview data to improve the credibility, validity, and accuracy of the data. I reviewed each interview question, summarized responses, and revised the interpretations by changing or adding more information to clarify responses and enhance research credibility. According to Roberts, Dowell, and Nie (2019), the integrity of data collection and analysis are demonstrated by collecting the data with honesty, openness, and with impartiality. I conducted member checking within 48 hours after the initial interview by providing the participants with a brief synthesized summary of my interpretation of their responses to the interview question. I scheduled a time to return to participants with the summary to

complete the member checking process and to review my interview data interpretation for accuracy. In the event information needed to be corrected or added, the participant was able to do so during this time, and I included their changes or updates in the data analysis.

## Data Organization Technique

Qualitative researchers can use a combination of tools to compile and organize single case study data. Tools such as Microsoft Word, Microsoft Excel, Atlasti, and NVivo are standard and robust software applications used to organize and process data (Bree & Gallagher, 2016; Ose, 2016). According to Bree and Gallagher (2016), Microsoft Excel is a standard tool used to organize, code, and classify data for the thematic analysis used in analyzing qualitative data. Microsoft Excel is an electronic software application used primarily for creating electronic documents and allows researchers to organize and analyze semistructured data into workbooks (Ose, 2016). The Microsoft Excel application is a standard tool researchers use to promote triangulation (Bree & Gallagher, 2016; Robins & Eisen, 2017; Saunders et al., 2016). I used the Microsoft Excel software to capture, store, sort, code, and analyze participants' responses and to review the documentation data to reveal themes and trends.

Following the participant interviews, I organized data by first creating generic Microsoft Excel workbook folders for each participant using alphanumeric pseudonym labels such as Par1 through Par 5 to protect personal identification and to ensure confidentiality. Compiling, categorizing, labeling, and storing data in a usable, accessible

form is the first step of data organization (Castleberry & Nolen, 2018). I compiled the study data by (a) pasting the raw participant audio-recorded interview responses in Microsoft Excel, (b) use descriptive headings such as participant codes, question numbers and corresponding responses, (c) compile interview notes and processes with a focus on workflows and participant mannerisms that signify greater importance of the subject matter,(d) compile document data such as surveillance reports that support the existing medical device surveillance process and performance metrics, and (e) label the transcriptions using participant color codes, question numbers, and responses. I disassembled the data by reading the transcripts to identify categories and gave each category a code name, including any unexpected exemplars. I reassembled the data into groups in a second sequential Microsoft Excel workbook folder by repeating the coding data for each participant interview and by identifying categories and patterns across all participant interviews. I created a workbook document in Microsoft Excel and set up sequential workbook folders to organize data for each participant. I organized and sorted the data into categories and logically coded the text to allow for patterns to emerge for accurate theme analysis.

For each participant workbook folder, I created consecutive Microsoft Excel workbook folders to separate the raw data collection from data processing categories for corresponding thematic data analysis. I embed hyperlinks to connect each supporting workbook folder file to the result Microsoft Excel document to establish single storage

location access. Each Microsoft Excel subfolder workbook was labeled with an alphanumeric participant identification code to store raw participant transcript data, relevant documents for each interview question, and iterative themes generated using Microsoft Excel and color coding for each participant.

## Data Analysis

The first step to analyzing data is establishing an analysis strategy. Data analysis planning and defining the analysis tools are critical for case studies and include triangulation and thematic analysis strategies (Hoeber & Shaw, 2017). I used methodological triangulation and thematic analysis as a strategy to analyze the qualitative data to produce significant themes in response to the research question. Researchers who engage in the methodological triangulation of data from several sources help ensure data reliability and validity (Abdalla, Oliveira, Azevedo, & Gonzalez, 2018). Collecting data from more than one source is a way to achieve triangulation and validate the study's findings (Rosenthal, 2016). I ensured methodological triangulation by collecting and analyzing relevant data from the semistructured interviews and the documents.

Thematic analysis is a data coding method to analyze large sets of textual data. The purpose of thematic analysis is to identify meaningful or emerging themes or patterns across the textual data set to answer the research question (Castleberry & Nolen, 2018; Saunders et al., 2016; Yin, 2018). In qualitative research, the researcher applies an iterative data analysis process of preparing and sequentially coding data to determine

patterns of meaning (Vaismoradi, Jones, Turunen, & Snelgrove, 2016). According to Vaismoradi et al. (2016), thematic analysis is a systematic and continual process of developing data codes to explore and interpret descriptive phenomenon meaning through the emergence of significant themes. I followed the five data analysis steps recommended by Yin (2018), which include (a) compiling, (b) disassembling, (c) reassembling, (d) interpreting, and (e) generalize conclusions to analyze the data accurately. I used the Microsoft Excel software application to complete the thematic data analysis. According to Bree and Gallagher (2016), using Microsoft Excel for thematic analysis is a practical approach to code and classify data for analyzing qualitative material. Using Microsoft Excel to help conduct thematic analysis is simple and accessible without the complexity of having to learn new software applications.

Conducting a thematic analysis is an iterative process. The thematic analysis involves creating data categories for emerging themes and analyzing the data further to determine subthemes (Vaismoradi et al., 2016). Kozleski (2017) posited that using the software as a labeling and coding tool in identifying themes and subthemes is practical. I analyzed the study data using Microsoft Excel to compile, sort, and reduce the data into color-coded categories to identify emerging themes. For each interview data analysis, I followed the steps below.

1. Read the collected data for understanding.
2. Pasted the interview audio files verbatim into a Microsoft Excel workbook folder.
3. Prepared the Microsoft Excel document workbook for coding.
4. Coded data into categories using colored labels.
5. Prepared the coded data for sorting into categories.
6. Sorted the coded data into logical categories.
7. Combined similarly coded categories.
8. Sorted the coded categories by frequency.
9. Interpreted the data to reveal patterns of meaning and identified emerging themes.
10. Identified overarching themes.
11. Compared the data against other studies using the BPR conceptual framework and with the other study's findings.
12. Reported the findings and drew general conclusions.

I used Microsoft Excel to determine emerging themes using color-coding to identify patterns and to compare emerging trends with existing research and through the lens of the conceptual framework of BPR. I followed a sequential process and added consecutive Microsoft Excel workbook folders for each thematic analysis iteration to easily see the previous analyses for faster and more accurate identification. I referred to

my literature review, conceptual framework, and the research question to help interpret the data to draw conclusions. Researchers draw conclusions from the analysis of data obtained through conducting the study and through exploring the existing data (Bree & Gallagher, 2016; Yin, 2018). Performing a consistent and thorough thematic analysis of the data is a process that researchers use to verify the validity of the emerging themes.

I delineated study data themes and derived meaning by interpreting the interview data analysis codes regarding adverse medical device events surveillance regarding Hammer's BPR concept and existing works. Using the five phases of data analysis, researchers have an opportunity to reflect on the research question and how the data analysis connects to the conceptual framework and existing literature (Gallagher, 2016; Vaismoradi et al., 2016; Yin, 2018). The final phase of the data analysis is when the researcher develops a conclusion from the findings. The study findings may improve business practices that support processes to reduce adverse medical events from medical device implants.

## Reliability and Validity

Reliability and validity are essential components of all qualitative studies. Two critical research elements that apply to qualitative studies to ensure the data's adequacy, trustworthiness, and accuracy (Cypress, 2017; Spiers, Morse, Olson, Mayan, & Barrett, 2018). Researchers engage in the methodological triangulation of data from several sources to ensure data reliability and validity (Abdalla, Oliveira, Azevedo, & Gonzalez,

2018). The researcher is responsible for creating a quality study through the process of providing accurate interpretations and eliminating personal bias to ensure a study's reliability and validity (Bengtsson, 2016; Cypress, 2017). My strategy to enhance reliability and validity included: (a) an interview protocol, (b) member checking, (c) methodological triangulation, and (d) achieving data saturation. Reliability comprised primarily of dependability, and validity, which consists of credibility, transferability, confirmability, and data saturation offer a deeper interpretation of rigor in qualitative studies.

**Reliability**

Researchers use reliability methods in qualitative research to improve the dependability and repeatability of the phenomenon under study. Reliability means generating consistent results using the same study process design, methods, or practices repeatedly and still achieving the same result (Cypress, 2017). An exhaustive description of the research process is an indication of a dependable design that allows researchers to produce reliable and consistent results (Cypress, 2017). Meticulously organizing and coding data are steps researchers should use to demonstrate consistent data analysis, which increases the dependability associated with repeatable outcomes (Amankwaa, 2016; Bengtsson, 2016). Methodological triangulation, using interview protocols, and member checking are tools researchers can use to improve a study's repeatability (Spiers et al., 2018). I documented each step of the research process, used an interview protocol,

asked probing questions, and engaged participants in member checking to ensure data dependability and consistent findings. Member checking allows the researcher to verify data accuracy with the participant after initial data collection takes place, and the material has been summarized for participant analysis (Abdalla et al., 2018; Gaikwad, 2017). The criteria used to select participants adds rigor and maximizes dependability (Amankwaa, 2016; Lavallee et al., 2017). Consistent data collection through several methods and processes provided the same results when repeated and ensured reliability.

**Validity**

The design method used in a study also allows the researcher to demonstrate rigor in a study. Gaining validity in a study relates to the links between data, results, and findings (Terwel, Schuurman, & Loeve, 2018). The depth and understanding of the phenomenon and the degree of the researcher's ability to adhere to the chosen design is necessary to produce in-context credibility and quality (Cypress, 2017). According to Gaikwad (2017), rigor is a product of a study's design aspects that include study method, setting, participants, data collection techniques, existing literature, and data analysis tools. Researchers must demonstrate rigor through affirming credibility, transferability, confirmability, and data saturation.

