2020

Pharmacy Manager Strategies for Reducing Financial Losses From Adverse Drug Events by Polypharmacy Patients

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This is to certify that the doctoral study by

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

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MBA, Strayer University, 2012

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AA, Lake Sumter Community College, 1999

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Every year over 100,000 deaths occur in the U.S. from adverse drug events derived from medication errors. Medication errors account for an annual cost of $100 to $200 billion. Healthcare pharmacists lack strategies to reduce adverse drug events and medication errors from taking place. Grounded in complex adaptive system theory, the purpose of this qualitative multiple case study was to explore strategies to reduce advere drug events and medication errors. The participants were 5 pharmacist managers in a county in central Florida. These pharmacists were from different community pharmacies, and each had a minimum of 5 years' experience in the field. The participants all responded to the same set of open-ended questions during semistructured interviews. Additional data sources for this study were field notes, business prescription literature, and analyzing observations of the participants. Data were analyzed using Yin's 5 analytic techniques. Themes identified included: polypharmacy and the unknown, HIPAA and legal constraints, and CAS, the edge of chaos and clarity. The findings from this study may enable pharmacy managers to increase patient counseling time, encourage patient medication adherence; thereby, decreasing liability costs and additional medical expenses for polypharmacy patients. Social changes that may occur as a result of this study include a decrease in adverse events for polypharmacy patients and an increase in the quality of life for these patients.

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Dedication

I would like to dedicate this effort to my mother, who encouraged me to never to give up; to my wife Dorothy, who has encouraged me and persevered with me for over 56 years; and to the good Lord, who has kept me alive to finish this project.

Acknowledgments

I take this opportunity to thank, with my most heartfelt appreciation, Dr. Kenneth Gossett, my chair and mentor. He has guided and prodded me throughout this journey. I would like to thank Dr. Edward Paluch and Dr. Roger Mayer for their invaluable assistance as my committee members.

I would also like to thank my children and grandchildren for their encouragement and learning experiences through this journey. And last, yet first, thank you Sister Mary Gabriel.

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Section 1: Foundation of the Study

The retail pharmacy portion of the healthcare industry has improved its performance in medication delivery and patient care since the implementation of the U.S. Department of Health and Human Services, Health Insurance Portability and Accountability Act (HIPAA, amended 2002), and the U.S. Department of Health and Human Services, Patient Protection and Affordable Care Act (ACA, 2010). Nonetheless, liability costs from medication errors and adverse drug events (ADEs) continue to increase (Ghormley, 2015). Pharmacy managers need strategies to reduce these costs, particularly in the area of counseling patients who receive one or more medications from more than one pharmacy and who use over-the-counter items.

Background of the Problem

With the inception of HIPAA, and the ACA, the medical industry met a myriad of growing pains, trying to cope with patients' rights, and the need for excellent medical care with minimal errors. The government and the medical industry are attempting to reach an understanding as to how to provide for patient protection while maintaining quality care. Using a patient's permission and information at medical entry, hospital, and healthcare facility managers, and physicians can obtain information for medical care and store it in a computerized system. In the most basic form, a patient's history resides in their general practitioner's (GP) computer history. With the permission of the patient, hospital X-rays, lab reports, and reports from specialized physicians (e.g., cardiologist), will be stored in the patient's profile. A patient has full access to the information and can

correct or eliminate information as desired, through their GP. With the concentration of medical information, medication reconciliation, and awareness of all parties concerned, improved patient medication transitions, and healthcare for the patient should ensue, with a decreasing chance of medical errors (Wittich, Burkle, & Lanier, 2014).

Pharmacists in the retail pharmacy industry continue to experience losses due to medication errors and omissions (Mansur, 2016). Serious preventable medication errors occur in more than 1.4 million inpatient and outpatient persons every year (Marasinghe, 2015; Padgett, Gossett, Mayer, Chien, & Turner, 2017). There is no system in effect to prevent contraindication of drugs, on a multi-corporate level. Patients who take more than one medication, or use different pharmacies for medications are at higher risk for ADEs (Lowe, Taylor, & Hill, 2016). Addressing the strategies of pharmacy managers that have been found to be effective on how to reduce the financial losses associated with ADEs incurred from polypharmacy patients may lead to lower costs from ADEs.

Problem Statement

Medication errors and omissions of prescription drugs, dispensed from the hospital and retail pharmacies, contribute to more than 100,000 deaths and more than 1.5 million serious patient injuries every year (Marasinghe, 2015). ADEs that result from these medication errors and omissions are a contributing factor to a business cost of more than $100 billion annually (Young, Barnason, Hays, & Van Do, 2015). The general business problem for hospital and retail pharmacies is the financial liability incurred from prescription medication errors and omissions. The specific business problem is some

pharmacy managers have limited strategies on how to reduce the financial losses associated with ADEs incurred from polypharmacy patients.

Purpose Statement

The purpose of this qualitative exploratory multiple case study was to explore the strategies pharmacy managers use to reduce the financial costs associated with ADEs incurred by polypharmacy patients. The population included community pharmacy managers living in central Florida. Input from five of these pharmacy managers, who have successfully addressed this problem was used for this case study. Their inputs provided sufficient information to infer possible solutions and areas for future exploration. In addition to discovering options for reducing the financial costs, the study may lead to a reduction in ADEs and improve the quality of life for polypharmacy patients.

Nature of the Study

Yin (2018) indicated that there are generally three types of research that are typically done (quantitative, mixed methods, and qualitative). Yin stated the idea that qualitative research is the study of people or situations in their natural setting and attempting to understand or make meaningful data from this research. This method outweighed the quantitative method of collecting numerical data to examine the relationships between variables and to test hypotheses, which under normal circumstances would be statistical and inanimate (Fusch & Ness, 2015; Bennett & McWhorter, 2016). This circumstance is also true of mixed-methods research. Mixed

methods most often combine qualitative and quantitative studies to present a complete study (Halcomb &Hickman, 2015). I chose a qualitative method for my study to explore the behavior and actions of pharmacists and pharmacy technicians in their natural setting to understand the strategies pharmacy managers use to reduce the financial costs associated with ADEs incurred by polypharmacy patients.

I considered four research designs for a qualitative study of pharmacy manager strategies. Focused ethnography, also referred to as mini-ethnography, is the study of a subculture (group-specific) which requires shorter field research, but more intensive data collection and analysis (Wall, 2015). This method did not meet the requirements for a specific strategic inquiry. Focus group research involves a group of people who express their views on a subject, mediate their stance, and according to the inputs, reach a suitable consensus (Ritchie, Lewis, & McNaughton Nicholls, 2014). A focus group method was not satisfactory for research where analysis requires individual strategic inputs from seasoned and experienced pharmacy managers. The narrative inquiry involves listening to the stories of others, where one can interpret and understand their situation in a larger culture (Ison, Cusick, & Bye, 2014). This type of inquiry was not appropriate for use with semistructured interviews. A multiple case study afforded the opportunity to use various sources of inputs. Semistructured interviews combined with the documented research and information gathered specifically to the case provided for a better exploratory study (Yin, 2018). My study met the standards for an exploratory case study.

Research Question

The following overarching research question provided the basis for this study:

RQ: What are the strategies pharmacy managers use to reduce the financial losses associated with ADEs incurred by polypharmacy patients?

Interview Questions

The following open-ended, semistructured interview questions were used:

1. As a pharmacy manager, how would you describe a "polypharmacy patient"?
2. What percentage of these prescriptions would you estimate are for polypharmacy patients?
3. From your perspective as a pharmacy manager, to what extent do the current HIPAA laws aid or hinder confidential counseling of polypharmacy patients?
4. From your perspective as a pharmacy manager, to what extent does your company/corporate policies and methods aid or hinder confidential counseling of polypharmacy patients?
5. From your perspective as a pharmacy manager, to what extent does the written literature provided with medications, aid in your counseling of polypharmacy patients?
6. From your perspective as a pharmacy manager, what strategies do you use to improve and enhance polypharmacy patient counseling to decrease potential ADEs?

7. From your perspective as a pharmacy manager, what strategies do you use to lessen your company's liability costs?
8. What other issues regarding polypharmacy patient counseling do you think I should be made aware of?

Conceptual Framework

The intended goal of this study was to explore the strategies that pharmacists use to provide needed counseling to polypharmacy patients to reduce the financial losses associated with ADEs incurred by these patients. I selected the complex adaptive system theory (CAS) as the framework for my study. CAS came into the realm of study in the early 1990s. Gel-Mann, Holland, and Waldrop are most often cited as the authors of CAS (Wallis, 2008). Page (2009) infers that Holland's study "Adaption in Natural and Artificial Systems: An Introductory Analysis with Applications to Biology, Control, and Artificial Intelligence" was the initializer into the study of the complex adaptive system.

In basic terms, an organization's complexity is: when every level of the organization's hierarchy, whether by internal or external inputs, can grow or shrink, evolve or devolve, strengthen or weaken and through positive or negative feedback can sustain its position in the business world (Davis, Dent, & Wharff, 2015). This is a good example of CAS, which can be used to understand how organizations have the ability to adapt complexity and accommodation into cohesiveness to achieve equilibrium and stability.

Community pharmacies vary from sole proprietorships to full corporations. These businesses range from low complexity to high complexity and at various levels of provider and patient communication forte. The strategy of the pharmacy manager requires examination from two viewpoints: (a) business hierarchy to business hierarchy and (b) community pharmacist to the patient (stakeholder). Pype et al. (2017) implied support for the use of CAS to study the integration of these parts in a healthcare organization.

Operational Definitions

Adverse drug effects (ADe). An adverse drug effect is some attribute of a drug, or the use or misuse of a drug (Edwards, 2014).

Adverse drug event (ADE). An adverse drug event is any unexpected medical occurrence associated with the use of a drug, even if considered not related to the drug (Yu et al., 2016).

Adverse drug reaction (ADR). An adverse drug reaction is a noticeable harmful or unpleasant reaction, occurring from an intervention related to a medicinal product, usually predicting discontinuance of the product and specific treatment or alteration of product dosing (Edwards, 2014).

Medication error. A medication or any error in prescribing, dispensing, or administering a drug, irrespective of whether such errors led to adverse consequences (Cloete, 2015).

Polypharmacy. Polypharmacy is the prescribing and use of more than one medication for an individual at the same time, including over-the-counter remedies and herbal supplements, which may have a potential for drug interactions (Duerden & Payne, 2014).

Assumptions, Limitations, and Delimitations

Assumptions

Assumptions are beliefs a researcher holds to be pertinent, knowing that complements to the belief may exist that may be difficult to prove (Cantonini & DeVito, 2014). The first assumption in this study was that the subject pharmacy managers were well versed in their profession. The second assumption was that the pharmacy managers had a professional concern for the well-being of their patients. The third assumption was that a private interview situation would ensure confidentiality and openness of responses. The fourth assumption was that the pharmacy managers' companies had a written policies concerning patient counseling.

Limitations

Limitations are the probable flaws, defects, vulnerabilities, and shortcomings of a research project that could affect the reliability of the findings (Marshall & Rossman, 2016). One limitation of this study was that all the pharmacy managers were from one county in Florida. Their responses may not apply to other areas of the United States. These pharmacists may have patients from a different economic base, and this patient economic difference could magnify or attenuate their polypharmacy experience. The

study included five pharmacy managers, with a minimum of 5 years of experience in the position, who have successfully managed situations in reducing financial loss with polypharmacy patients.

Delimitations

In a qualitative single case study, delimitations clarify the boundaries and intentions of the study (Zanon, Filho, Jabbour, & Jabbour, 2013). This study included semistructured interviews, data collection, and observations. Pharmacists, not in a managerial status, or with less than 5 years tenure did not qualify for the study. These pharmacists are not likely to have the necessary experience and familiarity with their organization's policies and commitments.

