ANALYSIS OF EXPERIENCED PHARMACIST CLINICAL DECISION-MAKING FOR DRUG THERAPY MANAGEMENT IN THE AMBULATORY CARE SETTING

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ABSTRACT

Objectives: The overarching objective of this research study was to document drug therapy decision-making processes of experienced pharmacists in the ambulatory care setting. The specific aims of this study were to examine the current clinical decision-making of experienced pharmacists in the context of the ambulatory care clinic setting, to compare and contrast pharmacist clinical decision-making with current decision-making models, and to identify enabling factors and barriers to clinical decision-making in the specific context of ambulatory care.

Methods: This study used the thematic hermeneutic phenomenological human science methodology influenced by Dr. van Manen. After a feasibility pilot study of two experienced pharmacists in the Twin Cities of Minnesota, the main component of the dissertation research project included six experienced pharmacists throughout Minnesota and Iowa. Recruitment was done via e-mail request of eligible pharmacists known by faculty in Minnesota or Iowa and public information with a state association (the Minnesota Pharmacists Association). Three audio-taped data collection methods of participant observation, semi-structured interview, and personal audio-taping were utilized and exactly transcribed to provide textual data for analysis. Thematic analysis provided emerging themes of experienced pharmacist clinical decision-making which were further subdivided into subsuming themes after much reflection and interpretation of the entire study data.

Results: Other health professions have identified experienced clinical decision-making to encompass the Hypothetico-Deductive Reasoning Model, Decision Analysis, intuition and pattern recognition. Pharmacists' clinical decision-making processes are considered in light of other health professionals' decision-making techniques; however the results show that experienced pharmacists use a different model of clinical decision-making using constant dialogue between two different types of knowledge (objective and

context-related). The pharmacist must perform an active modification step necessary to combine the objective, factual information with the contextual, patient-related knowledge. With this modification, pharmacists are able to have complete situational understanding necessary for the final clinical decision. Although experienced, the pharmacist may have inadequate information to conduct the modification step necessary for understanding to make the clinical decision. The analysis suggests that the enabling factors and barriers to clinical decision-making are unique for each context. The availability of time to spend with patients and the effort in consulting with other health professional colleagues have enabled experienced pharmacists to ensure more patient-centered decisions in the general ambulatory care clinic setting; however, practicing within certain disease specialties and potential limited knowledge presented possible barriers in making more optimal clinical decisions.

Conclusions: This research study may ultimately increase interprofessional work since there may be significant similarity between pharmacists' and other health professionals' experienced clinical decision-making. The cross-communication between different health professions may further improve decision-making processes and collaborative practice agreements. Also, this research may guide pharmacy education necessary to advance patient experiences for clinical decision-making based on better understanding of the practices of those experienced pharmacists with 5+ years of practice. Increased objective teaching should be encouraged in classrooms to provide for longer-lasting learning experiences for students. Finally, this study provides evidence for better understanding of the current pharmacy practice including clinical decision-making in the ambulatory care clinic setting, which may further expand the success of pharmacists' contributions to improving patient care.

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CHAPTER 1: INTRODUCTION

In the United States (U.S.), there is a variety of divisions within the health care system and every sector plays a role in the larger network. Each branch has a vital grasp on patient health, customer service, and quality administration and pharmacists are among these. Ambulatory care pharmacists, as you will see in this chapter, help to lower the costs of the nation's hospital expenses and help to make critical decisions about human physical health. They also offer experiences and skills, in their own field, which strengthen the interconnected national community of health care workers as a whole.

Health care in the U.S. is a large financial part of the nation's economy. For instance, the Centers for Medicaid and Medicare Services (CMS) illustrated that of the 2009 U.S. Gross Domestic Product of $14.283 trillion, 17.6% (or $2.51 trillion) was allotted to Health Care Expenditures, 10% of which went toward spending for prescription drugs (American Hospital Association [AHA], 2011). The share of the nation's total production devoted to health care and medications has more than tripled since 1960. This demonstrates a great increase in the country's devotion toward health and medicine.

Beginning in the 1980s, health care system delivery processes are moving from the acute, inpatient institutional setting to more continuous, integrated care across settings. Many of the changes are occurring because of the development of payment and financial mandates under managed care, new diagnostic and treatment tools, advanced technology, population and individual management of preventative care, and an increase in the elderly with polypharmacy for multiple chronic medical conditions (Shi & Singh, 2008; Sultz & Young, 2009). The health care system spends most of its resources on chronic conditions for individuals that are expected to have the illness(es) for over one year, are limited in what they can do, and require continual medical care (Kovner & Knickman, 2005).

A brief discussion on the amount of funds spent for certain services and products will provide a better understanding of the structure of the United States (U.S.) health care delivery system. Outpatient physician and clinical services, (partly known as ambulatory care services), along with other health professional services, increased from 18.5% of the 1980 national expenditures for health services and supplies to 22.8% in 2009; however, the inpatient hospital care decreased from 42.7% in 1980 to 32.6% in 2009 (Centers for Medicare & Medicaid Services [CMS], 2012). This comparison illustrates that outpatient care is becoming a key player in the nation's health care delivery.

About four-fifths of all ambulatory care services are conducted in physician offices, and of the 963.6 million visits, about 70.5% of them included providing, prescribing, or continuing medication (Cherry, Woodwell, & Rechtsteiner, 2005). People use medication therapy, but the drugs are not always indicated, effective, or safe. About 16.2% of hospital admissions are drug-related, and 50% or more are preventable (Bates et al., 1995; Nelson & Talbert, 1996; Winterstein, Sauer, Hepler, & Poole, 2002).