**Credibility**

Qualitative researchers must demonstrate the credibility of a study. Researchers can establish credibility during the data collection process to achieve greater confidence

in the results (Amankwaa, 2016). According to Yin (2018), using an interview protocol, methodological triangulation, and the member checking process improves the credibility of the study's results. Researchers use qualitative methods such as methodological triangulation and member checking to confirm that the data used in a study is credible, reliable, and truly represents solid results (Spiers et al., 2018). Member checking is a method comprised of asking a participant clarifying questions to close any gaps in interpretation (Fusch et al., 2017). I provided participants with a summary of my interpretation of the transcript material to ensure my understanding of what they have shared and to foster greater credibility in the study's findings. To further ensure credibility, I used an interview protocol for participant engagement consistency and methodological triangulation by collecting data from several sources. I completed an exhaustive literature review, collected interview data, and reviewed relevant documents to establish the credibility of the findings.

**Transferability**

Transferability is an important component in conducting a qualitative study. Transferability refers to the degree to which study results may apply to other researcher study settings (Bengtsson, 2016; Marshall & Rossman, 2016). According to Bengtsson (2016), the degree of potential study transferability relies on the level of result dependability, credibility, and confirmability present. Researchers can increase transferability in a study by meticulously documenting the research process and

collecting rich data to reach data saturation (Yin, 2018). Collecting rich data using the appropriate participants and participant number ensures the accurate descriptions of the phenomena under study, increasing transferability (Gaikwad, 2017). Varpio, Ajjawi, Monrouxe, O'Brien, and Rees (2017) posited that methodological triangulation, member checking, and reaching data saturation are ways for researchers to improve the transfer of the results of a study to research settings. I meticulously documented the research process step by step to augment confirmability to increase the potential for the transferability of the findings to other settings.

**Confirmability**

Confirmability is a critical component that researchers strive to obtain to improve the level of confidence in a study. According to Korstjens and Moser (2018), the level of confidence to which other researchers can confirm the study's findings establishes confirmability. Researchers establish confirmability by avoiding bias and using supporting evidence derived from an objective interpretation of the data (Korstjens & Moser, 2018). The researcher can increase the confirmability of the study by using methodological triangulation and member checking to evaluate the data accuracy to ensure the trustworthiness of the results (Amankwaa, 2016). Brear (2019) posited that member checking is a technique to establish qualitative research validity by checking the accuracy of data in raw form through to the final results of the research. I used member

checking, asked probing questions to achieve deep insight from the participants, and attempted to be rigorously honest to achieve the confirmability of the study.

**Data Saturation**

Qualitative researchers aim to attain data saturation. Failure to reach data saturation impacts the validity of a study (Fusch et al. 2018). Reaching data saturation is the point in which no new themes appear, or no unique information emerges concerning the phenomenon under study (Saunders et al., 2017). When a researcher reaches data saturation, there is no need for more participants because there is enough data to explore and understand the phenomenon under study (Fusch et al., 2018). A thorough description of the processes used in the study by collecting relevant data until data saturation is achieved promotes truthfulness, improves validity, and increases the degree of study transferability (Bengtsson, 2016). Data saturation signifies that adequate data containing all the information necessary to answer the research question and occurs when no new themes or patterns emerge (Lowe, Norris, Farris, & Babbage, 2018). According to Fusch et al. (2018), the application of methodological triangulation enables the researcher to reach data saturation to enhance the quality of the study. I demonstrated methodological triangulation by conducting semistructured interviews using a consistent interview protocol, asking probing questions, reviewing relevant organization documentation, and using member checking to reach data saturation. I continued to collect data from the

participants until the data obtained became repetitious, and no new themes or patterns became evident.

## Transition and Summary

In Section 2, I outlined and documented the research design and execution of my research study. The subsections of Section 2 consisted of an opening project statement, the purpose statement, the role of the researcher, a review of the study participants, the research methodology and design, population and sampling, ethical research, data collection, data organization, data analysis, reliability, and validity. In Section 2, I described and justified my study design and supported the objective of my study. I selected a single qualitative case study design to explore the strategies hospital managers use to redesign the implant recall notification process to reduce adverse medical events and revision costs. My function was to serve as a professional primary data collection instrument. I am responsible for using my experience and academic knowledge to conduct ethical research while mitigating research bias. I implemented data collection after I received IRB approval. After receiving IRB approval, I engaged with the selected study design by first recruiting and interviewing participants following the guidelines of the interview protocol. I collected interview data and reviewed organization documents relevant to the study and used Microsoft Word Excel to organize data and complete thematic coding for analysis. I used methodological triangulation, member checking, and data saturation to enhance the reliability and validity study.

In Section 3, I present my findings, discuss how the findings apply to professional practice, the implications for social change, recommendations, reflections, and provide a summary. In the presentation of results, I discuss the data analysis process, results, and emerging themes that link to the literature and the BPR conceptual framework. Finally, I conclude the section by explaining how the study results apply pragmatically and offer recommendations for future study, reflective thoughts, and conclusions.

## Section 3: Application to Professional Practice and Implications for Change

The purpose of this qualitative single case study was to explore strategies that managers in hospital health care organizations used to redesign the implant recall surveillance processes that reduced adverse medical events and revision costs. Hammer's (1990) business process reengineering (BPR) was used as the conceptual framework for this study. To prompt study participants to provide rich information to address the research question, I followed an interview protocol and used open-ended semistructured interview questions. During the interview and member checking sessions, I asked probing questions and reviewed documents relevant to the participant responses. The conduction of interviews and gathering of data occurred until no new themes emerged, and enough data was produced for theme analysis. Yin's (2017) five stages of qualitative data analysis to was used to define themes and draw conclusions from the data.

A qualitative analysis of data from interviews and documents resulted in four themes: (a) effective data communication process, (b) central data repository integration, (c) continuous process improvement, and (d) end-to-end surveillance process. The findings were supported by data details collected from interviews and documents. This section encompasses a presentation of the thematic data analysis of the results, application for professional practice, and implications for social change. It also includes reflections of my doctoral experience and closes with a final concluding statement.

## Presentation of the Findings

The principal research question for this study was: What strategies do hospital managers use to redesign implant recall surveillance processes that reduced adverse medical events and revision costs? The sample consisted of five hospital managers in the northeastern United States, with strategic expertise in redesigning and executing medical device surveillance processes. To obtain rich data from the five study participants I used an interview protocol and conducted semistructured interviews containing open-ended questions. Researchers use open-ended questions and ask probing questions in a semistructured format to encourage participants to offer their experiences and perspectives (Gaikwad, 2017; Rosenthal, 2016). Relevant organization documents related to existing standard surveillance operating procedures and policies that managers use as a process map to trigger actions that hospital managers should take during a medical device recall notification were reviewed. To protect participants each received a code name, Par1, Par2, Par3, Par4, and Par5 and the health care organization received the code name H1. The conduction of interviews and collection of data occurred until data saturation was reached, and no new themes emerged.

I analyzed all participant interview comments and detected emerging themes as well as which themes were supported by relevant process workflow documents. I used a 5-step thematic analysis process to identify emerging common themes. I became familiar with the data by reviewing the collected data, color coded unique keywords, identified

code patterns, and combined codes to identify emerging themes. According to Bree and Gallagher (2016), color coding qualitative data in an Excel workbook is an effective method for identifying themes. Analysis of the collected data revealed that the adoption of the strategic themes enhanced universal medical device surveillance processes that are essential to monitoring device longitudinal data for patient safety. All themes support a BPR model to improve device surveillance processes continuously. The four themes that emerged from the data collection process included: (a) effective data communication processes, (b) central data repository integration, (c) continuous process improvement, and (d) end-to-end surveillance processes (see Tables 3 through 6 below).

**Theme 1: Effective Data Communication Process**

The first theme to emerge was implementing an effective data communication process. The characteristics of an effective data communication process includes delivering data to the exact destination with accuracy, in a timely manner, and without real-time variation. All participants emphasized the importance of defining regulatory and internal data communication processes as part of their strategy. All participants expressed the concern regarding the use of an effective data communication process strategy to establish persistent medical device data-sharing internally with other departments and externally with manufacturers, vendors, distributors, FDA, insurance plans, and the patient. Table 3 illustrates the most frequent strategies used by participants regarding their effective data communication surveillance strategy.

Table 3.

*Participants' Strategies for Effective Data Communication Process*

| Most frequent strategies | Participants | Frequency of occurrence |
|---|---|---|
| Continuous data-sharing | Par1, Par2, Par3, Par4, Par5 | 89 |
| Continuous real-time data | Par1, Par3, Par4, Par5 | 65 |
| Internal & external data | Par1, Par2, Par4, Par5 | 51 |

Theme 1 aligned with previous research that medical device surveillance and delivery requires available evidence and standard communication protocols that increase data sharing for communication effectiveness (see Sturmberg, 2018). Drozda et al. (2016) also posited that the complex and stochastic aspects of health care data require knowledge translation and communication that is unambiguous and effective for sharing data. While further research by Alaba et al. (2017), illustrated that effective communication is about establishing a continuous integrative network process that incorporates interoperable data sharing communication software protocols between all surveillance members for greater data visibility. Additionally, Sayle (2016) concurred that data sharing requires the right communication network design and connecting medical data rich resources is the best place to start medical device identification. Establishing an internal and external communication process is an effective way to increase data sharing capability in a rapidly change business environment (Salvoto & Vassolo, 2017). Implementing an effective data communication process allows hospital

organizations to obtain medical device performance feedback quickly, which helps managers create strategies and objectives to achieve optimum results.

