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Strategies for Shipping Temperature-Sensitive Medical Devices Using Cognitive Mapping

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This is to certify that the doctoral study by

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Walden University
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Abstract

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MBA, University of La Verne, 2005

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

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Abstract

Supply chain management (SCM) practitioners who ship temperature-sensitive diagnostic medical devices (DMDs) to clinicians must use effective cold chain management (CCM) strategies to avoid temperature excursions that contribute to medical device errors. Such errors have caused patient harm and death, which costs the U.S. health care system billions of dollars per year. The purpose of this qualitative multiple case study was to explore strategies for selecting and managing cold chain shipping solutions (CCSSs) requiring SCM executives to trade cost for regulatory compliance and predictability when mitigating temperature variations that occur during shipping. The conceptual framework for the study was the 6-change approaches, and its underpinnings that framed the exploration into the strategies some medical device executives use for shipping temperature-sensitive DMD tests and controls. Data were collected from in-depth interviews, field notes, and existing literature. The target population was 3 SCM executives working in California, New Jersey, and Ireland with at least 5 years of CCM experience in the medical device industry. A purposive sampling procedure guided the selection of participants for in-depth interviews. The data analysis included pattern matching techniques, central analysis, and collapse analysis. The results of this study indicated 3 successful strategies: validation of CCSSs, compliant shipping of DMDs, and CCM best practices. The study was socially significant because the findings may prevent medical device failures that have caused U.S. Food and Drug Administration recalls and patient harm.

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Dedication

I dedicate this doctoral study to my parents Dr. Luther Guynes and Mary Guynes who instilled in me the importance of education, trustworthiness, courageousness, and perseverance during my childhood. I will be forever grateful to Johnna Morse for keeping me grounded in life; and to my sister, Carey Guynes, Esq. who always found the right words of encouragement to stay the course during my doctoral journey. I dedicate my achievement to my two precious sons, Eric J. Guynes and Ethan C. Guynes who are the center of my universe and source of motivation. I hope my doctoral study will be a source of inspiration for my children and future generation of our family. To my parents, children, siblings, colleagues, and friends who were great supporters. I will always appreciate your love, prayers, support, encouragement, and motivation provided to me while obtaining my doctoral degree.

Acknowledgments

I would like to thank the supply chain executives who encouraged and challenged me to make a difference in the cold chain management of temperature-sensitive diagnostic medical device tests and controls in the medical device industry. I would also like to thank Dr. Christos Makrigeorgis, my doctoral study chair, for his mentoring, encouragement, and authentic interest in helping me complete my doctoral study. Dr. Makrigeorgis is an amazing facilitator of knowledge, which makes him a true gift to higher education and his students. I would also like to acknowledge Dr. Charles Needham, Dr. Doll, and all of my committee members for providing invaluable input into my doctoral study.

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Section 1: Foundation of the Study

Supply chain management (SCM) practitioners use cold chain shipping solutions (CCSSs) to distribute temperature-sensitive diagnostic medical device (DMD) tests and controls to clinicians who work in hospitals and doctor offices. Clinicians use DMD tests and controls to diagnose various diseases, such as cardiovascular, respiratory, toxicology, autoimmune, and infectious diseases presented in patients. Some of these DMD tests and controls contain monoclonal antibody technology, reagents, antigens, serums, and other biological compounds, many of which are temperature sensitive. The temperature requirements for some DMD tests and controls can range from 2 to 8, –20, and –80 °C, as well as ambient or control room temperature. The temperature sensitivity of DMD tests and controls requires SCM executives to implement consistent cold chain management (CCM) strategies and execute these strategies throughout the global supply chain. To achieve this objective, SCM executives working in the medical device industry should collaborate to align U.S. and international CCM strategies. The global alignment of CCM strategies may increase the probability of SCM practitioners using validated CCSSs for the distribution of temperature-sensitive DMD tests and controls. The objective of this doctoral study was to explore the strategies used by SCM executives in the selection of CCSSs in the medical device industry.

Background of the Problem

Agents for the U.S. Food and Drug Administration (FDA) are responsible for regulating the medical device industry in the United States. These agents use premarket approval (PMA) and the 510(k) clearance process to regulate the medical device industry

(Kramer, Xu, & Kesselheim, 2012a). Agents also employ the PMA and 510(k) clearance process to ensure medical device manufacturers are compliant with temperature storage and distribution (FDA, 2011). The temperature requirements for the storage and distribution of DMDs originate from the stability studies conducted by scientists (Schofield, 2009). Consequently, agents for the FDA require medical device manufacturers to have compliant product labeling for temperature storage and distribution (FDA, 2011).

Problem Statement

Clinicians using defective DMDs contribute to medical errors, a leading cause of injury and death that cost the U.S. health care system approximately $17.1 billion in 2008 (Van Den Bos et al., 2011). Agents for the FDA recorded 659 instances of medical device recalls in 2006, which contributed to 116,086 injuries and 2,830 deaths (FDA, 2006; Sullivan, 2014). Medical device recalls increased 80.6% from 2006 through 2012 (Sullivan, 2014). Proper CCM can prevent some medical errors by protecting proteins, antigens, and assays used in DMD tests and controls from temperature excursions (O'Connell et al., 2012; Smit et al., 2013). The general business problem was executives lack CCM standardization in distributing DMDs in the medical device industry. The specific business problem was some medical device executives lack strategies for shipping temperature-sensitive DMD tests and controls.

Purpose Statement

The purpose of this qualitative multiple case study was to explore medical device executives' strategies for shipping temperature-sensitive DMD tests and controls. The

target population consisted of three SCM executives working in the medical device industry. The geographic locations for participants were California, New Jersey, and Ireland.

Insight into the diversification or lack of standardization of CCSSs used by SCM executives in the medical device industry may contribute to CCM strategies, new knowledge, increased quality, and financial savings. The identification of CCM strategies could fast-track SCM executives' adoption of CCSSs that mitigate DMD temperature excursions and associated medical errors. SCM executives who adopt CCM strategies could advance social and economic benefits on a global scale by reducing the medical errors that cause patient harm and death.

Nature of the Study

I used the qualitative research methodology to guide this study because little was known about the phenomenon and the industry niche, and there was a lack of structured archival and survey data. Quantitative methodology is to measure variables through statistical analysis, which made this research method inappropriate for this exploratory study (see Brédart, Marrel, Abetz-Webb, Lasch, & Acquadro, 2014; Yilmaz, 2013). Mixed-methods research includes quantitative and qualitative approaches, which made the mixed-methods approach inappropriate. Terrell (2012) confirmed that researchers use qualitative methods to explore how and why a phenomenon occurs or occurred. Qualitative methodology was appropriate for exploring an under-researched phenomenon in a niche industry.

I considered narrative, phenomenological, ethnographic, and case study designs. I constrained the research design choice by using cognitive mapping as my primary technique in exploring the phenomenon. The use of cognitive mapping narrowed the design option to phenomenological and case study. Next, I considered that researchers use the phenomenological design to analyze interview data and draw conclusions based on participants' lived experiences (Ackermann, Eden, & Cropper, 1992). After ruling out the phenomenological design, I chose a case study design to support the qualitative nature of my research question and the real-time cognitive mapping of participants. The case study design is an excellent framework to explore health and social science phenomena to understand the shared practical experiences of participants (Baxter & Jack, 2008; Halkier, 2013; Wolgemuth et al., 2014). The application of cognitive mapping across individual participants helped me to generalize the strategies across all participants.

Research Question

I applied a qualitative multiple case study design with cognitive mapping to explore strategies SCM executives deploy in the selection, management, and utilization of CCSSs in the medical device industry. The research question should dictate the research method and design (Kaczynski, Salmona, & Smith, 2014). The following overarching research question directed this study: What are the strategies some medical device executives use for shipping temperature-sensitive diagnostic medical device tests and controls?

Interview Questions

I constructed cognitive maps through in-depth and prolonged interviews with informants to discover new facts and personal insights into the phenomenon. Prolonged interviews can take researchers 2 hours to complete (Yin, 2014). The case study design is appropriate for asking *how* and *why* interview questions, which is fitting for cognitive mapping (Yin, 2014). Prolonged case study interviews use propositions and semistructured interview questions that are open-ended to achieve a conversational tone with informants (Yin, 2014). By definition, a *proposition* is a statement or assertion that expresses judgment or opinion and is synonymous with hypothesis, theory, premise, and construct ("Proposition," n.d.). A prolonged interview requires the use of propositions, which guide an interviewer by encouraging him or her to ask spontaneous follow-up questions that align with the study (Yin, 2014). Baxter and Jack (2008) indicated that propositions provide focus and structure in answering the overarching research question.

I developed three propositions and constructed *how* and *why* interview questions to guide this case study. Proposition 1 was that CCSSs used in the medical device industry are validated, nonvalidated, or poorly validated. This use may indicate a lack of standardization and inconsistent distribution strategies. Proposition 2 was that organizational and educational requirements for SCM executives in the medical device industry might be inconsistent, which leads to the use of nonvalidated or poorly validated CCSSs. Proposition 3 was that SCM executives in the medical device industry have varying competency regarding the distribution requirements for DMD tests and controls from a regulatory and stability perspective, which may contribute to inconsistent industry

standards and health risks to patients. I then created and categorized *how* and *why* interview questions based on the three propositions, as shown in Table 1.

Table 1

Creation and Categorization of Interview Questions Based on Propositions

Propositions		Interview questions	
P1.	Cold chain shipping solutions (CCSSs) used in the medical device industry are validated, nor validated, or poorly validated, which may indicate a lack of standardization and inconsistent distribution strategies.	Q1.	What types of CCSSs do you deploy in your supply chain?
		Q2.	What methods do you use to evaluate CCSSs intended to protect against extreme temperature ranges?
		Q3.	How do you monitor the effectiveness of CCSSs used to ship diagnostic medical device (DMD) tests and controls?
		Q4.	How do you validate CCSSs used in your supply chain?
		Q5.	What cold chain shipping innovations are you considering for your organization?
P2.	Organizational and educational requirements for supply chain management (SCM) executives in the medical device industry may be inconsistent, which leads to the use of nonvalidated or poorly validated CCSSs.	Q6.	How did you learn about cold chain management (CCM) as it pertains to the medical device industry?
		Q7.	How do you identify CCM deficiencies within your organization?
		Q8.	How does education influence your selection of CCSSs for DMD tests and controls?
		Q9.	How do you increase CCM awareness within your organization?
		Q10.	How do you develop CCM expertise within your organization?
P3.	SCM executives in the medical device industry have varying competency regarding the distribution requirements for DMD tests and controls from a regulatory and stability perspective, which may contribute to inconsistent industry standards and health risks to patients.	Q11.	How do you determine the need for temperature-controlled shipping?
		Q12.	How does the FDA influence the shipping of DMD tests and controls?
		Q13.	How do you ensure internal CCM compliance when shipping?
		Q14.	How does temperature excursion on DMD tests and controls affect patient safety?
		Q15.	Why do you ensure temperature-compliant shipping for DMD tests and controls?
		Q16.	How do governmental regulations influence the CCM of DMD tests and controls?

Conceptual Framework

I used Kotter and Schlesinger's (1979) six-change approaches (SCA) model as the conceptual framework for this study. The premise for the SCA model is that leaders who seek sustainable change must select strategies that diminish the resistance to change, which is inherent in people who do not want internal and or external forces that disrupt the status quo (Kotter & Schlesinger, 1979). Propositions that supported the selection of the SCA model were (a) education and communication, (b) participation and involvement, (c) facilitation and support, (d) negotiation and agreement, (e) manipulation and cooptation, and (f) explicit and implicit coercion (see Kotter & Schlesinger, 1979).

I used the SCA model to construct propositions and interview questions grounded in the conceptual framework for the study. Leaders can use the propositions in the SCA model as strategies to prevent or decrease an individual or group's resistance to change (Kotter & Schlesinger, 1979). As applied in this study, the SCA model included organizational change management strategies that SCM executives can use to standardize the CCSSs for shipping temperature-sensitive DMD tests and controls.

Operational Definitions

510(k): 510(k) is a clearance process used by FDA agents for ensuring the safety and effectiveness of medical devices entering the market that are equivalent to existing medical device technology (Kramer et al., 2012a).

Cold chain management (CCM): CCM is the process of ensuring temperature control of perishable and temperature-sensitive goods, from storage through distribution, in active or passive CCSSs (White & Cheong, 2012).

Cold chain shipping solutions (CCSSs): CCSSs are containers that maintain the required temperature of goods during transit (Lis, Gourley, Wilson, & Page, 2009).

Premarket approval (PMA): PMA is a clearance process used by FDA agents during the premarket review to ensure high-risk medical devices pass clinical trials without adverse events (Kramer et al., 2012a).

Stability study: A stability study is a regulatory licensure requirement to determine product shelf life through a study of the effects of temperature on products during the storage and shipping of products and use conditions of those products for consumers (Schofield, 2009).

Temperature excursion: A temperature excursion occurs when a product encounters an undesirable temperature during transit because of cold storage failure and mishandling (Schofield, 2009).

Assumptions, Limitations, and Delimitations

This qualitative multiple case study included assumptions, limitations, and delimitations. The assumptions, limitations, and delimitations presumed facts, and unintentional and intentional boundaries associated with this study.

Assumptions

A number of key assumptions were required to conduct this doctoral study. Dusick (2015) defined *assumptions* as unverifiable assertions claimed by a researcher in conducting his or her study. The assumptions for this study involved the phenomenon under investigation and the participants.

I made the following assumptions based on the phenomenon under investigation. DMD tests and controls have specific temperature requirements for storage and distribution. The improper storage and distribution of DMD tests and controls may adversely affect patient safety. The risk to patient safety could provide a rationale as to why SCM executives use CCSSs to maintain specific temperature ranges for DMDs during transit.

I made the following assumptions based on participant participation in this qualitative multiple case study. Purposive sampling of participants resulted in voluntary participants. I assumed that SCM executives who participated in the study were knowledgeable and truthful in their interview responses. I also assumed that SCM executives had CCM responsibilities in their respective companies in the medical device industry, and that the participants were familiar with the phenomenon under investigation.

Limitations

This doctoral study had a number of limitations. Kirkwood and Price (2013) explained that limitations represent deductions in the absence of proof. The limitations of this study were the number of participants and representativeness of the industry in the study.

The number of participants interviewed in this multiple case study was a limitation. The risk associated with having a small number of participants correlates with the type of case study design. The population of SCM executives formed each individual case study for this multiple case study. A case study is an empirical exploration of a

phenomenon (Yin, 2014). A single case study is an investigation of a phenomenon based on a single case while a multiple case study is an investigation of a phenomenon occurring in multiple cases. The multiple case study is less susceptible to limitations than a single case study design (Yin, 2014). Yin (2014) described a multiple case study design as a robust and compelling way for researchers to use two or more cases studies to conduct research. The purpose of this multiple case study design was to explore and synthesize a contemporary phenomenon occurring in organizations within the medical device industry. The limitation is the qualitative methodology used to explore an under-researched phenomenon in a niche industry.

Delimitations

This doctoral study had a number of delimiting factors. Dusick (2015) defined *delimitations* as boundaries within the researcher's control. The delimitations for this study were the population and geographic location. The population for this study was SCM executives working in the medical device industry who had 5 years of CCM experience.

I selected the geographic locations for this multiple case study based on the following factors. The medical device industry for rapid diagnostic testing is a niche industry, which justifies the broadest geographical consideration to protect the confidentiality of companies and participants. Thus, SCM executives must have a national or global understanding of the phenomenon because regional views are too narrow in scope.

Significance of the Study

Students who publish business doctoral studies may contribute to business practices and social change. My doctoral study is significant for its potential contributions to the practice of CCM in the medical device industry. The identification and adoption of CCM strategies by SCM executives may prevent a medical device failure, which improves patient safety.

Contribution to Business Practice

Medical errors have become one of the foremost causes of patient injury and death throughout the world (Zineldin, Zineldin, & Vasicheva, 2014). DMDs contribute to medical errors, which cost the U.S. health care system $17.1 billion in 2008 (Van Den Bos et al., 2011). SCM executives who enhance their CCM acumen may increase the profitability of their organization through improved product reliability and regulatory compliance. Improvements to business practices could also include functional areas in an organization, such as research and development (R&D) and SCM.

R&D executives may perform new stability testing on DMD tests and controls to improve profitability. For example, R&D executives may consider broadening the temperature ranges for new DMD tests and controls, which could reduce or eliminate the need for refrigerated shipments. R&D executives may also perform a cost-benefit analysis to justify new stability studies on existing DMD tests and controls to reduce supply chain costs.

Managers ensure temperature-sensitive products arrive at the customer on time and in good condition (Lis et al., 2009). SCM executives who oversee managers have the

responsibility for ensuring temperature-sensitive DMD tests and controls arrive at the final destination without temperature excursions. SCM executives may improve business practices that reduce supply chain costs while mitigating the risk of temperature excursions. SCM executives who increase their CCM acumen may improve business practices by adopting CCM strategies that increase the use of validated CCSSs. The procurement or development of validated CCSSs may give SCM executives increased transit time flexibility when shipping DMDs, which may improve shipping strategies. New shipping strategies for DMDs may improve product quality and safety while reducing supply chain costs. For example, a decrease in transit time could reduce DMD exposure to extreme heat and or cold, which would improve product quality. Conversely, an increase in transit time could reduce shipping costs through the optimization of less expensive transportation modes.

Implications for Social Change

SCM executives can improve patient safety by adopting CCM strategies by using innovative CCSSs designed to mitigate temperature excursions for DMD tests and controls (O'Connell et al., 2012; Smit et al., 2013). A decline in injuries and deaths associated with medical device failures may correlate to a reduction in FDA recalls, liability claims, and legal proceedings against the medical device industry. Reduction of FDA recalls and litigations may encourage medical device executives to invest in new business opportunities. The funding of new business opportunities may increase manufacturing capacity and support R&D advancements in medical device technology. Such a shift may create new jobs, reduce health care costs, and bring to market new

diagnostic technologies that could save additional lives or improve patients' standard of living. Better CCM may increase profitability, patient safety, and technological advancements in DMDs.

A Review of the Professional and Academic Literature

Proper CCM can prevent temperature excursions to DMD tests and controls that contain temperature-sensitive proteins, antigens, and assays (O'Connell et al., 2012; Pruett et al., 2014; Smit et al., 2013). Exploring the reasons SCM executives select certain CCSSs in the medical device industry could reveal new strategies in CCM. The identification of CCM strategies could provide insight into the proper temperature control of DMD test and controls. Conversely, improper CCM could cause temperature excursions to DMD test and controls, which could lead to medical errors that adversely affect patient outcomes. The purpose of this qualitative multiple case study was to answers the following research question: What strategies do SCM executives use to ship temperature-sensitive DMD tests and controls? Answering the research question required a thorough review of scholarly literature. The literature review includes the framework and rationale for conducting this study.

The search strategy for the literature review included analysis of the literature related to the conceptual framework and study topic, followed by the recognition of key words to characterize each theme. These key words and terms became the searchable inputs into Walden's library databases. The steps of this top-down search strategy of themes, key words, and phrases were as follows.

The first step was to classify the literature review themes. The five themes were (a) conceptual framework of the six-change approaches model, (b) CCM from a distribution perspective, (c) regulatory requirements governing the medical device industry, (d) SCM executives' influence on CCM, and (e) overview of cognitive mapping. The selection of these five themes allowed me to understand the phenomenon of how and why DMD tests and controls lack standardized shipping practices in the medical device industry from a peer/practical review and scholarly perspective. More importantly, these five themes helped me develop a set of effective interview questions needed to explore the phenomenon with SCM executives who have responsibilities for CCM in the medical device industry.

The next step was the identification of key words and phrases for each theme. I summarize these key words and phrases in Table 2. These key words and phrases became the inputs into searches of databases accessible through the Walden University library. The databases accessed in this study were Thoreau, ProQuest Central, ABI/INFORM Complete, ScienceDirect, Science Citation Index Expanded, ERIC, and LexisNexis Academic.

Table 2

Key Words and Phrases Used in Databases Searches

Key words	Phrases
Cold chain management Cold chain shipping Diagnostic device Diagnostic tests Diagnostic controls Food and Drug Administration/FDA World Health Organization Conformité Européenne Product stability Cognitive mapping Concept mapping Six-change approaches model Catalytic innovation Distribution Warehousing Transportation Validations	History of cold chain management Challenges of cold chain management in the medical device industry Product stability of diagnostic medical devices Diagnostic tests and the effects of extreme heat and cold Food and Drug Administration governance of the medical device industry Cold chain management of diagnostic medical devices (DMD) tests and controls Cold chain management education and seminars Using Decision Explorer as a research instrument Distribution of temperature sensitive DMDs Warehousing of temperature sensitive DMDs Transportation of temperature sensitive DMDs Validating temperature sensitive DMD test and controls

The final step was to analyze and synthesize the literature from the databases. I then organized the literature review by themes and subthemes.