Significance of the Study

Contribution to Business Practice

Reduction of medication errors and omissions within the retail pharmacy portion of the healthcare industry is a shared responsibility between healthcare practitioners and their corporations. Health practitioners, medical service providers, pharmacists, pharmacy technicians, and medication insurers are obligated to ensure the highest quality of medical care to patients. Co-operation is needed among medical provider corporations to provide a better form of checks and balances in the medication prescription dispensing methods, which needs exploration.

An exploratory qualitative case study of pharmacy managers' methods can identify individual experiences and organization proprietary structures that provide for

the minimization of medication errors and omissions for the patient. Findings from this study may provide causal information leading to the decrease of ADEs from medication errors and omissions. This action on the part of pharmacy managers may provide a reduction in liability costs from corporate lawsuits and settlements (Mansur, 2016). This reduction might also reduce liability insurance costs.

Implications for Social Change

While there is ongoing training, as well as checks and balances, in the medication phase of pharmacy services to decrease ADEs, there are financial losses that continue to be incurred by pharmacists' and medical service providers' inability to properly counsel patients on medication use. Approximately 100,000 deaths and 2 million serious patient injuries occur annually from medication problems and ADEs (Alexander & Wang, 2014). Inadequate counseling of patients, particularly polypharmacy patients is a serious factor in these figures. Addressing this situation would, in effect, help to reduce medication costs, insurance premiums, and aid in lowering Medicaid expenses. The quality of life for pharmacy and polypharmacy patients may improve both physically and financially.

A Review of the Professional and Academic Literature

The review of literature is an integral part of a study. The foundation for this study was built upon the information and background within the review. The reader can peruse the study and understand the purpose of the research question and the need to explore methods for an answer.

This review of literature is a means to explain and provide an articulate analysis of CAS and this theory's application in the management of the care of polypharmacy patients. Two other theories entertained as possible frameworks were total quality management theory (TQM) and the communication accommodation theory (CAT). However, TQM and CAT did not fulfill the overall requirements for this conceptual framework. There are interrelated areas in this review. The first is the discussion of CAS which clarifies community pharmacists' and corporations/companies' interactions and communications with polypharmacy patients. TQM and CAT are then discussed, and the reason they were not were not selected is given. The review follows with a discussion of the problems of medical and medication errors, ADEs, reactions, and effects, and the cost of medication errors. Finally, a discussion of community pharmacies, pharmacists, polypharmacy, polypharmacy patients, and polypharmacy patient management occurs in the latter part of this literature review.

This case study explored the methods that pharmacy managers use to provide the most beneficial management of polypharmacy patients. The methods of these pharmacy managers would be a determining consideration in seeking the goal of excellent counseling. The increase of purposeful management and counseling may lead to a decrease in their companies' financial liability costs and better health outcomes for polypharmacy patients.

I conducted a major portion of my research through online libraries and Google Scholar. Among the data bases used were PubMed, ProQuest Central, Walden DBA

Dissertations, ABI/Inform, Sage book collection, and the government National Institute of Health (NIH) publications. These databases provided a large amount of information for the study. This research included journal articles, books, health management dissertations, and pharmacy literature. Over 300 journals, books, and published articles were reviewed and scrutinized. Of these, 146 comprise the body of this literature review. Over 85% were peer reviewed; 69% were less than five years old as of my study's approval date (Appendix C).

Complex Adaptive System

I selected CAS for the framework of this research study**.** Waldrop (1992) explained that a complex system is where a great many independent agents interact with each other in many ways. The richness of these interactions allows the system as a whole to undergo spontaneous self-organization. However, a complex system lacks innovation (Poutanen, Soliman & Stahl, 2016). Complex self-organizing systems are adaptive. They turn whatever happens into an advantage (Waldrop, 1992). Cleveland (1994) provided the information that complex systems have a way of bringing order and chaos into a special kind of balance. This balance point is the *edge of chaos*. The edge of chaos is a zone where a complex system can be spontaneous, adaptive and alive: a complex adaptive system.

Cleveland (1994) indicated that CAS is a refining of the complexity theory. This theory delineated a system that is on the edge of chaos and has several characteristics. They are autonomous agents like a nest of ants made up of many independent individuals

who make decisions about their actions based on information in their environment. They provide parallel processing, and this process limits or influences one another's actions (autonomous agents). These agents do not act randomly; they make decisions based on some rules of nature. These rules connect the agents and allow a cohesiveness to emerge without any central source of direction (Cleveland, 1994).Cleveland (1994) provided the information that there are multiple- systems within the category of complex systems. These are: (a) Entropy- No System, a system without useable energy; (b) Closed Systems, which does not take in or give out energy within its system; (c) Open System; which inputs or outputs energy across its boundaries, uses that energy to maintain its structure. (d) Self-Organizing System; which generates new forms of order within the system and maintains the system throughout its changes; dissipative structures, and autopoetic systems are other names used by researchers for a self-organizing system.

CAS is an adaptive system that is open, self-organizing, on the edge of chaos, able to process high levels of information, and reforms itself continually. The CAS has the most viable attributes of complexity theory, yet is different because it has a high capacity for learning. Complex adaptive systems are refined complex systems (Davis, Dent, & Wharff, 2015). Davis et al. (2015) explained that CAS is a superior connection of networks of partially independent agents that produce system-wide patterns capable of adapting and learning. The agents of CAS are independent and incomparable with a common direction and they are nonlinear, self-organizing, and fully adaptable to the present situation (Davis et al. 2015).

Cleveland (2005) presented the features of CAS as: (a) emergence, patterns exhibit themselves to solve existing problems; (b) exploitation, the mastery of the problem spreads quickly and standards set; (c) equilibrium and stability is achieved between the system and the environment; (d) disequilibrium, new problems arise that cause the system to become disruptive; and (e) reintegration or Disintegration, the system adapts to the problems and emerges at a higher level, or it fails to adapt and collapses into chaos.

Davis et al. (2015) asserted that the CAS is such a viable, nonlinear system that it is fully capable of being at the edge of chaos in disequilibrium, and is able to resolve and renew itself internally and externally and adapt to the situation, and rise to a new level of equilibrium. Cleveland (2005) also stated that evolution to a new level of achievement occurs when a CAS is at the edge of chaos. Keshavjee, Kuziemsky, Vassanji, and Ghany (2016) concluded that the CAS is a near optimum means of studying the issues of health information technology and the delivery of healthcare services. Gossett, Padgett, Pierce, and Scott (2019) used CAS theory to identify current independent variables that were related to access issues, safety and quality issues, cost considerations, and stakeholder satisfaction that were both directly (+) and inversely (-) related to one another to show why the U.S. healthcare system has the problems of inefficiency, ineffectiveness, being excessively costly, and having poor satisfaction in the delivery of healthcare services. For example, if preventable medical errors go up, safety and quality will go down, costs will go up, and stakeholder satisfaction will go down. This cycle of events will also

cause or contribute to access for new patients to also go down and the healthcare system will find itself bordering on the edge of chaos. Recommendations were made in this study to use evidence based practices to address these problems in improving safety and quality, bending the cost curve, and increasing stakeholder satisfaction.

Poutanen et al. (2016) concluded in his research of CAS utilization, that organizations can be successful (innovative) when operating under CAS. CAS is non-linear and cannot reduce to it's component parts. An organizations using CAS has a better chance of success when it adapts to changing internal and external influences in the form of feedback loops and coevolves (Poutanen et al., 2016). Oughton, Usher, Tyler, and Hall (2018) concurred with the use of CAS as an application to the infrastructure of an organization. CAS can be delineated as a large number of forces that interact, learn, and adapt to changes within their environment so they can be successful (Oughton et al., 2018). The infrastructure of an organization has the same inputs (forces) as CAS in the relationships of independent variables to dependent variables that are either (+) directly related or inversely (-) related to one another.

Community pharmacies vary from sole proprietorships to full corporations. These businesses range from low complexity to high complexity and at various levels of provider/ patient interaction. The strategy of the pharmacy manager requires examination from two viewpoints: (a) business hierarchy to business hierarchy and (b) community

pharmacist to the patient (stakeholder). Pype et al. (2017) supported the use of CAS to study the integration of all of the parts of a healthcare organization.

A sole proprietorship pharmacy is a CAS. This type of pharmacy illustrates a basic complex adaptive system. The owner, pharmacy manager and pharmacist could be titles held by one person with pharmacy technician to assist. These two people constitute the internal operations of the system. There are constant outside influences. Among these influences are inputs and outputs for local, state, and federal licensing and regulations; inputs and outputs from and to medical and hospital prescribers; outputs and inputs to and from patients in the form of medication, advice, and management; inputs and outputs to and from supply and demand; and other miscellaneous external influences. There are also constant internal interactions that influence the output of the company. Every day, the pharmacy manager must address multiple complex situations and crisis and achieve solutions that improve their output and enhance their perpetuity.

A C class corporation is a multilevel and highly intricate complex adaptive system. A corporation presents an illustration of a typical healthcare corporation. The chief executive officer under the guidance of the board of directors leads the presidents of the pharmacy corporation division, the president of the mail-order prescription division, and the president of the insurance division. The executive level of the pharmacy corporation has some divisions such as the chief operating officer, chief financial officer, human resources, etc. The executive level receives direction from the pharmacy president and passes on directives and guidance to upper, middle, and lower management. The

managers of upper middle management are responsible for various areas of the United States and its territories. The managers in middle management are responsible for regions within the areas of upper middle management, and the managers in lower middle management are responsible for districts within the regions of middle management. Lower management consists of various community pharmacies in a district. The internal complexity of the corporation is extensive. The added external inputs are also greater because multiple inputs at every level and the additional input from shareholders, patients, and employees. The daily regimen of the local pharmacy is consistently on the edge of chaos, yet reaches equilibrium, and completes all its tasks without falling into disequilibrium.

Because the infrastructure of pharmacy companies and organizations, large and small, encounter the same active forces on a daily basis, CAS is well suited to be the framework for my research. Multiple inputs occur daily in a pharmacy, and these inputs have an effect (directly or indirectly) with the intercourse and association between pharmacist and polypharmacy patient.

Rival Theories

Communication accommodation theory. CAT first made publication in the 1970s (Giles & Ogay, 2007). This theory is a broad framework designed to predict and explain the manner in which individuals make allowances in creating, maintaining, or increasing/decreasing social distance in verbal/nonverbal interactions (Giles & Ogay, 2007). Giles and Ogay, (2007) stated that the situation the participants are in and the

context in which the communication is happening influences the verbal intercourse. The situation is not uncommon for a conversant to start a communication as the person he/she is and change to the context of the situation (e.g. a pharmacist may speak to a patient as the pharmacist and then change the conversation to where he is a representative of the pharmacy), subject/object discourse (Giles & Ogay, 2007).

CAT is a unique framework for comprehending the interpersonal dynamics of communication (Farzadnia & Giles, 2015). CAT illuminates a person's credulity and influence beneath their communication behavior either toward or against those present in a conversation (Farzadnia and Giles (2015). Chevalier, Watson, Barras, and Cottrell (2015) and Farzadnia and Giles (2015) espoused that CAT has five unique features, approximation, interpretability, interpersonal control, discourse management, and emotional expression.

Both Chevalier et al. (2015) and Farzadnia and Giles (2015) offered similar explanations for the five strategies: Approximation refers to how persons adjust their speech methods such as pitch, tone or dialect in a conversation with others; Interpretability is the manner in which a speaker changes their language to match the communication level of the recipient so as to enhance understanding on the part of the recipient; Interpersonal control is the method in which the speaker adjusts their speech and manner to match the status and role of both persons; Discourse management involves the speaker's concern for the recipient and how to maintain the conversation in

such a manner that it is not one sided; Emotional expression is the way the speaker responds to the emotional and relational needs of the recipient.

Additionally, Chevalier et al. (2015) provided some examples of each strategy, Approximation strategy is when a pharmacist slows down and enunciates his speech to match the slow speech of an elderly patient; Interpretability is when a pharmacist deciphers complicated pharmaceutical definitions to the understanding level of their patient when speaking with them, Interpersonal control is when a pharmacist does not permit his authority to interrupt or change the subject when conversing with a patient, Discourse management is when the pharmacist ensures that the conversation involves turn-taking and back channeling, and Emotional expression involves the pharmacist's appropriate level of empathy and reassurance to a patient's healthcare concerns.