The preferred method among participants for effective data sharing was through a real-time communication process using web services, electronic mail, and software applications for alert and audit purposes. All participants articulated the importance of combining internal and external resources to increase the effectiveness of data communication for medical device surveillance. Par1 and Par5 indicated that exchanging information continuously within both the organization and external businesses using electronic communication web service tools provides real-time communication that is essential for monitoring medical device performance and notifying a patient proactively before an adverse event occurs. Additionally, Par2 stated, “Data-sharing must reach beyond the internal organization walls to be effective and by using web based electronic communication services, we are able to monitor medical devices with greater transparency.” Par3’s response further confirmed the importance of effective communication practices, “External data sharing is just as important as internal data sharing for monitoring medical device performance and electronic communication using web services is a great tool to share data.” The five participants consistently stated that they used some form of electronic data communication, whether internally or externally, as an effective strategy to mitigate adverse medical device risk and to control revision costs. Par3 described the redesigned surveillance process strategy as an effective data

communication process regarding internal and external relationships with manufacturers, vendors, internal business resources, and end-users symbiotically for real-time monitoring.

Managers combined innovative sustainable communication processes by linking persistent data-sharing resources using software data-sharing applications to share data continuously. According to Verstegen, Dailey-Hebert, Fonteijn, Clarebout, and Spruijt (2018), combining data sources is an effective way for individuals to communicate in an intensive continuously contributing manner for more in-depth discussions and to brainstorm without guidance. Continuous real-time data communication is becoming a practical reality for health care (Aceto, Persico, & Pescape, 2018). Participants emphasized the importance of timely, constant real-time data communication and assembling critical data information from device surveillance sources anywhere, anytime, using connectivity anytime. Both Par1 and Par2 referenced the effectiveness of implementing data communication processes across vertical and horizontal organization barriers in a continuous real-time manner. Par3's response further indicated the importance of continuous real-time sharing and stated, "We need to establish a data-sharing system that is continuous in real-time with complete transparency, visibility, and accessibility to close the data communication effectiveness gap." Par4 identified streamlining the data integration process as important for smoothing the transmission of data communication.

Furthermore, participants indicated the importance of communication regarding potential issues with devices. Par4 stated, “We follow explicit regulations and software surveillance requirements for sharing postmarket recall notifications and revision feedback data.” Similarly, Par5 responded that they used transparent data communication pathways, such as the internet and private configured networks, to access proprietary application data silos internally and externally as a strategy to mitigate risk and control of medical device recalls and revisions. Par5 said, “We closed the disjointed data communication gaps using Managed Recalls software to improve the medical device surveillance data-sharing process and evolved from a passive, reactive surveillance process to a more dynamic real-time surveillance process. Managers preferred a proactive data-sharing communication process for informed decision-making.”

Additionally, proactive data communication may help managers mitigate the impact of potential uncertainty. Par 4 stated, “Medical device data communication started as a slow manual process that morphed into a timely internal and external process using the Managed Recalls surveillance software application allowing managers to share and access data to make informed decisions.” Par3 concurred by stating, “The surveillance process continues to be disjointed and linearly constricted and the speed of data-sharing communication must be addressed further to improve medical device surveillance processes effective in the most comprehensive proactive way.” While Par1 stated, “We have a variety of medical device data communication processes in place but it is basically

an alert surveillance process and is not efficient from a real-time surveillance perspective to trigger proactive activity to mitigate potential adverse medical events." To address this issue Par2 suggested increasing data communication effectiveness by merging real-time data with medical diagnosis intervention to proactively reduce adverse medical device events.

A review of documents supporting the participant interview responses illustrated how the participants' organization shared internal and external data regarding effective data communication alignment between manufacturers, regulators, implementor operations, and end-users to maximize process flow. The documents supported theme 1 as the information included within them provides managers with data-sharing communication links between internal and external resources. For example, medical device surveillance documents illustrated FDA medical device recall data, message logging, and managers response to department physicians who were accountable for implanting the device. Information found in the surveillance documents also indicated historical recalls of similar devices and current device inventory information.

Viewing theme 1 via the BPR conceptual framework further supported the findings. In health systems, researchers commonly use BPR to identify and redesign ongoing process models to enhance service quality by improving process speed and safety, while reducing costs (Grocott et al., 2017). The effective data communication process strategy H1 managers used aligned with BPR because the radical surveillance

process changed the process and caused the implementation of a software management system.

Better data communication is essential for managers to make critical decisions to mitigate adverse medical device events. Managers who redesign strategies and persistently integrate combinations of ubiquitous business ecosystems employ radical change but can create better process performance and holistic value for the end-user (Dedehayir, Ortt, & Seppanen, 2017). The resolution of medical device lifecycle surveillance could be beneficial to health care managers who lack strategies for combining relevant data sources and communicating the information effectively to meet care demands to reduce adverse medical events and revision costs.

Developing an efficient and less complex data-sharing process is critical for a successful and efficient data-sharing communication surveillance process. Medical device surveillance managers leverage process improvement and reengineering methods to reduce and manage complexity (Szmelter, 2017). The findings aligned with the literature review indicating the surveillance evolution of evidence-based medical processes that produce data managers could use as an informing mechanism to make effective medical, resource, cost, and reimbursement decisions regarding medical devices. The result of such implementation is potentially better device quality, treatment diagnosis, and reimbursement enquiring through an effective data communication

process. As the business world becomes increasing interconnected, managers can leverage the capability of data communication.

**Theme 2: Central Data Repository Integration**

The second theme that emerged from the analysis of interview and document data was the need for a central data repository. A central data repository is a collection of diverse stored data from existing database sources integrated into a single location for sharing information throughout an organization. According to all participants, a central data repository integration was critical because integrating various internal and external data sources for single source decentralized accessibility potentially closes the gap between static and actionable medical device surveillance information for recall decision making. Table 4 illustrates the most frequent responses from participants regarding their central data repository integration surveillance strategy.

Table 4.

*Participants' Strategies for Central Data Repository Integration*

| Most frequent strategies | Participants | Frequency of occurrence |
|---|---|---|
| Data access centralization | Par1, Par2, Par3, Par4, Par5 | 73 |
| Health record & UDI data interfacing | Par1, Par3, Par4, Par5 | 58 |
| Integration of data & distribution | Par1, Par2, Par3, Par4 | 44 |

This theme supported previous research including Dagher et al. (2018), who argued that accessing electronic health care data in real-time requires the right

connectivity via technology using the right integration platform to collect decentralized data into a central accessible repository. Desveaux and Gagliardi (2018), also posited that medical device surveillance data collection and notification functionality requires integrating various data repositories to reduce information accessibility fragmentation and discrepancies. Further research by Trajkovic and Milosevic (2018) indicated that the interconnected business environments demand sharing data through less complex standardized central processes to capture and exploit knowledge through a single resource. The primary need is to integrate data from ubiquitous sources and process the data into an insightful central repository platform as a single accessible source to improve performance, speed, and service.

All five participants have used and implemented interface application tools as a strategy to integrate data repositories to centralize data access for improving the medical device life cycle surveillance process. Additionally, all participants articulated the need to integrate proprietary software data repository silos to further enhance the device surveillance process outside of the FDA database. Par1 stated, “The implementation of technology solutions to integrate data repositories from manufacturers, electronic health record data silos, insurance claims, providers, surgery protocols, device UDI, and patient wearable mobile devices is necessary to establish a robust life cycle surveillance process.” Par2 supported Par1’s assertion and stated, “Using integration technology to capture the device UDI and combining that data with health system historical record data

establishes a way to make device recall decisions based on evidence." Table 4 illustrates the participants most frequently used data repository integration strategies. All participants posited that integrating data sources into a centralized repository improves continuity within the medical device surveillance process and promotes a sustainable model moving forward. Par1 stated, "The UDI regulation establishes fundamental and interfaceable medical device identification parameters to conduct surveillance to identify and find the patient and product on a global scale." Figure 3 illustrates the current documented and compiled medical device surveillance integration strategy at H1.

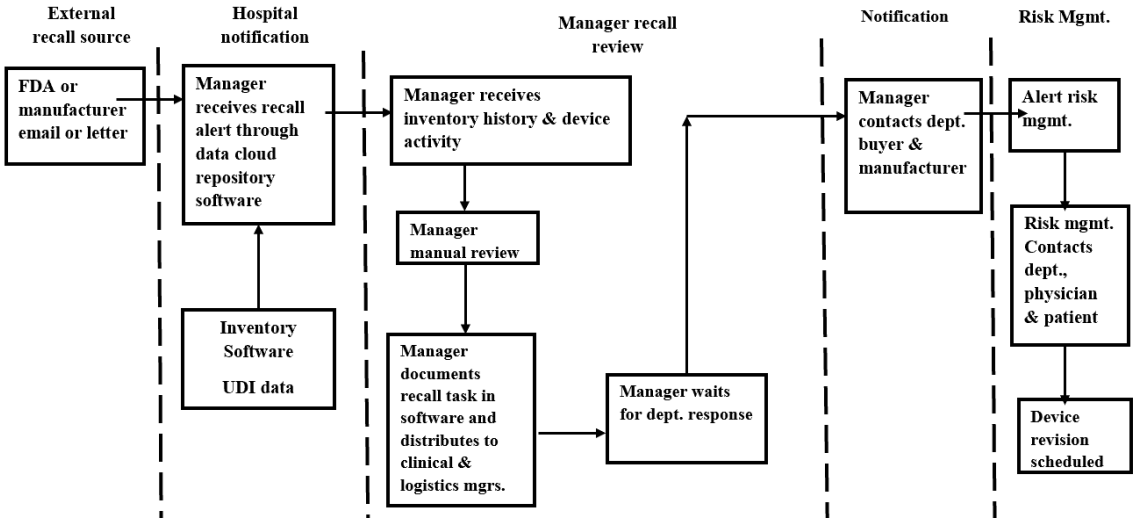


*Figure 3.* Current medical device surveillance integration strategy compiled from process mapping documents and interview findings.