The first theme was the conceptual framework used to conduct the study. I used the six-change approaches model as the conceptual framework for the study. The conceptual framework of the study helped me create a systematic view of the phenomenon.

The second theme was CCM from a distribution perspective. The second theme had two supporting subthemes. The subthemes included the challenges associated with CCM and cold chain layouts and design.

The third theme was the regulatory requirements governing the medical device industry. The third theme had three supporting subthemes. The subthemes were the nature and scope of medical device regulations, the impact of regulations on the medical device industry, and the regulatory gaps in the medical device industry.

The fourth theme was the influences of SCM executives on CCM. The fourth theme had supporting subthemes that provided additional insight into the propositions associated with this study. The subthemes were CCSSs used in the medical device industry, organizational and educational requirements in the medical device industry, and the distribution requirements of DMD tests and controls from a regulatory and stability perspective.

The fifth theme was cognitive mapping. The fifth theme had two supporting subthemes. The subthemes were cognitive mapping and the scholarly applications of cognitive mapping. The organization of themes and subthemes are in Figure 1.

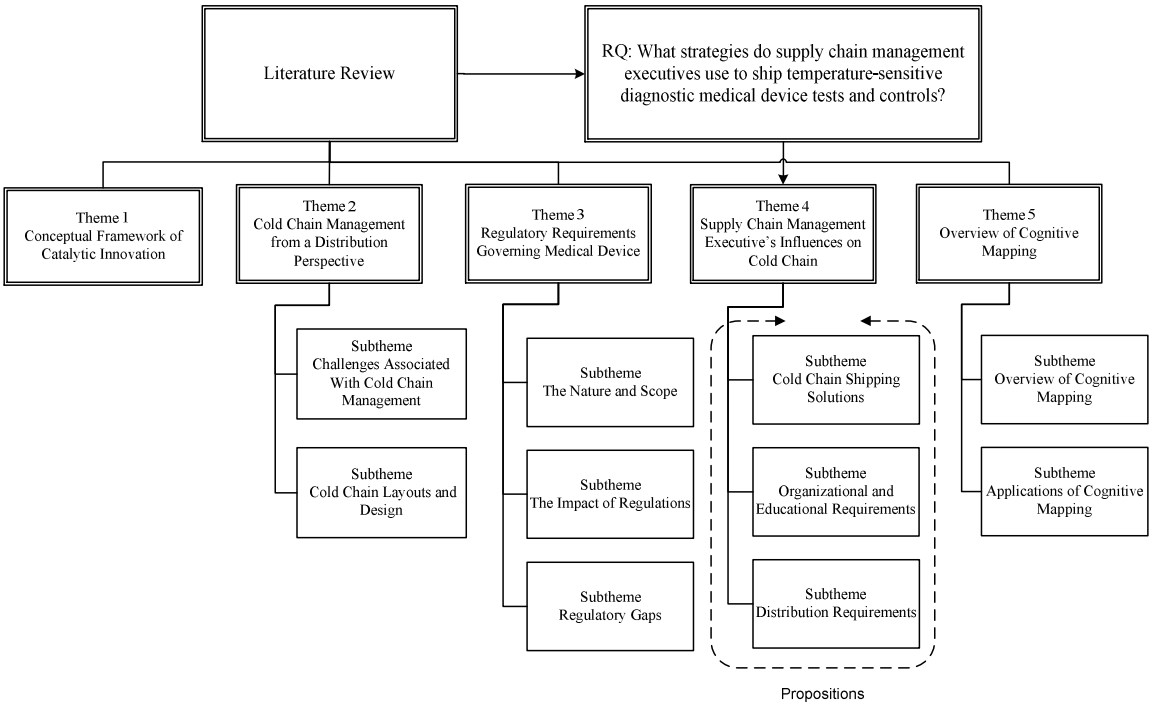


Figure 1. Themes and subthemes.

The literature review addresses the themes and subthemes that support the propositions and interview questions designed to answer the research question. In addition, the literature review includes an analysis of studies that helped me understand the phenomenon. I based this study on 131 references, with 84 references contributing to the literature review. Of those 131 references, 94% were from peer-reviewed sources at the anticipated completion date of this doctoral study, as shown in Table 3.

Table 3

Synopsis of Sources Used in the Literature Review

	Age of references based on anticipated graduation		
Reference type	Total	< 5 years	> 5 years
Peer-reviewed articles	124	108	16
Non-peer-reviewed articles	0	0	0
Dissertations	0	0	0
Books	2	2	0
Other	5	2	3
Totals	131	112	19

Conceptual Framework of Six-Change Approaches Model

CCM in the medical device industry could become stagnant without innovation. Reddy, Malliyala, Naresh, Raghunandan, and Jinadatharaya (2012) found that effective CCM involves good storage and distribution practices. Innovation in cold chain shipping and widespread adoption of innovation is a necessity given the critical nature of temperature-sensitive DMD tests and controls. The first theme in the literature review is the conceptual model of six-change approaches.

I used Kotter and Schlesinger's (1979) six-change approaches (SCA) model as the conceptual framework for this study. The premise of the SCA model is leaders need to manage issues based on the internal and external forces that disrupt the status quo of people in an organization (Kotter & Schlesinger, 1979). The SCA model is a strategy that leaders can use to prevent or decrease an individual or group's resistance to change (Kotter & Schlesinger, 1979).

Kotter and Schlesinger (1979) defined six propositions to support the SCA model. The first proposition of the SCA model is education and communication. Leaders

commonly use education and communication to persuade employees to accept organizational change when there is a lack of information or information is interpreted inaccurately (Kotter & Schlesinger, 1979). The education and communication proposition is time-consuming to implement because leaders must engage most employees throughout the organization (Kotter & Schlesinger, 1979).

The second proposition of the SCA model is participation and involvement. Leaders commonly use participation and involvement to secure employee ideas and commitment to change (Kotter & Schlesinger, 1979). Leaders typically use participation and involvement when they lack the necessary information to design the change, and there is considerable resistance to the change (Kotter & Schlesinger, 1979). The participation and involvement proposition is time-consuming to implement because leaders must use employee participants to develop the appropriate organizational change (Kotter & Schlesinger, 1979).

The third proposition of the SCA model is facilitation and support. Leaders commonly use facilitation and support to help employees with adjustment problems to adapt to organizational change (Kotter & Schlesinger, 1979). The facilitation and support proposition is time-consuming and expensive to implement because leaders may need to provide new skills training, time off, listening sessions, and emotional support (Kotter & Schlesinger, 1979).

The fourth proposition of the SCA model is negotiation and agreement. Leaders commonly use negotiation and agreement to avoid resistance to change by meeting the demands of an individual or group who have considerable power to resist change (Kotter

& Schlesinger, 1979). The negotiation and agreement proposition is expensive to implement because leaders create an organizational culture that encourages compliance through negotiations (Kotter & Schlesinger, 1979).

The fifth proposition of the SCA model is manipulation and co-optation. Leaders commonly use manipulation and co-optation to counteract resistance to change by providing select information to employees or giving an individual from an influential group a key position in exchange for his or her endorsement of the proposed organizational change (Kotter & Schlesinger, 1979). The manipulation and co-optation proposition is an inexpensive and easy way to obtain the support of organizational change by an individual or group (Kotter & Schlesinger, 1979). The downside of this proposition is that leaders who use manipulation and co-optation must contend with employees feeling tricked or lied to (Kotter & Schlesinger, 1979).

The sixth proposition of the SCA model is explicit and implicit coercion. Leaders commonly use explicit and implicit coercion to overcome all resistance to change by threatening an individual or group with termination, job transfer, and loss of promotional opportunities (Kotter & Schlesinger, 1979). Leaders who use the explicit and implicit coercion proposition cause employees to have resentment, which may result in new resistance to change (Kotter & Schlesinger, 1979).

I used relevant propositions from the SCA model to ground the case study. These propositions guided the construct of *how* and *why* interview questions. SCM executives may use the insight gained from interview questions to support the implementation of

CCM strategies in their respective organizations. However, some SCM executives may resist change in their organization, based on CCM misconceptions.

Kotter and Schlesinger (1979) theorized two misconceptions that prevent change. First, people resist change when they do not understand the implications of a problem based on a misunderstanding or a lack of trust (Kotter & Schlesinger, 1979). People also resist change when they incorrectly analyze a problem and determine that the cost of change is more expensive than they originally anticipated. SCM executives who misunderstand or fail to assess a problem are more likely to form misconceptions that prevent change. I was able to identify three CCM misconceptions of SCM executives from the literature.

The first misconception of SCM executives is that the addition of a few gel packs at room or frozen temperature into Styrofoam coolers meets the temperature stability requirements for national and global distribution of DMD tests and controls (Hidestrand et al., 2012; Jansen et al., 2010). The second misconception of SCM executives is the use of existing CCSSs meets the regulatory owner or regulatory compliance requirements, even though these solutions lack empirical evidence that supports temperature control (Jadhav, Gholve, & Kadam, 2009). The third misconception of SCM executives is that the act of improving existing CCSSs might cost too much money (Joshi, Banwet, Shankar, & Gandhi, 2012). SCM executives who understand the underpinnings of the SCA model are more likely to identify misconceptions that may prevent the implementation of new CCM strategies in their organization. SCM executives must educate and align people with CCM strategies to prevent misconceptions that impede

change. SCM executives working in the medical device industry should have direct responsibility for CCM strategies. With this responsibility, SCM executives who use the SCA model could improve business strategies in their organization.

I considered a variety of models and theories to ground the conceptual framework of the study. Theories help researchers make sense of a phenomenon of interest (Chicksand, Watson, Helen, Radnor, & Johnston, 2012). The rival theory to the conceptual model of SCA is catalytic innovation. Leaders who use catalytic innovation theory can achieve social change on a national scale (Christensen, Baumann, Ruggles, & Sadtler, 2006).

Leaders have an inherent resistance to social change that prevents organizations from realizing catalytic innovation (Christensen et al., 2006). Resistance to social change is a fundamental premise of the catalytic innovation theory. The premise for preventing catalytic innovation is that leaders in all industries prefer to maintain existing practices, which makes it difficult to change or improve upon those practices (Christensen et al., 2006). For example, executives maintain existing practices because the act of making any change to those practices disrupts them or their teams (Christensen et al., 2006). Leaders' resistance to catalytic innovation might prevent their organization from improving business strategies because those strategies relate to social change. Moreover, leaders can develop a good-enough mindset toward the optimization of existing business practices and processes. For example, a leader with a good-enough mindset believes improving existing business practices would lead to organizational disruption, which is unacceptable to the status quo (Christensen et al., 2006).

Christensen et al. (2006) found that business leaders who resist catalytic innovation with their good-enough mindsets also fail to address social problems. On the other hand, Lee, Trimi, and Kim (2013) concluded the catalytic innovation of goods and services could drive quicker adoption, which could then change the behavior of an entire industry. Furthermore, Klassen and Vereecke (2012) established that SCM executives could actively mitigate social challenges by improving SCM practices. Therefore, SCM innovation correlates with a leader's ability to identify and eliminate the behavioral patterns that prevent catalytic innovation.

Although catalytic innovation theory is a supportive conceptual framework applicable to this research, the conceptual model of SCA was more fitting for this study. I used the SCA model to explore and gain insight into the methods that SCM executives used to address resistance to change and the various choice strategies that helped them to overcome resistance to change (Kotter & Schlesinger, 1979). The SCA model includes methods of organizational change management for SCM executives working in the DMD industry who are interested in adopting CCM strategies designed to increase patient safety.

Cold Chain Management From a Distribution Perspective

In conducting this literature review of CCM, I discovered many industries in which leaders demonstrated a proficient level of understanding. My new level of understanding of CCM added creditability and led to new insights into CCM strategies. The second theme in the literature review is the challenges associated with CCM and cold chain layout and design.

CCM involves two levels of problem solving. The strategic level includes a broad plan of action and a tactical or operational level that renders the means for carrying out the prescribed strategy. At the tactical level, SCM practitioners use product labeling to identify the proper CCSSs needed to maintain product temperature. The failure to maintain proper temperatures could affect assay performance, which could lead to a diagnostic error (Raizada et al., 2014). The use of faulty DMD tests and controls increases the probability of clinical misdiagnoses. As a result, SCM executives are under immense pressure to select the most appropriate CCSSs. The proper selection of CCSSs depends on the SCM executive's knowledge of CCM at both the strategic and tactical level.

Reddy, Malliyala, Naresh, Raghunandan, and Jinadatharaya (2012) asserted that CCM is required for maintaining the shelf life of agricultural products, frozen foods, chemicals, and pharmaceuticals. SCM practitioners use CCM practices in the delivery of fresh produce and meats, frozen foods, industrial chemicals, pharmaceuticals, biologicals, and medical devices. CCM involves the continuous temperature control of perishable and temperature-sensitive goods in the supply chain. Uçar and Özçelik (2013) found that consumers of cold chain products were unfamiliar with proper refrigeration and labeling. The proper distribution and storage of perishable and temperature-sensitive goods throughout the supply chain requires SCM practitioners to use a variety of CCSSs, refrigerators, and freezers.

CCSS designs vary from passive to active temperature control. Hidestrand et al. (2012) used a Styrofoam box and gel packs to protect products from extreme

temperatures during transit. Reddy et al. (2012) explained that SCM practitioners used dry ice, phase change, and ice packs to maintain product temperatures. Passive CCSSs consist of thermal blankets, Styrofoam coolers, polyurethane coolers, vacuum insulated panel shippers, phase change shippers, dry ice shippers, and nitrogen shippers. In addition, passive shipping solutions use various types of refrigerant, such as gel packs, foam bricks, phase change panels, dry ice, and nitrogen to maintain product temperature for a fixed duration of time. Hidestrand et al. concluded the distance to a shipping location and weather could adversely influence product quality. The amount of time a passive shipping solution can maintain product temperature is dependent on its packaging design, exposure to external temperatures, and transit time.

In contrast to passive CCSSs, active CCSSs have integrated technologies designed to monitor and regulate product temperature to counteract the effects of external temperatures during transit. Active shipping solutions can mitigate the effects of extreme heat and cold. An active shipping solution is essentially a refrigerator or freezer that is transportable. Liu, Higgins, and Tan (2012) found that SCM practitioners use refrigerated trucks to transport temperature-sensitive products. Transportable refrigerated solutions can range from ocean containers, railcars, tractor trailers, pallet-sized bulk containers, or unit load devices.

SCM practitioners use active and passive CCSSs to transport goods domestically and internationally (White & Cheong, 2012). It is likely that SCM executives use various active and passive shipping solutions to distribute temperature-sensitive DMD tests and controls globally. SCM executives select CCSSs based on the product labeling and

distance. For example, temperature-sensitive products in the medical device industry require specialized storage and distribution practices throughout the supply chain. Therefore, SCM practitioners in the medical device industry use CCM practices to store and distribute temperature-sensitive DMD tests and controls.

Reddy et al. (2012) remarked SCM practitioners find it increasingly important to use proper storage, handling, and distribution for temperature-sensitive products. SCM practitioners employ specialized storage, packaging, refrigerant, and transportation throughout the storage and distribution process. Packing engineers have designed specialized cold chain solutions to mitigate the effects of hot and cold weather and mechanical temperatures on DMD tests and controls from the factory to the clinician. Reddy et al. found that effective CCM involves good storage and distribution practices. The global distribution of DMD tests and controls to clinicians often require extensive CCM strategies. SCM executives take into consideration the modes of transportation, refrigeration strategies, transit times, and weather conditions when developing CCM strategies. Transportation modes for shipping products can range from ocean to rail, road, and air. Transportation modes of transportation also require a refrigeration strategy. Refrigeration strategies consist of active and passive CCSSs. CCSSs must account for transit time and weather conditions to ensure DMD tests and controls maintain their specified temperatures during transit. SCM practitioners face numerous challenges to employing specialized storage, packaging, refrigerant, and transportation throughout the supply chain.

Challenges associated with cold chain management. The challenges associated with CCM affect a wide spectrum of industries. To understand these challenges, I explored CCM from a historical perspective across various industries. My exploration into CCM from a historical perspective provided scholarly insights into the phenomenon associated with this study. The historical evolution of CCM could potentially help SCM practitioners in their decision making.

Rees (2013) noted that the earliest form of CCM was the manufacturing of ice in underground icehouses, which dates back to 1100 BCE in China. In the early 1800s, Tudor created the natural ice industry (Rees, 2013). The natural ice industry quickly became a societal necessity. The use of salt, drying, smoking, and preservatives (sulfuric acid, borax, and formaldehyde) destroyed the nutrients in food and caused serious health problems, including botulism (Rees, 2013).

During the Industrial Revolution, leaders in the food industry used natural ice to mitigate some of the health risks associated with preservatives. The Industrial Revolution led to new and innovative manufacturing processes, many of which benefited the natural ice industry. Innovations in the natural ice industry were critical to the agriculture, restaurant, storage, and distribution industries in the 1870s–1920s because of extreme pressures to improve food safety (Rees, 2013). The storage and distribution industries were able to achieve steady advancements in cold chain technology as it relates to the control and monitoring of perishable goods throughout the supply chain (Rees, 2013). Advancements in cold chain technology helped reduce temperature excursions (Stanger, Wilding, Yates, & Cotton, 2012) and helped to modernize the CCM practices

used by the pharmaceutical, biological, and medical device industries (Rees, 2013). The classification of CCM practices typically resides in the body of knowledge for CCM or SCM.

Some scholars dispute the classification of CCM practices. For instance, Raab, Petersen, and Kreyenschmidt (2011) believed CCM practices require additional information for handling perishable products, while SCM only requires the exchange of product information from the transaction to the location. Conversely, Diehl and Spinler (2013) concluded that SCM starts with the sourcing of materials from suppliers to the fulfillment of manufactured products to customers. Stanger et al. (2012) suggested that a transfusion laboratory manager is responsible for the SCM activities of forecasting, sourcing, inventory control, quality, and CCM. The lack of continuity among scholars could cause a difference in opinion of whether CCM practices exist within or without the context of SCM. Differences in opinion among scholars could cause confusion in the cold chain and or supply chain bodies of knowledge. This potential for confusion increases the need to define CCM.

CCM is the continuous temperature control and monitoring of perishable and temperature-sensitive goods such as fresh produce and meats, frozen foods, industrial chemicals, pharmaceuticals, biologicals, and DMD tests and controls. The literature contains various other scholarly definitions of CCM. For example, Joshi et al. (2012) defined CCM as a linear process that starts with the complete temperature control of produce from the harvest to the end consumer.

Temperature control is active or passive. Active temperature control requires temperature monitoring and active temperature control to ensure product quality and shelf life (Raab et al., 2011). Jadhav et al. (2009) concluded that actively refrigerated trucks, cars, ships, containers, and passively controlled shipping containers need validating. Passive CCSSs lack proactive regulation of temperature during transit (Raab et al., 2011). SCM practitioners have industry-specific challenges relative to active and passive temperature control; these challenges affect a multitude of industries, such as the food, chemical, pharmaceutical, biological, and medical device industry.

Leaders in the food industry face a variety of risks on a global scale. For example, the food industry must contend with product recalls based on the magnitude of the food safety risk (Wang, Li, & Shi, 2012). Consumers also pose a risk to food safety. Uçar and Özçelik (2013) found that consumers are not familiar with their responsibilities for the proper CCM of the food they purchase and consume. Moreover, consumers are not aware of the proper temperature requirements for their refrigerator, which could result in a foodborne illness (James, Onarinde, & James, 2017). The lack of consumer knowledge in CCM and proper refrigeration may adversely affect the safety and cost of food (Shukla & Jharkharia, 2013; Uçar & Özçelik, 2013). Overall, CCM challenges are more prevalent in developing countries than in industrialized countries (Joshi et al., 2012).

The pharmaceutical, biological, and medical device industries must conduct clinical trials and receive FDA approval before bringing new products to market. Clinical trials that include CCM requirements are complex. SCM practitioners must

devise CCM strategies to overcome the long lead times associated with personalized medicines and small-molecule drugs that must reach the final destination on time, untampered, and at the right temperature (Hager, 2011). For example, poor CCM could result in temperature excursions that could alter the efficacy of samples used in clinical trials (Hager, 2011). Therefore, SCM practitioners must have the logistical expertise to manage the global shipping of temperature-sensitive products (Hager, 2011).