Farzadnia and Giles (2015) analyzed some of studies involving the communication accommodation theory in the healthcare provider to patient communication area. Six of the studies were qualitative, six were quantitative, and one was mixed methods. The result of the study was that provider and patient had difficulties approximating with each other, yet they respected the others' knowledge and manner. There was an apparent effort for control of the conversation by the provider (Farzadnia & Giles, 2015). Farzadnia and Giles (2015) also concluded that the analysis showed that providers were better managers of discourse than patients and that the studies concentrated on the emotions of the providers and not on those of the patient.

In context, discourse is very important in the management of polypharmacy patients. Many polypharmacy patients understand the indications for their medications. However, they may be unaware of any contraindications or complications in combined use of their medications. The pharmacist has the responsibility to counsel and clarify the proper medication use to a polypharmacy patient in a manner to preclude stress and apprehension. CAT was not selected because the theory did not consider the integration of the company/corporation's involvement in the research question.

Total quality management. TQM is a management theory that seeks to sustain the continuous quality of the product through quality management (Marinkovic, Bekcic, Pejovic, Majstorovic, & Tasic, 2016). TQM enhances the aspect of quality products and techniques can be achieved by continuous quality management and workforce improvement (Marinkovic et al., 2016). Staff at healthcare organizations may use it to identify customer requirements, benchmark them, and make improvements (Mosadeghrad, 2015). Mosadeghrad (2015) implied this could lead to lower occurrences of medical errors.

Many of the companies that have instituted TQM feel there has been minimal or less than average quality improvement since inception (Talib & Rahman, 2015). TQM might be compared to the Burman et al. (2016) explanation of complexity science. Total quality management has a linear interaction (input-production-output), and does not readily interact with non-linear interactions that are not predictable. Talib and Rahman

(2015) indicated that certain barriers hindered the implementation and outcome of TQM in many businesses. These barriers have three main categories: people orientated issues, managerial issues, and organizational issues (Talib & Rahman, 2015). Talib and Rahman (2015) have one barrier in the people-oriented issues labeled "*employee's resistance to change";* and one barrier in the organizational issues category labeled "*lack of continuous improvement culture."* Some researchers feel that the cultural change required is difficult to obtain (Barouch & Kleinhans, 2015). Barouch and Kleinhans (2015) stated that many of the failures of TQM occur because the culture of many areas is not conducive with the culture in which TQM was created. Cultural awareness and accommodation are main requirements in the daily duties of a pharmacy manager. TQM would not be a favorable theory for the research of polypharmacy patient management and counseling by pharmacists. Pharmacist management and counseling of patients requires constant cultural awareness and interpersonal awareness.

Medical Errors

Researchers from John Hopkins indicated that medical errors had replaced respiratory disease as the third greatest cause of death behind heart disease and cancer (Sorrell, 2017). Zikhani (2017) indicated that medical errors take 250,000 to 400,000 lives annually at the cost of approximately $1 trillion. Medical errors are generally classified into five groups: operative errors, drug-related (medication) errors, diagnostic and therapeutic errors, procedural errors and other miscellaneous errors (Starmer et al., 2014). Medication errors account for approximately 50%-53% of all medical errors, but

only about 10% of the cost (Starmer et al., 2014). The medication error group is the pertinent group for this study.

Bari, Khan, and Rathore (2016) explained that a medical error is the inability to complete a plan of action as intended or the developing of the wrong plan to obtain a desired result. Medical errors are a serious problem that need addressing. The magnitude of this problem is considerable, and there has been limited progress in reducing medical errors (Ghormley, 2015).

To illustrate the possibility of the interrelation between medical errors, Singh, Meyer, and Thomas (2014) conducted a study on outpatient diagnosis errors. The summation of three previous studies indicated diagnostic errors in at least 5% of outpatient diagnosis (Singh et al. 2014). A person may then hypothesize that any medications prescribed, as a result of the diagnostic error, is a medication error.

Starmer et al. (2014) proposed that incorrect communication is a leading cause of medical errors. Implementation of a handoff program would lead to a reduction in errors. This program would oversee the transmission of the patient's diagnosis, from beginning to culmination, and interject corrections if required, as the process progressed (Starmer et al., 2014). The program would involve written communication, audio recordings of medical orders, and a form of second opinion. The implementation of a test handoff program led to a reduction of medical errors by approximately 23% (Starmer et al., 2014).

Medication Errors

Medication errors are the most common source of ADEs and ADRs (Wittich, et al., 2014). Cloete (2015) explained a medication error is a preventable medication situation that causes harm or has the opportunity to cause harm to a patient. Mansur (2016) clarified that a medication error might be associated with professional practice, procedures, and systems that include prescribing, communication of orders, labeling and packaging of a product, nomenclature, compounding, and dispensing. This review concentrates on medication errors (mistakes) that occur in the prescription process. Any mistake in the process of medication use, whether by omission or commission is a medication error (Wittich et al., 2014).

A medication error can occur at any point of the prescription process. The error can occur in the origin of the medication, where the prescriber may order the wrong medication or the incorrect strength or dosage of the medication (Goedecke, Ord, Newbould, & Brosch, 2016). Errors can occur in the initiation and the transmission of the medication prescription, in the reception of the order, and handwritten prescriptions may require some interpretation, due to legibility (Mathaiyan, Jain, Dubashi, Reddy, & Batmanabane, 2014). There may be a conflict in the drug name. Medication may not be available in strength specified. Dosing instructions may be out of parameters (Cruz & Nagarathnam, 2015).

Medication errors are any error of commission or omission as it pertains to a prescribed medication during the origination of a prescription, its transmission, and

reception to the producer, its production, through use of the medication by the designated receiver. A prescribing authority could make a wrong diagnosis (medical error) and prescribe a non-appropriate medication for the incorrect diagnosis (medication error). This prescription could have a strength stated that is incorrectly interpreted in the pharmacy (medication error) and delivered to the recipient. Cruz and Nagarathnam (2015) included the formulary, manufacture, and labeling of the medication as sources of medication errors. A medication could be manufactured with an inappropriate ingredient and then have an incorrect strength on the label (medication errors).

Medication errors do not occur only in the pharmacy or hospital setting. They occur in the home setting also. Medication adherence by patients is a problem. The problem is more so with elderly patients (Pasina et al., 2014). Pasina et al. (2014) declared that adherence to medication regimen is very important in the care of acute illness and disease. However, elderly patients taking more than one medication for chronic illnesses or disease have a proclivity to greatly decrease their adherence to medication regimen after approximately six months (Pasina et al., 2014). These are errors of medication that can easily lead to hospital events.

Another form of medication error has to do with the use of over-the-counter (OTC) drugs and self-treatment (Schmiedl et al, 2014). Schmiedl et al. (2014) explained that the use of OTCs and prescribed medications can easily lead to self-inflicted medication errors and hospitalization from an ADR. Most of these errors happen in elderly females aged 70-79, and men in the age group of 60-69 (Schmiedl et al. 2014).

Ellis et al. (2015) concurred with this information and added that the sharing of medications is an additive to the probability of a medication error by the elderly.

Adverse Drug Events

There are a number of healthcare situations which are of concern to healthcare providers. The ones to be discussed here are ADE, adverse drug reaction (ADR), and adverse drug effect (ADe). Yu et al. (2015) described an ADE as an injury caused by giving or an error in giving or taking medication. Abubakar, Simbak, and Haque (2014) referred to an ADE as any ill occurrence that becomes present during the treatment with medicine but is not necessarily related to the treatment. Adis Medical Writers (2013) described an ADE as any uncontrollable, medical situation related to a drug even if it is not directly connected to the drug.

Edwards (2014) defined ADe, as an ill effect attributed to a drug or the taking or incorrect taking of a drug (p 7). Another similar definition for ADe is possible harm arising from the use of a drug or mistakes in the administration itself which may or may not associate with the drug (e.g. label warning: this drug may cause nausea), (Adis Medical Writers, 2013).

Edwards (2014) described an ADR as a harmful or noxious reaction, as a result of an intervention from the use of a medicinal product. An adverse drug reaction is the human response of a patient to a drug, described as a hurtful or negative reaction, culminating from the use of a medicinal product that depicts a danger from future use (Edwards, 2014). The staff at Adis Medical Writers (2013) stated that an ADR is an

atypical, possibly harmful reaction to medication by a patient. Dedefo, Mitke, and Angamo (2016) stated that all ADRs come under the label of ADEs. Therefore, all adverse drug reactions, adverse drug effects, and medication errors are considered ADEs.

Business Cost

Medication errors and the resulting adverse events associated with the elderly incur an annual cost of approximately $177 billion (Young, et al., 2015). The IMS Institute for Healthcare Informatics, (2013) expanded on this generality to point out that the cost is more than $200 billion every year. Patients not adhering to doctor's medication guidance and obtaining pharmacist's counseling account for an estimated $105 billion of the total mentioned (IMS, 2013). Staff at IMS, (2013), further stated that another $35 billion occurs with the misuse and inappropriate prescriptions of antibiotics.

The IMS Institute for Healthcare Informatics believed that improved medication use could improve the savings in healthcare costs (IMS Institute for Healthcare Informatics, 2013). The organization puts forth six methods of improvement to effect this: improving medication adherence of patients through the addressing of their beliefs and behaviors when prescribing and during use; ensure timely use of medications by patients with diseases or conditions that require strict adherence; optimize antibiotic use and decrease overuse; lower medication errors from the point of medication prescribing through administration; provide optimal use of generic drugs whenever possible; instill a competent management system for polypharmacy that is safe and encompasses the polypharmacy patients' requirements (IMS 2013). Of the estimated $900 billion- plus in

annual healthcare cost the IMS (2013) estimated that incorporating these qualifiers could reduce the avoidable multibillion-dollar healthcare costs by approximately $269 billion.

Polypharmacy

Gillette, Prunty, Wolcott, and Broedel-Zaugg (2015) presented, along with their definition, that there exist a minimum 25 explanations for the term polypharmacy. Definitions for polypharmacy have been used to describe methods of inferred inappropriate medication therapy, evidenced based therapy, as well as the use of multiple pharmacies (Gillette et al., 2015). For many years, scholarly investigations of polypharmacy using various approaches and definitions have provided inconclusive results in the study of polypharmacy (Mortazavi et al., 2016).

Multimorbidity is the presence of two or more chronic medical conditions in a patient (Wallace et al., 2015). Chronic medical conditions are identified as heart disease (hypertension), chronic obstructive pulmonary disease (COPD), diabetes, etc. (Wallace et al., 2015). Brown (2016) indicated that two-thirds of the population over the age of 65 had two or more chronic illnesses. The result is that the patient is most likely under the care of two or more medical professionals. Also, each condition requires at least one maintenance medication sometimes of complex formulary. Wallace et al. (2015) promoted multimorbid patients as polypharmacy patients in their journal article and, thus identified the complexity of their situation. The management of multimorbidity is complex because the medication needed for each condition has to be prescribed in

consideration with the medication for other conditions to obviate or minimize possible adverse interactions (Wallace et al. 2015).

Agur, McLean, Hunt, Guthrie, and Mercer (2015) conducted a study in Europe on multimorbidity from within an age group of 25 to 75 years. Conclusions obtained from this study indicated that through all age groups, especially within the 65 plus age groups, women had a greater amount of multimorbidity (Agur et al., 2015). Agur et al. (2015) proposed that the difference may arise from the fact that women had more medical and mental multimorbidity than men.

St Sauver et al. (2015) consolidated a 14-year multimorbidity study conducted in America. The study indicated less difference in multimorbidity between men and women than the European study. One item of note in this study was that multimorbidity in Medicare patients greatly increased from 62% in the age group 65-74 to 82% in the age group 85 and older (St Sauver et al., 2015).