Figure 3 is a depiction of the current medical surveillance process managers use based on process mapping documents and information gathered during the interviews. The illustration outlines the data workflow that H1 managers use to monitor medical

device surveillance activity. The Managed Recalls application links the external medical device data from the FDA and device manufacturer into a central data repository. The central data repository serves as a surveillance integration tool for managers to monitor device performance failures. The software application automatically gathers device UDI inventory data and notifies the surveillance manager via electronic messaging. The manager reviews the inventory and sends an electronic message to all clinical and device supporting departments to remove device from use and to contact the patient for revision.

All five participants stated they used the process flow found in Figure 3 for medical device surveillance as a strategy to monitor device recalls but emphasized the need to redesign the data repository integration to improve the surveillance process. All participants concurred that the redesigned medical device surveillance process should incorporate a centralized device data repository to increase the speed of recall notification to reduce adverse medical events and the potential increases in costs related to revisions or liabilities. Par5 stated, “The medical device surveillance strategy was designed to share data information in a standard way by integrating data into a centralized repository for decentralized access,” However, Par2 indicated the lack of a centralized device repository and stated, “We need to establish a device repository that is trusted like a world trust data bank that is centralized, updated persistently, and is accessible for fast location of device and patient to reduce medical device adverse events proactively.”

All participants emphasized the use of a secure distributed ledger technology (DLT), which is a database shared and synchronized across multiple sites, to establish an interoperable, digitally persistent, centralized data repository fit for single access purpose but decentralized for multiple users. For example, Par4 stated, “We are investigating the use of DLT as a secure protocol for medical device data storage and transactions.” A review of process mapping documents and compiled interview data regarding data repository integration architecture confirmed the effort to connect disparate data sources to one central accessible data location is beneficial. Figure 4 illustrates the medical device surveillance integration strategy managers are investigating as the desired state based on process mapping documents and compiled interview data yet plans to move in this direction have not been established completely.

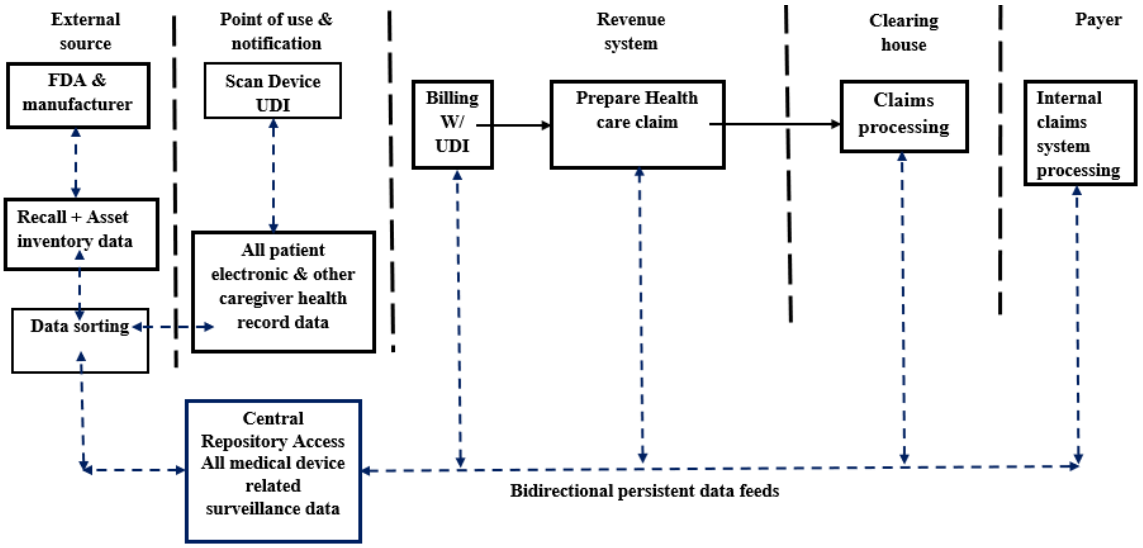


*Figure 4.* Desired future state of medical device central data repository integration strategy based on process documentation and compiled interview data.

Figure 4 is a depiction of further investigation of medical device central data repository integration based on process mapping documents and information gathered during the interviews. The illustration in Figure 4 outlines the data workflow strategy that H1 managers are developing to establish a completely integrated medical device central data repository. The main difference compared to the existing surveillance process illustrated in Figure 3 is the central data repository having bidirectional decentralized data communication access. Other workflow components to note include integration with the patient electronic health record, billing, claims processing and health plan payor to complete the device surveillance life-cycle. Par2 stated, “Designing a quality medical device postmarket surveillance process is about data integration and simultaneously sharing data from a central repository back to all caregiver stakeholders.” Par3 added,

> …using DLT integration establishes a digitally persistent data repository transfer protocol that is a secure, valid, and trustworthy. Data transparency, visibility, and availability is critical to improving the speed at which the information is disseminated effectively to all recipients in the caregiver communication chain.

While Par5 posited, “Establishing valid process guidelines for integrating various databases are critical to producing consistent data-sharing results to maintain process quality.” According to Vijayasree et al. (2017), a process validation protocol ensures consistent results and the effectiveness of the process design for producing the desired quality results. The use of process validation establishes a way to control and document evidence that the performance of the process design is effective or indicates a need for change.

A review of process mapping documents supported the desired future state medical surveillance process in Figure 4 as did data collected from the participant interviews. Sources of supporting desired state process documents included illustrations from power point slide deck presentations to inform executive management of the process improvements and raw whiteboard drawings. The medical device surveillance software documentation illustrated that all external alert and device recall data source repository interfaces allow managers to continuously monitor medical device recall data and revision alerts. Par2 stated, “Each capturing data system enhances the transparency and visibility of medical device surveillance process by allowing managers to identify the

device, user, and collect reports of device performance events from several integrated data systems into a central database." A review of the internal process mappings of the current medical device surveillance process before and after the redesign confirmed the participant interview data.

These findings are supported by the literature. Sharing medical device life cycle data is desirable and involves redesigning and building an accessible, integrated data repository platform to collect and distribute information without communication restrictions (Sayle, 2016). Medical device surveillance managers can use the BPR framework as a model to redesign and centralize device data repositories. Researchers, such as Brown et al. (2015), Rensnic et al. (2017) and Lau (2017), posited that linking data sources creates value by gaining informative decision insights to reduce medical device errors, improve adverse medical events reporting, provide rapid resolution of recalls, and reduce revision costs. Managers can leverage process reengineering methods to reduce complexity and manage data from multiple data repositories.

Each study participant discussed the importance of tracking medical device UDI information from a central data repository. According to Ibrahim and Dimick (2017), the most significant process redesign included UDI data interoperability and transparency between the manufacturer, the point of care, electronic health records, and claims to confirm that medical device data is centrally available. Basatneh et al. (2018) posited that a centralized device data platform simplifies device communication variation and the

adoption of standard protocols to enable device connection that eliminates the burden of integration configuration and accessibility away from the care givers and consumers of care. Additionally, Dagher et al. (2018) posited that redesigning a connectivity platform using central access or DLT is a radical strategy to address health care data accessibility, integrity, and security to centralize data collection. Data collected using the blockchain or DLT is important for processing and sharing by addressing speed, scale, and convenience concerns. Managers can use a central data repository integration strategy to develop further an intelligent ubiquitous communicative surveillance platform to simultaneously coordinate multiple devices, manufacturers, service providers, patients, and numerous protocols for processing data into insightful, proactive surveillance levers to reduce adverse medical events and revision costs.

**Theme 3: Continuous Process Improvement**

Continuous process improvement emerged as a theme for avoiding the occurrence of medical device recall surveillance errors. Continuous process improvement is about improving the quality and reducing process complexity through implementing incremental breakthrough changes over time. According to participants, a continuous process improvement strategy was critical because the goal of a medical device surveillance process is to stay updated with the current business technology and operation environment. Table 5 illustrates the most frequent responses from participants regarding their continuous process improvement surveillance strategy.

Table 5.

*Participants' Strategies for Continuous Process Improvement*

| Most frequent strategies | Participants | Frequency of occurrence |
|---|---|---|
| Regulatory UDI labeling | Par1, Par2, Par3, Par4, Par5 | 74 |
| Process continuity | Par1, Par2, Par4, Par5 | 47 |
| Eliminate fragmentation | Par1, Par2, Par3, Par4 | 45 |

The need for assurance in quality medical devices has brought focus to the need for the postmarket surveillance process to stay up to date regarding device design and regulations while reducing recall response time and reducing revision costs (Mendonca, Gallagher, & Hendryx, 2019). Continuous diagnosis validation magnifies the need for an effective clinical surveillance process for the health industry (Vijayasree et al. 2017). Diagnostic device manufacturers are not just suppliers of medical devices but must facilitate the quality management of the device through continuous process improvement with the health care service (Holdsworth, Glisson, & Choo, 2019). Mendonca et al. (2019) posited that quality, performance, and costs of device contribute to the value of medical devices. The need for assurance in medical device quality, regulation compliance, cost reduction, and performance has increased focus on postmarket device surveillance. Table 5 illustrates the most frequent responses from participants regarding their continuous process improvement strategy for medical device surveillance.