"*A drug-related problem is an undesirable patient experience that involves drug therapy and that actually or potentially interferes with a desired patient outcome*" (Strand, Morley, Cipolle, Ramsey, & Lamsam, 1990, p. 1094). A drug-related problem that is unrecognized could even lead to a drug-related morbidity as the outcome (Hepler & Strand, 1990). Using a probability pathway model, Johnson and Bootman (1995) performed a cost-of-illness analysis of drug-related morbidity and mortality in the ambulatory care setting. With direct cost estimates and probabilities of drug-related problems causing negative therapeutic outcomes of treatment failure and/or new medical problems, it was estimated that endpoints of further physician visits, additional prescription medication treatment, urgent care or emergency department visit, hospital or long-term care admission, or death cost $76.6 billion in the ambulatory care setting in the U.S.. Furthermore, a sensitivity analysis of the cost accounting for an estimated range of negative outcomes demonstrated a variation of $30.1 billion to $136.8 billion cost

associated with those drug-related problems. From the analysis, the largest part (62%) of the cost was from drug-related hospitalizations which may have been preventable.

Ernst and Grizzle (2001) updated the cost-of-illness study demonstrated by Johnson and Bootman (1995). They included additional studies and data, such as outcome-specific costs and resources (i.e. # physician visits) at a standardized 2000 United States (U.S.) dollar estimate. This adjustment updated the prior study that used standardized data at the 1992 dollar value. The cost of morbidity and mortality in the ambulatory care setting increased 131.7% to $177.4 billion ($159.6 billion to $195.1 billion), with hospital admissions continuing to represent the largest cost sector -- $121.5 billion (69%). Even with increased attention to drug-related errors and suggested prevention techniques (National Research Council, 2000), an increase in drug-related cost was evident. This demonstrates the significant impact of the pharmaceutical sector in overall U.S. health care costs and patients' safety.

These studies suggest that health care professionals may have a potential role in reducing costs while contributing to better health outcomes. One such health professional is the ambulatory care pharmacist who works in the outpatient hospital or primary care clinics and community health centers and makes clinical decisions that may reduce patient death and lower overall costs. If true, it may be important to ensure that these professionals are empowered to utilize their knowledge and experience, and to maximize their own decision-making, for the sake of their patients' lives.

Pharmacists work in a variety of settings, including academia, community, clinic, hospital, industry, laboratory, etc.; however, those pharmacists working in outpatient ambulatory care settings are increasing and they provide expanded pharmacy services (Carter & Helling, 1992; Carter & Helling, 2000; Murphy et al., 1999). Generally, pharmacists agree that the ambulatory care and primary care settings offer many opportunities for pharmacists, including occasions to perform preventative care services

(Murphy et al., 1999). The American Society for Health-System Pharmacists [ASHP] (1999) determined a standard set of guidelines to define the minimum requirements of pharmaceutical services in an ambulatory care setting. The guidelines established conditions for services of effective leadership and practice management, assessment, education and monitoring of medication therapy through the provision of pharmaceutical care and medication therapy decision-making, drug distribution and control, and adequate facilities, equipment, and other resources for functions related to medication use.

With the presence of clear and uniform minimum standards, the provision of pharmacy services in different ambulatory care settings may be adjusted to match and guide increased pharmacist participation in a particular environment. Pharmacists perform direct patient care functions, such as medication reviews, drug information explanations, and population-specific tasks like designing pharmacy benefits and reviewing immunization histories in varied ambulatory care settings (Knapp, Okamoto, & Black, 2005). The ASHP 2004 national survey of ambulatory care practice in health systems (Knapp et al., 2005), demonstrated a 31% routine pharmacist inclusion in ambulatory care settings of community facilities, government, nonfederal organizations, integrated health networks, group or staff Health Maintenance Organizations (HMOs), federal facilities, teaching institutions, or Veterans Affairs (VA) locations. Pharmacists participated in ambulatory care services differently in various organizations: from 15% in government, nonfederal facilities to 100% in VA facilities. Their participation is associated with many enabling factors that may promote pharmacist involvement, such as advanced pharmacist training, documentation of outcomes, reimbursement for services, collaborative practice agreements, and multidisciplinary relationships. Although pharmacists in federal VA facilities demonstrate the most ambulatory care pharmaceutical services, due to those potential facilitating factors, services in other ambulatory care settings continue to expand (Knapp, Blalock, & O'Malley, 1999; Knapp, Blalock, & Black, 2001; Knapp et al., 2005; Reeder, Kozma, & O'Malley, 1998).

Specifically, Minnesota's ambulatory care clinic pharmacists perform patient activities like medication review, in general patient care clinics and specific disease management settings, with a collaborative practice agreement (45%), scope-of-practice agreement (32.5%), or referral service (22%) (Ward, Harris, & Guay, 2005). This role or responsibility not only utilizes factual knowledge and merely follows prescription orders but also these pharmacists review medications to formulate an informed patient-specific recommendation to improve health outcomes.

Ambulatory care may provide important settings for pharmacists to contribute to patient care and potentially address the United States (U.S.) high health care costs related to medication use. In these settings, pharmacists can play an important role in identifying drug-related problems which are partially caused by society's large medication usage. An ambulatory care setting is an "out of hospital" locale, such as an outpatient clinic associated with an inpatient hospital (i.e. Fairview Clinics in Minnesota or Veterans Affairs) or a community pharmacy (i.e. Walgreens, CVS, or Cub Foods) with patient care services in addition to drug therapy dispensing activities. To demonstrate the need for pharmacists in this ambulatory care setting, an additional cost analysis study shows that the pharmacist provision of pharmaceutical care and the increased pharmaceutical services in all ambulatory care settings would decrease drug-related cost of morbidity and mortality by 53-63%, or $45.6 billion (from $76.6 billion estimate) in direct health care costs (Johnson & Bootman, 1997). With their knowledge and understanding of medication therapy, a pharmacist is potentially the most likely health care professional to decrease drug-related problems leading to morbidity and mortality. In addition to this cost analysis study, other resources have also demonstrated economic, clinical, and humanistic outcomes of clinical pharmacy services and interventions in the ambulatory care setting (Ellis et al., 2000a; Galt, 1998; Hatoum & Akhras, 1993; Isetts et al., 2008; Lee, Boro, Knapp, Meier, & Korman, 2002; Mason & Colley, 1993; Mutnick et al., 1997; Schumock, Meek, Ploetz, & Vermeulen, 1996; Schumock et al., 2003; Singhal, Raisch, & Gupchup, 1999).