The term polypharmacy has come to mean multiple prescribed medications, multiple morbidity, multiple use of over-the-counter (OTC) medications with prescription medications, and the use of multiple pharmacies to obtain medications (Brown, 2016; Gillette et al., 2015; Payne & Duerden, 2015; Turner et al., 2016). A note of fact is that there are multiple numbers used to quantify the term polypharmacy. They range from two to more than five (Brown, 2016; Gillette et al., 2015). There have been numerous conclusions as to the proper number to quantify the term polypharmacy. Multiple (n.d.) is defined in the Merriam-Webster online dictionary as “more than one”.

The use of multiple medications by the population of the United States considered middle aged and older has greatly increased (Cadogan, Ryan, & Hughes, 2016). Duerden & Payne (2014) commented that polypharmacy is so widespread it is considered common in most patients using medications. Brown (2016) stipulated that nearly one-third of all prescriptions filled in the Unites States are used by older adults. Research has shown 38.1% of Medicare D patients use multiple pharmacies for their medications (Brown, 2016). The use of polypharmacy has historically had a negative connotation because of the propensity of ADEs (Cadogan, Ryan, & Hughes, 2016). Pereira (2016) indicated that some OTC herbal products could alter some medication's absorption, metabolism, and excretion. The use of OTC medications and herbals continue to complicate polypharmacy with concurrent use being a possible source of harmful reactions and addiction (Pereira, 2016). In the past few years polypharmacy has also gained a negative reputation, due to under prescribing as a cause for a patient not receiving necessary medication to maintain a patient's wellbeing (Cadogan, Ryan, & Hughes, 2016).

The Beers criteria update of 2012 provided an update on drugs used in geriatric care (Chitra, Sowmya, Sathyan, & Srisha, 2015). The Beers criteria aids doctors and other healthcare professionals to more accurately recognize and classify drugs used for geriatric patients. The Beers criteria also places medications used for geriatric patients into three groups: group one lists drugs that are a potential danger to older patients; group two lists drugs that should not be considered for use in specific drug or disease state;

group three lists medications that should always be used with care and caution (Chitra et al., 2015).

Community Pharmacy and Pharmacist

Major reforms have occurred in healthcare systems in recent years (Rutter, Brown, Howard, & Randall, 2014). Rutter et al. (2014) explained that, as a result of changing economic and political pressures in the 21st century, existing resources had been optimized to ensure more effective and efficient healthcare. This is reflected in the pharmacy profession. Community pharmacists have prioritized patient care and health in conjunction with their regular medication supply mandate (Rutter et al., 2014).

Pharmacists are no longer just a provider of medication. Their role has grown immensely in the past few years. Now pharmacists are again at the forefront of providing an active part in the healthcare of patients on medications (Almarsdittir & Babar, 2016).

Pharmacists have received excellent training in the management of patients in the proper use of medications, over-the-counter medications, and herbal treatments. Pharmacists have also received special training in medication therapy management (MTM) (Isetts, 2017). Almarsdittir and Babar (2016) explained that pharmacists are better able to counsel a patient, not only on a particular medication; they have exceptional competence in managing patients' use on all their medications and drugs, as to interactions and any contraindications of combined use.

The pharmacy profession, especially the community pharmacy, is a very active and evolving profession (Rensburg, Kotze, Lubbe, & Cockeran, 2017). The profession

has progressed from just medicine preparation and selling, to a patient centered service industry. Rotta, Salgado, Silva, Correr, & Fernandez-Limos (2017) stated this change had enabled the pharmacist to adjust their focus on patient centered service requirements as they exist in their community.

Kiel and Phillips (2017), in their research, described the demand for more attention in healthcare that older patients are now requesting regarding their use and understanding of their multiple medication uses. Pharmacists have a responsibility to conduct a comprehensive medication review (CMR) for older patients in their use of multiple medications and adherence thereof (Kiel & Phillips, 2017). Kiel and Phillips (2017) completed their research with the conclusion statistics indicated that CMR conducted by pharmacists, as well as patient counseling, led to a decrease in medication related problems.

There have been many reviews evaluating the outcome of pharmacist initiated patient care outcomes (Rotta, et al., 2015). Rotta et al. (2015) implied that pharmacists are attempting to expand their role of service past the point of simply distributing and dispensing medications. The pharmacist is playing an intricate role now in the area of patient medication safety and management (Rotta et al., 2015). Rotta et al. (2015) researched 49 systematic reviews of pharmacist care, and derived an outcome that pharmacy services were more successful when addressing a specific condition, such as hypertension.

Shiyanbola, Mott, and Croes (2016) declared that patients play a more active part in healthcare and their understanding of healthcare quality is very important. Shiyanbola et al. (2016) conducted six focus group interviews. These focus groups were composed of adults 65 years and older. The object of the interviews was to get the subjective opinions of these adults on their pharmacy preferences. The results of these adult inputs were they preferred a pharmacy where the pharmacist provided patient centered care (the pharmacist had an interpersonal relationship with them), and convenience and location of the pharmacy was their second option (Shiyanbola et al., 2016). A questionnaire survey conducted by Nitadpakorn, Farris, and Kittisopee (2017) supported the results of Shiyanbola et al. (2016), by concluding that pharmacist's services increase pharmacy service and pharmacy customer devotion.

However, some limitations exist. Yang, Kim, Choi, and Chang (2016) conducted a cross sectional descriptive survey of 252 patients and 462 pharmacists regarding patient-pharmacist counseling. The findings of Yang et al. (2016) indicated that only 47.3% of the pharmacists and 34% of the patients felt satisfied with the medication counseling that occurred on a routine basis. 51.2% of the patients felt that more time was needed to provide a satisfactory medication consultation, while 24.3% of the pharmacists concurred that more time to properly counsel was required (Yang et al., 2016).

Antunes, Gomes, and Cavaco (2015) conducted a study of pharmacists' ability to combine professional communication with cultural exchange in the execution of their duties. The study included 59 interviews with participants of an average age of 65+ years.

Antunes et al. implied that pharmacists with a high degree of medication related competency and a low degree of social amenities communication ability were less likely to encourage pharmacy loyalty. Kerr et al (2017) agreed that pharmacist communication skills may be more attuned to professional expertise than social communication and need improvement (re: communication accommodation). Although studies on pharmacists' communications with pharmacy patients are limited, Kerr et al (2107) recommended that there exists a need for improved pharmacist psychosocial and clinical communication training.

Polypharmacy Patient Counseling

Approximately twenty percent of all patients under physician care that are over the age of 65 receive sixty percent of all prescription drugs (Rose et al., 2015). These patients take multiple medications every day. Rose et al. (2015) explained that polypharmacy and multimorbidity have the possibility of many consequences: non-appropriate drug use, less than optimal drug treatment, medication errors, less than optimal use of medications, errors in medication, poor drug interactions, and ADRs. As a result, pharmaceutical patient care systems such as medication review (MR) and medication therapy management (MTM) have evolved into prominence to provide help for patients and the community. Medication reviews are performed by pharmacists using a polypharmacy patient's medication list. A pharmacist gathers all the information on the medications that a patient uses, confirms same with the patient, and make a list for review and consolidation (MR) (Kiel and Phillips, 2017). The pharmacist then places the

medications in an order of use that is most beneficial for the patient's care and well-being. The pharmacist then counsels the patient on the proper taking and timing of the medications, and precautions to be observed (MTM) (Rose et al., 2015). Routine follow-ups between pharmacist and patient are scheduled to ensure observance and adjustments (Huiskes, Burger, van den Ende, & van den Bemt, 2017).

A different program criteria, as described by Kiel and Phillips (2017), is the START/STOPP criteria. This is an acronym for Screening Tool to Alert doctors to Right Treatment/Screening Tool of Older Persons' Prescriptions. A pharmacist conducted a review of 52 patients with the average age of 76 years. A comprehensive medication review (CMR) using the START/STOPP ensued for 26 of the patients. The 26 in the control group did not receive the CMR. The results of the medication review indicated a large decrease in medication-orientated problems compared to the control group (Kiel & Phillips, 2017).

Ros, Koekkoek, Kalf,van der Bemt, and Van Kan (2017) conducted a study of 49 polypharmacy patients. General practitioners referred 49 of their patients, who had problems with their medications, for the study. A clinical pharmacist and a clinical geriatrician assessed these patients' medications and regimen (Ros et al., 2017). Upon completion of the assessment, 82% of the recommendations made by the pharmacist were agreed on by the geriatrician and instituted. These recommendations involved approximately 6.6 interventions per patient (Ros et al., 2017). These interventions

resulted in a reduction of drug related problems with these particular patients (Ros et al., 2017).

Lau, Htun, Chan, and Klainin-Yobas (2017) iterated that the World Health Organization (WHO) specified there were five main factors that affected patients' adherence to medication therapy. These 5 factors are: (a) health care team related, (b) patient related, (c) disease related, (d) therapy related, and (e) socioeconomic related. The names readily evidence that the pharmacist is directly involved in three of these factors namely: healthcare team, patient, and therapy. The pharmacist is also somewhat related to the socioeconomics factor. The pharmacist therefore plays a principle role in the healthcare of polypharmacy patients.

Polypharmacy patients often fail to adhere to their medication regimen (Kooy, Geffen, Heerdink, Dijk, & Bouvy, 2014). Kooy et al. (2014) stated that non-adherence diminishes the effectiveness of long-term medication therapies. Pharmacists play an extremely important role in encouraging these patients the importance of taking their medications correctly and timely to ensure a quality of life. Marcum, Hanlon, and Murray (2017) concur that poor medication adherence is a major health problem with older adults. Almost 50% of older adults are non-adherent in the taking of their medications as prescribed (Marcum et al., 2017). Non-adherence and poor adherence have a deleterious effect on older adults. The estimate for the annual cost of the resulting morbidity and health services cost for has been given at over $100 billion (Wenger et al., 2017).

Marcum et al. expand the cost by including ADEs and other health issues to non-adherence and poor adherence to between $100 billion and $300 billion.

Wenger et al. (2017) estimates that approximately 12% of elderly men and women (over age 65) take at least 10 medications per week. This amount of medication includes prescribed medications, over-the-counter medications, and herbal/vitamin medications. The ensuing problems that occur from this medicinal overuse result in over 170,000 emergency room visits, by the elderly, annually (Wenger et al., 2017).

Antunes, et al. (2015) implied that pharmacists, in daily interaction with patients, often only give brief counseling measures to their patients. This short period of information exchange is, at times, insufficient to cover the needed therapy information that the patient requires (Antunes et al. 2015). However, it should provide the opportunity for the pharmacist to arrange, with the patient, a personal consultation time for further information and recommendations to enhance the patients understanding of use and adherence of the medication.

Pharmacists need to provide more and complete counseling to polypharmacy patients. Medication counseling is paramount for the effective outcomes by polypharmacy patients (Yang et al., 2016). A cross sectional survey by Yang et al. (2016) indicated that the present method of counseling of patients by pharmacists yielded a low level of satisfaction by both parties. This indicates that there is an immediate need for the community pharmacist to have their workload adjusted so that the polypharmacy

patient receives the necessary counseling to sustain their quality of life (Yang et al., 2016).

Transition

Section 1 provided information on the necessity of pharmacy managers to explore possible ways to improve counseling of polypharmacy patients, and thus be able to cause lower costs to the company through the lessening of ADEs. Section 1 also described that this study would be a multiple case qualitative study (Yin, 2018). The review of literature explained medication errors and ADEs, and correlates them to pharmacy managers and polypharmacy patients. The conceptual theory was expanded in the review to clarify the paradox of a pharmacy manager's position in an organization's hierarchy.

Section 2 expanded upon the order and conciseness of the project. Section 2 also expanded on the role of the researcher, and the methods and design of the research. The section concluded with an explanation of the requirements of reliability and validity. Section 3 explains the results of the study and recommendations for the future.

Section 2: The Project

In Section 2, I discuss the role of the researcher and the participants in the research. The research method and design are discussed at length. The criteria for ethical research data collection and analysis will be expanded upon, providing the basis for validity and reliability of the research.