SCM executives working in the pharmaceutical industry must overcome the CCM challenges associated with over-the-counter and prescription drugs. CCM challenges consist of increased shipping volumes, diverse product temperature requirements, and the complexity of global logistic (Reddy et al., 2012). Despite these challenges, SCM executives should focus on introducing cross-industry CCM strategies to their respective organizations. The adoption of cross-industry CCM strategies by SCM executives could mitigate known and unknown CCM issues.

Cold chain layout and design. SCM executives must be knowledgeable about CCM strategies to coordinate the storage and shipping of temperature-sensitive DMD tests and controls nationally and globally. Reddy et al. (2012) found that effective CCM involves good storage and distribution practices throughout the global supply chain. CCM strategies must take into consideration all activities from inbound sourcing of temperature-sensitive raw materials to the factory through the distribution of temperature-sensitive DMD tests and controls to the clinician.

CCM strategies must incorporate active and passive temperature control for the storage and shipping of DMD tests and controls throughout the supply chain. Hidestrand

et al. (2012) found that weather could adversely influence product quality. Therefore, CCM strategies must be capable of mitigating weather conditions of extreme heat and cold from the beginning of the supply chain to the end. To address this requirement, SCM practitioners can develop cold chain maps to document the temperature profiles for the proper storage and shipping of temperature-sensitive products. Cold chain maps are an example of the performance improvement systems managers can use to reduce the complexity of maintaining CCM strategies (Joshi et al., 2012). Effective CCM requires SCM executives to understand cold chain mapping strategies.

The cold chain mapping of a DMD supply chain begins with the identification of each waypoint in the supply chain and the length of time a product dwells at each waypoint. I first elaborate on how I have performed cold chain mapping and then illustrate the process (see Figure 2). Cold chain mapping of a DMD supply chain requires the identification of the final waypoint or destination, which is typically the clinician's office or hospital. Next, there is a need to identify the waypoints that represent the physical structures in which products may dwell, such as factories, warehouses, and hospitals. Then, there is a need to identify the most optimal route and time for transporting products to the clinician or hospital. Then, the selection of active and passive shipping solutions to ensure products maintain their temperature requirements must be determined. Finally, there is a need to identify each mode of transportation for moving products through each waypoint in the supply chain.

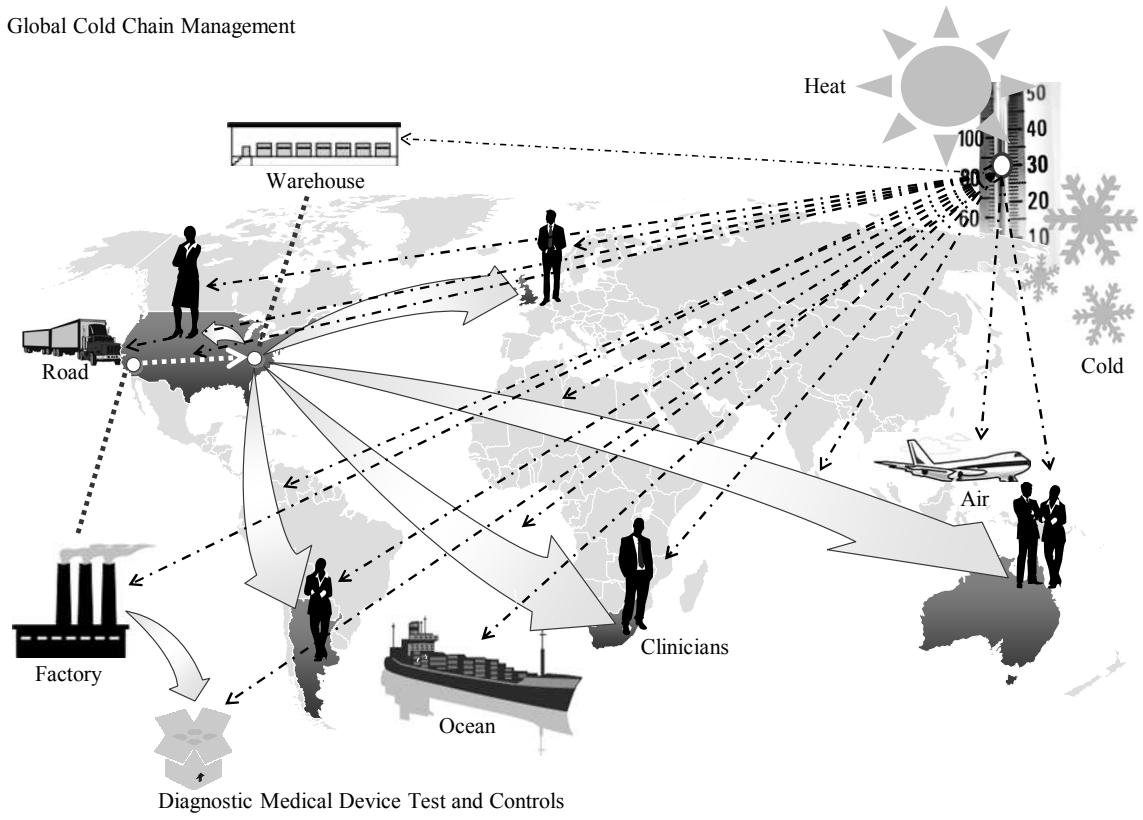
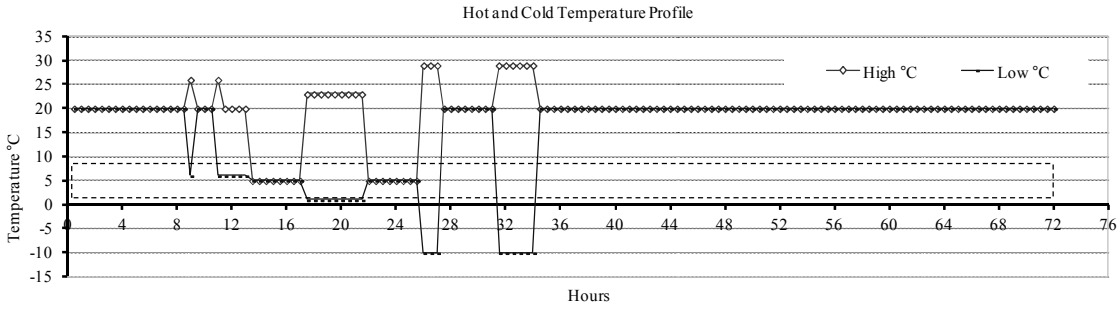


Figure 2. Global distribution of temperature-sensitive DMD tests and controls.

SCM practitioners can create temperature profiles to help determine the most effective shipping solutions for transporting temperature-sensitive DMD tests and controls. The development of temperature profiles requires SCM practitioners to identify the storage and shipping temperatures for DMD tests and controls. In addition, SCM practitioners must collect weather data to extrapolate the external temperature ranges for each waypoint on the cold chain map. Furthermore, SCM practitioners need to isolate active or passive temperature control solutions used to transport products through each waypoint in the supply chain. Cold chain mapping gives SCM executives the ability to understand the most optimal CCM strategy. I developed a second cold chain mapping

illustration based on workflows, locations, temperatures, and transits times (see Figure 3). Optimal CCM strategies help SCM executives in the development and procurement of validated CCSSs.



		High °C	High °F	Sate/Country	Low °C	Low °F	Sate/Country	Duration	Changes	Time	Time
1	Pick order	20	68	Controlled	20	68	Controlled	0.75		8:00 AM	8:45 AM
2	QC order	20	68	Controlled	20	68	Controlled	0.5		8:45 AM	9:15 AM
3	Pack order	20	68	Controlled	20	68	Controlled	0.75		9:15 AM	10:00 AM
4	Hold in DC for pickup	20	68	Controlled	20	68	Controlled	6		10:00 AM	4:00 PM
5	Carrier collection at DC	20	68	Controlled	20	68	Controlled	0.5	8.5	4:00 PM	4:30 PM
6	Transport to carrier DC	26	78.8	California	6	42.8	California	0.5	9	4:30 PM	5:00 PM
7	Carrier sort	20	68	California	20	68	California	1.5	10.5	5:00 PM	6:30 PM
8	Transport to airport/ramp	26	78.8	California	6	42.8	California	0.5	11	6:30 PM	7:00 PM
9	Loading of aircraft	20	68	California	6	42.8	California	2	13	7:00 PM	9:00 PM
10	Air	5	41	Controlled	5	41	Controlled	4	17	9:00 PM	1:00 AM
11	Unload and sorted	23	73.4	Indiana or Tenessee	1	33.8	Indiana or Tennessee	3	20	1:00 AM	4:00 AM
12	Hold in carrier DC	20	68	Indiana or Tenessee	20	68	Indiana or Tennessee	4	31	4:00 AM	8:00 AM
13	Deliver	29	84.2	NA	-10	14	NA	3	34	8:00 AM	11:00 AM
11a	Connection upload	23	73.4	Indiana or Tenessee	1	33.8	Indiana or Tennessee	1.5	21.5	4:00 AM	5:30 AM
11b	Air	5	41	Controlled	5	41	Controlled	4	25.5	5:30 AM	9:30 AM
11c	Unload and sorted	29	84.2	NA	-10	14	NA	1	26.5	9:30 AM	10:30 AM
11d	Transport to carrier DC	29	84.2	NA	-10	14	NA	0.5	27	10:30 AM	11:00 AM
14	Clinicians	20	68	Controlled	20	68	Controlled	38	72		

Note. SCM practitioners develop temperature models utilizing various data sources, such as the International Safe Transit Association (ISTA), National Oceanic and Atmospheric Administration (NOAA), and transportation carriers (ocean, road, rail, and or air) to define temperature variations (hot and cold) that perishable and temperature-sensitive products may encounter during transit. SCM practitioner's use temperature models for the design and or validation of CCSSs.

Figure 3. Cold chain temperature model.

Regulatory Requirements Governing the Medical Device Industry

The medical device industry must comply with a multitude of regulations on a global basis. The third theme in the literature review is the nature and scope, impact, and gaps associated with global medical device regulations. The literature provided insights into the regulatory requirements and challenges associated with the phenomenon that was the focus of this study.

Nature and scope. The FDA began regulating the medical device industry in 1938 (Challoner & Vodra, 2011). In the 1970s, the FDA found that the existing regulatory governance of medical devices was no longer suitable for the level of innovation occurring in the medical device industry (Challoner & Vodra, 2011). As a result, Congress passed the Medical Device Amendment of 1976, which established the current regulatory framework for the medical device industry in the United States (Challoner & Vodra, 2011).

The FDA regulates medical device registration, listing, premarket approval, 510(k), quality system adherence, and good manufacturing practices (FDA, 2006). FDA (2006) regulations require medical device manufacturers to document the storage and shipping requirements of their products. Agents for the FDA require all medical devices to have regulatory clearance before any sales or distribution activities occur in the United States (Alfa, 2013). The FDA uses regulatory standards to govern the medical device industry. For example, the FDA uses the PMA and 510(k) processes to regulate the medical device industry (Kramer et al., 2012a). The PMA regulation requires clinical

testing and inspection approval before the sale of any new medical device. Clinical trials must meet the scientific standards set in the Belmont report (Berry, 2015). In contrast, 510(k)-cleared medical devices must be substantial equivalents to existing medical device technology (Kramer et al., 2012a). Clearance of the 510(k) process deems that a new medical device is equivalent to a pre-existing approved medical device (Challoner & Vodra, 2011). Therefore, a medical device that is a substantial equivalent is as safe and effective as the previously approved medical device (Challoner & Vodra, 2011).

The FDA is responsible for defining medical devices. The FDA views a medical device as anything that performs the diagnosis of disease, condition, cure, mitigation, treatment, and prevention in humans and animals (Reed & Kaufman-Rivi, 2010). There are three different classes of medical devices: Class I devices are low risk, Class II devices are a moderate risk, and Class III devices are high risk (Kramer et al., 2012a). In 1996, the FDA started tracks event problem codes associated with medical device failures by class. Event problem codes give consumers, health care professionals, and device manufacturers access to medical device failures via the MedWatch reporting system (Reed & Kaufman-Rivi, 2010). Since 1996, the FDA has recorded millions of event problem codes; medical device malfunctions link the majority of these events (Reed & Kaufman-Rivi, 2010). Medical device malfunctions could lead to the misdiagnosis of a patient, which could lead to injury or death.

Like the FDA, the European Union (EU) has several classifications of medical devices. The EU oversees the classifications of medical devices through a dual regulatory approach. The EU Competent Authority is responsible for approving all low-

risk medical devices while notified bodies approve all high-risk medical devices (Kramer et al., 2012b). The EU regulatory authorities require medical devices to display Conformité Européenne (CE) markings to signify that these devices are safe and fit for their intended purpose (Kramer et al., 2012a). Each EU member state must enforce these regulations (Heneghan, Thompson, Billingsley, & Cohen, 2011).

The FDA and EU Competent Authority usually represent industrialized countries. Consequently, developing countries typically rely on the World Health Organization (WHO) for the prequalification of medical devices (Jaros & Saberwal, 2013). Developing countries rely on the WHO because these countries lack local regulations governing medical device innovation (Jaros & Saberwal, 2013).

Impact of regulations. The policies that govern the medical device industry have both positive and negative consequences. These positive and negative consequences affect the safety of patients and the speed of innovation. For example, the Center for Devices and Radiological Health (CDRH) is a department in the FDA that is responsible for regulating the medical device industry. Agents for the CDRH aggressively regulate the medical device industry (Cruise, 2011). Agents for the FDA issue warning letters to increase public knowledge and place pressure on medical device companies to comply. Some consumer advocate groups believe that the FDA has not effectively managed the medical device industry from an oversight and approval perspective (Cruise, 2011). The CDRH responded to this criticism by implementing a total product life cycle methodology to manage medical devices, which should help

reduce medical device failures (Cruise, 2011). Medical device recalls increased 108% over a 7-year period, from 572 recalls in 2005 to 1,190 recalls in 2012 (Sullivan, 2014).

The issuance of 510(k) approvals by the FDA may lead to innovative technology that improves testing outcomes at the expense of overly complicated medical devices (Suter et al., 2013). Challoner and Vodra (2011) asserted 510(k) clearances issued by the FDA are insufficient to ensure patient safety. As reinforcement to their claim, Challoner and Vodra found that several thousand medical devices are approved by the FDA each year, with one-third being approved by the 510(k) process without significant evidence that the new product is a substantial equivalent. This lack of regulatory oversight could adversely affect patient safety. Patient safety concerns are global, and the effect of these concerns impacts both industrialized and developing countries.

In the EU, the Competent Authority addresses patient safety issues through the CE process because malfunctioning medical devices cause patient harm. Government authorities in the United Kingdom reported 447 medical device alerts between 2006 and 2010, and nearly half of the alerts resulted in serious adverse health consequences or death (Heneghan et al., 2011). Medical device recalls that adversely affect patient safety are on the rise in the United Kingdom. Although the existence of the data are known, there is a lack of transparency in the data associated with these recalls; this lack of transparency prevents the full understanding of how and why these failures occur (Heneghan et al., 2011).

Agents for the WHO (as cited in Jaros & Saberwal, 2013) reported that nearly all modern medical devices used in developing countries come from industrialized countries

and that developing countries lack the infrastructure to ship these medical devices within their borders. For example, India is a developing country that imports more than 75% of its medical devices from the West (Jaros & Saberwal, 2013). The lack of cold chain infrastructure in developing countries could result in temperature excursions during the storage and distribution of DMD tests and controls.

Regulatory gaps. Government agencies such as the WHO, FDA, and Competent Authority might lack regulatory policies that allow agents to enforce CCM compliance in the medical device industry. Conversely, there are specific regulatory and product stability requirements directly associated with DMD tests and controls. Smit et al. (2013) suggested that performance testing of diagnostic tests should focus on the accuracy of the results, reliability of equipment, cold chain requirements, and ease of use. Despite the PMA and 510(k) approval process, there is a lack of consistency in performance testing in the medical device industry. As such, medical device manufacturers can use temperature stability studies and accelerated aging methods to determine the shelf life of diagnostic tests (Goarant et al., 2013). One objective of stability studies is to establish labeled storage temperatures on products (Schofield, 2009). Stability studies also provide guidance related to product quality when a temperature excursion occurs in the supply chain (Schofield, 2009).

Chemicals and reagents in DMD tests and controls react differently to high temperatures than to ambient or cold temperatures. Stability studies help with determining thermal degradation (Dabhi et al., 2013). Lateral flow diagnostic tests are susceptible to extreme temperature (Miller & Sikes, 2015). Antigens used in DMDs are

susceptible to temperature, which could adversely affect the performance of DMD tests (Miller & Sikes, 2015).

Reagents used in DMD tests may have various levels of thermal instability (Miller & Sikes, 2015). Furthermore, diagnostic tests contain antibodies and macromolecules that become inactive when exposed to heat and humidity, which makes the adherence to product storage and shipping conditions critical to the proper functionality of medical device tests and controls (Bissonnette & Bergeron, 2012). Similarly, storage conditions can adversely affect the stability of a drug (Lin, Hsu, & Lin, 2013).

Stability testing revealed that some antibodies require strict CCM to prevent irreversible denaturation caused by high temperatures, which reduces shelf life (Wongphatcharachai et al., 2013). For example, a robustness study might expose an assay to a temperature of 25–35 °C for a specific duration of time (Dabhi et al., 2013). Results of such a study might indicate that a particular assay used in DMD tests and controls would only be stable for 48 hours at room temperature or eight days at 4 °C (Dabhi et al., 2013). In addition, diagnostic devices that require the use of DNA samples need to have cold chain practices that can support 4 °C storage and shipping (Sokhna et al., 2013). Lastly, all products should have their storage temperatures specified on the label and or the primary packaging. Temperature stability requirements create the need for specific CCSSs for the distribution of DMD tests and controls.

Supply Chain Management Executives' Influences on Cold Chain Management

SCM executives have influences on CCM. The fourth theme in the literature review is SCM executives' influences on CCM strategies—more specifically, how SCM

executives influence CCSSs for the shipping of DMD tests and controls, organizational and educational requirements needed to ship medical devices, and the distribution requirements needed to ship temperature-sensitive DMD tests and controls from a regulatory and stability perspective. Lastly, the synthesizing of these subthemes directed the study and helped further refine the interview questions needed to understand the propositions and the phenomenon (Yin, 2014).

Cold chain shipping solutions used in the medical device industry. SCM practitioners use cold chain strategies to store and ship temperature-sensitive products. CCM is the controlled methodology for properly storing and distributing temperature-sensitive products (Reddy et al., 2012). Effective CCM prevents temperature excursions. DMDs have product labeling to indicate appropriate storage temperatures (Maltha et al., 2013). Thus, SCM practitioners must adhere to product labeling as part of a CCM strategy.

Cold chain shipping solutions are either active or passive. Passive shipping solutions are less complex and offer some protection against extreme temperatures, as compared to active temperature-controlled shipping solutions. For example, validated shipping solutions can protect products against extreme heat and cold (Jadhav et al., 2009). Validated shipping solutions are also cheaper than a truck on a per-unit basis. Agents for the FDA require passive shipping containers to have validation protocols (Jadhav et al., 2009). Certified packaging laboratories use environmental chambers and temperature profiles to validate passive shipping containers (Jadhav et al., 2009).

Validated shipping solutions help eliminate temperature excursions that occur during the storage and shipping of temperature-sensitive products.

Active CCSSs such as temperature-controlled trailers and containers can maintain product temperatures during transit (White & Cheong, 2012). These active CCSSs offer real-time temperature control and monitoring, which reduces the likelihood of temperature excursions. SCM practitioners using CCM strategies have fewer medical device failures from a temperature excursion perspective.

SCM practitioners use refrigerants, such as gel packs, foam bricks, phase change panels, dry ice, and nitrogen to keep products within specified temperature ranges in CCSSs. For example, some passive cold chain shipping containers use –20 °C gel packs to keep products in the 2–8 °C range during transit (Jansen et al., 2010). Many companies mass-produce shipping containers for the medical device industry. For example, Coleman manufactures several various types of passive cold chain shipping containers. Coleman Model 5272 can maintain product temperatures below 10 °C for 35 hours when utilizing two –20 °C gel packs, even when exposed to ambient temperatures (Jansen et al., 2010). In some instances, customized CCSSs used in hot climates will only maintain temperature for 24 hours (Wei Teng, Foley, O'Neill, & Hicks, 2014). Thus, the ability of passive shipping containers to maintain product temperature correlates with the design of the container, the type of refrigerant, transit time, and external temperatures.