Demonstrating that pharmacists currently make a large number of decisions in health care does not demonstrate *how* pharmacists make their decisions--or whether pharmacists take responsibility for making decisions. Since 1994, pharmacists have agreed to take ethical responsibility (American Pharmacists Association [APhA], 2005) to work with individuals in order to achieve the best health outcomes from his/her medications. However, evidence demonstrates that some pharmacists may not be engaged or may lack decision-making abilities for proper drug therapy (Campagna, 1995). Although pharmacists may agree that it is their professional duty to identify, resolve, and prevent drug therapy problems, barriers such as the absence of clear standards (i.e. pharmacy laws and regulations, practice standards, and treatment guidelines) and lack of perceived control to make professional decisions in certain environments are reasons for pharmacist to take responsibility for drug therapy outcomes (Planas et al., 2005).

Health care professionals make clinical decisions in their practice by answering specific patient problems at unique points in the patient's life (Weiner, 2004) or they make decisions to solve or create an action item for a patient's chronic condition (Kushniruk, 2001). In general, making a decision indicates the presence of different alternatives which call for a choice in order to reach a particular outcome. Each health care professional is taught a specific decision-making process uniquely based upon their scope of practice. For example, the medical profession has a scientific method and linear process in their diagnostic decision-making while the nursing profession delivers a caring model in the Nursing Process of making decisions.

In their professional work, pharmacists in the ambulatory care setting can make decisions on drug therapy with the prescriber, patient, and/or other health care professionals. For many years, pharmacists have been performing clinical decision-making related to patient drug therapy with some kind of interprofessional relationship (Kiel & McCord, 2006). Depending on the organization and state law and regulations, this established relationship may include a collaborative practice agreement or guideline that is "between one or more

physicians and pharmacists wherein qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for performing patient assessments; ordering drug-therapy related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens" (Hammond et al., 2003, p. 1210). A collaborative relationship enables a pharmacist to participate in health care decisions, and in some cases allows shared prescriptive authority between the prescriber, who understands diagnostic health illnesses, and the pharmacist, who is the expert on drug therapy (Galt, 1995). In many ambulatory care settings, the patient contact and access to medication information allow a pharmacist and another health professional with prescriptive authority to work together to provide effective drug selection and administration. This type of collaborative effort may be offered to a unique patient with general drug therapy needs (Isetts, Brown, Schondelmeyer, & Lenarz, 2003) or with specific disease conditions, such as asthma (Pauley, Magee, & Cury, 1995; Knoell, Pierson, Marsh, Allen, & Pathak, 1998), depression (Finley et al., 2002), diabetes (Coast-Senior, Kroner, Kelley, & Trilli, 1998; Kiel & McCord, 2006), dyslipidemia (Bluml, McKenney, & Cziraky, 2000; Bozovich, Rubino, & Edmunds, 2000; Ellis et al., 2000b), or uncontrolled hypertension (Okamoto & Nakahiro, 2001) among other disease state areas.

Pharmacists in more than forty states have authority for collaborative drug therapy management (American Society of Health-System Pharmacists [ASHP], 2012). Since 1999, Minnesota pharmacists have regulations to acquire written collaborative rights from dentists, optometrists, physicians, podiatrists, and veterinarians in all practice settings for any drugs (Minnesota Practice of Pharmacy, 2005). Since 2006, Iowa pharmacists have similar authority to obtain protocols from medical practitioners for authority in the community and hospital settings for drug therapy management (Iowa Collaborative Drug Therapy Management, 2006). An ambulatory care pharmacist with this shared prescriptive authority can demonstrate his/her full clinical capacity and decision-making abilities to manage a patient's drug therapy.

The Pharmaceutical Care Process

The pharmacy profession had been product-focused instead of patient-focused until the clinical pharmacy movement of the mid-1960s, identifying more with patient care similar to the medicine and nursing health professions (Hepler, 1987). In the 1960s, the professional responsibilities of pharmacists began to transition to that of health professionals who have the social responsibilities of patient care and drug-use control rather than a primary focus on the drug product (Brodie, 1967). Brodie, Parish, and Poston (1980) discovered that pharmacists make various decisions based on their position level and practice setting. Specifically, some pharmacists make clinical decisions relating the drug treatment of individual patients. Thus, pharmacy as a profession needed a method to permit decision-making in the clinical arena that would be consistent with other health professions in the areas of communication and standardization (Strand, Cipolle, Moorley, & Frakes, 2004).

In response, Pharmacy developed the Pharmaceutical Care Process as a landmark method used to provide definition and guidance to the patient work-up and to illustrate how the pharmacy practitioner should make health care decisions after the physician's diagnosis. Pharmacists using the Pharmaceutical Care Process use the specific activity and expertise of drug therapy in the patient care process to determine and focus on decisions for proper drug therapy. The Pharmaceutical Care Process is a philosophy of pharmacy practice created to define the rules, roles, relationships, and responsibilities of the professionals in the pharmacy profession (Cipolle, Strand, & Morley, 1998). The pharmacist uses assessment to acquire cues of drug therapy problems which guide the specific interpretation and hypothesis of the care plan. After the care plan and sufficient time, the pharmacist evaluates the original interpretation and hypothesis of the care plan to continually generate new hypotheses for the best drug therapy for the patient.

Table 1. The Pharmaceutical Care Process

Establish a Therapeutic Relationship

ASSESSMENT	CARE PLAN	EVALUATION
Ensure all drug therapy is indicated, effective, safe and convenient	Resolve drug therapy problems	Record actual patient outcomes
Identify drug therapy problems to resolve and prevent	Achieve therapeutic goals	Evaluate progress in meeting therapeutic goals
	Present drug therapy problems	Reassess for new problems

Continuous Follow-up

Source: Cipolle, Strand, & Morley, 1998

The Pharmaceutical Care Process (Table 1) provides a map for pharmacists delivering patient-centered general and comprehensive drug therapy guidance in the prescribed therapy (Cipolle, Strand, & Morley, 1998). The pharmacist guarantees a commitment to an honest and reliable patient-pharmacist relationship where s/he can utilize drug therapy expertise to assist the patient in identifying, resolving, or preventing any drug-related problems. The pharmacist has the professional responsibility for patients' proper drug therapy management and depends on continual dialogue with the patient to formulate a specific drug therapy plan for him/her. The Pharmaceutical Care Process is fluid and allows for continual assessment, planning, documenting, and evaluation. The pharmacist and patient work as a team to determine patient drug therapy experience, concerns and needs, to collect demographic information and current medical problems, establish a review of systems, and to document a medication (prescription and nonprescription)

record. After data collection, the pharmacist can utilize his/her professional knowledge and understanding of drugs to assess and to identify any current or future drug-related problems.