Purpose Statement

The purpose of this qualitative exploratory multi-site case study was to explore the strategies pharmacy managers use to reduce the financial costs associated with ADEs incurred by polypharmacy patients. The population included community pharmacy managers living in central Florida. Inputs from five of these pharmacy managers, who have successfully addressed this problem was appropriate for this study. Those inputs provided sufficient information to infer possible solutions and areas for future exploration. In addition to discovering options for reducing the financial costs, the study results may provide methods to improve the quality of life for the polypharmacy patient.

Role of the Researcher

In qualitative research, the researcher is responsible for the collection of data, from the formation of the questions in a semistructured format, through the analysis of the data, and the use of valuable, relevant documents for the triangulation of the data (Malagon-Maldonado, 2014; Yin, 2018). An excellent review of literature is an essential requirement for a researcher (Donges, 2015). However, researchers must be aware of their interpersonal and interactional actions with the research and interviewees and the

effects that may arise from these interactions (Kiikkala, & Astedt-Kurki, 2015). The researcher must strive to maintain neutrality and objectivity in all semistructured interviews (Lehna et al., 2015). Bias was of great concern to me as a novice researcher, such as I. Obtaining and maintaining a personal degree objectivity was a constant concern. I endeavored to use my literature review, member checking, and a most careful objectivity during the interviews to minimize my personal lens.

I am a certified pharmacy technician (CPhT) and have 8 years of direct service in a community pharmacy. However, I did not have any personal relationship with any of the potential participants of this study. McDermid, Peters, Jackson, and Daly (2014) stated that an insider is considered well acquainted with the background of the research and has an exceptional amount of knowledge of the community and its members. This situation can provide the basis for rapport, professional respect, and a sense of familiarity (McDermid et al., 2014). An outsider may take a prolonged period to establish this familiarity and insight (Marshall & Edgley, 2015). Elimination of professional and personal conflict occurred because all participants were in superior positions of respect and authority to this researcher. Additionally, I consistently reflected on my experiences and worldviews to minimize my bias and keep my professional association limited within the proper research bounds (Lehna et al., 2015).

I maintained the highest standard of ethics and ensured the protection of the rights of research participants. I supported fairness, practiced beneficence, aided justice, and did more good than harm when interacting with all the participants (U.S. Dept. of Health and

Human Services, [NIH], Office of National Research Protection, 2014). The Belmont Report was the guideline for ethics in research of human participants and for understanding the unique situation of participants (Bromley, Mikesell, Jones, & Khodyakov, 2015; U.S. Dept. of Health and Human Services NIH, Office of National Research Protection, 2014). I renewed my NIH certificate #2052088 in April 2016.

I was aware of my personal beliefs, professional ethical standards, and biases regarding medication errors and omissions and patient counseling before beginning the process of participant interviews, and the review of documents. As the data collection instrument, I mitigated bias through determined objectivity in the semistructered interviews, paying particular attention to the appearance of saturation and member checking (Fusch & Ness, 2015). Management of biases and beliefs is of the utmost importance for maintaining the integrity of data collection and the process of analysis (Bromley et al., 2015).

My personal biases were a belief that pharmacists could not provide proper counseling to any patient regarding the medications they take. Similarly, I believed that polypharmacy patients, as well as regular patients were unaware of their situation and unwilling to acknowledge it for the sake of economics (cheaper drug cost). Also, retail pharmacy corporations appeared to accept the ADE costs and escalation rather than to expose proprietary information. There may be a solution to lower costs (losses) and increased the health of patients without negative ramifications to corporate stability. The diminishment of these biases occurred through the review and approval of the interview

questions by the research committee (Yin, 2018). The conduct of the interviews included techniques to mitigate bias at all times. I provided the interview questions in a monotone manner. I recorded the questions and responses without interjection. If a statement made, was not clear, I obtained amplification or clarification through member checking (Fusch & Ness, 2015). Review of peer-reviewed journals and documents further mitigated bias (Fusch & Ness, 2015). The interviews were in person, one-on-one, and recorded. Phone interviews were not required. The interviews were of the shorter case type.

Participants

Bromley et al. (2015) and Newington and Metcalf (2014), explained that a participant should be knowledgeable and focused on the subject of the research. The participants of the study were registered pharmacists with 5 years of experience, designated as the pharmacy manager and successful in addressing ADRs with polypharmacy patients. These pharmacy managers had a minimum of 2 years' experience in that position. Of these pharmacists in central Florida, five participated in the study.

Newington and Metcalf (2014) mentioned that a socio/professional familiarity between researcher and participant is often helpful in obtaining a working relationship. This familiarity can help ease any reticence, on the part of participants, encouraging them to be forthcoming in their responses (Chereni, 2014). The status of the researcher and participants was ideal for this type of semistructured interviews.

I sent a letter to the proposed participants (Appendix A) introducing myself, describing the research, and providing a brief overview of its purpose. The letter gave the

main research question, the criteria for participation, and a stipulation that the participants would remain anonymous and their information would be kept confidential. The letter closed with a request for a personal appointment. Eight pharmacy managers were sent letters of request, with a response rate of 62.5%.

Research Method and Design

Of the three research methods put forth by Yin (2018), namely qualitative, quantitative, and mixed methods, I selected the qualitative approach. The qualitative method provided a means for seeking insights into the business problem of the inquiry. An exploratory single case study design was the most appropriate means to investigate this inquiry.

Research Method

I chose a qualitative method for my research. Allen (2015) stated that a qualitative researcher tries to provide clear and sensible information about a phenomenon. Kornbluh (2015) implied that qualitative research is the study of a phenomenon using clear and understandable language to describe human experiences. Qualitative research provides a more interpersonal and direct method to gain insight, and observation of the participants in their setting (Grossoeh0me, 2014). The benefit of these observations during the interview questions assists the observer in member checking and triangulation (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2014). This method and observations led to a collection of rich data for analysis.

A quantitative study would not provide sufficient interpersonal data and observation. The quantitative method examines a phenomenon through statistics and variables and obtains data that is quantifiable (Ingham-Broomfield, 2014). Fusch and Ness (2015) concurred that quantitative research addresses questions and pertinent relationships through statistics, objective measurement, and observation. This method does not provide for sufficient exploration of a phenomenon.

The mixed-methods form of research is a combination of both the quantitative and qualitative methods (Halcomb & Hickman, 2015). Mixing the two methods of research complements the research and offers a richer insight into the research question (Thonon et al. 2015). Halcomb and Hickman (2015) implied that the two methods interlink during the research process, and this enables a more comprehensive understanding of the responses to the research question. The mixed methods format is very laborious and time-consuming (Thonon et al. 2015). This method would not be satisfactory for a multiple case exploratory qualitative research endeavor.

Research Design

The exploratory, multiple case study design was most appropriate to investigate the research question. The multiple case study enabled the use of multiple inputs from participants employed in different organizations replying to the same questions to obtain rich analysis (Cope, 2015). Documented research obtained from various sources, combined the participants' interview replies and observations, creates a better exploratory study (Kruth, 2015). Kruth (2015) implied that a multiple case study could give a clear

understanding of the phenomenon by examining multiple cases from varied perspectives. These strategies aligned well with this study.

Focused ethnography is an adaption of ethnographic design (Wall, 2015). Wall (2015), stated that participants might share a cultural perspective, and as a part of a broader culture, may share differing views of the study. Focused ethnography involves learning about people by learning from them (Wall, 2015). Focused ethnography, like ethnography, requires a study over an unspecified period (Leslie, Paradis, Gropper, Reeves, & Kitto, 2014). A focused ethnography did not meet the needs of this study because of its more intensive data collection and analysis.

A focus group study involves some people in a determined group who discuss a particular subject guided by a moderator (Vander Laenen, 2015). Vander Laenen (2015) stated that the focus group derives a collective view on the subject matter, through discussion and negotiation of their inputs. Focus groups are a small number of participants who discuss a specific topic, provided by a moderator and reach a collective guided consensus of the topic (Vander Laenen, 2015). Dube, Roberts-Lombard, and van Teander, (2015) described a focus group as a group where interaction of the group's inherent symbiotic energy leads to a guided solution, meaning and insight on a specific subject. However, a focus group design does not explore an individual's experiences on a specific matter.

Kruth (2015) stated that a narrative study concentrates on an individual or group over a period and chronicles and identifies information through documentation, thus

obtaining the goal of achieving clear themes and experiences. The narrative is the study of how people experience the world and the manner in which they interpret their experiences (Joyce, 2015). Joyce (2015) stated that this may be an excellent design to use in healthcare as pertains to studies of patients reflections of their healthcare over an extended period. Narrative inquiry helps in the understanding of how people or groups construct and represent activities among each other (Stankiewicz, 2016). This method does not seek to encourage exploration of an individual's experiences on a particular subject.

Fusch and Ness (2015) remarked that without reaching data saturation, the conducted research will not be true. Gentles, Charles, Ploeg, and McKibbon, (2015) implied that a researcher must be fully aware that the achievement of data saturation happens when little or no new information develops from the semistructured interviews. Data collection should cease when this saturation point is reached (Dasgupta, 2015).

Population and Sampling

Purposeful sampling is a technique widely used in qualitative research (Palinkas et al., 2015). Palinkas et al. (2015) explained that purposeful sampling provides for the identification and selection of information with rich use for the most effective use of limited resources. Gentles et al. (2015) defined sampling in qualitative research as the collection of particular data sources where data are gathered to address the research objectives. Gentles et al. (2015) described purposeful sampling as sampling that occurs at two levels: the case itself and the data sources from within the case.

Palinkas et al. (2015) developed a list of 15 purposeful sampling strategies to address various aspects. Palinkas et al. (2015) listed six of these as having an emphasis on similarity, seven having an emphasis on variation, and two as having a nonspecific emphasis. The similarity strategy "*Criterion-I"* has an objective that the cases all meet some predetermined criteria of importance, which meets the criteria of this study (Palinkas et al., 2015).

Gentles et al. (2015) made specific mention of the fact that Yin (2018) mentioned in his sixth edition, that he was using the words purposive and selection in place of purposeful and sample. Yin (2018) felt that purposeful and sample were more consonant to quantitative and purposive and the selection was more attuned to qualitative research. Gentles et al. (2015) noted that the dictionary indicated that purposive and purposeful had the same definition, as did sample and selection. However, this researcher continued to use purposeful and sample in this study, as those terms are more in consonance with the required formatting of this study.

The population, of this exploratory multi case study, was five pharmacy managers. The pharmacists work in central Florida. These pharmacy managers had a minimum of 2 years' successful experience as a counselor of polypharmacy patients and team leading and, had 5 years as a registered pharmacist in the state of Florida. Qualified pharmacists who accepted to participate did so without regard to race, gender, age, sex, or remuneration. Purposeful sampling was utilized, due to the specifics and size of the participants required for this study.

Ensuring data saturation was of prime importance. Fusch and Ness (2015) stated that data saturation happens when there is no new information put forth and the repetition of the data collected occurs. When no new information becomes known, one can interpret that data saturation has been reached (Spilland, Larkin, Corcoran, Matvienko-Sikar, & Arensman, 2017).

Ethical Research

Haintz, Graham, and McKenzie (2015) wrote that ethics is the prime consideration in research. Ethics is especially vital in qualitative, case studies. The participants in a qualitative study must receive personal ethical consideration for their participation and confidentiality. An informed consent process was required. Participants were made fully aware that their participation in the research was entirely voluntary; that they were not obligated in any way to participate in the study (Donges, 2015). Participants had the right to withdraw from the study at any time, before, during or after the research (McDermid et al., 2014).

For this reason, a Walden IRB approval for the research had to occur before attempting contact with any potential participant. The final manuscript includes the Walden IRB approval number: IRB 05-22-19-0411989. Throughout this study, the ethical standards set down by the Walden IRB and the *Belmont Report* from the NIH, including fundamental ethical principles (a) respect for beneficence, (b) justice, and (c) fairness to participants ensured the protection of the participants.