CCSSs help maintain product temperatures, but the effectiveness of CCSSs is not easily measured (Joshi et al., 2012). SCM practitioners can improve their cold chains by

collecting performance data on shipping solutions to identify gaps and weaknesses in their processes (Joshi et al., 2012). These gaps and weakness correlate to the lack of CCM standards for CCSSs used to mitigate extreme heat and cold during transit. Hidestrand et al. (2012) defined *extreme cold* is any temperature lower than 0 °C, and extreme heat is any temperature higher than 35 °C. Temperature extremes can affect the performance and quality of perishables (Joshi et al., 2012).

SCM practitioners can use information technology (IT) to track temperature excursions. The e3-control redesign methodology is an IT-enabled data collector, capable of both real-time temperature monitoring and global positioning (Liu et al., 2012). SCM practitioners can use IT to inform themselves of a problem, which gives SCM practitioners the ability to stabilize the shipment through re-icing or active refrigeration.

Organizational and Educational Requirements in the Medical Device Industry

SCM executives in the medical device industry could inadvertently cause harm to patients by failing to train their SCM practitioners in CCM from a regulatory and shipping perspective. Educated and experienced SCM practitioner have a working knowledge of the regulatory requirements needed to ship temperature-sensitive products globally from a storage and transportation perspective (Lis et al., 2009). These SCM practitioners are familiar with the International Air Transport Association regulations that govern packaging and labeling of DMDs (Lis et al., 2009). Knowledgeable SCM practitioners use CCSSs designed to maintain specific temperature ranges during transit (Lis et al., 2009). Properly selected shipping solutions ensure temperature-sensitive

products have fewer temperature excursions when shipped to hospitals and physicians' offices.

Medical device failures caused by temperature excursions could result in the misdiagnosis of a patient. To prevent these failures, SCM practitioners need advanced information systems and software to identify substandard supply chain performance and monitor expensive cold chain inventories (Zaffran et al., 2013). The utilization of supply chain technology requires well-trained SCM practitioners. Zaffran et al. (2013) suggested that hiring entities in developing countries should target professionally trained SCM managers. Ultimately, management is responsible for hiring employees into functional areas of the organization. Likewise, management hierarchy exists to allocate resources, including tools and education, necessary to help employees achieve performance standards (Zaffran et al., 2013). Thus, SCM executives must hire professionally trained SCM practitioners who can achieve organizational performance standards through the right technology to maintain all aspects of the cold chain.

SCM practitioners with CCM competency are invaluable to organizations that ship temperature-sensitive medical devices. The lack of CCM competency was a factor in how workers handled temperature-sensitive vaccines in India (Rao, Naftar, Baliga, & Unnikrishnana, 2012). Workers in India failed to store temperature-sensitive vaccines properly 10% of the time (Rao et al., 2012). The proper storage of temperature-sensitive vaccines is critical to the effectiveness of vaccines used in controlling preventable diseases. The gap associated with the improper storage of vaccines requires additional training in CCM (Rao et al., 2012).

SCM executives who are responsible for shipping temperature-sensitive products have some level of competency in CCM. Sharing of competency throughout the organization improves performance (da Silva Gonçalves Zangiski, de Lima, & da Costa, 2013). Therefore, SCM executives with specific CCM objectives are more likely to drive organizational learning to improve performance. Organizational learning starts with an individual's self-awareness into specific objectives (da Silva Gonçalves Zangiski et al., 2013). In consequence, there is a direct correlation between a leader's awareness and his or her action or inaction, which fits with the theory of the SCA model. Ultimately, SCM executives are responsible for CCM innovation within their organizations.

Regulatory Requirements for Distribution

SCM practitioners must be able to distribute DMD tests and controls while meeting regulatory and stability requirements. The FDA requires medical device manufacturers to ensure proper storage and distribution of DMD tests and controls (FDA, 2011). Storage and distribution requirements may vary for temperature-sensitive DMD tests and controls. For example, DMD test and controls may require ambient, cold, frozen, and ultra-low (cryogenic) temperatures for storage and distribution. Neri et al. (2013) explained that ambient shipping with long lead times and exposure to extreme heat could cause temperature-sensitive products to have false high readings. Therefore, temperature-controlled infrastructure and shipping solutions are required for compliant distribution of medical devices in warmer regions (Albertini et al., 2012). SCM practitioners who fail to use CCSSs for ambient or control room temperature products have higher frequencies of temperature excursions.

Temperature-sensitive diagnostic tests that use reagents and quality control panels require CCM (Palamountain et al., 2012). However, there are challenges associated with effective CCM, such as the lack of SCM expertise, product traceability, and poor health care infrastructure (Palamountain et al., 2012). These challenges can adversely affect the quality of DMD tests and controls (Palamountain et al., 2012). For example, inadequate infrastructure, transportation, training, and quality can undermine clinicians' ability to perform effective laboratory screening (Pruett et al., 2014).

In many countries, the lack of quality control in the supply chain has led to clinicians distrusting the precision of DMDs from a test results perspective (Palamountain et al., 2012). Maltha et al. (2013) asserted that diagnostic tests lacked information regarding the required storage temperatures on the outer packaging and the instructions for use. The lack of quality control may require regulatory agencies to increase their governance over the medical device industry. Strengthening of regulatory governance would encourage SCM executives to make improvements to their SCM practices (Palamountain et al., 2012), such as through the attachment of temperature control monitoring tags in a CCSS to indicate temperature excursions during transit (Maltha et al., 2013). End users might need training on how to manage temperature-sensitive products that arrive at their hospitals, laboratories, and physician offices (Maltha et al., 2013).

Developing countries struggle with the adoption of modern diagnostic technologies because of limited access to diagnostic laboratories, poorly trained health care workers, insufficient quality systems, and inadequate SCM capabilities (Mabey et

al., 2012). These modern diagnostic tests can use either blood from a finger prick or urine to generate test results (Singh et al., 2013). For example, there are diagnostic devices that use enzyme-linked immunosorbent assays, indirect immunofluorescent antibody tests, and direct agglutination tests that require CCM from the factory to the clinician (Singh et al., 2013). In addition, there is a functional difference between a diagnostic test and a rapid diagnostic test.

Laboratories run diagnostic tests on large analyzers while rapid diagnostic tests provide results within minutes in an environment that has minimal infrastructure (Yansouni et al., 2013). For example, GeneXpert and Abbott manufacture a test that helps in the diagnosis of trachoma, which is a preventable disease that causes blindness (Dize et al., 2013). Test specimens for trachoma were collected in Tanzania and shipped to the United States for analysis at Johns Hopkins University (Dize et al., 2013). SCM practitioners for Johns Hopkins University required frozen transit and the utilization of –80 °C storage (Dize et al., 2013). Complicated global shipments require SCM practitioners who are knowledgeable about CCM strategies. Cognitive mapping can identify SCM executives' knowledge of CCM strategies.

Cognitive Mapping

Leaders require various types of data to make decisions (Grötsch, Blome, & Schleper, 2013). Consequently, the cognitive rationalization of various types of data influences a leader's decision making (Grötsch et al., 2013). The fourth theme in the literature review is cognitive mapping as a tool used to gather unique insights into the how and why leaders make decisions that positively and or negatively influence their

organizations. In this section, I offer and contrast several mapping variants as a tool used in conducting this study.

Overview of cognitive mapping. Tolman (1948) introduced the concept of cognitive maps in a comparative analysis of rats and the clinical behaviors of human beings. The study drew a stark comparison between the natural tendencies of rats to those of human beings. Tolman established that rats and human beings have three dynamics in common: regression, fixation, and displacement. Regression leads to individuals' inability to cope with difficult situations, causing individuals to revert and to act in childish ways. Fixation leads to a strong focus on learned behaviors, making change difficult. Displacement of aggression onto other groups leads to individuals strictly aligning their goals, life, and immorality to those of the group while shunning all other groups. Consequently, Tolman warned that society should make every effort to prevent discriminatory behaviors among the races. Tolman's research led to various other cognitive map-based studies in the areas of psychology, education, urban planning, history, business, and management.

Ackerman et al. (1992) traced the technique of cognitive mapping to 1955 and Kelly's theory of personal constructs. Winter (2013) explained that the construct theory establishes that individuals actively construct their world. Therefore, researchers can use the construct theory to better understanding how individuals view the world (Ackermann et al., 1992). Constructs support a mixed-methods approach to research, making construct theory suitable for both quantitative and qualitative analysis (Winter, 2013). The use of cognitive mapping helps unravel constructs into meaningful insight.

Cognitive mapping is a key technique used by consultants to develop corporate strategy. Consultants use cognitive maps in live interviews to explore the decision maker's thought process for key strategies. Cognitive mapping is a versatile approach to operational research; it allows the researcher to understand the phenomenon from the interviewee's perspective (Ackermann et al., 1992). According to Ackermann et al. (1992), a researcher achieves insight into the phenomenon when he or she generates cognitive maps that are graphical representations of the interviewee's thoughts regarding a particular phenomenon. Researchers can use these maps to structure, organize, and analyze the interviewee's perspective of the phenomenon (Ackermann et al., 1992). The participative nature of cognitive mapping makes interviewees participants.

Participants who are decision makers may have direct influence over the activities of their respective organization (Grötsch et al., 2013). For the present study, I made sure participants had a direct influence on the phenomenon within their respective organization. Therefore, the cognitive maps generated by participants may lead to new knowledge or insights into a phenomenon, which may improve business practices or provide a better understanding of business decisions.

Mapping variants. I used Decision Explorer, a software product, to create different mapping variants. The three types of mapping variants are mind mapping, concept mapping, and cognitive mapping. I used Decision Explorer to explore each mapping variant to determine the most fitting mapping technique to conduct this study.

The first mapping variant explored was mind mapping. Mind mapping is a tool for exploring the central idea. Decision Explorer generates mind maps as a form of

brainstorming. Using Decision Explorer, I constructed a mind map and connected all of the associated variables surrounding my central idea. The identified outcomes of mind maps rendered this mapping variant unsuitable for conducting this study.

The second mapping variant explored was concept mapping. Concept mapping using Decision Explorer is similar to cognitive mapping. Concept and cognitive maps have nodes and links to illustrate concepts and relationships (Jones, van Kessel, Swisher, Beckstead, & Edwards, 2014). I used Decision Explorer to generate concept maps, which required the use of descriptive words for the nodes and relational labels for the links. Wood, Bostrom, Bridges, and Linkov (2012) described concept mapping as nodes that represent concepts or key ideas and links that represent the relationships between the concepts or key ideas. The identified outcomes of concept maps rendered this mapping variant unsuitable for conducting this study.

The third mapping variant explored was cognitive mapping. I used Decision Explorer to generate cognitive maps, which required the use of phrases for the nodes and directional labels for the links. Wood et al. (2012) explained that nodes represent the key ideas, while links express the relationship to the nodes in the form of arrows to indicate influences. The identified outcomes of cognitive maps rendered this mapping variant suitable for conducting this study. The application and assessment of cognitive mapping vary among scholars (Jones et al., 2014). Therefore, I explored the application of cognitive mapping for this study.

Application of cognitive mapping. The application of cognitive mapping in the areas of business and management is diverse. For example, cognitive mapping can

improve navigation tools by understanding how participants react cognitively to various navigational outputs (Ooms, De Maeyer, Fack, Van Assche, & Witlox, 2012). In addition, cognitive mapping has provided insight into how engineers perceive the strategic goals of management from an execution and obtainment perspective (Village, Salustri, & Neumann, 2013). Cognitive mapping helps users to understand how to build and improve trust in business relationships (Huang & Wilkinson, 2013). Additionally, cognitive mapping provides a comparative analysis of how marketing decisions may affect consumers (Usunier & Sbizzera, 2013).

Cognitive mapping is a tool and method used to understand the phenomenon from a research perspective. Buckley and Waring (2013) asserted that researchers could use mapping to capture multiple viewpoints when exploring a social phenomenon. Researchers use cognitive maps to probe deep into the nature of a phenomenon (Jones et al., 2014). The cognitive exploration into the phenomenon generates large amounts of information. I used Decision Explorer to manage, synthesize, and interrupt participants' cognitive maps associated with the phenomenon.

Cognitive mapping requires in-depth inquiry into the phenomenon, which could result in long interviews. For example, Septer, Dijkstra, and Stokman (2012) conducted 2-hour interviews when cognitively mapping participants. The time commitments associated with cognitive mapping could negatively influence the number of participants willing to partake in a study (Jetter & Kok, 2014). For example, Bostrom et al. (2015) solicited 100 interviewees through e-mail, but were only able to secure nine participants who shared a common interest and understanding of the phenomenon. Participants with

competing interests in a shared phenomenon can negatively affect the reliability of a study (Wood et al., 2012). Additionally, participants with overarching agendas can distort their recollections associated with the phenomenon (Jetter & Kok, 2014). The usage concerns of cognitive mapping expand beyond the selection criteria for participants. I address the various challenges associated with cognitive mapping in Section 2 of this study.

Transition

Section 1 of this study included the background, the problem, purpose, nature, conceptual framework, assumptions, limitations, delimitations, the significance of the research, and literature review. The foundation of this study tied directly to the literature review. I synthesized conceptual framework of six-change approaches model, historical overview of CCM, regulatory governance of medical devices, influences on CCM, CCSSs, organizational and educational requirements, product stability of tests and controls, and the application of cognitive maps from a research perspective in the literature review. The foundation of this doctoral study also lends to the development of the research methodology. In Section 2, I focused on the research methodology on the role of the researcher, participants, research method and design, population and sampling, ethical research considerations, data collection, data analysis technique, and reliability and validity of the doctoral study.

Section 2: The Project

Section 2 includes the methodology used for conducting this doctoral study. In this section, I revisit the purpose statement, explain my role as the primary data collection instrument, and review the participation requirements. Next, I explain the research method and research design, clarify the sampling plan and population, and review the plan for ethical research. I cover the data organization technique using Banxia Decision Explorer Version 3.3.2 and explain data analysis using cross-case synthesis to ensure reliability and validity. Lastly, I describe how the data analysis procedures follow the same linear sequence of steps presented in Section 3.

Purpose Statement

The purpose of this qualitative multiple case study design was to explore medical device executives' strategies for shipping temperature-sensitive DMD tests and controls. The target population consisted of SCM executives who work in the medical device industry. The geographic locations for participants were California, New Jersey, and Ireland.

Insight into the diversification or lack of standardization of CCSSs used by SCM executives in the medical device industry may contribute to CCM strategies, new knowledge, increased quality, and financial savings. The identification of CCM strategies could fast-track SCM executives' adoption of shipping solutions that mitigate temperature excursions that result in medical errors with patients. SCM executives who adopt CCM strategies may promote social and economic benefits on a global scale by reducing the medical errors that cause patient harm and death.

Role of the Researcher

I served as the primary data collection instrument in this qualitative multiple case study. Peredaryenko and Krauss (2013) characterized researchers as the primary data collection instrument in facilitating in-depth interviews. My objective as the primary data collection instrument was to provide a holistic account of the phenomenon of how and why DMD tests and controls lack standardized shipping strategies in the medical device industry. Fusch and Ness (2015) suggested that researchers should take steps to mitigate personal views during data collection and analysis. In this section, I account for (a) data collection, (b) associations with the phenomenon and participants, (c) personal bias mitigation, (d) ethical safeguards, and (e) rationale for the interview protocol. The effective execution of my role as the primary data collection instrument gave me an unbiased opportunity to understand the strategies used by SCM executives in shipping temperature-sensitive DMD tests and controls.

As the primary data collection instrument, I developed a trustworthy process for data collection. Data collection procedures improve the trustworthiness of research findings (Power & Gendron, 2015). The development of data collection procedures must occur before the presentation of case study findings (Hott, Limberg, Ohrt, & Schmit, 2015). Yin (2014) suggested that researchers should document the major tasks associated with the data collection procedures. Purposive sampling is a method used to categorize and target potential participants within a population (Harvey, Marshall, Jordan, & Kitson, 2015; Robinson, 2014). My first major task was to purposively identify SCM executives working in the medical device industry from my professional network, send participants'

an invitation letter, and formally evaluate participants eligibility to contribute to this doctoral study (see Appendix A and Appendix B). Brédart et al. (2014) described informed consent as a process that seeks individuals' participation while explaining the potential disadvantages, risks, and benefits associated with a study.

My second major task was obtaining participant consent for a 2-hour online interview designed to generate real-time cognitive maps. Baskarada (2014) explained that cross-case analysis is an iterative pattern-matching process that involves the use of case study data. My third major task was rendering conclusions through pattern and theme analyses of cognitive maps, triangulations, and cross-case analysis. Terrell (2012) noted that researchers must keep data confidential and available for an undisclosed amount of time. My fourth major task was the safeguarding of research data and participant information for 5 years beyond the conclusion of the study. Peredaryenko and Krauss (2013) found that researchers were susceptible to bias based on their personal experiences with the phenomenon. I disclosed my experience and association with the phenomenon and participants to help mitigate personal bias.

I am an SCM executive with more than 22 years of experience implementing across-the-board savings, innovation, and turnaround activities regarding people, process, systems, and infrastructure. I have managed ambient and temperature-controlled distribution centers totaling 1.7 million square feet and transportation fleets up to 140 trucks. I am responsible for distribution, import and export, logistics, refrigerated storage and transportation, flexible manufacturing, postponement, reverse logistics, inventory management, warehousing, R&D of CCSSs, and dry ice manufacturing. I have more

than 8 years of experience using CCM methodologies to ship and store DMDs in the medical device industry. CCM is a controlled methodology for properly storing and distributing temperature-sensitive products (Reddy et al., 2012).

Knowledgeable SCM practitioners use CCSSs designed to maintain specific temperature ranges during transit (Lis et al., 2009). I developed validated CCSSs that incorporated the latest innovations regarding materials, durability, insulation, packing efficiencies, year-round usability, and shock absorption. These validated CCSSs maintain DMD temperatures while mitigating flash freezing, excessive packaging, weight, and damage. I also developed an extensive network of SCM executives who work in the medical device industry. I purposively identified and selected participants from my network of SCM executives who have CCM experience in the medical device industry.

The rendering of unbiased conclusions is paramount to documenting new business strategies and social change. My direct knowledge and experience in CCM in the medical device industry could have caused me to introduce bias based on my personal experience of the phenomenon. I took steps to mitigate personal bias. Wolgemuth et al. (2014) advised that researchers should follow interview questions, accurately capture interview data, and validate captured interview data in real-time. In response to that advice, I developed interview protocols that helped me to ask probing questions based on my personal experience and propositions while avoiding leading questions. Baxter and Jack (2008) explained that researchers establish credibility by incorporating member checking into the data collection process, thereby validating the shared experiences of

participants. The proper rendering of conclusions is an important criterion in conducting research. I rendered conclusions based on the collected data and not my personal perceptions.

Administrators at Walden University promote the highest ethical standards for doctoral research by having students seek approval from the institutional review board (IRB). I ensured the humane and ethical treatment of participants through personal initiative and IRB review (see King, 2015). Representatives of the IRB ensure that students of Walden University comply with all ethical standards and other applicable laws and regulations (Walden University, 2012). All students attending Walden University must receive IRB approval before the collection or analysis of data (Walden University, 2012). Administrators at Walden University also require students to take the National Institutes of Health web-based training course on protecting human research participants and following the standards of the Belmont report. I completed this training on June 26, 2017 (Certificate Number 2424395). Brakewood and Poldrack (2013) defined the standards of respect, justice, and beneficence in the Belmont report. I met the standards of the Belmont report by (a) ensuring ethical data collection, (b) obtaining informed consent, (c) maintaining participant confidentiality, (d) preventing harm, and (e) ensuring equitable participant selection (see Yin, 2014).

Participants

I selected participants who could provide insights into the strategies used to ship temperature-sensitive DMD tests and controls. The selection of participants requires great care and rigor (Noonan, 2015). Properly selected participants are critical to

obtaining real-world insights into the phenomenon (Yin, 2014). To ensure appropriate selection of participants, I developed strategies for participant eligibility, accessibility, and collaboration.