Identification of drug-related problems is the point within the Pharmaceutical Care Process and Pharmacotherapy Workup which necessitates pharmacist clinical decision-making based on complete patient information (Cipolle et al. 2004). Existing drug-related problems are classified into seven categories regarding the indication, effectiveness, safety, and compliance of patient drug therapy (Table 2). The categories in the Pharmacotherapy Workup gives more organization and assistance to pharmacist decision-making with acknowledged groupings for identification and placement of the various drug-related problems unique to each patient. These static labels provide a common language for all drug-therapy problems recognized by the pharmacist.

The Pharmacotherapy Workup is the rational guideline for the decision-making process of drug-problem identification and is the standard process pharmacists can use when making decisions for the patients' drug therapy (Cipolle, Strand, & Morley, 2004). Each medication should have a clearly defined indication and provide effectiveness, safety and convenience to the patient. The pharmacist continually determines these qualities of each medication. If any part is absent from the four indicators of proper drug therapy, the pharmacist must identify the correct drug-related problem and design a plan of modification including various therapeutic alternatives.

Table 2. Categorization of Drug-related Needs and Drug Therapy Problems

	Category of Drug-related Problem	Description of Drug-related Problem
Indication	Unnecessary drug therapy	• No medical indication • Duplicate therapy • Nondrug therapy indicated • Treating avoidable adverse drug reaction • Addictive/recreational
	Needs additional drug therapy	• Untreated condition • Preventative/prophylactic • Synergistic/potentiating
Effectiveness	Needs different drug product	• More effective drug available • Condition refractory to drug • Dosage form inappropriate • Not effective for condition
	Dosage too low	• Wrong dose • Frequency inappropriate • Drug interaction • Duration inappropriate
Safety	Adverse drug reaction (ADR)	• Undesirable effect • Unsafe drug for patient • Drug interaction • Dosage administered or changed too rapidly • Allergic reaction • Contraindications present
	Dosage too high	• Wrong dose • Frequency inappropriate • Duration inappropriate • Drug interaction • Incorrect administration
Compliance	Inappropriate compliance	• Directions not understood • Patient prefers not to take • Patient forgets to take • Drug product too expensive • Cannot swallow/administer • Drug product not available

Source: Cipolle, Strand, & Morley, 2004

After the assessment and determination of any drug-related problems, the pharmacist can create care plans for drug-therapy interventions, patient and pharmacist-identified goals of therapy, and recommendations for the patient and other health professionals in managing current and/or future drug therapy. For team effort and patient motivation, both the pharmacist and patient work together to accomplish mutual therapeutic goals and outcomes in the individual's drug therapy.

Lastly, the pharmacist needs a system for follow-up evaluation of the patient's drug therapy and determination of past interventions. To accomplish the proper drug therapy of all the indicated medications, the pharmacist and patient can make changes in drug therapy at this time. There is also continuous assessment of drug-therapy problems during the evaluation period.

Medicare Prescription Drug, Improvement, and Modernization Act

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was enacted in the United States (U.S.) as an attempt to establish an outpatient service to provide optimal health care outcomes with a reduction in adverse effects for the public. Even if the legislation provided a drug benefit for the elderly and the disabled Medicare populations, it did not specify a complete definition for particular Medication Therapy Management (MTM) Programs giving service to those with multiple chronic diseases, on multiple long-term part D medications and likely to incur annual part D Medicare drug costs over $4,000 (Medicare Prescription Drug, Improvement, and Modernization Act of 2003). Some employers and other drug plans agreed with the general therapeutic goals of MMA, so they developed like MTM services according to their own objectives and eligibility criteria for those not eligible for Medicare part D plans (Abt Associates, Inc., 2008).

Pharmacists are the only health professional providers specifically mentioned in the MMA to collaborate with physicians and to deliver MTM services utilizing their medication knowledge to provide patient-centered care (APhA, 2005). The definition of a MTM program was vague until a consensus definition from eleven national pharmacy organizations in the Pharmacy Stakeholders Conference was determined in 2004 (Bluml, 2005). Based on the philosophy and practice of pharmaceutical care, this definition included the following nine services of MTM:

Table 3. Medication Therapy Management (MTM) Services

Performing or obtaining necessary assessments of the patient's health status
Formulating a medication treatment plan
Selecting, initiating, modifying, or administering medication therapy
Monitoring and evaluating the patient's response to therapy, including safety and effectiveness
Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events
Documenting the care delivered and communicating essential information to the patient's other primary care providers
Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medication
Providing information, support services, and resources designed to enhance patient adherence with his/her therapeutic regimens
Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient

Source: Bluml, 2005

Since January 2008, pharmacists are able to receive reimbursement for face-to-face professional MTM services with category I permanent CPT (Current Procedural Terminology) codes (APhA, 2007). With possible additional compensation, pharmacists are available to provide patients with better access to comprehensive medication review.

Phenomenon of Interest and Need for Study

Pharmacists have been instrumental to clinical decision-making especially after the 2003 passing of the Medicare Prescription Drug, Improvement, and Modernization Act. However, the current knowledge of pharmacist decision-making is limited and assumed to rely on either prescriptive numerical probabilities or the Pharmaceutical Care Process of pharmacist procedures including a checklist to accomplish decisions of proper drug therapy for each unique patient. Numbers and philosophies do not always support the decisions made in the health care practice setting. Since real-life situations in this setting are complex, ill-defined and not linearly planned, discussion with actual pharmacists can highlight realistic decision-making processes and cognitive maps.