This researcher renewed the NIH certification, #2052088, in April 2016. The participants received a letter of introduction as well as a consent form. The participants received information that they would be a part of a research study that was voluntary. The consent form included the nature of the inquiry, the absolute privacy and protection provided; their right to terminate participation in the study at any time and, that there is no remuneration for participation in this study.

Participants are numbered, not named to maintain privacy. Places of employment are lettered, not named. All hard copy notes, recordings, and password protected flash drives are stored in a secure, fireproof, lockbox for 5 years. At that time, destruction of the contents of the lockbox occurs.

Data Collection Instruments

I was the data collecting instrument. Semistructured interviews, most often, have the researcher as the instrument (Fusch & Ness, 2015). The interview was informal with semistructured, open-ended questions. The questions were open-ended, to provide the participant with the ability to explain and to expand on the questions. Semistructured interviews, the gathering of pertinent documents, and participant observation were the responsibilities of the data collecting instrument (Colorafi & Evans, 2016). A pilot study was not needed because I am not developing an instrument where I need reliability and validity data. During an interview, the participant had the opportunity to make sure that I have understood what they said correctly (transcript review), or given a chance to add to their comments and remarks to the researcher's interpretation of the participant's inputs

(member checking). The interview consisted of eight semistructured, open-ended questions. The interview questions and protocol appear in appendices (A & B).

Data Collection Technique

The interviews were face to face, in an informal manner, at a time and place convenient for the participant. The situation and the questions provided the participant with the impetus to converse freely (Rimando et al. 2015). Rimando et al. (2015) warned that fatigue and stress might occur, on the part of the researcher and the participant, if the duration of the interview is long and the questions are lengthy. The responses were recorded and then transcribed. Upon completion, the recording(s) and the flash drive(s) of the interviews have been stored in a secure fireproof locked box in my home/office for 5 years. Destruction of the contents will then take place. The interview questions appear in Appendix (A). Pharmacy managers with a minimum of 2 years' experience in their position were the participants. These pharmacists had the knowledge regarding the topic of the research question and served well as participants in this purposeful sample. Elo, et al., (2014).

Data Organization Technique

The data and information collected during the research was organized and collated in a manner that themes and patterns developed during the research were organized and stored in a manner, which facilitated their use and interpretation. All participants are identified by an alphanumeric numbering method to ensure privacy and security. All data, paper, DVD, USB, electronic recording, or hard drive will be stored for

a 5 year period in a fireproof safe in my home/office. Destruction will occur at the end of 5 years, for all data and references used in the study.

Data Analysis

The data analysis commenced upon completion of the collection of all data. Data analysis conforms to the methodological triangulation often used in case study research. Triangulation is the method used to complement or supplement data obtained from the semistructured interviews. Such data is obtained from sources such as peer reviewed journals, observations, and field notes made during the research process (Petrescu & Lauer, 2017). In this manner, data is collected from more than one source, not just from semistructured interviews (Fusch & Ness, 2015). Collecting data from multiple sources such as semistructured interviews, direct observation, and peer-reviewed documents provided an excellent framework for analysis (Colorafi & Evans, 2016).

Yin (2018) provided a five-step data analysis technique: pattern matching, explanation building, time-series analysis, logic models, and cross-case synthesis to enhance coding, categorizing data and, building themes. Qualitative data analysis software such as Atlas.ti or NVivo can assist in achieving thick analysis (Evers. 2016). Chandra and Shang (2016), detailed that computer assisted qualitative data analysis software (CAQDAS) can assist in the handling, storage, manipulation, and retrieval of data. CAQDAS software can be used to improve the rigor, transparency, and credibility of qualitative research (Chandra & Shang 2016). Paulus & Lester (2016) inferred that Atlas.ti is a user-friendly computer assisted, data analysis tool, especially for numerous

varied input sources. However, other sources encourage the use of NVivo in qualitative research (Owen, 2014). This study was conducted using Atlas.ti as the CAQDAS.

The recorded interviews were transcribed with the researcher's comments. After rereading for correctness, a summary was given to the participant for review. Once the coding and themes from the interviews were developed, interview observations were entered, as will correlating documentation to enhance the data, triangulation and, provide a pathway to saturation for proper analysis.

Reliability and Validity

Reliability

The evaluation of a study's findings demands the researcher judge the foundation of the research and determine that the results are appropriate to the completion (Noble & Smith, 2014). The results can then indicate a case for dependability and repetition. There are some concerns that the terms validity and reliability have a greater association with quantitative research (Noble & Smith, 2014). Noble and Smith (2014) and Leung (2015) put forth the suggestion that in qualitative research, the term consistency with the sub headings of trustworthiness and confirmability might be more appropriate to ensure reliability. Reliability, in research, indicates that the researcher has shown that they have used research procedures and methods that are appropriate for the study, and results in accurate documentation and interpretation of data (Kihn & Ihantola, 2015). Trustworthiness is a term used to encompass the diligent acquisition of triangulation,

member checking, keeping a strict audit trail, and providing a thick and rich description of the research (Hadi & Closs, 2016).

The stability of research data when used over/in similar situations and circumstances determines if it is dependable (Cope, 2014). Elo et al. (2014) provided a slightly differing explanation in that it is the stability of the data over time and different conditions that ensures dependability. Participant transcript reviews, member checking, with data interpretation and following the rigor of a case study design will enhance the outcome of dependability (Yin, 2018). This audit trail of participant review evaluation, member checking, and triangulation establish a firm aura of dependability (Anney, 2014).

Validity

Kihn and Ihantola (2015) made the statement that validity is the correct and factual representation of a situation under investigation in a report or research. Noble and Smith (2014) referred to the veracity and application of the methods used to present accurate findings of the data enhances validity. Triangulation is a means of obtaining qualitative validity (Carter et al., 2014). Triangulation is the collecting of interviews, journals, pertinent data, and other inputs on the research subject. When triangulation provides no further new information, the process of data saturation can be considered. Of the four types of triangulation, data source, analyst, theory/perspective, and methods triangulation, Carter et al. (2014) remarked that the data source and methods triangulation are better served for a case study, qualitative research.

Credibility. Credibility refers to the reality of research data, or how the researcher presents and connotes the participant's views and the data (Cope, 2014). Triangulation and member checking are the primary methods of ensuring credibility. The reader should be able to substantiate credibility through the richness of the data and an association with the subject of the research (Cope, 2014). The data should be vivid and faithful to the research so that a reader who has experienced the situation will recognize and understand the fullness of the data (Hussein, Jakubec, & Ouji, 2015). Carter et al. (2014) emphasized that triangulation is an excellent method to enhance credibility, and superior member checking is an excellent part of triangulation.

Transferability. Anney (2014) provided the information that a researcher needs to provide a rich description and thorough purposeful sampling of the contents of the research to be capable of any transference. The researcher must provide clear and full information about the study (Cope, 2014). The study then must include rich and concise research, so that the reader can make a responsible decision as to whether it has merit for transfer to a future study or research (Cope, 2014).

Confirmability. Donges (2015) provided the information that data obtained has to come from multiple sources to provide triangulation of information and ensure the correctness of the study and be confirmable. Hussein et al. (2015) stated that the researcher needs to keep clear and concise records of all research decisions. The researcher has to keep a complete listing of all sources, procedures, and decisions, and the means used to show the pathway to a decision (Hussein et al., 2015). Cope (2014)

explained that the researcher has to demonstrate that all the data represents participants' responses and not any of the researcher's bias or viewpoints. The difficulty of the situation is minimized through proper member checking (Cope, 2014).

Data saturation. Saturation is the construction of fulfilling information during the investigation process, by encompassing the strength of the data until the point occurs where the participants' responses form a commonality (Morse, 2015). Cope (2014), maintained that the data gathering must be thorough and sampling must be more than adequate to attempt saturation of data. When no new data is obtained through sources of triangulation of information, saturation of information can be considered as achieved (Fusch & Ness, 2015).

Transition and Summary

Key parts of the research are explained in section 2. The purpose of the research was restated. The role of the researcher and the participants of the research were clearly explained. The design, ethics, collection of data and the analysis there in, was clarified for the reader, and the capability of the research to be utilized in further studies was put forth.

The findings of the research are covered in section 3. These findings includes the potential for professional improvement and further study, and the possible impetus for social change in the area. The study concludes with recommendations for actions and further study.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The purpose of this qualitative exploratory multiple case study was to explore strategies pharmacy managers use to reduce financial costs associated with ADEs incurred by polypharmacy patients. I conducted semistructured interviews with five pharmacy managers who had a minimum of 2 years serving in that capacity. These interviews were face-to-face with open-ended questions that gleaned spontaneous and in depth answers from the participants. I combined those answers with my after-interview notes and review of literature to reinforce the data analysis. I was able to obtain three emergent themes: (a) polypharmacy and the unknown, (b) HIPAA and legal constraints, and (c) CAS: the edge of chaos and clarity.

Presentation of Findings

The overarching research was: What strategies do pharmacy managers use to reduce the financial losses associated with ADEs incurred by polypharmacy patients? I collected data from five experienced pharmacy managers who worked in five different community pharmacies, in one county, in central Florida. The construct of the research was founded on CAS. Data for the research were comprised of semistructured interviews with open-ended questions, notes and observations from the interviews, and peer-reviewed information from my literature review. Three themes with eight strategies enabled the use of CAS to provide how pharmacy managers included incentive

counseling to their patients, mostly polypharmacy patients, to provide healthy opportunities for the patients and to decrease the chances of company loss from ADEs.

Theme 1: Polypharmacy and the unknown

Polypharmacy and the unknown captures how difficult it is for pharmacists to perceive the need for understanding their patients' situation and well-being when it comes to properly addressing the needs of their polypharmacy patients. Yang, et al, (2016) indicated that only 47.3% of pharmacists and 34% of patients felt satisfied with medication counseling that occurred on a routine basis.Theme 1 responses indicate that the participants have their own differing individual perceptions of polypharmacy and the needs of polypharmacy patient.

Strategy 1: Discovering the instances of polypharmacy. Polypharmacy has two general definitions. The first is the taking of multiple medications. The second definition is the use of multiple pharmacies to obtain various medications. The term polypharmacy should not be construed in a negative sense. The use of multiple medications in many instances is indicated for the control of various chronic ailments (e.g. diabetes, heart disease). The misuse or the incorrect use of multiple medications can lead to the negative connotation for the term polypharmacy.

Participant 1 defined a polypharmacy patient as someone who "in the course of their normal business, they see either many doctors or frequent several different pharmacies in an attempt to work around the system to conceal personal data." When dealing with a polypharmacy patient, medical professionals do not have visibility to all of

the patient's medications because systems are not integrated under one pharmaceutical umbrella. Participant 1 suggested the percent of their patients that they would consider as polypharmacy patients, using their definition would only be approximately 15%.

Participant 2 suggested professionals could ascertain from a discussion with the patient or a profile review that a polypharmacy patient is someone who, on an ongoing basis, acquires multiple medications and has multiple disease conditions. Participant 2 considered 60 to 70% of their patients to be polypharmacy patients. Participant 3 categorized a polypharmacy patient as a person who is consuming multiple medications for the same or different diseases. Participant 3 felt that identification is determined by the number of filled prescriptions, or whether a person used one or several avenues to acquire the medications. Participant 3 said only 20% to 25% of their patients were considered polypharmacy patients.

Participant 4 suggested that the term *polypharmacy patient* consisted of a wide range of patients. Characteristics could range from a person who is deceptive by knowingly attempting to fill duplicate prescriptions, to someone who innocently searches for the best price. The same medication could cost $4.00 at one pharmacy and more than double at another pharmacy. Participant 4 knows that a number of their patients fill prescriptions while shopping at a large food chain store for groceries or household items, indicating that filling prescriptions at one location over another could also be a matter of convenience. Participant 4 felt that only 20% of their patients were polypharmacy patients.

Strategy 2: Work with one pharmacy. Experience indicates that a pharmacist needs to communicate honestly with customers about how they are acquiring medications and advise them how important it is to remain with one pharmacy when taking certain medications. According to Participant 4, pharmacists are aware "there are some people who try to beat the system and play one pharmacy against the other to acquire drugs". Participant 4 inferred that pharmacists have a responsibility to educate people on the problem of addiction, especially in young patients, because "the pharmacist has an obligation to protect the welfare of people."