The eligibility criteria for participants should coincide with the phenomenon under investigation. Faulkner, Tremblay, and Latimer-Cheung (2014) noted that participatory eligibility of participants correlates to their familiarity with the phenomenon under investigation. Greiner et al. (2015) explained that outlining the eligibility criteria ensures enrollment of appropriate participants. Murphy, Hevey, O'Dea, Rathaille, and Mulcahy (2015) identified the need to define eligibility criteria for the selection of participants.

I developed four eligibility criteria for this study. First, participants must have worked in the medical device industry. Second, participants must have had at least 5 years of CCM experience. Third, participants must have had national or global SCM responsibilities at the executive level. Finally, participants were required to have influence over CCM strategies in their respective organizations.

Addressing potential access limitations to participants was an important consideration for this study. Friedman, Lulinski, and Rizzolo (2015) found that unidentified access limitation adversely influences research results. Researchers should anticipate participant accessibility issues when determining a focus group (Savage, Moro, Boyden, Brown, & Kavanaugh, 2015). Power and Gendron (2015) found that researchers improve participant access when they select informants from their personal network. I used LinkedIn as a source for participants. My LinkedIn network includes more than

1,230 professionals. I narrowed my LinkedIn connection network to identify only SCM executives whom I had met during medical device conferences and forums over the past 8 years. I then purposively selected three SCM executives from my LinkedIn professional network who met the eligibility criteria. My selection tactic increased access to participants, based on the large population size of my professional network. As a result, a strategy for establishing a working relationship with participants was necessary.

I established a working relationship with participants through frequent and open communications that were welcoming and considerate. Deakin and Wakefield (2013) noted that researchers improve participant familiarity with a study through increased communications. The initial communications with participants in the current study consisted of an invitation letter, participatory eligibility form, and consent form. Informed consent is as important as respectful interactions (Brédart et al., 2014). My collaboration with participants included respecting their professional and personal time. Increased collaboration improves trust (Huang & Wilkinson, 2013). Kaczynski et al. (2014) found that gaining trust from a participant takes time. I maintained a professional working relationship with participants for the duration of the study.

Research Method and Design

I constructed the study by identifying the most fitting research method and design. The research methods considered for this study were quantitative, qualitative, and mixed-methods. The qualitative paradigm led to the consideration of the following qualitative research designs for collecting data: (a) narrative, (b) ethnographic, (c)

phenomenological, and (d) case study. From these choices, I determined that the multiple case study was the most appropriate design.

Research Method

I initially considered quantitative research as the paradigm to answer my research question of what strategies SCM executives use to ship temperature-sensitive DMD tests and controls. Terrell (2012) noted that quantitative research is the longstanding mainstay of the social sciences. Yilmaz (2013) defined quantitative research as a method used by researchers to gain an understanding of a phenomenon through statistical analysis. Statistical analysis involves examining variables to explain, fit, or predict another variable rather than to explore the various dimensions of a phenomenon. Fassinger and Morrow (2013) used quantitative methodology with large representative samples. Researchers typically ask a large number of participants a set of closed survey questions when performing quantitative studies (Brédart et al., 2014).

I then considered qualitative research as a method to answer my research question. Terrell (2012) used qualitative research to understand a phenomenon from a how or why perspective. Astalin (2013) defined qualitative research as a method used to construct a holistic and narrative view of a social or cultural phenomenon based on a researcher's observations, interviews, and review of documents. In conducting a study using a qualitative method, researchers ask participants in-depth and open-ended interview questions (Brédart et al., 2014).

I also considered mixed-methods to answer my research question. Thamhain (2014) explained that mixed-methods research includes both quantitative and qualitative

methods to investigate a phenomenon. Researchers approach the phenomenon with a quantitative perspective that is rational and a qualitative perspective that is intuitive (Thamhain, 2014). Cox (2012) found that researchers performing mixed-methods studies would incorporate the qualitative research components into a more dominant quantitative framework.

Having an in-depth understanding of each research method helped me choose the most fitting method. The appropriate application of a research method to a study is contingent on the researcher's knowledge of quantitative, qualitative, and mixed-methods research (Fassinger & Morrow, 2013). Researchers should consider the phenomenon, as well as the data collection and analysis methods when choosing a research method (Allwood, 2012). I rejected quantitative methodology based on the uniqueness of the nature of my study, including a small sample size, intrinsic data, and open-ended interview questions. I also rejected a mixed-methods approach because this method requires both quantitative and qualitative data.

I found the qualitative research method more fitting than the quantitative research method or mixed-methods. Halkier (2013) and Wolgemuth et al. (2014) noted the qualitative research method affords researchers a high degree of control and flexibility in constructing studies. Consequently, the analysis and synthesis of rich data may lead to new learnings, which could influence policies and or business practices. Yin (2014) asserted researchers obtain new knowledge when they use a qualitative method. Any new knowledge from this case study might apply to the medical device industry and the CCM bodies of knowledge.

Research Design

The qualitative research designs considered were narrative, ethnography, phenomenological, and case study. The initial constraint of the research design began with a baseline understanding of narrative and ethnography design. I conducted a literature review to understand the narrative and ethnography research designs.

Narrative research is a research design that primarily uses transcripts and interviews to explore the phenomenon (Smyth & McInerney, 2013). McClelland et al. (2015) concluded that narrative research is useful for understanding the lived experiences of participants. Fassinger and Morrow (2013) noted scholars are skeptical of narrative data that lack validity. I excluded narrative research based on the literature review and the phenomenon of interest.

Ethnography research is a research design used to interpret the social and cultural context of the phenomenon within the environment of occurrence (Astalin, 2013). Ethnography design requires the researcher to speak directly to participants, reflect, and draw a comparison to the larger community (Wolgemuth et al., 2014). Smyth and McInerney (2013) used ethnography to explore the lived experiences and viewpoints of disadvantaged young people. I excluded ethnography research based on the literature review and the phenomenon of interest.

Having an in-depth understanding of each research design helped me constrain the study to the most fitting research design. Baskarada (2014) explained the research design must include a means for evaluating the phenomenon. I constrained the research design choice by using cognitive mapping as my primary technique to explore the

phenomenon. Ackermann et al. (1992) remarked that consultants develop a corporate strategy by using cognitive mapping. Consultants use cognitive maps in live interviews to explore a decision maker's thought process by asking *how* and *why* questions. Village et al. (2013) noted researchers use cognitive maps to explain how participants gain knowledge. The use of cognitive mapping helped me to narrow the research design to phenomenological and case study.

The phenomenological design is a research design used to understand the lived experiences of individuals who share a common phenomenon (Wolgemuth et al., 2014). Researchers use phenomenological research to survey data and draw conclusions from the lived experiences of participants, which is ineffective for the real-time validating of cognitive views (Ackermann et al., 1992; Wolgemuth et al., 2014). Astalin (2013) concluded that researchers using phenomenological research design would generate awareness and not an in-depth understanding of the phenomenon. As a result of having conducted a review of the literature on this design method, I was able to narrow the research design to a case study.

Case study design is a research design used to study a recent phenomenon of interest within the environment of occurrence (Yin, 2014). The research design of case study is an excellent framework for exploring health and social sciences to improve the human condition (Baxter & Jack, 2008; Halkier, 2013; Wolgemuth et al., 2014). Yin (2014) explained that researchers use case study design to explore a phenomenon to add new learning. The selection of cases study design still required additional constraint.

I considered single case study and multiple case study designs based on a contemporary phenomenon. Single case study designs are typically less rigorous than multiple case study designs (Yin, 2014). Goffin, Raja, Claes, Szwejczewski, and Martinez (2012) asserted that methodological rigor is critical to qualitative research. A single case study is an investigation of a phenomenon based on a single case while a multiple case study is an investigation of a phenomenon occurring in multiple cases (Yin, 2014). Furthermore, case studies with one case are less rigorous than case studies with multiple cases. As a result of this distinguisher, I was able to narrow the case study design to a multiple case study.

Multiple case study is a research design used to provide a holistic understanding of how and why contemporary events occur through in-depth analysis (Yin, 2014). A multiple case study is an investigation of a phenomenon occurring in multiple cases. The purpose of this multiple case study design was to explore and synthesize a contemporary phenomenon occurring in the medical device industry. Applying a multiple case study design enabled me to obtain a deeper understanding of the shared experiences of participants, in each organization, through Skype interviews (Wolgemuth et al., 2014).

I used a multiple case study design to achieve data saturation through the number of cases analyzed. More specifically, I achieved data saturation by selecting and interviewing three SCM executives, familiar with the phenomenon, as independent case studies for their respective organization. McClelland et al. (2015) explained that data saturation occurs when three participants have closely aligned experiences to the phenomenon in a qualitative case study. Furthermore, participants are more likely to

reflect on their day-to-day decisions and experiences in a multiple case study design (Wolgemuth et al., 2014). Klassen and Vereecke (2012) retrospectively achieved data saturation after interviewing three to four managers in a multiple case study. Researchers use interviews to achieve data saturation (Fusch & Ness, 2015). Consequently, I asked qualified participants in-depth questions and followed up with member checking.

According to Yin (2014), multiple case studies are less susceptible to criticism than a single case study. For example, Klassen and Vereecke (2012) retrospectively obtained data saturation after interviewing three to four managers in a multiple case study. The application of cognitive mapping across individual participants helped me generalize the strategies across all participants. Therefore, a multiple case study design was fitting for this research.

I applied the typology for a case study to support my overall research design (see Figure 4). G. Thomas and Myers (2015) asserted that researchers use a case study to explore a subject of interest. I selected a key case as the subject of the study. G. Thomas and Myers (2015) claimed that a key case is a subject matter or topic that is of inherent interest to the researcher. The objective of this case study was CCSSs. The objective constitutes the analytical frame within the case (Thomas & Myers, 2015).

I selected an exploratory approach as the purpose for the study. The purpose of the study was to explore existing strategies and perhaps to identify or seek desirable strategies (Thomas & Myers, 2015). G. Thomas and Myers (2015) suggested a researcher's approach to conducting a case study influences the importance of the theory associated with the study. I selected theory building as the approach for the study. The

approach to the study may help identify the best CCM strategies for executives working in the medical device industry.

I selected multiple case study as the methodological choice for the study. G. Thomas and Myers (2015) remarked that researchers must choose between single and multiple case study as the methodological choice. The process supports the interviewing of multiple subjects separately (Thomas & Myers, 2015). I chose multiple parallels as the process for the study. Multiple case study design was fitting for this study because I was able to explore a specific case of interest and gain new insights into CCSSs.

G. Thomas and Myers (2015) remarked that researchers use a case study to explore a subject of interest. I was able to identify new CCM strategies and advance these strategies within the medical device industry. Yin (2014) proposed researchers use theory building to explore theories and propositions. I used the theory established in the SCA model by conducting interviews with executives who worked in the medical device industry.

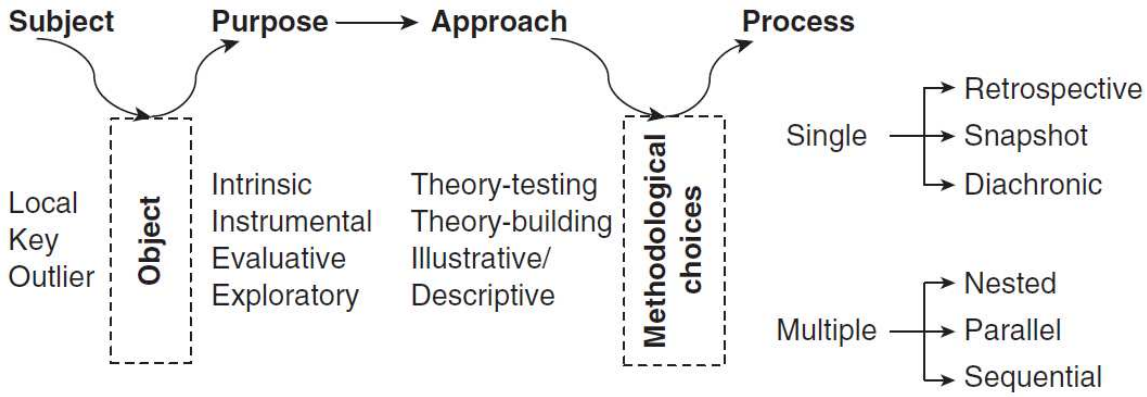


Figure 4. A typology of case study. Reprinted from *The Anatomy of the Case Study*, by G. Thomas and K. Myers, 2015, p. 64. Copyright 2015 by G. Thomas & K. Myers. Reprinted with permission (see Appendix C).

Population and Sampling

In this multiple case study, the population was SCM executives who worked for global medical device companies and met the defined eligibility criteria. The geographic locations for participants were California, New Jersey, and Ireland. Poulis, Poulis, and Plakoyiannaki (2013) advised researchers to consider the population that is most capable of providing insight into the research question designed to explore a phenomenon of interest. Olsen, Orr, Bell, and Stuart (2012) suggested researchers could achieve external validity when the targeted population determines the participating company. The population came from three medical device companies, which could include subsidiaries. The population had life history homogeneity in the cognitive connections to the phenomenon, regardless of proximity (Robinson, 2014). Therefore, the sample frame was SCM executives who oversee CCM and cold chain strategies in the medical device industry.

I selected purposive sampling on the assumption that voluntary participants were knowledgeable and more truthful than participants who do not have a rich understanding of the phenomenon. I also considered the study was representative of a niche within the medical device industry, which made only uniquely qualified executives capable of addressing my overarching research question. As a result, I purposively selected three SCM executives from my LinkedIn professional network who met the criteria of the population and sample frame.

Using a purposive sampling strategy is appropriate for a qualitative multiple case study design (Baxter & Jack, 2008). Yilmaz (2013) concluded that purposive sampling is appropriate for conducting qualitative studies with a unique case or few participants. For example, Jaros and Saberwal (2013) used purposive sampling as a means of targeting participants who had the first-hand experience with a shared phenomenon in a qualitative case study. Purposive sampling is a method used to categorize and target potential participants within a population (Harvey et al., 2015; Robinson, 2014).

I achieved data saturation from a sample size of three SCM executives. I have illustrated the process of obtaining data saturation by coding each SCM executive as Case 1, Case 2, and Case 3. Data saturation occurs when three participants have closely aligned experiences to the phenomenon in a qualitative case study (McClelland et al., 2015). Morse (2015) indicated that saturation occurs when the scope and replication are rich in data. Researchers can obtain scope that is comprehensive and in-depth through open-ended interviews (Morse, 2015). Researchers use interviews to achieve data saturation (Fusch & Ness, 2015).

The literal replication of this case study required each of the three SCM executives to function as an independent holistic case study (Yin, 2014). As stated previously, I coded each SCM executive as an independent case study, with each case study forming a cognitive map. Thus, I achieved data saturation by combining the first cognitive map, Case 1, with the second cognitive map, Case 2, to form a single cognitive map of Case 1 and Case 2.

Next, I incorporated the third cognitive map, Case 3, and reviewed for any potential changes. The complete incorporation of the third cognitive map resulted in the final cognitive map for Case 1, Case 2, and Case 3. Therefore, the sample size of three SCM executives as individual case studies was fitting, based on Yin's (2014) perception that multiple case studies are less susceptible to criticisms than a single case study. The replication of this study also ensured each participant was familiar with the phenomenon (Morse, 2015). Klassen and Vereecke (2012) retrospectively achieved data saturation after interviewing three to four managers in a multiple case study. Lastly, researchers achieve data saturation through data triangulation (Fusch & Ness, 2015).

In this section, I elaborate on criteria for participant selection based on the reviewed literature and the phenomenon of interest. Jessiman (2013) targeted participants based on personal experience and the review of the literature. The purposive sample size of three SCM executives correlated with their first-hand experiences with DMD tests and controls lacking standardized shipping practices in the medical device industry. Purposive sampling is a method used to target potential participants within a population (Harvey et al., 2015; Robinson, 2014). Jaros and Saberwal (2013) explained

that purposive sampling is effective for targeting participants with first-hand experience about a specific phenomenon. Consequently, I selected SCM executives who had 5 years of CCM experience in the medical device industry.

Defining the interview setting occurred before scheduling interviews with participants. The interview setting for this study was online rather than in person, which gave flexibility to each participant regarding his or her physical setting. Brédart et al. (2014) noted that data collection improves when participants feel safe and comfortable in the interview setting. In addition, Janghorban, Roudsari, and Taghipour (2014) found that researchers could help key informants improve their interview setting through the utilization of Skype as a free online service for conducting real-time interviews. I contacted each of the participants through an e-mail to determine a mutually convenient date and time for his or her online interview.

Each online interview conducted via Skype lasted approximately 2 hours. Akard, Wray, and Gilmer (2014) noted that web-based communication tools are effective for data collection. For example, Skype is an effective real-time interviewing medium for conducting interviews that may range from 30 minutes to 2 hours (Nind, Wiles, Bengry-Howell, & Crow, 2013). I also contacted participants through e-mail 48 hours before their online interview to reconfirm the scheduled interview date and time. My proactive follow-up with participants might have helped to eliminate any potential scheduling conflicts that could have jeopardized my ability to engage each participant for the full 2 hours.

Ethical Research

I obtained my IRB approval number 10-06-17-0352801 before conducting this study. Akard et al. (2014) explained that IRB approval is an institutional requirement. IRB administrators ensure researchers meet ethical and regulatory standards (Cseko & Tremaine, 2013). King (2015) noted that the IRB provides ethical guidance to researchers to protect the welfare of research participants. Ethical research is a critical component in the overall process of protecting participants. I covered the ethical mechanisms for protecting participants through informed consent, participant withdrawal, individual and organizational confidentiality, and data security.

I protected human research participants by ensuring informed consent and explaining voluntary withdrawal. Brédart et al. (2014) outlined informed consent as a process through which the researcher seeks individuals' participation while explaining the potential disadvantages, risks, and benefits associated with a study. Janghorban et al. (2014) concluded that researchers could obtain informed consent online or through e-mail. Failure to obtain informed consent could result in participant harm (King, 2015).

I obtained informed consent by sending participants an e-mail explaining the ethical research process and having them sign my IRB-approved consent form. Brédart et al. (2014) outlined voluntary withdrawal as a right that participants have to end their participation in a study. Janghorban et al. (2014) expressed that participants who experience uneasiness during an online interview could withdraw with a push of a button. I ensured all participants were aware that their participation in this study was voluntary and that they could withdraw at any time from the study for any reason whatsoever.

I purposively selected participants who wanted to provide free insights into CCM strategies. Cseko and Tremaine (2013) explained that researchers should justify compensation when the research may pose a minimal risk to participants. Hadidi, Lindquist, Treat-Jacobson, and Swanson (2013) found that compensation did not adequately account for participants' time in a study. Jessiman (2013) suggested thanking participants and sharing results as a substitution to compensations. Therefore, participants did not receive monetary compensation for their participation in this study. However, I thanked participants and committed to sharing the published doctoral study in recognition of their contributions.

The process of collecting data required me to protect the privacy of participants and confidential data. Cseko and Tremaine (2013) concluded that researchers are responsible for protecting the privacy of participants while keeping data confidential. I protected the identity of each participant and their employer by coding their identities. I also coded participants and their employer as Case 1, Case 2, and Case 3, followed by the participant's geographical area of responsibility, as shown in Table 4. Brakewood and Poldrack (2013) noted that researchers must have effective database security to maintain confidentiality. I maintained electronic data on a password-protected computer and physical data in a locked, tamper-proof, and fire-resistant safe throughout the study period. Terrell (2012) noted that researchers must keep data confidential and available for an undisclosed amount of time. I will ensure electronic and physical data undergoes destruction 5 years from the publication date of this study.

Table 4

Confidential Coding for Each Participant and Employer

Participant and employer	Geographical responsibility	Interview questions and answers
Case 1	TBD	0001–0999
Case 2	TBD	1000–1999
Case 3	TBD	2000–2999

Data Collection Instruments

I served as the primary data collection instrument in this qualitative multiple case study. Kaczynski et al. (2014) remarked that researchers are the human instrument in qualitative studies, based on their data collection methodology and analysis. Peredaryenko and Krauss (2013) theorized that human instruments that were researcher-centered would take a methodical approach to data collection, based on their existing knowledge of the phenomenon. Peredaryenko and Krauss classified researchers as the primary data collection instrument. As the primary data collection instrument, I collected, organized, and analyzed in-depth interviews with the aid of Decision Explorer.