With a philosophical orientation of how decision-making "should" be accomplished by a pharmacist, the Pharmaceutical Care Process (while being created) did not probe experienced pharmacists to discover the real decision-making process that those pharmacists used in practice for preventing, identifying, and solving drug therapy problems. With primary grounding in philosophy and theory, the Process needs to be validated in current practice to identify whether the Pharmaceutical Care Process is the actual methodology of pharmacist decision-making. Specifically, pharmacist decision-making from various therapeutic alternatives of drug therapy is important and a minimally studied subject.

Benner (1984) suggests that that five or more years of experience in a specific environment is adequate for development of expertise in that environment. Thus, pharmacists practicing in the ambulatory care clinic setting for at least five years are expected to demonstrate experienced (or expert) decision-making in current practice. All pharmacists have the potential to add value to patients and society with their drug therapy knowledge, while experienced pharmacists can offer their unique ability to reflect / cogitate on their long history of patient care, in addition to offering knowledge.

A qualitative research study, based on in-practice situations, can exhibit the human science of actual pharmacists in a way that a quantitative research study cannot. These experienced pharmacists who would be participants of a qualitative study could provide direction for future clinical decision-making processes in the ambulatory care clinic setting, which would reflect actual activity and actual practice.

Significance of This Research Study

A deeper understanding of pharmacist clinical decision-making should confirm the influence that pharmacists have on patient health care, should guide pharmacy policy and education, should contribute to educating less experienced pharmacists on decision-making processes, should promote more interprofessional work, and should encourage pharmacist decision-making toward the wisest selections of patients' medication therapy.

This study may allow pharmacists to compare and contrast their current clinical decision-making opportunities with other, updated, models and influencing factors. It may also give a more comprehensive picture of what is needed in the educational setting to enhance pharmacist clinical decision-making techniques. This may also identify experienced pharmacists' unique approaches to decision-making based on a number of personal and contextual differences.

Research Objective/Aims

The ***research objective*** of this study was to analyze how experienced pharmacists in the ambulatory care setting make clinical decisions for drug therapy.

The ***specific aims*** of the study were:

1. To analyze drug therapy decision-making process(es) of experienced pharmacists in the ambulatory care clinic setting
2. To compare and contrast pharmacists' clinical decision-making with current decision-making models
3. To specifically identify enabling factors and barriers to clinical decision-making in the ambulatory care clinic context

Researcher's Interest and Perspective

Discussion of personal preconceptions is necessary in research, especially for the specific qualitative type of this study. Understanding the suppositions and prior assumptions before analyzing and interpreting the data make biases explicit to the readers and critics of the published work (van Manen, 1997). With the researcher's professional view as a pharmacist, this dissertation used a practice-close methodology in the data collection (Lykkeslet & Gjengedal, 2007). In the further chapters of the study, the professional advantages and pitfalls (of the researcher also being a pharmacist) are discussed.

After a problem-solving graduate course in the College of Education and Human Development, the researcher questioned the current pharmacist decision-making modus operandi. Literature searches and questioning of various pharmacists provided evidence of very few studies of clinical decision-making in the pharmacy literature, and no studies in the literature had yet questioned how a pharmacist thinks in the cognitive domain of clinical decision-making. Pharmacists in the ambulatory care clinic setting have the opportunity for interprofessional relationships that may be different from other pharmacists working in other professional settings. This contextual fact provided increased researcher curiosity, regarding that specific setting. All pharmacists are

encouraged to develop close association with other health professionals by using collaborative practice agreements, so the researcher found it especially crucial to discover how ambulatory care clinic pharmacists utilize these agreements for clinical decision-making purposes.

The researcher is a University of Minnesota Doctor of Pharmacy graduate, and is working part-time at retail, community pharmacies, operating with a specific decision-making process common to many pharmacists employed by the Walgreens company. She is not aware of pharmacist practices and clinical decision-making in the ambulatory care clinic setting, apart from the minimal advanced pharmacy practice experiences in the final year of the Doctor of Pharmacy curriculum from 2001-2002. With this vague idea of the ambulatory care clinic setting, it became a personal interest area already noticed by many others in health, policy, and education. Education and extracurricular activities at the University of Minnesota provided evidence to the researcher that many other pharmacists may also be attracted to this type of research question. So, with the advice and assistance of her advisor and other pharmacists, the study began.

CHAPTER 2: LITERATURE REVIEW

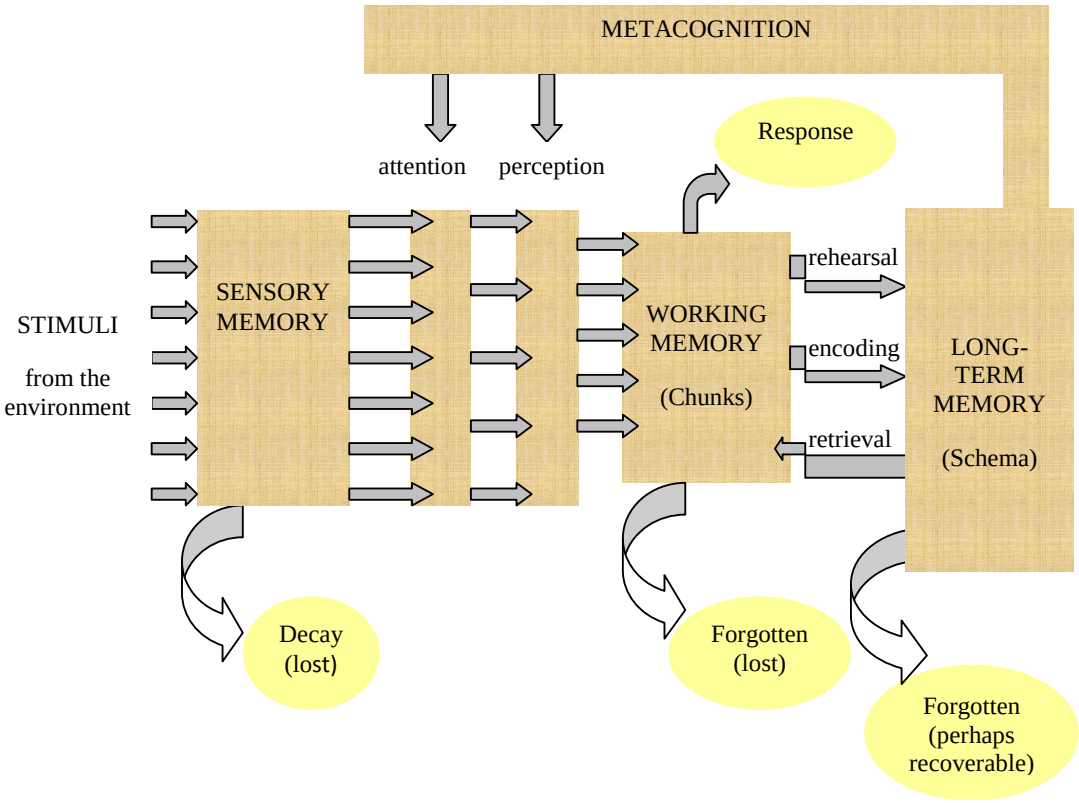
In this chapter, the reader will find a detailed review of relevant literature in the area of clinical decision-making. As previously noted, most of the following studies are shared knowledge and are available in the literature of non-pharmacy health professions, specifically in medicine and nursing. The following literature and surveys reveal the common decision-making models and factors that affect patient care in various health care settings, as well as the various techniques the human brain utilizes when making those final decisions. Despite the availability of such studies in other health professions, there is a need for conducting a similar study focused solely on decision-making in the field of pharmacy—due to the unique dynamics and the different purposes of the pharmacy profession. That study can be found in Chapter 4 of this dissertation. In the