All participants posited that consistently monitoring UDI medical device data is the foundation and common denominator of their continuous process improvement

strategy to remain competent with changing device surveillance technologies. Participants asserted medical device surveillance managers should use a continuous investigative, iterative process implementation strategy approach to improve device monitoring. Par1 stated,

> …if the difference between the redesigned UDI surveillance process and legacy systems was greater from a safety improvement perspective, then the new system was adopted and integrated into the overall system as a process improvement; otherwise the legacy system remained in place.

While Par2 said, “Existing surveillance mechanisms do not usually shed light on the denominator of the device used but rather the numerator of issues reported.” According to Javaid and Haleem (2019), the medical device industry exploits the manufacturing of newly customized implants and requires continuous surveillance process improvements to remove data fragmentation and increase system communication continuity for all devices using a complete sustainable monitoring system. Current business technology produces a need for continuous process improvement which is critical for reducing data communication complexity to fill device surveillance gaps.

Medical device technology and patient needs change. Continuous augmentation of the medical device surveillance process fulfils the individual requirements of the patient, medical industry, and regulatory reporting with optimized time and cost (Javaid & Haleem, 2019). Par3 stated, “Our strategy is not to become complacent and accept an

underperforming medical device surveillance process which can induce managers to potentially become insensitive to errors which normalizes process deviance." Further supporting the strategy identified by Par3, Par5 stated,

> …the existing medical device surveillance process is a matrix of integrated parts that includes manual intervention and automating some of these parts in conjunction with diagnosis intervention is the continuous process improvement strategy balance we try to achieve each day.

Developing a continuous process improvement strategy for medical device surveillance must involve all stakeholders, including all individuals who authorized, implanted, and had contact with the device from the manufacturer to the patient, to create a higher degree of ownership and accountability. Equally important is continuously improving the process to integrate human intervention, automation, and data repositories to help managers understand the data and make decisions regarding the medical device life-cycle based on informed insights.

A review of documents and medical device packaging illustrated medical devices using different labeling formats and barcodes. Documentation review of UDI inventory logs that illustrated medical device label codes supported the participant interview data and confirmed the need to continuously improve the UDI format process to develop one source of data truth. Par2 stated, "Standard UDI medical device labeling provides managers with a valid device identification number to match the physical product to the

patient, and right now there is a lot of trust in the process and can always be improved," while a review of documents indicated that UDI identification is not standard. However, a continuous process improvement strategy could ensure medical device validation that the device implanted in the patient is the device under recall.

The study findings correlated with results in the literature review and confirmed that a continuous process improvement strategy is an innovative approach to generate new medical device surveillance processes through the integration of technologies, intelligent software applications, and monitoring software as developments in the medical field advance. Continuous process improvement is an integral part of BPR and fits with Hammer's (1990) redesigning business process concept. The application of the BPR model enables the facilitation of exploring the unpredictable nature of medical device surveillance processes and the need for continuous improvement. According to Hammer (1990), managers can use the BPR model to redesign and create process value through improved performance, speed, and service. In the literature review, Alaba et al. (2017) supported a continuous innovative technology approach to establish an integrative medical device surveillance network that incorporates continuous interoperable communication software and manual caregiver intervention protocols between all surveillance members. This approach serves to collect both physical and internet connected device data that may influence device performance (Alaba et al., 2017). Additionally, Tyndall and Tyndall (2018) showed that innovative medical device

surveillance strategies that adopt a combination of continuous improvement monitoring services helped managers track and exchange information flow, make inquiries, and share database information without compromising database silo functionality. The whole concept is to continually improve the medical device surveillance process comprehensively.

**Theme 4: End-to-End Surveillance**

The final theme that emerged from an analysis of interview and document data was end-to-end surveillance of medical devices. End-to-end surveillance of medical devices is a process used to reliably monitor the life-cycle of the device. Managers use data collection software called Managed Recalls as an end-to-end surveillance strategy to continuously and automatically collect medical device surveillance data from internal and external resources. Table 6 illustrates the most frequent responses from participants regarding their end-to-end surveillance strategy.

*Table 6*

*Participants' Strategies for End-to-End Surveillance*

| Most frequent strategies | Participants | Frequency of occurrence |
|---|---|---|
| Device real-time life-cycle monitoring | Par1, Par3, Par4, Par5 | 74 |
| Software & IoT | Par1, Par2, Par3, Par4 | 47 |
| Internet web services, Blockchain & DLT | Par1, Par2, Par4, Par5 | 45 |

All participants stated that software functionality is limited to subscription members and lacks interface ability with abundant information data resources, such as electronic health records, claims, provider notes, and patient feedback, for complete medical device surveillance visibility. Par5 articulated,

> …the health industry is behind the commercial retail industry regarding product surveillance. For example, Amazon can track a tomato from farm to table. Still, we have difficulty monitoring the life-cycle of a medical device in a patient's body from the moment of implantation.

Par3 indicated that technology is available, but proprietary software creates data silos, and present health care data-sharing standards are not allowing healthcare managers to implement integrated end-to-end surveillance processes to gather pertinent device life-cycle information to make informed decisions.

Hospital managers realize that data resource silos alone are not enough to provide a comprehensive medical device surveillance process that creates value from a

postmarket perspective. The use of UDI establishes a consistent identification system foundation for medical devices that ensures that the available information about an implant is accessible throughout the health care supply chain (Brown, Kaushiva, & Chi, 2015; Resnic et al., 2017). Par2 said, “as of now, the UDI is the only source of truth that establishes a feedback mechanism that links the medical evidence to the device.” Par4 posited,

> …our strategy is to continuously evaluate and use an end-to-end surveillance process that includes central repository access for effective UDI data sharing and the plethora of internal and external medical device data resources including wearable monitoring devices such as the Apple iWatch.

The revolution of medical device advancements provides physicians with new therapeutic opportunities prompting hospital managers to embrace new medical device surveillance process strategies (Javaid & Haleem, 2019).

All participants mentioned the need to augment the end-to-end medical device surveillance strategy through implementing the Internet of things (IoT) and internet cloud web services. Par1 stated,

> …we need to redesign the medical device surveillance process strategy and simplify connectivity to disparate data resources and data exchange with the help of new software, sensors, robots, and other advanced information technologies such as blockchain and DLT for real-time surveillance.

Par2 shared comparable insights, “We can create new opportunities and innovative new routes for patient care by redesigning the existing surveillance process to include software, internet web services, blockchain, and DLT technology to establish an inclusive end-to-end surveillance process.”

Other key findings from the participants included the identification of challenges to implementing a redesigned end-to-end medical device surveillance process. These challenges include resistance from vendors to share patient health care data stored in proprietary data silos and lack of management buy-in to implement new technologies such as FHIR, blockchain, and distributed ledger technology as leading issues. Par3 stated, “we need to extract data from rich sources and exploit the data to generate useful information, and this requires an end-to-end medical device surveillance process.” Interoperable resources such as FHIR, blockchain, and DLT allow managers to query and share database information beyond data ecosystem silos without compromising database functionality (Tyndall & Tyndall, 2018). Additionally, all participants shared that their organization is currently utilizing software tools designed for the medical device industry surveillance as it relates to design controls and risk management of medical devices for reactive rather than proactive measures. All participants said that the strategy is to patch legacy software tools together to form a complex, fragmented, end-to-end network configured for limited access. Par2 stated, “our current medical device surveillance process is a patchwork of various manual and software solutions to fill in real-time

surveillance gaps and to remove data silos is our strategy to improve data transparency and access for end-to-end surveillance." Fragmentation of the surveillance interoperability process usually leads to inefficient use of data, people, process, and technology as multiple resources work independently without instantaneous information knowledge from other postmarket databases.

I reviewed documents that outlined an end-to-end digital interoperable data strategy and supported data collected from the participants during the interviews. The study findings aligned with results in the literature review and confirmed that the end-to-end surveillance process strategy is an approach that provides managers with the agility to integrate various technologies to create an intelligent surveillance ecosystem. The use of Hammer's (1990) BPR concept allows managers to identify and evaluate the medical device surveillance processes across all organization data communication links to distinguish value and non-value activities. Research completed by Dagher et al. (2018) indicated that the evolution of internet connectivity and applications such as blockchain and DLT technology have allowed managers to redesign the medical device surveillance process from a passive data collection system to a real-time data system. Furthermore, Dagher et al. (2018) posited that real-time medical device data accessibility provides managers with end-to-end device life-cycle surveillance to collect valuable patient medical device data and process the data into insightful patterns and passing information to participants, caregivers, and device users. Additionally, Sayle (2016) illustrated that

safety is the desirable medical device surveillance process value proposition and involves redesigning and building a platform to collect device data for speed, scale, and convenience, and sharing medical device life cycle data on a wide scale. Following Hammer's BPR concept, medical device surveillance managers in this study could then eliminate non-value activities and implement activities that add value.