Participant 5 was not quite sure how to define polypharmacy patient. After considering the term, Participant 5 provided the characteristics as, a patient taking different or multiple medications, or a patient taking medications and over-the-counter drugs or vitamins, or a patient undergoing medication therapy management (MTM). Participant 5 estimated that at their pharmacy, approximately 95% of patients were polypharmacy patients because the vast majority of them were from a retirement community.

The varying understanding of the term *polypharmacy* by all the participants is not particularly common, but their definitions are not outside the norm. Masnoon, Shakib, Kalish-Ellett, and Caughey (2017) performed a systematic review of the definition for polypharmacy. Of the 110 peer-reviewed articles that were finally selected as meeting the requirements to provide definitions for polypharmacy, 80 provided a numerical definition

ranging from two to 11, and nine provided descriptive definitions (e.g. using two or more different pharmacies).

Shrestha, Shrestha, and Khanal (2018) reported that the prevalence of polypharmacy varied widely from 10% to 96%. Chia0ng-Hanisko, Williams, Newman, and Tappan(2015) indicated that the overall prevalence of polypharmacy among African Americans, Afro-Caribbean, European American and Hispanic American patients researched was 47.5%. The average percentage derived from the five participants of this research averaged 43.1%. The elder population comprises approximately 13% of the U.S. population, yet they account for over 33% of the prescription medications dispensed (Golchin, Frank, Vince, Isham & Meropol, 2015). These figures are based on 2009 statistics taken from the Administration of Aging in the U.S. Department of Health and Human Services, and based on the projections, that the elder population in the United States will grow from 40 million to 72 million in 2030 (Shah & Hajjar, 2012).

Theme 2 HIPAA and legal constraints

HIPAA provides for the privacy of patients and their medical/medications records with strict guidelines and consequences. However, there is a codicil, whereby, the patient may permit their private records to be accessed by authorized personnel. Usually, on the first visit a patient makes with a doctor or other healthcare provider, within the history paperwork is a form that requests authorization to obtain/give information to other healthcare providers in consonance with the patient's treatment. HIPAA and the proprietary rights of the pharmacy corporations prevent pharmacists from having

visibility to all the medications a patient consumes. Without this knowledge, a pharmacist often feels disadvantaged because of government regulations and other legal constraints.

Strategy 1: Counseling space must be private and confidential. According to Participant 1,the company does not have visibility to all medications patients consume because HIPAA precludes sharing protected patient medical records. Patients often are happy to provide pharmacists with a list of all medications as a normal course of practice when they are filling prescriptions. Some patients also list medications purchased from other establishments, such as competitor locations, pharmaceutical outlets, and supplement stores. Some polypharmacy patients might also purchase mail-order medications, which are not documented in a patient's medical record.

Participant 2 suggested "HIPAA laws probably hinder me because I do not have computer access to all their prescriptions," which ironically necessitates the contributor to procure some patients' medication from the Veterans Administration. Participant 2 said that some patients order from mail order, and unfortunately, other pharmacies, which closes the window into a patient's total procurement of medications. Participant 2 related that HIPAA prohibits pharmacists from sharing patient information so "there is no real way to ascertain what medication a patient has been provided." Counseling patients also becomes problematic for several reasons. When dealing with the elderly population, especially when medical complications begin, such as dementia. Participant 2 must rely on the patient or caregiver to voluntarily provide one's medical history or consent for the practitioner, in compliance with HIPAA regulations, to enquire about prescription use.

Participant 2 said that experience has shown that early dementia patients are “definitely polypharmacy patients who do not believe they have any underlying mental health conditions which could prevent them from understanding medication instructions”. Participant 2 remarked that, not having a patient recognize possible drug interactions, nor willing to provide the pharmacist consent to discuss potential concerns with a caregiver, certainly puts a patient at risk.

Participant 4 does not believe that laws significantly hinder their ability to perform their job. Participant 4 admitted there is a slight risk in a retail location of others overhearing conversations if the facility does not offer “a nice, quiet, private place to hold conversations. HIPAA requires patient confidentiality, and this should be a primary concern for pharmacists when speaking with patients about their medications and one’s health related ailments”.

Participant 5 did not have any concerns about adhering to HIPAA regulations because they rarely speak with patients, and if the situation does arise, communication is done in a private area. Moreover, Participant 5 believes that “People are over the edge about HIPAA. The fact that someone is listening to them or has ‘hawk eyes’ and sees information over the counter is not a concern.”

Participant 2 said they do not see a problem associated with following the corporate policy in protecting patient rights. Counseling a patient in an area outside of the general public helps protect them. Participant 3 supported the practice because their organization has a separate counseling area, where HIPAA concerns about protecting a

patient's right to privacy is not a factor. However, Participant 2 said many larger pharmacies do not have sufficient space or time to act in accordance with patient protection regulations.

Participant 2 noted:

> There are times when warnings surface while processing insurance approvals of potential drug interactions and the pharmacist must investigate the problem. HIPAA laws do not restrict a pharmacist from contacting the healthcare provider to make sure filling the current order would not create a duplicate or contraindicating therapy.

Strategy 2: Use of electronic technology. Participant 1 purported that "universal healthcare will mimic the new [Electronic-Florida Online Reporting of Controlled Substance Evaluation Program] E-FORCSE that we are currently doing for controlled substances." Technology will provide a pathway into a patient's medical record where doctors will view all the medications provided by all the pharmacies in one electronic platform. Participant 1 claimed "There will come a time very soon where every prescription, for every patient, will be listed in a single database. Then polypharmacy will become universal healthcare".

I was interested to hear Participant 2 suggest that not having an automated communication system helps mitigate liability. I was curious to learn how underutilizing modern technology seemed to shift to a positive approach to reducing errors. When Participant 2 purported that calling patients versus sending texts or e-mails regarding

one's prescriptions spurred questions that could alter dosage or require a different drug overall because of insurance restrictions, and helped provide an expedient way to update information and improve patient satisfaction.

Participant 2 remarked that systems have certainly changed over the last 40 years. The technology once consisted of an IBM typewriter producing one prescription label at a time. There was a Bates machine where the technician stamped the number on the prescription and the label so the numbers matched. There was no literature printed from a computer outlining possible side effects of the medication.

Participant 2 stated:

> Everything the patient knew about a drug, you personally told them, from the name of the drug to the frequency and the dosage the doctor wanted the drug to be taken. There was no print outs from a computer. That is how much pharmacies have changed.

Participant 3 utilizes a computer program that "flags" possible drug interactions. The "flagged" information is passed on to the pharmacist who in turn can review the information and provide better consultation with the patient. Human interaction strategies also seem to be critical in mitigating errors where a nurse on staff oversees the patients' MTM plan.

Participant 4 remarked that having kind, experienced technicians are especially helpful when filling new prescriptions. These technicians are constantly learning new technologies to improve efficiency in the workplace. The technician is usually the first

person a patient encounters. Participant 4 stated that the technician facilitates the pharmacists encounter with a patient when the patient is receiving a new medication by straight forwardly asking the patient if they would care to or mind speaking with the pharmacist regarding the new medication they are receiving.

Hospitals in the area are in the process of encouraging the medical professionals within their circle of operation to join their electronic information system to facilitate the care and wellbeing of their patients. Not so with medication facilities, hospital pharmacies, independent pharmacies, and corporate pharmacies all have their own non-interfaced computer systems. With the exception of E-FORCSE, which is Florida's new watch-dog for the dispensing of all controlled substances in the state, there is no interface between pharmacies of different stature. A pharmacist must rely on the patient to inform them of any drug that might contraindicate the drug being dispensed. There is an exception. Some insurance companies, if the patient has medication insurance, will send a "hard stop" and notify the pharmacist that the patient is taking a drug that is contra-indicated with the drug to be dispensed.

Strategy 3: Use of double check and three-fold check procedures. Participant 2 has regularly scheduled meetings with all team members to discuss patient problems or concerns. This provides a proactive pathway toward preventing a repeat of any mistakes. Reports showing the number of prescriptions completed in a given day or hour helps in scheduling staff members for the busier times of the day.

Participant 2 showed that establishing process and workflow procedures, such as developing a good check and balance practices helps mitigate liability by reducing errors. For instance, unlike other establishments, Participant 2 has a double check technique where one technician inputs the prescription into the system, pulls the medication, and verifies the National Drug Code. Then the second technician confirms the information before the prescription is routed to the pharmacist. Finally, the pharmacist provides an overview of the prescription prior to final verification. Participant 2 stated "This is termed a double check, three fold verification check system".

Participant 3 does not have to conform to work policy or procedures, except to ensure there are no HIPAA violations. When patients pick up certain prescriptions, perhaps controlled drugs, the computer system or what Participant 3 has in place is a "red stop note," which flags the technician that the pharmacist must consult with the patient.

Participant 4 suggested that holding quarterly staff meetings, which are required by the State of Florida, is helping to make sure people were following policies and would illuminate problems, such as "close-call or miss-fill" situations to develop processes or provide training to improve quality assurance issues. Participant 4 believes that communication through the chain of command allows them to ask questions or bring suggestions for improvement and to implement change. There were times when superiors were unable to accept different opinions that fell outside of company paradigm. Participant 4 acknowledged that being persistent in pursuing strategies that improve the

patient's experience sometimes requires working with people who must change their worldview.

Participant 2 stated that following every procedure "to the letter" is crucial when filling forms documenting errors revealing what went wrong and why the error occurred. Communicating such problems to the patient that could influence a patient's health and to the patient's physician if the patient did consume the drug in the wrong manner is necessary. Participant 5 seemed to be against the policies and practices the company had in place and did not believe the information either helps or hinders their performance. Participant 5 tends not to use training materials provided because they feel that they are more than capable of performing their job.

Although HIPAA rules and permissions work well in the medical field, there is little or no success in the medication field. Each pharmacy corporation, LLC, or sole proprietorship, has its own computer/patient system. This system not only contains a patient's medications, it contains information about insurance pay, medication co-pays, and estimated medication costs, that determines a patient's co-pay based on contractual agreements. Thus proprietary concerns, at present, preclude a cooperation that the medical field has.

However, some instances of potential medication errors or problems are addressed for the pharmacist here in Florida. The first occurs with the pharmacist when they verify a medication for a patient before dispensing. Some med D insurance companies will place a "hard stop" on the process by notifying the pharmacist the patient

is taking a medication that is contraindicated with the medication that is being processed. The pharmacist then has to contact the patient the prescribing doctor correction. The second occurs with a prescription for a controlled substance. The state of Florida has instituted a system called E-Forcse, whereby all controlled substances, CII through CV dispensed in the state are recorded and saved in the system. The system is made to save the name of the patient, the drug dispensed, the date, the strength and quantity of the drug, and the dispensing pharmacy. The system is very helpful in preventing overdosing and multiple dosing of controlled substances.

Theme 3: CAS: The edge of chaos and clarity

The complex adaptive system theory (CAS) delineates a system to a pharmacist that is on the edge of chaos, but is very reflexive and capable of achieving a stable outcome. Communication strategies, such as patient literature and establishing a patient dialog, allows the pharmacist the ability to educate polypharmacy patients in the dangers of drug interactions to reduce the financial loss associated with adverse drug events incurred by polypharmacy patients.

Strategy 1: Talking with the patient. Participant 2 believed "you have to be willing to talk to the patient," ask difficult questions about what medications are taken, and who is helping the patient with those medications. Participant 2 commented that larger pharmacies do not have the time capability to perform satisfactory individualized services. Participant 2 explained that there was a time when this pharmacist was unable to converse with patients regarding their medications due to the fact that the participant's

time was completely absorbed with filling and verifying the correctness of the medications. The size of a pharmacy may be inversely related to the ability to effectively provide satisfactory individualized services to patients. As the size of the pharmacy goes up, the time a pharmacist has to consult with a patient goes down.