I conducted in-depth interviews in real-time using a semistructured approach and posing open-ended interview questions. Interviews took place online and utilized video conferencing by Skype. Yin (2014) asserted that prolonged case study interviews are effective in gaining a rich and in-depth understanding of the nature of the phenomenon. Yin (2014) suggested that researchers using a semistructured approach and open-ended interview questions should adopt a conversational tone with informants. Yilmaz (2013) defined posing open-ended interview questions as an unbiased means for researchers to gain an understanding of participants' experiences. Wolgemuth et al. (2014)

recommended that researchers should follow interview questions, accurately capture interview data, and to validate captured interview data in real-time. Therefore, I recorded each online interview should future data verification be required.

I could also have collected secondary sources of data. Yin (2014) stated that secondary sources of data help researchers corroborate multiple sources of information. The collection of secondary sources of data such as company information affirms or refutes primary data through triangulation. Stanger et al. (2012) explained researchers triangulate multiple sources of data to understand the phenomenon without bias. Kaczynski et al. (2014) determined that researchers who triangulate data sources improve the rigor and creditability of their study. Therefore, I triangulated primary data inputted into Decision Explorer with secondary data made available by participants.

Decision Explorer is a data analysis instrument (Ackermann et al., 1992). I purchased Decision Explorer from Banxia to obtain software usage rights. I attached a copy of my receipt that indicates my purchase of Decision Explorer (see Appendix D). I presented data entered into Decision Explorer in the appendices, as indicated in Section 3 of this study. Baskarada (2014) noted that researchers are responsible for performing the research procedures associated with collecting data. Peredaryenko and Krauss (2013) asserted researchers are the primary data collection instrument. Hence, it was my responsibility to collect and input data directly into Decision Explorer. As a result, I did not need to provide software usage training to participants or to make adjustments or revisions to the functionality of Decision Explorer.

I inputted real-time interview data into Decision Explorer. I then used Decision Explorer to construct cognitive maps based on my real-time collaboration with participants. These cognitive maps are in the appendices. Septer et al. (2012) established that cognitive maps could capture a participant's rationale, which in turn provides insight into the participant's decision-making process. Ackermann et al. (1992) remarked that researchers could use Decision Explorer to understand the phenomenon from the interviewee's perspective. Researchers can then structure, organize, and analyze each interviewee's perspective on the phenomenon (Ackermann et al., 1992).

I used the collaborative functionality of Decision Explorer to improve the validity of collected data. Brédart et al. (2014) achieved validity by performing in-depth interviews that elicited patients' experiences. I obtained validity by giving participants an opportunity to member check the real-time construction of cognitive maps. Houghton, Casey, Shaw, and Murphy (2013) defined member checking as an acknowledgment from participants that the transcriptions of their interview are accurate. I entered real-time interview responses into Decision Explorer and gave participants the opportunity to acknowledge the accuracy of my inputs through member checking. Baxter and Jack (2008) reported that researchers establish credibility by incorporating member checking into the data collection process, thereby validating the shared experiences of participants in real-time. The use of an in-depth interview improved the reliability of the study from a consistency perspective.

Furthermore, I ensured reliability by using Decision Explorer as a database and by recording interviews. Baxter and Jack (2008) concluded that databases and recordings

improve the reliability of case studies by giving researchers the ability organize, store, search, and retrieve collected data. For example, a recording of a member-checked interview gave me the ability to reconstruct a cognitive map previously generated in Decision Explorer. I reconstructed a cognitive map by inputting recorded data from an interview into Decision Explorer. I used a transcriber from TranscriptionPuppy.com to transcribe my interviews. Lastly, I obtained a signed confidentiality agreement from the transcriber who worked for TranscriptionPuppy.com before utilizing the transcription services (see Appendix E).

Triangulations of scholarly works function as converging lines of inquiry to the cognitive data obtained in each case study (Yin, 2014). Yin (2014) determined researchers achieve reliability by performing an individual case question and answer process on the overarching research question, interview questions, and the theory that supported the conceptual framework for this study. Yin (2014) asserted that the question and answer process gives readers the ability to perform cross-case analysis on the data collected in a study. The analytical technique of cross-case synthesis may provide new understanding into the phenomenon of how and why DMD tests and controls lack standardized shipping practices in the medical device industry.

I did not conduct a pilot test or study. Yin (2014) defined a pilot study as an initial case study for determining research questions and the protocol. Poulis et al. (2013) found that pilot studies help to determine the population. For example, Bowden and Galindo-Gonzalez (2015) used a pilot study to target participants based on limited funding.

Data Collection Technique

I used the data collection technique to provide a credible explanation on how and why SCM executives thoughtfully select, manage, and control the cold chain shipping of DMD tests and controls. I also explained the advantages and disadvantages associated with the data collection technique. Elo et al. (2014) suggested researchers improve the trustworthiness of a study by designing an effective data collection process. Platt and Skowron (2013) found researchers gain interview consistency when they use an interview protocol.

Fusch and Ness (2015) explained that data collection, coupled with the correct research design, increases the likelihood that a researcher will be able to answer his or her research question. Elo et al. (2014) suggested purposive sampling could lack trustworthiness when the researcher fails to elaborate on the sampling method. Therefore, I ensured my data collection technique was consistent and provided insight into the overarching research question. The overarching research question that directed this study was, "What are the strategies some medical devise executives use for shipping temperature-sensitive DMD tests and controls?"

I conducted in-depth interviews via Skype. Wolgemuth et al. (2014) found researchers could effectively use Skype to conduct in-depth interviews lasting 1 to 3 hours. In addition to the real-time interviews, participants either member-checked the real-time construction of their cognitive maps or I scheduled a follow-up meeting. Baxter and Jack (2008) explained researchers establish credibility by incorporating member checking into the data collection process, thereby validating the shared experiences of

participants. Furthermore, Wolgemuth et al. suggested that researchers should follow interview questions, accurately capture interview data, and validate captured interview data in real-time.

I now elaborate on the disadvantages associated with the data collection technique. Fusch and Ness (2015) explained that data collection is unique, which makes data saturation inconsistent between studies. Moreover, defective data collection can adversely influence the trustworthiness of a study (Elo et al., 2014). Wolgemuth et al. (2014) found that researchers who shared their experiences associated with the study provoked participants to be less forthcoming during the interview. As a result, I followed my participant scheduling and online interview protocol (see Appendix F).

A data collection technique begins with the scheduling of participants. Granot, Brashear, and Cesar Motta (2012) remarked that participants are stakeholders in determining the interview schedule. I collaborated with participants to determine the feasibility of an online interview via Skype. Wolgemuth et al. (2014) found researchers could effectively use Skype to conduct in-depth interviews lasting 1 to 3 hours. I determined a mutually acceptable date and time for a 2-hour online interview with each participant.

Granot et al. (2012) noted researchers must determine if participants are willing and capable of using Skype as a means of conducting the interview. Therefore, I confirmed each participant was familiar Skype and, if necessary, provided a link for participants to download Skype before their interview. I also contacted the participants 48 hours before their scheduled interview. Finally, 24 hours before each scheduled

interview, I ensured all interviewing essentials, such as a laptop, Skype, and Decision Explorer were fully functional.

I followed my interview protocol to conduct each of the three online interviews using Skype. Condie (2012) explained that the interview protocol is a series of verbal prompts that researchers use to interview systematically. I followed these steps to collect the interview data. First, I asked an interview question, as outlined in the interview protocol. Next, I recorded the participant's response directly into Decision Explorer.

Baxter and Jack (2008) asserted that member checking increases the credibility of a study by giving participants an opportunity to clarify and correct shared data. I confirmed with the participants that I accurately captured their answers to my questions. I posed follow-up questions as needed. The purpose of these follow-up questions was to gain an in-depth understanding of each interview response to each question, which corresponded to a specific proposition (Yin, 2014). I then asked follow-up questions aligned to the proposition, such as how or why questions to obtain additional insight into the original answer and enter participant feedback into Decision Explorer. Once again, I confirmed with the participants that I accurately captured their answers to my follow-up questions. I followed this reiterative process for each interview question and performed real-time member checking until there were no new data.

Data Organization Technique

Data collected for this study included Skype interviews, electronic journals, company information, and supporting literature. I organized the collected data on my computer with the aid of qualitative data analysis software. Baxter and Jack (2008)

remarked that researchers could improve case study reliability by using computer-aided qualitative data analysis software for data collection and organization. Baxter and Jack asserted that databases improve the reliability of case studies because databases provide researchers the ability to organize, store, search, and retrieve collected data. Ackermann et al. (1992) suggested researchers could use Decision Explorer to structure, organize, and analyze each interviewee's perspective on the phenomenon. Therefore, data organization occurred directly within Decision Explorer, which is software designed for data collection, organization, and analysis.

Because I collected the data, I was obliged to protect the privacy of participants and their confidential data. Cseko and Tremaine (2013) asserted researchers are responsible for protecting the privacy of participants while keeping data confidential. Furthermore, Brakewood and Poldrack (2013) stated that researchers must have effective database security to maintain confidentiality.

Terrell (2012) noted that researchers must keep data confidential and available for an undisclosed amount of time. I will maintain electronic data on a password-protected computer and physical data in a locked, tamper-proof, and fire-resistant safe for 5 years. I will wait for 5 years from the publication date of this study before I destroy all electronic and physical data.

Data Analysis

I used data triangulation to analyze the data collected for and generated in this study. Yin (2014) suggested that researchers should conduct data triangulation when they use multiple sources of data, such as documents, field notes, archival records, and

open-ended interviews to develop converging evidence that explains the phenomenon. Yin (2014) stated that secondary sources of data help researchers corroborate multiple sources of information. Furthermore, the use of multiple sources of evidence improves the internal validity associated with case study research (Yin, 2014).

Goffin et al. (2012) explained that researchers could increase internal validity by incorporating multiple sources of data in their study. The collection of secondary sources of data such as company information could affirm or refute primary data through triangulation. Stanger et al. (2012) recommended that researchers should triangulate multiple sources of data to understand the phenomenon without bias. Kaczynski et al. (2014) asserted that triangulated data sources improve the rigor and creditability of a study.

Chenail (2012) noted researchers who perform data collection must also perform data analysis. As such, after having completed the data collection process, I began my analysis of the data by using Decision Explorer as a tool to view the data. Ackermann et al. (1992) remarked that researchers use Decision Explorer to analyze large amounts of data collected during interviews. Decision Explorer requires researchers to define how the instrument is utilized (Ackermann et al., 1992). Ackermann et al. asserted researchers must use open-ended interview questions to construct cognitive maps.

The interview questions are in Appendix G. Yin (2014) suggested that prolonged case study interviews should be semistructured and involve open-ended interview questions to guide the conversation through a series of follow-up questions, such as *how* and *why* questions. The purpose of posing follow-up questions was to gain an in-depth

understanding of participants' responses to each interview question, which corresponded to a specific proposition (Yin, 2014).

Decision Explorer is a software program that researchers can use to help identify themes and patterns associated with the phenomenon (Ackermann et al., 1992). Yilmaz (2013) explained that researchers who perform proper data analysis could identify themes. Yin (2014) proposed researchers use theory-building to explore theories and propositions. I correlated key themes to the conceptual framework, propositions, and new literature supporting the study. Baskarada (2014) suggested that researchers should use data analysis to correlate themes to theories and propositions.

I used propositions to provide structure to the interview process. I coded each proposition to specific interview questions to analyze the interview data stored in Decision Explorer, as shown in Appendix H. Yin (2014) explained that researchers use propositions to provide structure in asking follow-up questions. Propositions are broad statements that summarize the goals a study explores (Yin, 2014). Ackermann et al. (1992) suggested that researchers list goals at the top of the cognitive map when they use Decision Explorer. I demonstrated how to create a link between a proposition and interview question using Decision Explorer (see Figure 5).

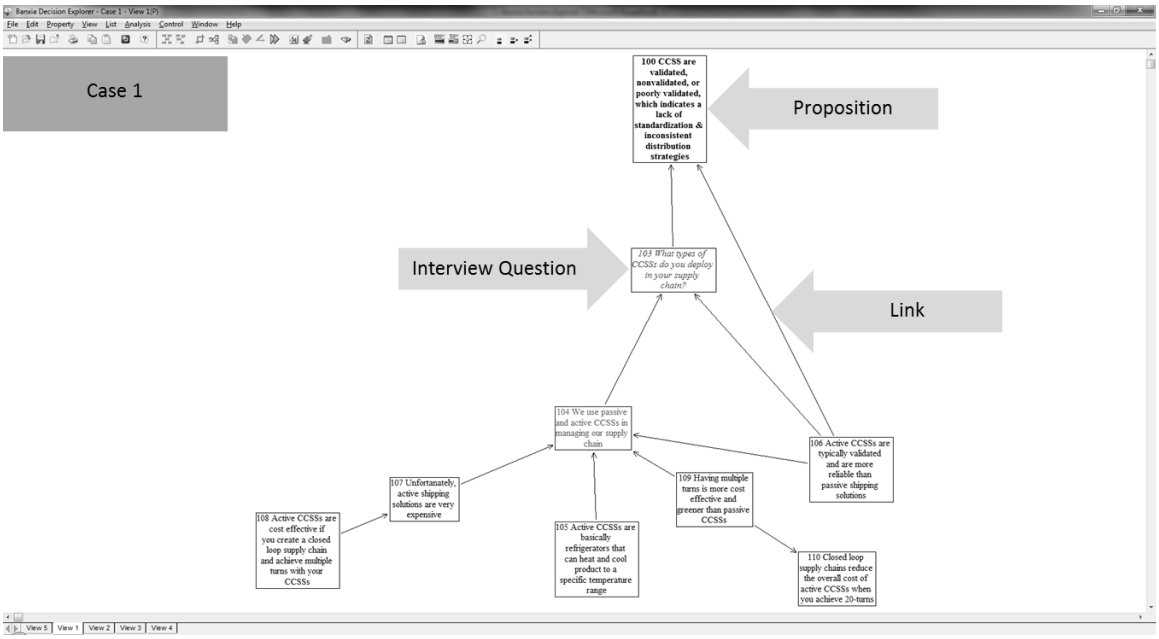


Figure 5. Cognitive map illustrating an interview question linked to a proposition.

I coded all interview data into Decision Explorer. I numerically coded the propositions, interview questions, and interview answers in Decision Explorer for each case, as shown in Appendix I. I also color-coded the text to help identify the data in each cognitive map generated in Decision Explorer. The text was color-coded as follows: (a) propositions are black, (b) interview questions or goals are red, (c) interview answers or key issues are green, and (d) follow-up answers or supporting facts are black. The last coding step is linking key issues and supporting facts to each goal. Linkage coding enabled me to explore the consequences of a particular concept from a how and why perspective. For example, *how* questions shown as downward arrows (↓) between linked concepts and *why* questions shown as upward arrow (↑) between linked concepts. The real-time coding of linked concepts provided me with additional insight into each

interview question. I now demonstrate the entry of follow-up answers and the linkage to the first interview answer entered into Decision Explorer (see Figure 6).

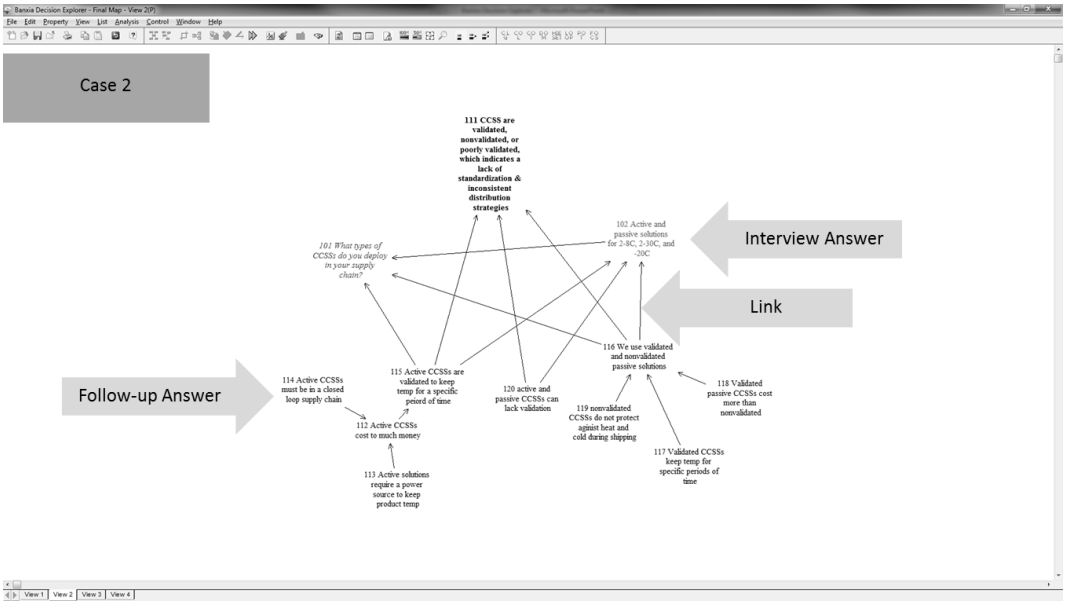


Figure 6. Cognitive map illustrating the entry and linkage of follow-up answers.

The last step in the cognitive mapping process results in the creation of the final map. Village et al. (2013) explained that researchers use cognitive maps to explain how participant obtain knowledge. To create the final map, I addressed the analysis of data on answering the propositions associated with this study. These propositions helped me to focus on and sort my data, which increases my likelihood of completing this study (Baxter & Jack, 2008). To complete this study, I needed to create case-specific maps by analyzing and synthesizing answers to each interview question.

Mullins and Soetanto (2013) found cognitive maps are a means to clarify issues and themes. I triangulated the three individual case-specific maps to help identify key themes. Then, I created a final map through cross-case synthesis. Septer et al. (2012) concluded that cognitive maps could capture a participant's rationale, which in turn

provides insight into his or her decision-making process. Therefore, the final map may contribute to new knowledge or insights, increased quality, financial savings, and improved patient safety from a social change perspective in the medical device industry. I now illustrate how to consolidate two case studies into a final cognitive map using Decision Explorer (see Figure 7). The cross-case analysis of all case studies into a final map helped me to gain insight into the goals and CCM strategies deployed by SCM executives in the medical device industry.

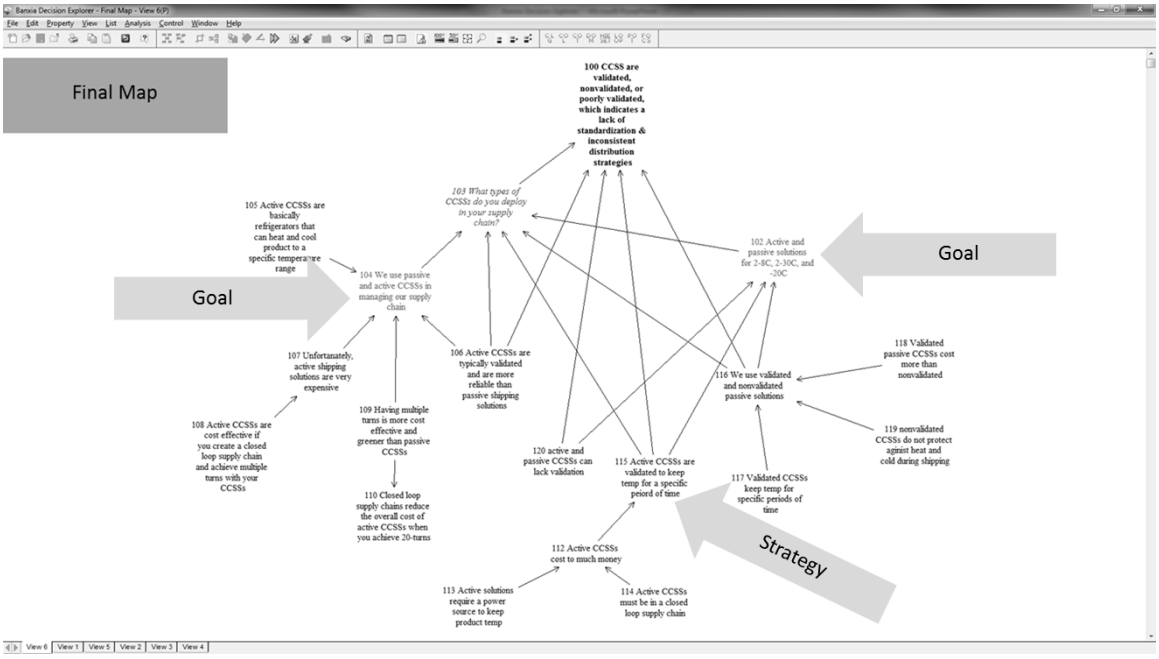


Figure 7. Two cognitive maps consolidated into a final cognitive map.