Overall, critical strategies managers implemented to improve medical device surveillance included standard medical device UDI labeling, capturing the medical device UDI label data, adding the UDI data to the patient medical record and claim, developing central data repository access, using IT software called Managed Recalls to improve the management and surveillance of medical devices to ensure meeting the safety demands of the patient, and end-to-end surveillance using current business social technology to capture real-time mobile device data. Regarding real-time medical device monitoring, research by Al-Gayar and Shubber (2019) indicated that medical social medial platforms deliver high medical monitoring by combining social networking systems, e-learning, mobile health, and health software applications for interaction empowerment resulting in safer product performance. The outcomes from this study could have a positive impact on how medical device manufacturers design devices, monitor the device lifecycle, and issue recalls, thereby reducing adverse medical events and revision costs.

These study findings tie to my conceptual framework and support manager use of BPR to redesign the communication and integration technology to gather ubiquitous

medical device surveillance information throughout the product life to reduce device revision costs. According to Javid and Haleem (2019), the benefit of collecting and using medical device data in more efficient ways provide process design flexibility to maximize multiple health care functions to reduce costs. Some notable functions to improve medical device surveillance operational efficiencies include minimizing nonvalue added workflow protocols. Three critical components that reduce medical device cost are communication technologies, process integration, and sustainable outcomes (Gawankar, Gunasekaran, & Kamble, 2020). Human and technology interactions, such as a device scanning process, monitoring real-time device performance, and paperwork reduction through digitalization can reduce operational cost by decreasing medical emergency management time, which reduces surgery time and risk (Javid & Haleem, 2019, Kamble et al.,2019). The added value of integrating fragmented medical device surveillance processes and sharing data to make insightful decisions proactively, potentially reduces device revision costs.

The current study findings confirm and extend the knowledge in the discipline of medical device surveillance and other health care services that can benefit from data traceability. A potential extended health care service is tracking diseases and viruses. Monitoring contagious viruses such as Wuhan Novel Coronavirus is possible through using distributed data access technology (Dai, Zheng, & Zhang, 2020). The findings indicate that managers have an opportunity to use the BPR concept to redesign the

surveillance process by applying advanced information and communication technologies to enhance medical device surveillance strategies that support social and economic sustainability. According to Alladi, Chamola, Parizi, and Choo (2019), the adoption of advanced information and communication technologies allows managers to monitor and verify processes by orchestrating resources, distributing insightful data, and augmenting existing processes to add human flexibility and capability. Dai et al. (2020) posited that as the technology to collect, analyze, distribute, and communicate information changes, the taxonomy of the medical device surveillance process potentially evolves into the next generation of monitoring transparency linking treatment directly to the patient. To fully utilize and apply the findings herein, further research is recommended to address the anticipated process challenges of implementing resilient technology techniques that have been mentioned as transformative for medical device surveillance.

## Applications to Professional Practice

The objective of the study was to explore strategies successful managers use to reduce adverse medical events and costs from implanted medical devices. The results of this study are significant to professional practice because the strategic objectives that emerged from this study in the current business environment may help hospital business managers enhance patient care, safety, and reduce adverse medical events and revision costs across the clinical industry. The findings of the study may add value to the success of manager strategies by considering the following four themes: (a) effective data

communication process, (b) central data repository integration, (c) continuous process improvement, and (d) end-to-end surveillance process.

The study results may help managers gain a better understanding and insights regarding good medical device surveillance practices, which may help them detect device failures proactively before a catastrophic adverse medical event and improve patient safety. Each theme supports medical device surveillance managers to increase their insightful knowledge from sufficient monitoring processes to mitigate potential device risks. Hospital managers can potentially reduce device risk by implementing an effective data communication process that allows data-sharing from internal and external sources in real-time for greater device performance visibility. Secondly, developing a ubiquitous central data repository without proprietary application constraints engages all caregiver stakeholders, and continuous process improvement ensures that managers update surveillance technologies that are compatible with the current business environment. Finally, an end-to-end surveillance process encompasses the complete life-cycle of medical devices and creates patient safety satisfaction.

Hospital medical device surveillance managers may find some of the themes to be strategies they could use to potentially deliver better health care. For example, the business application of using a central data repository for UDI information from the manufacturer to the patient that is accessible for all caregivers is the sensible and conscientious thing to do for patients. The UDI adds transparency and trackability to the

specific devices that are used in the patient's care and make it more likely that problems with implant devices can be detected, located, and responded to promptly. UDI data in all device-related data repositories can enable better device identification methods, better reporting on the denominators or total products used in a population, and better longitudinal outcomes for patients treated by multiple providers and institutions**.** Another business application **s**trategy is the integration of other health electronic data repository systems, including the manufacturer, FDA, EHR, mobile cloud data, third party payers, and claims. Hospital organizations can use a combination of databases and technology, such as blockchain and DLT, to conduct safety surveillance activities that will allow managers to make scientifically sound or evidence-based assessments of device safety in the future. Combining all the medical device data sources and transmitting the information through a bidirectional connected communication network engages all caregiver stakeholders and can provide a continuous device life-cycle surveillance process. The four themes presented provided the best practices for improving medical device surveillance consistency to match patient performance demands in the current business environment of the health industry. The themes that emerged fill the knowledge gaps about redesigning medical device surveillance strategies to reduce adverse medical events and revision costs.

## Implications for Social Change

Exploring strategies hospital managers use to redesign implant recall surveillance processes to reduce adverse event revision costs has implications for positive social change. The study results could help hospital managers improve medical device surveillance performance to produce several benefits, including regulatory compliance, better patient implant outcomes that stimulate business, and employment, thereby contributing to economic stability and improved social conditions. By developing and implementing a consistent medical device surveillance process, hospital managers can satisfy the patient demand for enhancing the quality of life through safer products. The use of quality products could reduce the number of recalls that may harm individuals who use the product, the organization's reputation, and profitability success (Wei, Wang, Yu, & Zhao, 2019). Organizations that deliver safer implant products build a sustainable business where individuals and the local population can benefit from a healthier community, create business stability, and employment growth.

Additionally, improved medical device surveillance process strategies to meet business and consumer needs across the United States and globally may allow managers to contribute to product development and quality professionals from across the world. Managers that share medical device surveillance strategies, tactics, and technologies potentially accelerate product research to ensure compliance, and promote product quality to reduce user vulnerability and costs. Successful businesses may contribute to the

advancement of social and human conditions by providing sustainable employment opportunities for individuals in local communities and stimulating economic growth (Polonsky, Grau, & McDonald, 2016). Satisfied patients may remain in local communities that provide sustainable employment and financial stability. Successful businesses and employed individuals within a community provide the government with tax revenue that can use to develop programs to enhance social and economic inclusion, which improves the social condition for underserved individuals, organizations, and communities.

## Recommendations for Action

The business problem addressed in this study was that ineffective medical device surveillance processes increase adverse medical events and revision costs. The continuous challenge for managers is to implement a standard medical device surveillance strategy that integrates multiple business processes to overcome the problems of data repository silos and time consistency for delivering persistent insights, validity, and auditability without communication dissemination restrictions. To achieve an effective surveillance strategic process for medical devices, I recommend that managers map the work processes to identify the pitfalls and bottlenecks in the surveillance process value stream. Secondly, I recommend a strategy that targets measures and activities to address the pitfalls and bottlenecks using best practices to improve data communication processes and centralizing data repository access using

technology, such as blockchain and DLT to decentralize access control. Thirdly, I recommend managers use a targeted iterative implementation strategy and continuous evaluation of performance measures to improve the process to match the level of potential device vulnerability.

The findings and recommendations that I propose in this study are relevant to medical device surveillance managers in the health industry, manufacturers, health plans, organizational leaders, caregivers, researchers, and scholars. To disseminate the study findings, I will provide participants and the organization leaders with an executive summary of the study results. I will discuss the results of the research with health care stakeholders, hospital managers, and professional consultants. I intend to submit articles for publication in the *Journal of Medical Devices* and the *Journal of the American Medical Association*.

## Recommendations for Further Research

The limitations of this study included a single case study and a sample size of five hospital managers who implemented strategies to mitigate adverse medical device events and revision costs in the health care industry. Future researchers could expand the scope of this study by using a multiple case study design and a larger sample size of hospital managers. Another limitation was the transferability of the findings to other health care organizations because of the limited study scope. I recommend that future researchers should consider using a sample of hospital managers in a different health care system

who use various surveillance strategies to monitor adverse medical events and revision costs. Future researchers could use a quantitative method to examine the significance of the relationships between an assortment of device surveillance performance variables, such as the number of medical device implant recall notifications, type of medical implant, number of adverse medical events, number of medical implant revisions, cost of corrections, readmission rates, and death. For this study, I only explored the strategies used by hospital managers. Perhaps future researchers could further expand this study by exploring other industry surveillance processes in use today. I recommend further research with an organization like Amazon to monitor item distribution lifecycles from manufacturer to customer to mitigate damage risk and warranty replacement and try to understand how these findings might apply universally.

## Reflections

I have worked in professional technical business roles for over 36 years, and the doctoral program has been one of my most challenging but rewarding life experiences. There were times when I thought about pausing indefinitely because of the amount of stress and time sacrificed away from family and friends. I learned immensely from the doctoral process, especially how to become a better researcher and writer. The doctoral process helped me grow professionally and personally. I developed a scholarly reflective approach to appreciate, understand, and value other individual perspectives about business and life social issues.

The literature review and my lack of knowledge about the study topic minimized personal biases and supported my claims, as stated in the introduction. This study provided me with an opportunity to learn outside of my experience comfort zone. Additionally, I used an interview protocol and the same open-ended interview questions for each participant to diminish personal preference. I was surprised how excited and willing the study participants were to offer their perspectives regarding the subject matter.