present chapter, the researcher depicts the various thought processes and decision-making methods that are currently employed in health care settings.

Human "Normal" Thought Process

The Information Processing Theory has its historic roots in cognitive psychology of the 1950s and is used to define the normal human mind processes and information systems necessary in decision-making (Newell & Simon, 1972). This theory, demonstrated in research, emphasizes how information or external stimuli shift from the environment to personal long-term memory and life-long understanding. According to these authors, The Information Processing Model is exact. It leaves little room for individual variation, apart from distinct environmental influences and experiences that leave the potential for unique information to sit in the long-term memory. It represents the "normal" human being's thought process and information highway. Figure 1 below illustrates the Model:

Figure 1. Information Processing Model.



Source: Eggen & Kauchak, 2004

A person who focuses on environmental stimuli can store an unlimited amount of the information for a very short time (seconds) in their sensory memory. With attention and individual perception of the stimuli, information becomes part of the short-term (working) memory storage space for further processing. Otherwise, the data are lost and not used for future memory applications in working memory or in personal long-term storage. The short-term memory storage has a restrictive capacity of 7 ± 2 pieces of information (Miller, 1956). To account for this limitation, the information is "chunked" into larger, more organized pieces that can be worked with and remembered in the future.

For emphasis, think of the normal seven-digit phone number and the ease with which it is memorized. However, when a friend has multiple phone numbers, it is easier to remember them under the friend's name instead of by three different seven-digit numbers. Without the organizational chunking, data-sets that are larger than the limited working memory capacity will be lost and possibly forgotten. It proceeds no further than the working memory, and does not reach the long-term memory for future use.

The unlimited amount of information in the long-term memory store is organized into larger, related chunks (schema) of different types of knowledge (declarative, procedural, and conceptual) for future reference and retrieval in similar occurrences (Eggen & Kauchak, 2004). Declarative knowledge is made of facts, rules, and definitions that govern decisions utilizing concrete and learned information. An individual learns much of their declarative knowledge in the educational environment, and it forms a necessary background for working in a certain profession. With a base of declarative knowledge, one then practices the process, which allows for development of personal usage and unconscious behaviors.

This practical type of knowledge is called "procedural," since it embodies a better understanding of the method and use of declarative information in a specific context for personal use. No longer is the information a declarative "know-that" data-set, but the procedural "know-how" is evident with increased understanding and personal use of information in identified environments. For example, a pharmacist has declarative knowledge that 5 mL equals 1 teaspoon, and has procedural knowledge that each liquid prescription with directions of 2 teaspoons by mouth 3 times daily for 10 days = 300 mL total liquid volume.

The different grouped schemas have individual meanings which can be used for future identification and shadowing of related stimuli or examples. These schemas determine how an individual perceives and attends to new data. Since there is a similar base and

pattern identified in the long-term memory store, it is easier to acknowledge the new information and to "fit" it in previous experiences without new trial-and-error practices. With more experience, a person's schemas become large and numerous, including many different baseline schemas that can easily influence the perception of future occurrences.

Metacognition is a kind of self-regulation and knowledge of one's own learning and understanding. It is self-discovery during a task--what a person sees about his/herself when performing that task. Reflections upon past personal experiences and behavior enhance metacognitive skills, since one can determine if past activity and actions were congruent with current personal understanding and knowledge (Price, 2004). A person knows what information is included in his/her long-term memory store and is able to use that data, when needed, to clarify new episodes and cases. Thus, during different decision-making processes, one can identify stored knowledge that may be useful in the future, or even for current decision-making.

Since the Information Processing Model is the "normal" thought process, Offredy (2002) used this framework in a study looking at differences between physician general practitioners (GPs) and nurse practitioners (NPs) in their cognitive processes of decision-making. The main differences between the GPs and the NPs working in the same United Kingdom primary health care clinic, were more education and higher pay for the physician GPs. After a pilot study, 11 NPs and 11 GPs were presented with six different patient care scenarios relevant to general practice and asked to "think aloud" regarding their decision-making processes. The results of the study identify many similarities in the cognitive pathways of NPs' and GPs' decision-making; however, there was the difference of greater GP experience and knowledge, thus yielding a broader capacity for the GPs to gather information from their "chunked" long-term memory. Forming diagnoses and evaluating the hypotheses took more time for the NPs, who may be considered novices in the general practice arena, while the GPs possessed more schema and chunked material from their wider range of experiences. This study demonstrates that different

practitioners use a similar method for human thinking and decision-making, yet they have diverse long-term memory which sets their knowledge apart, per each practitioner. Since this study used situations in paper scenarios, actual patient clinical cases may change some of the cognitive abilities because of the nonverbal cues that may nudge a person's long-term memory.