Not engaging in patient counseling hinders a pharmacist's ability to recognize potential problems. Participant 2 stated "if you can't even ask the patient a question, how could a professional recognize a potential problem"? Participant 2 provided the example: "if a person is buying a large bottle of tums, communicating with the patient could uncover a possible medical condition for the stomach problem such as a possible ulcer versus the common ailment of indigestion". This personal communication could uncover symptoms the person is ignoring or minimizing. So, pharmacist 2 felt that it was extremely important that pharmacists are "intentional with patient interaction".

Strategy 2: Drug interactions must be addressed. Participant 2 felt that pharmacists sometimes identify negative drug interactions when patients have not provided all medications or vitamins and encounter an ADE, "where we have to work backward". Pharmacists are aware of certain drug classes where they are known to have issues when mixed with other medications or over-the counter products. For example, if a patient was taking Coumadin and encountered a reaction, the pharmacist would ask if the patient was taking aspirin, a common over-the counter drug because both Coumadin and aspirin are blood thinning agents which slow down or prevent the body's process of making clots. Participant 1 suggested the practice of asking patients what they consume

“ is more of a reactive strategy than a proactive one.” Participant 1commented that some vitamins and over-the-counter medications could also have an adverse effect on certain prescribed medications.

Participant 2 feels that the greatest responsibility to a patient is to take the time necessary to ensure there are no harmful drug interactions “in addition to what the computer flags”. Identifying potential side effects is the primary responsibility of the pharmacist. Communicating with patients is an important element of what Participant 2 deems as a primary responsibility of the pharmacist to share patient experience and delve into an inquiry into over-the-counter drug use, for example, to help illuminate the cause and effect of drug interactions. Participant 2 recounted an experience where a patient was suffering from diverticulitis. Unfortunately, this was a recurring condition from 10 years earlier. The antibiotics prescribed by the physician could cause abdominal pain, cramping, gas, and diarrhea, which are common symptoms of diverticulitis. Participant 2 felt that providing this information to the patient could help reduce one’s anxiety if the symptoms worsened for a few days and could prevent the patient from discontinuing the medication if one believes it is an adverse effect.

Strategy 3: Reading the medication information in both Spanish and English. Patients must be concerned enough about their health to read the medical information supplied with the prescriptions. Participant 1 imagined “the percentage of the people that read the literature is relatively small.” Patients will ask questions at the register or call, rather than delving into the pamphlets provided, if they have specific questions to side

effects or drug interactions. Nonetheless, Participant 1believes pharmacists are at a disadvantage because they must rely on the patient providing accurate and truthful information about all of their medication history, often a patient does not recall all over-the-counter products.

Participant 3 suggested that the patient literature is useful and needs to be available to Spanish speaking patients. A large minority of patients in central Florida have English as their second language. Identifiers, such as monographs for new medications, showcase important information about the medication for first-time orders or the patient requests the datasheet. The pharmacist will also highlight important details when reviewing the literature during a consultation.

Participant 2 showed drug literature does help to provide useful information that patients can understand, but it fails to provide every possible side effect or drug interactions so more work must be done to help bridge the gap. The literature often provides vague information such as "if you are on cardiac medication, please consult with your doctor." Participant 2 indicated that information means very little to a patient needing a breathing treatment, which could suppress or even elevate a person's heart rate. Participant 2 felt that patients must become stewards of their own care and become more forthcoming with healthcare professionals about how and where they acquire all medications, even over-the-counter remedies.

As a prior school teacher, Participant 4 said that educating patients with literature is helpful because the pharmacist could highlight important information on the document,

which would draw a patient's attention to the subject. For example, if a patient were purchasing an ace inhibitor for the first time, I would flag a potential concern of developing a new or worsening cough because that is a potential side effect of the medication. Participant 4 stated that the patient should contact their healthcare professional, if they have a concern about this side effect. Participant 4 knows that the amount of literature could become confusing or overwhelming for the patient, so highlighting important information is a way of connecting with the patient and having the patient leave with the feeling that "the pharmacist has their best interest at heart".

Participant 5 suggested that the literature provided does not help him in his ability to counsel patients. What was amazing to discover was how negative Participant 5 was during the entire interview. Participant 5 admitted there might be a time when the pharmacist, prior to a consultation, needed to refer to the documents and literature, but overwhelmingly suggested that laws and regulations, policies and procedure, and documents were "a waste of time." Participant 5 purported "between you and me and the wall, no one ever reads the material. It's trash and should be tossed away anyway."

The strategies derived, from the statements of the participants, highlights the importance of communication with the patients. Pharmacies are nonlinear and dynamic. The pharmacist and the patient are independent and intelligent agents. Cooperation and conflict is evident at every level. Although appearing to be chaotic at times, the pharmacy continues to function and provide optimal output.

Applications to Professional Practice

The themes that developed for the study give evidence that the conceptual framework was most appropriate for the study. The three themes: (a) polypharmacy and the unknown, (b) HIPAA and legal constraints, and (c) CAS, the edge of chaos and clarity make a very good fit with the conceptual framework. Pharmacists may find the themes encouraging, and an incentive to seek better workloads for their team. A number of strategies support the adaptiveness of the complex situations; whereby, the pharmacist may find ways to better interconnect with their polypharmacy patients.

The results of the study and the strategies developed may assist pharmacy managers in refining their counseling strategies for their patients, particularly their polypharmacy patients through the integration of the medication literature provided, their knowledge of the patient's medication background, and the pharmacist's excellent knowledge of the various medicines.

Implications for Social Change

The implication for social change has two main areas. The first is the intent of better living and wellbeing for the polypharmacy patient through improved counseling and interaction. The second is the reality of improved quality of service by the community pharmacist and the pharmacy as sensed by the patient. These changes may lead to community improvement through better care.

Recommendations for Action

Pharmacy managers may want to integrate their counseling methods with the written literature (e.g., highlighting the written literature that aligns with their verbal counseling). This effort may help reinforcing the proper taking of the medication as well as when and how the medication should be taken. Also, pharmacy managers need to find a method to improve their allocated time for counseling a patient. A few moments spent in the counseling area with a patient is not sufficient for proper counseling. Lastly, provide the opportunity for the pharmacy technician to encourage counseling by having the technician introduce one or two of the highlighted items in the written literature during the checkout process. This may encourage the patient to seek counseling from the pharmacist.

Recommendation for Further Research

This research was limited to pharmacy managers in small community pharmacies, in one county, in central Florida. Further research is recommended on the subject with a larger population. Pharmacists from community pharmacies that are operated by larger corporations need to be included. A mixed method study may provide greater results with more themes and strategies to enhance this beginning. Enlarging the research and involving more persons may strengthen the basis of this or help cause new strategies to emerge that could also help community pharmacists deal with the limited strategies on how to reduce the financial losses associated with ADEs incurred from polypharmacy patients.

Reflections

I was surprised and taken aback by some of the responses by the participants. I had to control my surprise and refrain from interjecting unwise statements. I thank my training, at Walden, from preventing bias. I felt the responses by the participants were very professional, yet personal. I minimized my knowledge of the systems so that I could obtain the full import of the participant's dialogue. I also perceived from the responses of the participants, the great responsibility they carry in the care of their patients and the operation of their team.

Conclusion

The purpose of this qualitative multiple case study was to explore the strategies pharmacy managers use in reducing financial loss from ADEs by polypharmacy patients. By far, the most important outcome derived from this study is that pharmacy managers need to obtain more time, to combine the literature distributed with a patient's medication with their expertise, in affording the full measure of their personal counseling that the patient needs.

CAS is well-suited for the study of pharmacy strategies and counseling methods of pharmacy managers. CAS illustrates the complexity of the pharmacy quite well. CAS also illuminates the constant conflict within the pharmacy operations. Pharmacists work a 40-hour week, in 8- or 12-hour shift increments. They complete 100 to 300+ prescriptions a day, oversee and manage up to three technicians, perform all executive paperwork, maintain sole responsibility for all the controlled medications in the

pharmacy, and provide personal counseling to their patients as needed. A pharmacist's time is very limited, due to this heavy workload and patient counseling suffers from this.

Pharmacists should be able to adjust their workload by increasing the workload of their capable technicians. If the pharmacist would highlight the important aspects of the written literature on the brochure given with the medications, and the technician were allowed to reiterate and assist in the understanding, by the patient, of these items, extra time might be available for the pharmacist to counsel those patients who most need the pharmacist's advice (e.g., the polypharmacy patient with medium to high risk medications and/or the patient who requests counseling via the technician).

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Appendix A: Interview Questions

1. As a pharmacy manager, how would you describe a "polypharmacy patient"?
2. What percentage of your daily prescriptions would you estimate are for polypharmacy patients?
3. From your perspective as a pharmacy manager, to what extent does the present day HIPAA laws aid or hinder confident counseling of polypharmacy patients?
4. From your perspective as a pharmacy manager, to what extent does your corporate policy and methods aid or hinder confidential counseling of polypharmacy patients?
5. From your perspective as a pharmacy manager, to what extent does the written literature provided with a medication, aid in your counseling of pharmacy patients?
6. From your perspective as a pharmacy manager, what strategies do you use to improve and enhance patient counseling and decrease potential ADEs?
7. From your perspective as a pharmacy manager, what strategies do you use to lessen your company's liability costs?
8. What other issues regarding polypharmacy patient counseling do you think I should be made aware?

Appendix B: Interview Protocol

Interview Protocol

Protocol Steps	**Protocol Actions**
Select Participants	I will contact participants in accordance to established criteria.
Set Time and Place for Interview	Interviews will take place at participants convenience and neutral location
Introduce the interview and set the stage	I will restate the purpose of the research study, obtain verbal consent from the participant, retrieve signed written consent and provide copy to same.
Record the interview	I will explain to the participant the interview will be audio-recorded. The interview will start with the following background information. a. Title/Position b. Years of experience c. Educational background
Ask open-ended questions while watching for non-verbal cues, paraphrase as needed, ask follow-up questions to ensure rich and responses	1. As a pharmacy manager, how would you describe a "polypharmacy patient"? 2. What percentage of your daily prescriptions would you estimate are for polypharmacy patients ? 3. From your perspective as a pharmacy manager, to what extent does the present day HIPAA laws aid or hinder confidential counseling of polypharmacy patients ? 4. From your perspective as a pharmacy manager, to what extent does your corporate policy and methods, aid or hinder confidential counseling of poly-pharmacy patients?

	5. From your perspective as a pharmacy manager, to what extent does the written literature provided with a medication, aid in your counseling of polypharmacy patients? 6. From your perspective as a pharmacy manager, what strategies do you use to improve and enhance patient counseling and decrease potential ADEs? 7. From your perspective as a pharmacy manager, what strategies do you use to lessen your company's liability costs? 8. What other issues regarding poly-pharmacy patient counseling do you think I should be made aware of?
Wrap up the interview by thanking participant	Thank the participant and confirm all contact information. Inform participant of member check follow-up.
Transcribe the interview, perform member check	Transcribe the interview. Take to participant and verify correctness.
Perform synthesis of transcription from Personal notes and observations	Take to participant to review and see if participant concurs with synthesis and If there are any further inputs.

Appendix C: Five Year and Peer Reviewed Literature Information

Summary of Sources
(Current Source = 2015 or later; Noncurrent Source = 2014 or earlier)

Current peer-reviewed journal articles	94
Current non peer-reviewed journal articles	5
Non-current peer-reviewed journal articles	30
Non-current non peer-reviewed journal articles	4
Current Dissertations	0
Non-Current Dissertations	1
Current textbooks	2
Non-current textbooks	4
Current unpublished manuscripts	0
Non-current unpublished manuscripts	1
Current US Government Act/Regulation	0
Non-current US Government Act/Regulation	3
Total Current Sources	97
Total Non-current source	47
Total peer-reviewed sources	131
Total Doctoral Study sources	145

	Percentage Current
Total current sources/total sources: 101/145= .6966	70%

	Percentage Peer-Reviewed
Total peer-reviewed sources/total sources: 131/145= .9034	90%