The themes that emerged from the interview process were very insightful and connected back to the BPR conceptual framework. Insights that emerged and resonated with me were the dependency hospital managers place on timely data communication processes, not assuming more data without filters creates useful information and using current business technology in the health industry. I am satisfied with the results of this study because I believe the study will contribute to better health care. Future researchers could expand this study by researching other hospital organizations that monitor adverse medical events from implanted medical devices to reduce revision costs.

Working in the medical industry over the past decade of my career, I became motivated to complete this study by the prevalent medical implant surveillance issues facing patients and the desire to change health care even in a small way. The research conducted for this study was intense, and I experienced time setbacks regarding lengthier than expected study review processes and a lack of clarity regarding the order of the

study process. However, my chair mentor served as a good role model and provided me with guidance, motivation, and emotional support to get me through the most frustrating experiences. I am also thankful for the relationships I fostered with colleagues that will continue beyond this study process. I have met some incredible individuals along the path and look forward to the positive impact we will have on our communities from changes stemming from our studies.

## Conclusion

Through the lens of BPR, the purpose of this single case qualitative study was to explore strategies hospital managers use to redesign implant recall surveillance processes that reduced adverse medical events and revision costs. I used purposeful sampling to identify study participants and collected data using semistructured interviews with five medical device surveillance managers from one hospital organization. I used member checking to enhance the study reliability, and each participant provided supporting documents that I used for triangulation. Four themes emerged from the study data analysis: (a) effective data communication process, (b) central data repository integration, (c) continuous process improvement, and (d) end-to-end surveillance process. Each theme supports hospital managers seeking to develop strategies to improve medical device surveillance business process practices, which potentially reduce adverse medical events, revision costs, and creates positive social change by improving individual life quality through long term disease health management.

Existing medical device surveillance process strategies are not standard, or consistent, and prone to insufficient data communication, data access, continuous process improvement, and comprehensive end-to-end device surveillance. Medical device surveillance managers can use the study results to augment their existing device monitoring management capabilities if there is a lack of adequate surveillance process insights to improve device performance and reduce the safety risk. The medical device surveillance process is complex, and informative data can add enormous value. Capturing the right data continuously in real-time, using current business technology, extracting useful information, and communicating the results requires a continuous comprehensive end-to-end process improvement strategy to stay current with the ever-changing business environment and end-user needs. Because managers have redesigned the existing medical device surveillance processes for collecting data from multiple sources, employing an iterative and empirical approach serves as a strategy to understanding how the current surveillance process is performing and what changes potentially improve the process.

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# Appendix A: Interview Protocol

The purpose of the interview is for interviewees to answer the research questions regarding strategies hospital managers use to redesign implant recall notifications to reduce adverse medical events and revision costs. I will execute the following steps for each participant interview after IRB approval an obtaining permission from the organization executive leadership to gain access to participants.

1. I will identify and solicit individual participants willing to participate in the study by emailing each potential participant a recruitment letter and an informed consent form with details of the study. The email will contain instructions for the potential participant to respond via email if willing to take part in the study.
2. If the participant understands the study well enough to make a conscious decision to participate in the study, the participant can respond by replying to the email with the words *I Consent.* By responding with the words, *I Consent*, the participant acknowledges understanding the nature of the study, the potential risks as a participant, and the means by which participant identity will be kept confidential. The consent also indicates that the participant is 18 years old or older and gives permission and consent to voluntarily serve as a participant in the study described.

3. If the potential participant has not responded within five days, I will contact each participant via email or telephone call to explain the study, review the consent form, and answer questions. I will explain the informed consent participation components of the study in detail including the length of time needed for the interview and the purpose of audio recording of the interview. I will explain that handwritten notes will be taken if the participant prefers not to be audio recorded.
4. Following further informed consent explanation, the participant can reply to the informed consent email with the words *I Consent*.
5. Once consent is received, I will schedule interviews.
6. I will email the interview questions before the scheduled interview.
7. I will explain to each participant in an email that the study interview is voluntary and that a verbal or electronic withdraw notice from any participant is acceptable at any time without ramifications even after data collection.
8. I will provide my contact information for each participant in an email to contact me if the participant decides to withdraw.
9. I will reiterate the purpose of the study before conducting interviews.
10. I will start scheduling interviews within 48 hours of the participants consent.
11. I will conduct the interview in private offices during convenient times. I will use pseudonym participant coding to protect the participant anonymity. For

example, I will use Par1, Par2, Par3, and Par4 for all four interview participants to protect participant data confidentiality and privacy. I will explain that I will be the only one to know the true participant identities and responsible for keeping identities confidential.

12. At the start of each participant interview, I will begin with a brief review of the informed consent. I will give an overview of the research, the purpose, and time requirements.
13. I will request participant permission to review relevant documents that support their responses relating to strategies to redesign medical device surveillance such as charts, graphs, spread sheets, or other internal documents that the participant determines as important or adds to the participants point of view.
14. I will audio record the interview and start asking open-ended interview questions and probing questions to obtain rich information responses from the participant. If a participant chooses not to be recorded, I will take scrupulous handwritten notes.
15. At the conclusion of the interview, I will remind the participant that within 48 hours, I will schedule a 30-minute member checking session for more detailed response interpretation. Before the member checking meeting, I will provide a written summary of my interpretation of the interview responses for review to

validate responses and to make corrections as needed to reflect the participate perspective. During the member checking meeting, I will answer any additional participant questions or concerns and give the participant the opportunity to interpret any other responses.

16. I will end the interview by asking each participant if anything else can be added to the data collection and thank the participant for taking time to participate.

Interview Questions

1. How would you describe the existing surveillance process for medical device recalls?
2. What are your hospital's strategies to redesign the medical device surveillance process to reduce adverse medical events and revision costs?
3. What strategies were the most and least effective?
4. What situations influenced a change in strategy leading to redesigning the medical device surveillance process?
5. What were the barriers you encountered while implementing the strategies to redesign the medical device surveillance process?
6. What strategies did you use to overcome the critical process redesign challenges to mitigate medical device recall surveillance errors?

7. How does your organization redesign medical device surveillance processes for tracking consistency in a failsafe manner?
8. How did you measure the effectiveness of the redesigned medical device surveillance process to reduce adverse medical events?
9. What else can you share with me about your organization’s strategies to redesign medical device recall surveillance processes to reduce adverse medical events and possible revision costs?

# Appendix B: CITI Program Completion

## COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

### COMPLETION REPORT - PART 1 OF 2
### COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Gary Zack (ID: 8107976)
- **Institution Affiliation:** Walden University (ID: 2906)
- **Institution Email:** gary.zack@waldenu.edu
- **Phone:** 570-706-6846

- **Curriculum Group:** Student Researchers
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 31600874
- **Completion Date:** 14-May-2019
- **Expiration Date:** N/A
- **Minimum Passing:** 60
- **Reported Score*:** 94

| REQUIRED AND ELECTIVE MODULES ONLY | DATE COMPLETED | SCORE |
|---|---|---|
| History and Ethical Principles - SBE (ID: 490) | 13-May-2019 | 4/5 (80%) |
| Assessing Risk - SBE (ID: 503) | 13-May-2019 | 5/5 (100%) |
| Informed Consent - SBE (ID: 504) | 14-May-2019 | 5/5 (100%) |
| Privacy and Confidentiality - SBE (ID: 505) | 14-May-2019 | 5/5 (100%) |
| Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928) | 14-May-2019 | 5/5 (100%) |
| Belmont Report and Its Principles (ID: 1127) | 14-May-2019 | 3/3 (100%) |
| Research with Prisoners - SBE (ID: 506) | 14-May-2019 | 4/5 (80%) |

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

**Verify at:** www.citiprogram.org/verify/?kb040c4c2-128d-47c8-98ca-5def3253e7da-31600874

**Collaborative Institutional Training Initiative (CITI Program)**
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 2 OF 2
## COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Gary Zack (ID: 8107976)
- **Institution Affiliation:** Walden University (ID: 2906)
- **Institution Email:** gary.zack@waldenu.edu
- **Phone:** 570-706-6846

- **Curriculum Group:** Student Researchers
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 31600874
- **Report Date:** 14-May-2019
- **Current Score**:** 94

| REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES | MOST RECENT | SCORE |
|---|---|---|
| Belmont Report and Its Principles (ID: 1127) | 14-May-2019 | 3/3 (100%) |
| Assessing Risk - SBE (ID: 503) | 13-May-2019 | 5/5 (100%) |
| Informed Consent - SBE (ID: 504) | 14-May-2019 | 5/5 (100%) |
| Privacy and Confidentiality - SBE (ID: 505) | 14-May-2019 | 5/5 (100%) |
| Research with Prisoners - SBE (ID: 506) | 14-May-2019 | 4/5 (80%) |
| Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928) | 14-May-2019 | 5/5 (100%) |
| History and Ethical Principles - SBE (ID: 490) | 13-May-2019 | 4/5 (80%) |

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

**Verify at**: www.citiprogram.org/verify/?kb040c4c2-128d-47c8-98ca-5def3253e7da-31600874

**Collaborative Institutional Training Initiative (CITI Program)**
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

Appendix C: Informed Consent for Participants over 18 Years of Age

**Invitation to Participate and Background Description of the Study**

As a doctoral student at Walden University, I am concluding a research study to explore strategies hospital managers use to redesign the medical device surveillance process to reduce adverse medical events and revision costs using a single case study of a non-profit hospital system located in Northeast Pennsylvania. I am also an information technology manager in a non-supervisory role within the hospital system where I plan to complete my research. My present employment role is to investigate an advanced image viewing solution for the enterprise and to increase information technology application productivity. My role is separate from the study research involving the medical device surveillance process for the reduction of adverse medical events

I am inviting you to be a part of this study involving a select sample of managers of a hospital system successfully using post market medical device surveillance process strategies to reduce adverse medical events and revision costs. I obtained your name and contact information from the organization executive leadership. The purpose of the informed consent form is to outline the invitation, study background, purpose, procedures, voluntary nature, study benefits, non-compensation participation statement, confidentiality, contact information, and obtaining consent**.** I am seeking to interview hospital managers who fit the following expertise criteria:

- Must have 2 years management experience and familiar with medical device post market surveillance.
- Must support decision making to redesign the business processes.
- Must have successfully supported the implementation of medical device surveillance process redesign strategies.