Clinical Decision-Making Models

In the health care setting, clinical decisions exist in a complex environment of unstructured and complicated problems that are different for each unique patient. Specifically, for a decision of correct patient drug therapy leading to satisfactory health outcomes, the pharmacist must decide on the best drug therapy for a patient in his/her unique clinical, social, economical, environmental, and spiritual contexts. With existing therapeutic alternatives for most drug therapies, it is the responsibility of the pharmacist and the patient to decide which specific drug therapy is most appropriate, based on many patient-related clinical, personal, and societal factors.

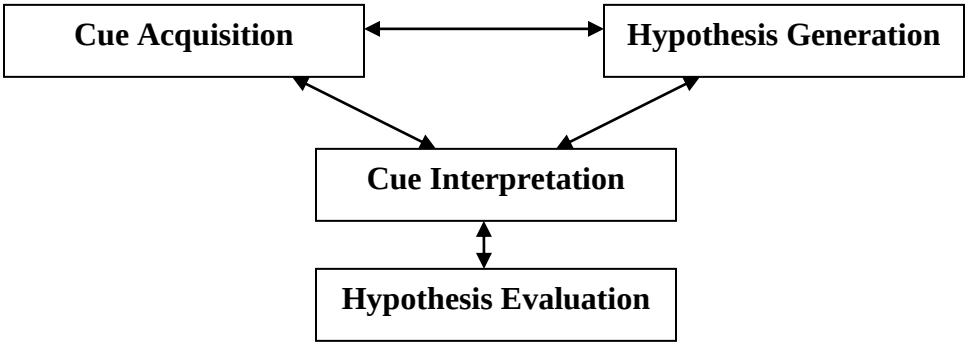
Studies and reviews of clinical decision-making are mostly located in medical and nursing literature (Bakalis, 2006; Banning, 2008; Buckingham & Adams, 2000a; Buckingham & Adams, 2000b; Elstein, 2004; Hancock & Durham, 2007; Harbison, 1991; Harbison, 2001; Kushniruk, 2001; Lamond & Thompson, 2000; Muir, 2004; Thompson, 1999). The three major processes that dominate decision-making studies include the Hypothetico-Deductive Reasoning Model (which spurred other health professional analytical decision-making processes, such as the Pharmaceutical Care Process), the probability focus of Bayesian Theory and Decision Analyses (sometimes depicted by decision trees), and the experience-guided methods of Pattern Recognition and Intuition.

Hypothetico-deductive reasoning.

Starting in the 1960s, leaders in medicine wanted to understand the skills, strategies, competencies, and attributes of clinicians. With the intention of developing learning tools, to illustrate decision-making skills for medical students, they also analyzed any similarities between the various psychological investigations of cognitive processes (Elstein, Shulman, & Sprafka, 1978). Through research, the psychological Information Processing Theory was modified to become the theoretical basis for the Hypothetico-Deductive Reasoning Model. The correlation of the two theories and the increased understanding of the physician's thought process in medical practice became important for future practical and educational applications. Like the Information Processing Model, the Hypothetico-Deductive Reasoning model is linear in process for physician determination of hypotheses guiding diagnostic decisions.

According to Elstein and colleagues (1978), in the Hypothetico-Deductive Reasoning Model, physicians apply a thought process of four activities (in continuous stages) to determine a definite diagnosis based on a patient's chief complaint, health history, physical examination, and tests (Sox, 1988). As Table 4 illustrates, each stage is dependent on the other three, and they are all interdependent during the entire clinician's decision-making process of final diagnostic determination.

Table 4. The Hypothetico-Deductive Reasoning Model.



During cue acquisition, few cues or external stimuli from observation of verbal and non-verbal patient communication (Hedberg & Satterlund Larsson, 2003) allow clinicians to generate one to three early hypotheses that guide future testing and diagnostic hypotheses (Aitken, 2003; Elstein, Shulman, & Sprafka, 1978; Lyneham, 1998). The clinician does not spontaneously make diagnoses inductively from presented data, but has a medical hypothesis for requesting various medical examinations to answer and understand patients' cues and symptoms. The Model allows fluid work in a deductive manner, starting with broad and general hypotheses regarding patient problems of a questionable nature, and continuously moving toward a more specific and definite hypothesis or diagnosis (Behi & Nolan, 1995).

Before a health professional can perform this deductive clinical decision-making, s/he must identify the problem which needs consideration. Schön (1987) presents professional identification of the deviation from normal (problem) as "framing the problem" since both the realization of the exact problem, as well the realization of factors around the problem, are necessary for forming the solution. The context is formed from personal knowledge and understanding of how to solve the problem, provided by formal education and professional training. Throughout the decision-making process, there are additional situations and discoveries which will occur, mandating that the professional "reframes the problem" to utilize a new problem-solving technique. The originally generated hypotheses are the beginning of the framed method and organized as data in a

person's long-term memory storage of declarative and procedural knowledge. Like the evidence of human thinking gathered in the Information Processing Theory, physicians concurrently consider a maximum of five to seven hypotheses for diagnosis of a patient's problem (Elstein, Shulman, & Sprafka, 1978). The early hypotheses rarely change unless there are considerable data to refute the questioned proposal. The clinician interprets the generated cues to discover laboratory data or patient symptoms that are in (dis)agreement with the original hypotheses. The clinician continuously massages the hypotheses in similar manner until a terminal and definite diagnosis is accepted from the cues and generated results.

The Hypothetico-Deductive Reasoning Model proposes the use of scientific data and results from guidelines, protocols, and available literature to guide the decision-making process. Students and new practitioners who are learning about the facts and biomedical knowledge of an area use this model in their decision-making since the facts and rules of regular and routine methods are guiding their behavior and cue monitoring (Manias, Aitken, & Dunning, 2004).