Reliability and Validity

The incorporation of reliability and validity into the construct of this qualitative multiple case study was critical to establish its trustworthiness and credibility. Qualitative research achieves trustworthiness and quality by rigorously applying the

concepts of dependability, credibility, transferability, and confirmability as common themes throughout the study (Thomas & Magilvy, 2011). Yin (2014) stated that reliability and validity are key criteria for judging the quality of a case study. E. Thomas and Magilvy (2011) noted that reliability and validity are methods for establishing trust and confidence in qualitative research.

Reliability

The collection of dependable data is paramount to the reliability of qualitative research (Thomas & Magilvy, 2011). Reliability allows an outside researcher to follow the protocols that guided a study and reach the same conclusions (Thomas & Magilvy, 2011). Protocols are operational steps that produce the same results when followed (Yin, 2014). The use of well-defined protocols can improve the dependability of a study by minimizing potential errors and personal biases (Yin, 2014). To ensure dependability, I thoroughly documented the protocols used to construct and conduct this study.

Validity

Validity is a key attribute of scientific research (Brédart et al., 2014). To ensure the validity of this qualitative study, I applied the concepts of credibility, confirmability, transferability, and data saturation. I also demonstrated the validity of this study by reviewing the protocols used for member checking, triangulation, participant selection, and data collection and analysis.

I established the credibility of this case study by conducting member checking, triangulation, and cross-case synthesis. E. Thomas and Magilvy (2011) stated that qualitative research becomes credible when researchers ensure the representativeness of

all collected data. Koelsch (2013) asserted that researchers achieve validity through member checking participants' responses during interviews. Therefore, I gave participants an opportunity to member-check their cognitive maps during the real-time construction of those maps to ensure the data were representative.

Baxter and Jack (2008) asserted that member checking increases the credibility of a study by giving participants an opportunity to clarify and correct shared data. This study has credibility because the interview data were member-checked and triangulated through the cross-case synthesis of each case (Yin, 2014). The triangulation of multiple data sources helps researchers understand the phenomenon without bias (Stanger et al., 2012).

I also performed cross-case syntheses for each case. Baskarada (2014) explained that researchers use cross-case analysis as an iterative pattern-matching process using case study data. Researchers perform cross-case analysis in a multiple case study after analyzing each case (Derqui, Fayos, & Fernandez, 2016). Researchers use cross-case analysis to obtain an in-depth understanding of the phenomenon (Derqui et al., 2016). Cross-case synthesis helped me understand how the research question, propositions, interview questions, and theory interrelate from a holistic view of the phenomenon (Yin, 2014).

E. Thomas & Magilvy (2011) indicated that confirmability is an achieved when a researcher establishes credibility, transferability, and dependability in a study. Moreover, confirmability serves as an audit trail that outlines the decision made by a researcher

throughout the study (Houghton et al., 2013). The audit trail justifies the rationale and methodological decision making of the researcher (Houghton et al., 2013).

Goffin et al. (2012) stated that researchers achieve conformability when interview data represent a participant's own words. To ensure the confirmability of raw data, I developed an audit trail that clearly outlines interview questions, propositions used to guide this study, coding, and the utilization of Decision Explorer during the data analysis. I also achieved confirmability by maintaining all electronic and physical data collected during this study and will continue to do so for 5 years from the publication date of this study.

Transferability is another important concept relevant to qualitative research. Transferability deepens the trustworthiness of a study (Thomas & Magilvy, 2011). E. Thomas and Magilvy (2011) noted transferability occurs when a researcher provides an in-depth description of the population, demographics, and geographic boundaries used to conduct a study. To improve transferability, I provided a rich description of the purposive sampling, identification, and screening of voluntary participants. Purposive sampling is a method used to categorize and target potential participants within a population (Harvey et al., 2015; Robinson, 2014). Jaros and Saberwal (2013) found purposive sampling is an effective means to target participants with first-hand experience about a specific phenomenon.

I achieved data saturation by selecting and interviewing three SCM executives, familiar with the phenomenon, as independent case studies for their respective organization. McClelland et al. (2015) explained that data saturation occurs when three

participants have closely aligned experiences to the phenomenon in a qualitative case study. Klassen and Vereecke (2012) retrospectively achieved data saturation after interviewing three to four managers in a multiple case study. Researchers use interviews to achieve data saturation (Fusch & Ness, 2015). Consequently, I asked qualified participants in-depth questions and followed up with member checking. I also reviewed multiples sources of data by conducting a comprehensive review of my interview notes and interview transcripts.

Transition and Summary

Section 2 of this study included a restatement of the purpose statement, followed by a discussion of the role of the researcher, participant selection process, research method and design, population and sampling, ethical research, data collection instrument, technique, and organization, data analysis, reliability, and validity. Section 2 also included a discussion of the in-depth research strategy the researcher employed to achieve a greater understanding of the central phenomenon associated with the lack of standardization of CCSSs, which creates inconsistent practices in the distribution of DMD tests and controls in the medical device industry. The research strategy and analysis supported the finding that may improve business practices while positively influencing social change. Section 3 of this study includes the findings of this study, how these findings can influence professional practices, the implication of these finding for social change, recommendations for action and further research, and the overarching conclusion of the research.

Section 3: Application to Professional Practice and Implications for Change

The objective of this qualitative study was to explore the strategies some medical device executives use for shipping temperature-sensitive diagnostic medical device (DMD) tests and controls. Section 3 details the research findings, applications to professional practice, implications for social change, and recommendation for action and further study. I present the strategies that medical device executive may use to ship temperature-sensitive DMD tests and controls. This section closes with self-reflection and a conclusion.

Introduction

The purpose of this qualitative multiple case study was to explore the strategies medical device executives use for shipping temperature-sensitive DMD tests and controls. The complexity of supply chain management (SCM) makes it difficult to identify with clarity the various interdependent strategies. To achieve this goal, I used the qualitative research methodology to identify the strategies SCM executives deploy in the selection, management, and implementation of cold chain shipping solutions (CCSSs) in the medical device industry. I recruited three SCM executives who work in the medical device industry in California, New Jersey, and Ireland. Findings indicated how to develop valid CCSSs, gain regulatory compliance, and achieve cold chain management (CCM) for shipping temperature-sensitive DMD tests and controls.

I collected, organized, and analyzed data to identify the strategies some medical device executives use for shipping temperature-sensitive DMD tests and controls. Ackermann et al. (1992) noted that researchers could identify corporate strategies using

Decision Explorer. I applied the tool's analytical workflow to develop and present the end-to-end strategies (see Figure 8). First, I identified 386 distinct concepts using the central analysis functionality in Decision Explorer. The central analysis focuses concepts on centrality to indicate how concepts influence the model. Then, I consolidated the concepts into nine themes using the collapse analysis functionality in Decision Explorer. Collapse analysis focuses concepts with meta-links into specific themes chained to an argument. Finally, I used pattern matching to group and synthesize the themes into three end-to-end strategies.

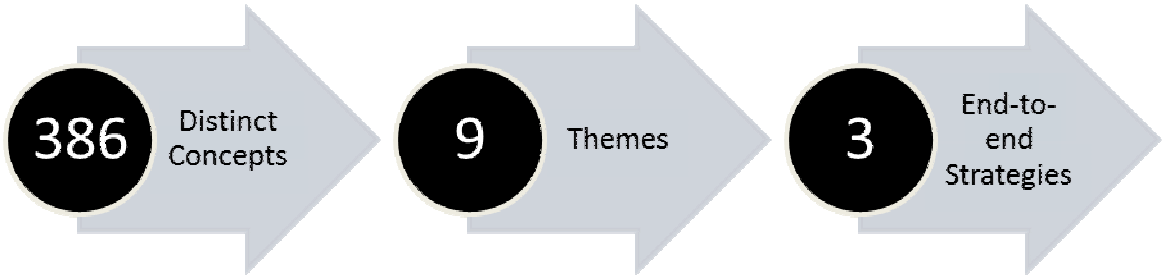


Figure 8. Analytic workflow from concepts to strategies.

The analysis of interview data in Decision Explorer revealed that 16 interview questions generated 386 distinct concepts, which led to the identification of three end-to-end strategies, as shown in Table 5. Nine themes emerged from the data analysis I conducted using Decision Explorer. I synthesized these emerging themes into the following end-to-end strategies: (a) validating CCSSs, (b) compliant shipping of DMDs, and (c) CCM best practices.

Table 5

Distinct Concepts Relating to the Three End-to-End Strategies of the Research Study

Case	Validating CCSSs	Compliant shipping of DMDs	CCM best practices
C1	34	45	57
C2	70	56	47
C3	27	23	27
Total	131	124	131

Presentation of the Findings

The overarching research question that guided this study was as follows: What are the strategies some medical device executives use for shipping temperature-sensitive DMD tests and controls? I constructed in-depth interview questions to discover new facts and personal insights from SCM executives who participated in this study regarding the strategies used to ship temperature-sensitive DMD tests and controls. Prolonged case study interviews involve the use of propositions to achieve a conversational tone with participants while ensuring alignment with the purpose of the study (Yin, 2014). In the sections that follow, I discuss the three end-to-end strategies, the nine associated themes, the conceptual framework, and the propositions that supported the study.

End-to-End Strategy 1: Validating Cold Chain Shipping Solutions

The first end-to-end strategy indicated the importance of validating CCSSs to executives responsible for the compliant shipping of temperature-sensitive DMD tests and controls. Three themes emerged from an analysis of the data, as shown in Table 6. The emerging themes were (a) third-party validation firms, (b) joint development of validation protocols, and (c) product labeling supports validation protocols, as shown in the final cognitive map (see Appendix J).

Table 6

Themes Relating to the End-to-End Strategy of Validating CCSSs

Case	Third-party validations firms	Joint development of validation protocols	Product labeling supports validation protocols
C1	20	26	23
C2	22	25	22
C3	23	23	35
Total	65	74	80

The theme of using third-party validation firms such as packaging manufacturers and packaging laboratories for the development of CCSSs was a concept emphasized by all three SCM executives in this study. Third-party validation firms conduct temperature chamber testing to validate CCSSs. Jadhav et al. (2009) explained that certified packaging laboratories use environmental chambers and temperature profiles to validate passive shipping containers.

Another theme linked the joint development of validation protocols to third-party validation firms. Validation protocols define the testing parameters for developing validated CCSSs. Participants mentioned several validation protocols, such as transit times, internal product temperature, and external hot and cold temperature ranges in developing CCSSs that prevent temperature excursions when shipping DMD tests and controls. Validated CCSSs help eliminate temperature excursions that occur during the shipping of temperature-sensitive products.

The final theme identified in this end-to-end strategy was SCM executives' assertion that validations protocols coincide with product labeling found on DMD tests and controls. Agents for the FDA require passive shipping containers to have validation

protocols. Consequently, DMDs have product labeling to indicate appropriate storage temperatures (Maltha et al., 2013).

These themes revealed that SCM executives take a systematic approach to developing CCSSs. However, data supported the proposition that CCSSs used in the medical device industry are validated, nonvalidated, or poorly validated, which may indicate a lack of standardization and inconsistent distribution strategies. The lack of standardization may stem from the use of nonvalidated CCSSs for shipping older products. Some SCM executives believe that nonvalidated CCSSs are appropriate for DMD tests and controls that have a complaint-free shipping history. The lack of standardization and inconsistent distribution strategies support the conceptual framework used to develop the propositions that guided the study.

I used the SCA model as the conceptual framework for this study. Relevant propositions from the SCA model grounded the conceptual framework to the case study. The SCA model includes organizational change management strategies that SCM executives can use to standardize the CCSSs for shipping temperature-sensitive DMD tests and controls. SCM executives who understand the underpinnings of the SCA model are more likely to identify misconceptions that may prevent the realization of new CCM strategies in their organization. SCM executives should educate and align people with CCM strategies to prevent any misconceptions that may prevent change.

End-to-End Strategy 2: Compliant Shipping of Diagnostic Medical Devices

The second end-to-end strategy of the study linked the concept of compliance to the efficacy of temperature-sensitive DMD tests and controls. Three themes emerged

from my data analysis, as shown in Table 7. The emerging themes were (a) employee training, (b) auditing of business processes, and (c) the monitoring of DMD tests and controls, as shown in the final cognitive map (see Appendix K).

Table 7

Themes Relating to the End-to-End Strategy of Compliant Shipping of DMDs

Case	Employee training	Auditing of business processes	Monitoring of DMD tests and controls
C1	30	22	35
C2	21	16	30
C3	31	30	28
Total	82	68	93

The theme of employee training was a concept emphasized by SCM executives relative to the end-to-end strategy of compliant shipping of DMDs. SCM executives reported that employees must train on standard operating procedures and work instructions to ensure compliant storage and shipping of temperature-sensitive DMD tests and controls. Educated SCM practitioners have a working knowledge of the regulatory requirements needed to ship temperature-sensitive products globally from a storage and transportation perspective (Lis et al., 2009). End users require training on how to manage temperature-sensitive products (Maltha et al., 2013). SCM executives also noted that they monitor the effectiveness of training for their employees through audits.

The auditing of business processes was another theme mentioned by SCM executives to ensure compliant shipping. Reddy et al. (2012) asserted that SCM practitioners find it increasingly important to use proper storage, handling, and distribution of temperature-sensitive products. SCM executives remarked that both internal and external audits are effective means of confirming and ensuring proper

storage conditions, warehouse temperature mapping, CCSSs validations, compliant shipping, and training effectiveness.

The final theme identified in this end-to-end strategy was SCM executives' assertion that the monitoring of DMD tests and controls during shipping provides meaningful insights into compliance. SCM executives can gain proactive insight into compliance by using temperature-monitoring devices. Attached temperature control monitoring tags in a CCSS could reveal temperature excursions during transit (Maltha et al., 2013). SCM executives noted that they receive reactive insight into compliance from their customer and technical services. Customer and technical service representatives typically generate reactive reports in response to customer complaints and announcements of patient harm. SCM executives affirmed that it is their responsibility to ensure compliant shipping of DMD tests and controls to prevent harm. Agents for the FDA recorded 659 instances of medical device recalls in 2006, which contributed to 116,086 injuries and 2,830 deaths (FDA, 2006; Sullivan, 2014).

These themes indicated that SCM executives take a methodical approach to ensure compliant shipping. However, data supported the proposition that organizational and educational requirements for SCM executives in the medical device industry may be inconsistent, which leads to the use of nonvalidated or poorly validated CCSSs. Some SCM executives acknowledged that they have no formal training in CCM and that training typically takes place on the job or through attending conferences that include CCM as an agenda topic. The inconsistent education of SCM executives in CCM

supports the conceptual framework used to develop the propositions that guided the study.

One of the propositions mentioned in the SCA model is education and communication. Leaders commonly use education and communication to persuade employees to accept organizational change (Kotter & Schlesinger, 1979). The education and communication proposition is time-consuming to implement because leaders must engage most employees throughout the organization (Kotter & Schlesinger, 1979). Therefore, leaders seeking sustainable change must select strategies that diminish the resistance to change, which is inherent in people who do not want internal or external forces disrupting the status quo (Kotter & Schlesinger, 1979).

End-to-End Strategy 3: Cold Chain Management Best Practices

The third end-to-end strategy of the study linked the concept of CCM best practices to the proper storage and shipping of temperature-sensitive DMD tests and controls. Three themes emerged from my data analysis, as shown in Table 8. The emerging themes were (a) regulatory requirements, (b) product storage and shipping conditions, and (c) temperature excursion, as shown in the final cognitive map (see Appendix L).

Table 8

Themes Relating to the End-to-End Strategy of CCM Best Practices

Case	Regulatory requirements	Product storage and shipping conditions	Temperature excursion
C1	23	31	28
C2	28	27	16
C3	24	35	22
Total	75	93	66

The theme for complying with regulatory requirements was a concept emphasized by SCM executives. According to the three SCM executives in this study, regulatory compliance in the area of CCM helps ensure DMD tests and controls function properly. SCM executives use a quality management system to align business practices with regulatory requirements. The FDA (2006) regulates quality system adherence and good manufacturing practices. FDA regulations require medical device manufacturers to document their storage and shipping requirements.

SCM executives also emphasized the theme that linked proper product storage and shipping conditions to patient safety. SCM executives determine proper product storage and shipping by referencing product labeling. CCM is a controlled methodology for the proper storage and distribution of temperature-sensitive products (Reddy et al., 2012).

The final theme referenced by SCM executives was to avoid temperature excursion when shipping DMD tests and controls. SCM executives noted that temperature excursion from improper storage and handling could result in DMD errors. SCM executives reported two types of errors: false negative and false positive. According to SCM executives, both types of error could cause patient harm. Proper

CCM can prevent some medical errors by protecting proteins, antigens, and assays used in DMD tests and controls from temperature excursions (O'Connell et al., 2012; Smit et al., 2013).

These themes revealed that SCM executives take a systematic approach to ensure proper CCM. However, data supported the proposition that SCM executives in the medical device industry have different levels of competency regarding the distribution requirements for DMD tests and controls from a regulatory and stability perspective, which may contribute to inconsistent industry standards and health risks to patients. Some SCM executives remarked that the FDA does not provide specific guidance regarding CCM. SCM executives had different levels of competency in regulatory requirements, which supports the conceptual framework used to develop the propositions that guided the study.

Regulatory complexity and change require SCM executives to make organizational changes. Leaders can use the SCA model to manage major issues based on the internal and external forces that disrupt the status quo of people in an organization (Kotter & Schlesinger, 1979). Therefore, SCM executives who use the SCA model can improve business strategies in their respective organization.

Applications to Professional Practice

Compliant shipping of temperature-sensitive DMD tests and controls could mitigate temperature excursion and the associated diagnostic errors that lead to patient harm. The in-depth exploration into SCM at the executive level generated valuable insights into validating CCSSs, compliant shipping of DMDs, and CCM best practices.

The insights gained from interviewing SCM executives who work in the medical device industry was pivotal to developing end-to-end strategies for shipping temperature-sensitive DMD tests and controls.

SCM executives responsible for shipping temperature-sensitive DMD tests and controls rely on the end-to-end strategy associated with shipping validations to ensure product efficacy. SCM executives commission and collaborate with packaging manufacturers and packaging laboratories to develop and test shipping validations. SCM executives ensure shipping validations are representative of the entire supply chain by confirming all external temperatures from the point of manufacturing to the end user. Therefore, validation protocols must define the testing parameters for developing validated CCSSs. Validation protocols can include transit times, internal product temperature, external hot and cold temperature ranges, and various modes of transportation as part of the testing parameters for developing CCSSs.

SCM executives emphasized compliance as an end-to-end strategy for ensuring the efficacy of temperature-sensitive DMD tests and controls. SCM executives working in the medical device industry use quality management systems, such as ISO 13485:2016 to ensure compliant shipping of temperature-sensitive DMD tests and controls. More specifically, quality management systems provide the framework for managing business processes and employee training. SCM executives use internal and external audits to ensure employee compliance with standard operating procedures and work instructions. SCM executives use audit findings to close gaps in the quality management system as it relates to people, processes, and systems. SCM executives also use quality management

systems to help ensure compliant shipping of temperature-sensitive DMD tests and controls to end users.

SCM executives reference CCM best practices as an end-to-end strategy for ensuring regulatory compliance of DMD tests and controls during storage and shipping. SCM executives achieve regulatory compliance when CCM activities adhere to the product labeling regarding storage and shipping. SCM executives use active and passive validated CCSSs to prevent temperature excursions, which helps ensure product efficacy at the point of care. Proper CCM can prevent some medical errors by protecting proteins, antigens, and assays used in DMD tests and controls from temperature excursions (O'Connell et al., 2012; Smit et al., 2013). The prevention of medical errors may improve patient safety.

Implications for Social Change

Clinicians using defective DMDs contribute to medical errors, one of the leading causes of injury and death around the world, which cost the U.S. health care system approximately $17.1 billion in 2008 (Van Den Bos et al., 2011). Consequently, the implications for positive social change as it relates to this study begins with SCM executives adopting CCM strategies and utilizing innovative CCSSs designed to mitigate temperature excursions for DMD tests and controls. A decline in medical device failures could correlate to a reduction in FDA recalls, liability claims, and legal proceedings within the medical device industry.

The end-to-end strategies associated with validating CCSSs, compliant shipping of DMDs, and CCM best practices could help SCM executives drive sustainable change

within the medical device industry. The identification and adoption of CCM strategies by SCM executives may prevent a medical device failure that results in FDA recalls. A reduction in FDA recalls and the resulting litigations could positively influence medical device executives to invest in new business opportunities.