Meeting the above inclusion criteria is the requirement for study participation.

**Description of Procedure**

Your participation will involve an audio-recorded interview of approximately 45 minutes in duration, preferably at your place of business. I will ask participants to share non-confidential information and documentation regarding medical device post market surveillance process workflow activities including device manufacturer and FDA recall notification letters, spreadsheets or other systems that managers use to monitor recall notification letters, internal recall notification time logs, internal notification emails, device removal or correction completion logs, aging medical device recall logs, unique device identification (UDI) data acquired in recalls, and the business process workflow mapping that illustrates the end-to-end device recall surveillance notification process. The review of relevant operational documents will be used to compare and support the interview data and to minimize bias. You will have an opportunity to perform member checking, by validating a summary and adding additional response interpretation of the

interview data to be e-mailed to you by the researcher. Member checking is a follow-up interview of approximately 30 minutes in duration to ensure accurate representation of your responses. After completion of the study, you will be provided with an executive summary of no more than two pages. The provided summary is a brief description of study findings, recommendations, and conclusions. All data collected will be coded and documents redacted to protect your identity, data confidentiality, and privacy. Study data, electronic and paper, will be maintained in a locked, confidential file by the researcher for a period of 5 years after final dissertation approval. After that time, the documents and data will be destroyed appropriately.

**Voluntary Nature of the Study, Risks and Inconvenience**

There is no reasonably foreseeable risk to you beyond those encountered in daily life such as fatigue, stress, or becoming upset. Participating in this study poses minimal risk to your safety or well-being. However, if you do feel fatigued, stressed, or uncomfortable, you can do any of the following: you can take a break and continue later, decline to answer any questions, you can choose to stop the interview, or you can remove yourself from the study without implication.

**Benefits**

Although there may be no direct benefit to you, the potential benefit of your participation is to help advance the understanding of present medical device post market surveillance process strategies to reduce adverse medical events and revision costs within a hospital enterprise system.

**Financial Payments (or other) Considerations**

No financial (or other) consideration is being offered to the hospital or managers for participation in the study.

**Confidentiality and Privacy**

Any and all information obtained from you during the study will be confidential and will not be used for any other purpose than research. The organization and each participant will be assigned a unique code to protect the participant data confidentiality and privacy. I will use H1 for the organization and Par1 through Par4 for each participant. Your privacy will always be protected. Any personally identifiable information (i.e. hospital and manager's names) will only be available to the primary researcher. I will have the ethical responsibility to keep identities confidential. All data obtained from the participant during and after the study will be confidential. The organization and participant privacy will always be protected. The data collected may be used in aggregate as part of publications and papers related to the medical device post market surveillance

process strategies some hospital systems use to promote reduction in adverse medical events and revision costs. No individuals will be identified in any reports of the findings.

**Voluntary Participation**

While I am enthusiastic about the study and your involvement as a manager of medical device recall surveillance, participation in this study is voluntary. If you choose not to participate or withdraw from the study at any time, there are no penalties or loss of benefit to yourself.

**Contacts and Questions**

If you have any questions concerning the research study, please email me at gary.zack@waldenu.edu or call my cellular telephone at 570-7026-6846. If you want to discuss privately about your rights as a participant, you can call the Research Participant Advocate at Walden University at 612-312-1210 or email IRB@mail.waldenu.edu. Walden University's IRB approval number for this study is 02-28-20-0614432 and expires on the given IRB date of February 27, 2021.

**Obtaining Your Consent**

If you understand the study well enough to make a conscious decision to participate in the study, please indicate your consent by replying to this email and accompanying attachments with the words *I consent.* By responding with the words, *I consent*, the participant acknowledges understanding the nature of the study, the potential risks as a participant, and the means by which participant identity and data will be kept confidential and private. The consent also indicates that the participant is 18 years old or older and gives permission and consent to voluntarily serve as a participant in the study described. Please do not hesitate to contact me with any questions or concerns.

Sincerely,
Gary J. Zack, MS
Walden University Doctoral Student

## Appendix D: Participant Recruitment Letter

Participant Recruitment Letter

Dear [Hospital Manager],

My name is Gary Zack, and I am a doctoral student pursuing a Doctor of Business Administration (DBA) at Walden University. To fulfill the requirements of the DBA program, I am conducting a doctoral research study that results in new knowledge, insight, or practice to address a business problem. My research topic is to explore strategies hospital systems managers use to redesign implant recall surveillance processes to reduce adverse medical events and revision costs using a single case study of a non-profit hospital system located in Northeast Pennsylvania. The contribution of this study is to provide hospital managers with a better understanding of how successful post market device surveillance management strategies could contribute to reducing adverse medical events from implanted medical devices.

I am seeking to interview hospital managers who fit the following criteria:

- Must have 2 years management experience and be familiar with medical device post market surveillance.
- Must support decision making to redesign the business processes.
- Must have successfully supported the implementation of medical device surveillance process redesign strategies.

The expectation for participation involves a 45 minute face-to-face interview, asking the participants to share any relevant documents that support their interview responses, and a 30 minute member checking follow up session. The interview will include nine open-ended questions (attached with this email) that you can provide your unique perceptive understanding on this research topic. Once the study is approved and posted in ProQuest database scholarly journal, I will share results and findings with the participant, other management executives, and other scholars. Participation in this study is voluntary and confidential. The participant can remove themselves from the study at any time during the research process without repercussions.

If you meet to above criteria and are interested in participating in this valuable research, please reply to the email accompanying this attachment. Upon receiving your reply of interest, I will contact you via email to provide additional information related to the research process and schedule the interview at a time and location of your convenience. Please read the enclosed consent form carefully and ask any questions that you may have before accepting the invitation. I appreciate taking the time to consider this invitation and please contact me directly with any concerns at 570-706-6846 or ary.zack@waldenu.edu.

Sincerely,

Gary J. Zack, MS,

Doctoral Candidate, Walden University

# Appendix E: Site Approval Letter

[redacted] [redacted]

**Exemption Granted**

October 23, 2019

Gary Zack
GMC - Information Technology

**IRB #: 2019-0992**, entitled ***Strategies for Reducing Adverse Events From Implanted Medical Devices***

RE: Submission Response for Initial Review Submission Form, 10/23/2019 09:21:00 AM EDT

Dear Gary Zack:

Your protocol was reviewed on 10/23/2019 and it was determined that your research protocol meets the criteria for **EXEMPTION** as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.104)]. You may now begin your research.

The specific exemption category under 45 CFR 46.104 is:

> **Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).**

| | | |
|---|---|---|
| Exempt Study Application | Version 1.1 | Approve |

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and Geisinger IRB policy.

[redacted]

Please be aware of the following policies and responsibilities for investigators:

1. Amendments are required for the following changes after an Exemption determination
   a. **Any Proposed Change to Research that Might Impact Exemption Status** – You must submit an Amendment/Modification form explaining any change to your research that might affect the exemption determination and might result in changing your research's eligibility for exemption status.

   b. **Key Study Personnel (KSP)** – You must submit all personnel changes, including both the addition of new personnel and removal of personnel no longer involved in the research that occur after the IRB has granted an Exempt determination. The KSP Amendment must be submitted and approved before any new personnel begin working on the study. Submit a KSP Amendment form and revised Exempt Study Application. This requirement is in place to facilitate compliance with and administration of Geisinger Policy 14.702 - Financial Conflicts of Interest in Research and Geisinger Policy 14.707 –Research Education and Training.

   c. **Sponsor/Funding Source** – You must submit any change in the study's sponsor/funding source to the IRB since this could impact the IRB's review process and/or determination. Submit an Amendment/Modification form and revised Exempt Study Application. This requirement is in place to ensure review under the correct regulations.

   d. **Data Collection Date Range (Category 4(iii) or "HIPAA Exemption")** – You must submit an amendment if you revise the date range for data collection to extend beyond the present date. This requirement is in place because HIPAA regulations apply to this research, and this change in your research might impact your justification of HIPAA waiver and/or require you to obtain HIPAA Authorization from participants.

2. **Record Keeping** - You are responsible for maintaining a copy of all research related records in a secure location in the event future verification is necessary. At a minimum, these documents include: the research protocol, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.

Please use your research protocol number (listed above) on any documents or correspondence with the IRB concerning your research protocol.

[redacted]

If you have any questions or need further help, please contact the Human Research Protection Program staff at 570-271-8663.

Sincerely,

H. Lester Kirchner PhD
IRB Co-Chair
Institutional Review Board

CC: Gary Zack