The funding of new business opportunities could increase manufacturing capacity and support R&D advancements in medical device technology. Such a shift could eventually create new jobs, reduce health care costs, and bring to market new diagnostic technologies that could save additional lives or improve a patient's well-being. Therefore, CCM strategies could increase profitability, patient safety, and lead to technological advancements in DMDs from a social change perspective.

Recommendations for Action

The recommendation for action is for SCM executives to initiate a comprehensive review of their CCM practices by focusing on the end-to-end strategies associated with validating CCSSs, compliant shipping of DMDs, and CCM best practices. SCM executives should obtain the master data for all DMD tests and controls that require CCM. SCM executives should then ensure master data matches product labeling. Finally, SCM executives should select validated CCSSs based on master data, transits time, and the final destination.

The lack of validated CCSSs emphasizes a need for SCM executives to form a partnership with a third-party validation firm for the development of compliant CCSSs. SCM executives should also ensure a quality management system support CCSSs through standard operating procedures, and internal and external audits. Finally, SCM

executives should create an adequate feedback loop for customer complaints and patient harm to drive continuous improvement from a CCM perspective.

The findings from this study are relevant to SCM executives and leaders seeking to improve CCM practices within the medical device industry. Participants of this study may seek to align global CCM practices, develop cold chain centers of excellence, and form strategic partnerships with packaging manufacturers and packaging laboratories. Third-party validation firms may use conferences or literature to share the results of this study with SCM leaders seeking to improve CCM practices in the medical device industry.

Future researchers may use the results of this study as a means to expand on the CCM body of knowledge. I will publish this doctoral study with ProQuest and further disseminate the study findings in peer-reviewed journals. I will also disseminate my findings to stakeholders in the medical device industry by way of seminars and conferences.

Recommendations for Further Research

The purpose of the study was to explore medical device executives' strategies for shipping temperature-sensitive DMD tests and controls. The results of the study revealed that validating CCSSs, compliant shipping of DMDs, and CCM best practices are effective strategies for SCM executives to drive compliant CCM of temperature-sensitive products. To advance the research associated with this study, I recommend further research using qualitative and quantitative designs to explore the limitations and delimitations acknowledged in this study.

Researchers use phenomenological research to survey data and draw conclusions from the lived experiences of participants (Wolgemuth et al., 2014). I recommend a qualitative phenomenological study to understand the types of risks associated with improper storage and distribution of temperature-sensitive DMD tests and controls. Further research may provide new insights to improve patient safety after a DMD malfunction.

Yilmaz (2013) defined quantitative research as a research method used to gain understanding into a phenomenon through statistical analysis. I also recommend a quantitative study to analyze the FDA reason codes for medical device failures. Further research could narrow the scope of medical device failures to those caused by temperature excursions. SCM executives and third-party validation firms can use these new finding to drive innovation in CCSSs.

Reflections

My objective for conducting a doctoral study through Walden University was to advance my professional and academic expertise and to distinguish myself as a scholar-practitioner in SCM. To that end, I conducted a qualitative multiple case study design using cognitive mapping to explain what strategies SCM executives deploy in the selection, management, and utilization of CCSSs in the medical device industry. The engagement with SCM executives was rewarding. However, the real-time data collection and entry into Decision Explorer was burdensome. The burden was prolonged case study interviews requiring propositions to achieve a conversational tone and the pace of my conversation not being conducive to real-time data entry into Decision Explorer.

Consequently, I had to transcribe recorded interviews and perform member checking to complete each cognitive map.

The rendering of unbiased conclusions was paramount as a scholar-practitioner reporting on strategies used by SCM executives working in the medical device industry. My direct knowledge and experience in CCM within the medical device industry created a risk for the introduction of bias. To prevent personal bias, I developed interview protocols, avoided leading questions, and rendered conclusions based on transcribed data that incorporated member checking.

Conclusion

Clinicians use DMDs to diagnose various diseases such as cardiovascular, respiratory, toxicology, autoimmune, and infectious diseases in patients. The use of defective DMDs contributes to medical errors, which is one of the leading causes of injury and death throughout the world. Consequently, medical errors cost the U.S. health care system approximately $17.1 billion in 2008 (Van Den Bos et al., 2011). Proper CCM can prevent some medical errors by protecting proteins, antigens, and assays used in DMD tests and controls from temperature excursions (O'Connell et al., 2012; Smit et al., 2013). The lack of proper CCM should be of concern to SCM executives responsible for shipping temperature-sensitive DMD tests and controls.

The purpose of this qualitative multiple case study was to identify successful strategies used by SCM executives to ship temperature-sensitive DMD tests and controls. The exhaustive exploration into SCM executives' understanding of CCM within the medical device industry made it possible to pinpoint end-to-end strategies to help

improve patient safety. The results of this study yielded strategies SCM executives and stakeholders can use for (a) validating CCSSs, (b) achieving compliant shipping of DMD tests and controls, and (c) implementing CCM best practices in the medical device industry. SCM executives who adopt the three end-to-end strategies identified in this study could develop a comprehensive strategy that improves patient safety within the medical device industry.

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Appendix A: Invitation Letter

Dear Supply Chain Executive,

As a supply chain executive in the medical device industry, you are invited to participate in a doctoral study regarding the distribution of temperature-sensitive diagnostic medical device tests and controls.

The purpose of this qualitative multiple case study design is to explore medical device executives' strategies for shipping temperature-sensitive diagnostic medical device tests and controls.

If you agree to participate in this voluntary doctoral study, I will send you a consent form and the eligibility form. These two documents further explain the study, interview duration, privacy protections, and consent.

Please note that your participation in this doctoral study is voluntary and that all information obtained up to and including your identity will remain strictly confidential. I appreciate the consideration you will give toward your participation in this doctoral study.

Sincerely,

Eric C. Guynes
Walden University School of Management and Technology
DBA Candidate, Specialization: Global Supply Chain Management

Appendix B: Participatory Eligibility Form

Dear Supply Chain Executive,

The intent of this eligibility form is to ensure that all participants meet the minimum qualification of a supply chain executive as defined in this study. The scrutiny of each participant helps protect the integrity and outcomes of this doctoral study.

Please check the box for each statement that applies

- ☐ I have worked in the medical device industry.
- ☐ I have 5 or more years of cold chain management experience.
- ☐ I have national or global supply chain management responsibilities.
- ☐ I can influence cold chain management strategies within my organization.

I have read the above statements, and I certify that each statement checked is true.

Participant's Printed Name: _____

Participant's Employer: _____

Participant's Job Title: _____

Date: _____

For Internal Use Only:

_____

Case Number: _____

Geographical Responsibility: _____

Appendix C: Permission for Reprint

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Eric Guynes [redacted]

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3. This Agreement states the entire agreement between the parties concerning the disclosure of Confidential Information. Any addition or modification to this Agreement must be made in writing and signed by the parties.
4. If any of the provisions of this Agreement are found to be unenforceable, the remainder shall be enforced as fully as possible and the unenforceable provision(s) shall be deemed modified to the limited extent required to permit enforcement of the Agreement as a whole.

WHEREFORE, the parties acknowledge that they have read and understand this Agreement and voluntarily accept the duties and obligations set forth herein.

Recipient of Confidential Information:
Name: Evolution World Wide Limited

Signature:

Date: 10/17/2017

Discloser of Confidential Information:
Name: Eric C. Guynes

Signature:

Date: 10/17/2017

Appendix F: Online Interview Protocol

What I will do	What I will say
Introduce the interview and set the stage	1. Welcome the participant. 2. Discuss confidentiality for the participant and their employer. 3. Discuss consent and voluntary withdraw. 4. Confirm permission to voice-record. 5. Explain how I will use Decision Explorer in real-time to construct three cognitive maps. 6. Explain that voice recording are to refine cognitive maps. 7. Explain interview rules to ensure participants understand (a) the structured set of open-ended interview questions; (b) the need for follow-up questions based on propositions; and (c) that answer deviations are acceptable, but must be limited. 8. Explain the use of a parking lot during the construct of real-time maps. 9. Explain how real-time member checking enhances the reliability and validity of each cognitive map. 10. Remind the participant that the interview will take 2 hours and that they can request a short break. 11. Confirm participant do not have any questions and or concerns. 12. Introduce the study and start the interview.
I will perform the following when interviewing (a) watch for nonverbal cues; (b) paraphrase as needed; (c) enter each interview response into Decision Explorer in real-time; (d) member check each interview response captured in Decision Explorer in real-time;(e) ask follow-up questions based on propositions and then repeat (c) and (d) above.	1. How do you evaluate if CCSSs can protect against extreme heat within the medical device industry? 2. How do you evaluate if CCSSs can protect against extreme cold within the medical device industry? 3. What types of CCSSs do you deploy in your supply chain? 4. How do validations prevent temperature excursions for your diagnostic medical device (DMD) tests and controls? 5. How do you innovate cold chain shipping within your organization over the next 5 years? 6. How did you learn about cold chain management (CCM) in relation to the medical device industry? 7. How do you identify CCM deficiencies within your organization? 8. How does education influence your selection of cold chain shipping solution for DMD tests and controls? 9. How do you increase CCM awareness within your organization? 10. How will you ensure that your organization has ongoing expertise in CCM?

	11. How do you determine if DMD tests and controls are temperature controlled? 12. How does the FDA influence the distribution of DMD tests and controls? 13. How do you ensure internal CCM compliance for the DMD tests and controls shipped? 14. How does temperature excursion on DMD tests and controls affect patient safety? 15. Why do you control the temperature stability for DMD tests and controls? 16. Futuristically: How will governmental regulations influence the CCM of DMD tests and controls over the next 5 years?
Wrap up interview thanking participant	I will verbally (a) thank the participant; (b) briefly discuss next steps; and (c) confirm the participant does not have any questions and or concerns.

Appendix G: Interview Questions

1. What types of CCSSs do you deploy in your supply chain?
2. What methods do you use to evaluate CCSSs intended to protect against extreme temperature ranges?
3. How do you monitor the effectiveness of CCSSs used to ship diagnostic medical device (DMD) tests and controls?
4. How do you validate CCSSs used in your supply chain?
5. What cold chain shipping innovations are you considering for your organization?
6. How did you learn about cold chain management (CCM) as it pertains to the medical device industry?
7. How do you identify CCM deficiencies within your organization?
8. How does education influence your selection of CCSSs for DMD tests and controls?
9. How do you increase CCM awareness within your organization?
10. How do you develop CCM expertise within your organization?
11. How do you determine the need for temperature controlled shipping?
12. How does the FDA influence the shipping of DMD tests and controls?
13. How do you ensure internal CCM compliance when shipping?
14. How does temperature excursion on DMD tests and controls affect patient safety?
15. Why do you ensure temperature compliant shipping for DMD tests and controls?
16. How do governmental regulations influence the CCM of DMD tests and controls?

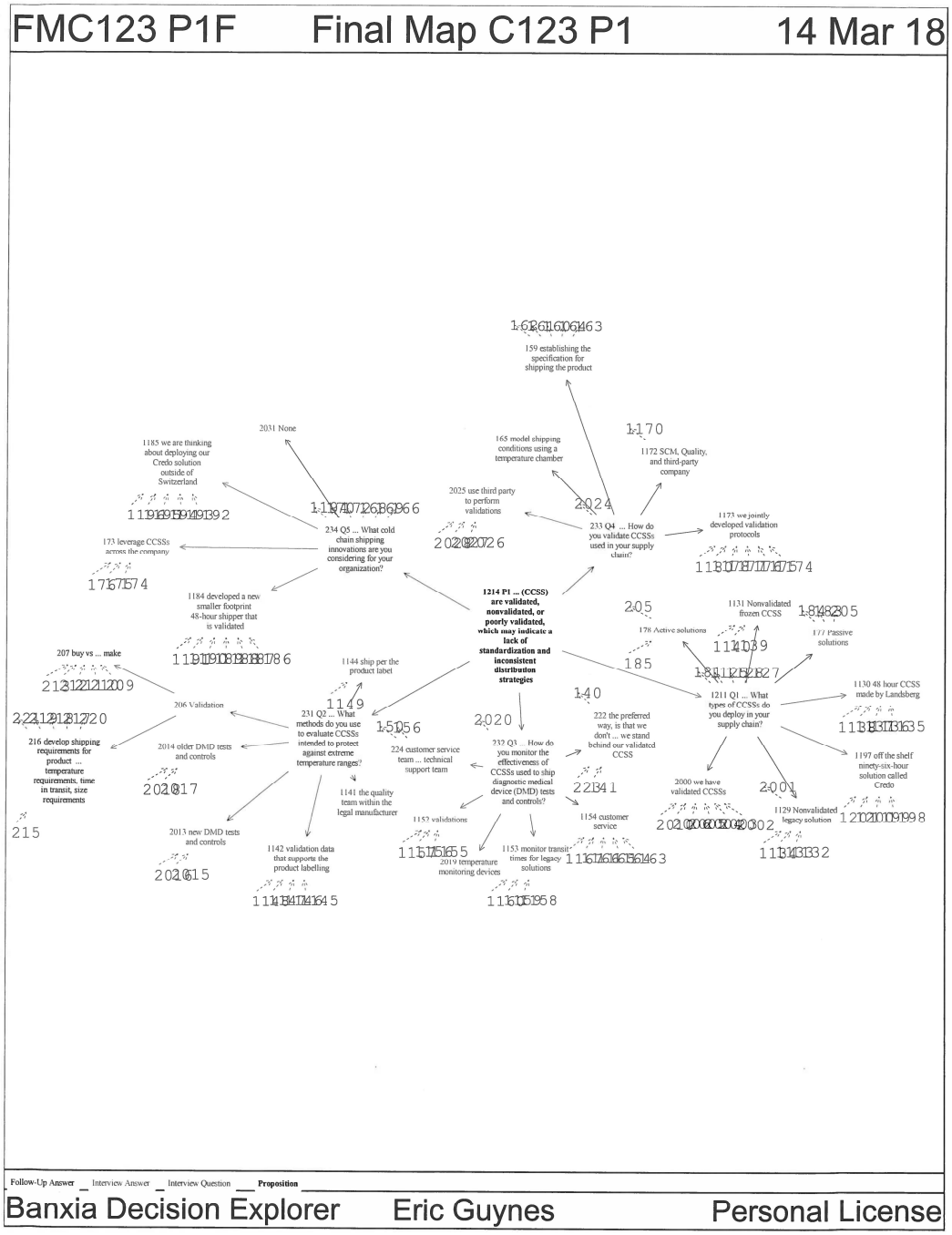
Appendix H: Coding of Propositions to Interview Questions in Decision Explorer

Propositions		Interview Questions	
P1.	Cold chain shipping solutions (CCSS) used in the medical device industry are validated, nonvalidated, or poorly validated, which may indicate a lack of standardization and inconsistent distribution strategies.	Q1.	What types of CCSSs do you deploy in your supply chain?
		Q2.	What methods do you use to evaluate CCSSs intended to protect against extreme temperature ranges?
		Q3.	How do you monitor the effectiveness of CCSSs used to ship diagnostic medical device (DMD) tests and controls?
		Q4.	How do you validate CCSSs used in your supply chain?
		Q5.	What cold chain shipping innovations are you considering for your organization?
P2.	Organizational and educational requirements for supply chain management (SCM) executives in the medical device industry may be inconsistent, which leads to the use of nonvalidated or poorly validated CCSSs.	Q6.	How did you learn about cold chain management (CCM) as it pertains to the medical device industry?
		Q7.	How do you identify CCM deficiencies within your organization?
		Q8.	How does education influence your selection of CCSSs for DMD tests and controls?
		Q9.	How do you increase CCM awareness within your organization?
		Q10.	How do you develop CCM expertise within your organization?
P3.	SCM executives in the medical device industry have varying competency regarding the distribution requirements for DMD tests and controls from a regulatory and stability perspective, which may contribute to inconsistent industry standards and health risks to patients	Q11.	How do you determine the need for temperature controlled shipping?
		Q12.	How does the FDA influence the shipping of DMD tests and controls?
		Q13.	How do you ensure internal CCM compliance when shipping?
		Q14.	How does temperature excursion on DMD tests and controls affect patient safety?
		Q15.	Why do you ensure temperature compliant shipping for DMD tests and controls?
		Q16.	How do governmental regulations influence the CCM of DMD tests and controls?

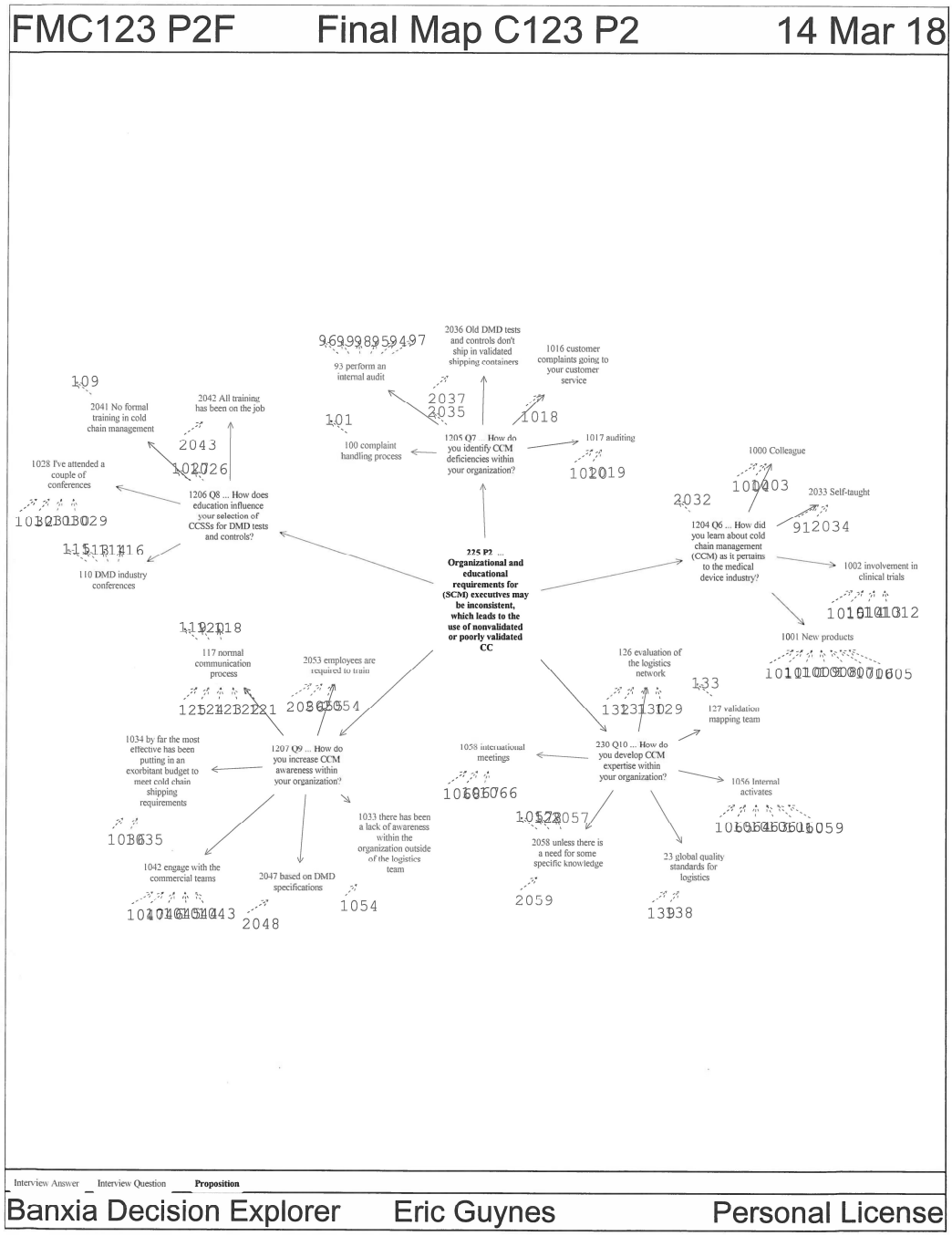
Appendix I: Coding of Case Studies in Decision Explorer

Participant and Employer	Geographical Responsibility	Interview Questions and Answers
Case 1	New Jersey	0001 – 0999
Case 2	Ireland	1000 – 1999
Case 3	San Diego	2000 – 2999

Appendix J: Final Cognitive Map C123 P1



Appendix K: Final Cognitive Map C123 P2



Appendix L: Final Cognitive Map C123 P3