Following the introduction of the Hypothetico-Deductive Reasoning Model to understand the diagnostic process in medicine, other health professionals have adapted its use in the decision-making practices specific to their own professions. For example, the Hypothetico-Deductive Reasoning Model was incorporated into the philosophy of the Pharmaceutical Care Process for medication therapy decisions by pharmacists (Cipolle, Strand, & Morley, 1998). At first, there were debates over the concept of Pharmaceutical Care (Penna, 1990), but the Process was found to be comparable to the Hypothetico-Deductive Reasoning Model in decision-making. It has similar patient work-ups and outlines, apart from the identification of decisions in practice to prohibit drug problems. The Pharmaceutical Care Process also provides an outline (The Pharmacotherapy Workup) to guide pharmacy practice in patient care activities. The philosophy and structure of the Pharmaceutical Care Process was briefly discussed in the introduction

chapter of this thesis and now a few examples of this Process will be identified in the current chapter.

Solomon and colleagues (1998) conducted a multicenter, randomized, ambulatory care study of pharmaceutical care services conducted in ten Veterans Affairs Medical Centers across the United States (U.S.) and in one university hospital. There were 133 patients with hypertension (63 in the treatment group receiving pharmaceutical care and 70 in the control group receiving traditional pharmacy care) and 98 with chronic obstructive pulmonary disease (COPD) (43 in the treatment group and 55 in the control group). Data were collected at five one-month intervals for the treatment group and twice (baseline and six-month follow-up) for those in the control group. Quantitatively, it was found that patients in the hypertension treatment group who received the pharmaceutical care intervention had a significant decrease in the systolic blood pressure at Visit Five compared to patients in the control group. In addition, there was a significantly higher rate of medication compliance, and significantly fewer hospitalizations and other visits to health care providers in the treatment group compared to the control group. There were no significant differences in medication compliance between the treatment and control groups of the COPD arms even though the treatment patients reported better control of their disease and less symptom interference with daily activities. Over the study period, study pharmacists identified 255 problems and needs in the hypertension study arm (accepted by patient or physician in 99% of situations) and 336 for the COPD study arm (accepted in 99.3% of situations). This was an early study of pharmacists' positive contributions to better management of the diseases of hypertension and COPD of patients in the ambulatory care setting. Using more patient care and the Pharmaceutical Care philosophy of pharmacist treatment, patients showed improvements in their drug therapy and overall health. This study demonstrated that methods of care do matter in health care.

The IMPROVE study (Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers) was an effectiveness study focused on clinical pharmacist care of patients at high risk of drug-related problems (Carter et al., 1998). Nine Veterans Affairs Medical Centers (VAMCs) participated in an examination of older adults' entire health outcomes, not disease-specific values. The study included 78 participating clinical pharmacists in the intervention group of 523 randomly chosen patients. The other 531 patients were randomized selected into the control group. The pharmacists met with the intervention group at least three times in twelve months: at baseline, at six months, and at twelve months and made the appropriate adjustments to improve patient health care and to identify and prevent drug therapy problems. Although the clinical pharmacists did not evaluate specific diseases, laboratory tests and medication use was documented which allowed determination of pharmacist interventions. The pharmacists provided over 3,000 drug therapy recommendations and resolved 69% of drug-related problems. A main outcome of the study demonstrated that the intervention group patients significantly rated lower health decline than those in the control group. Also, with the increased number of visits to the pharmacists, the intervention group patients did not incur significant increases in overall health care costs. Of the top three patient chronic medical problems (hypertension, dyslipidemia, and diabetes) addressed by the clinical pharmacists, dyslipidemia was the least managed by the VAMCs, providing increased pharmacist-specific intervention (Carter et al., 2001). The IMPROVE study enrolled 208 and 229 patients who had dyslipidemia (randomly assigned to the intervention and control groups, respectively). There was a significant reduction in total cholesterol (6.56% versus 1.21%) and low-density lipoprotein (LDL) (13.2% versus 5.47%) in the intervention group receiving pharmacist services versus the control group (Ellis et al., 2000b). Even though pharmacists did not concentrate on dyslipidemia, the IMPROVE study demonstrated that clinical pharmacists can work with patients of many disease states to provide needed pharmaceutical care without increasing the overall health care costs. Ultimately, this study demonstrated the positive influence that pharmacists can have in the ambulatory care clinic setting.

Probability analyses.

Unlike the Hypothetico-Deductive Reasoning Model, two quantitative and inductive methods express rational, numerical, objective or subjective probabilities to guide a caregiver in uncertain situations: Bayes' Theory and Decision Analysis, which is often depicted by decision trees (Sox, 1988). The statistical Bayesian Theory takes prior probabilities of choices (drugs) and compares this information to current probabilities of the exact patient. If the probabilities are unknown, Bayesian statistics weigh the unknown quantities and provide an estimated probability statement. This analytic technique demonstrates the necessity of evidence to guide health care decision-making.

In decision analysis, objective probabilities are combined with subjective probabilities, called utilities, to quantify an unpredictable effect and to pictorially depict the problem in a decision tree or decision table. Utilities are the numbers measuring the subjective preference from an individual (usually the patient) for the studied outcomes. The higher the number of a utility, the better the outcome; for example, utility measure is usually from 0 (death) to 1 (perfect health in life). Each branch of the tree demonstrates a decisional option and choice for the decision-maker. These options are quantified in probabilities, which are usually discovered in literature or prior experience. Decision analysis influences clinician decisions with more information regarding the best path or branch of medical choice to maximize the expected utility level for that scenario (Peterson, Kirkwood, & Hansen, 1991). Health care associations often employ cost-effective studies using the decision tree method for policy decisions regarding different drug therapies (Odedina, Sullivan, Nash, & Clemmons, 2002; Reed, Dillingham, Briggs, Veenstra, & Sullivan, 2003). When available, probabilities provide appropriate, exact data that guide decision-making behaviors away from personal biases (Brown, Carter, & Butler, 1995).

The problems with both probabilistic techniques are that the human patient is not present in the prescriptive decision-making, and that the statistics and probabilities of the literature do not allow personal uniqueness or the qualities of individualism (Einarson, McGhan, & Bootman, 1985). Instead, the probabilities are from groups of people with a certain number of health characteristics and diseases. A person seeing a health professional may have multiple health problems or comorbidities which complicate the basic quantitative analysis that does not treat the person as a unique individual. In addition, there are many instances where the actual probability is not determined beforehand and is instead estimated, producing an incorrect decision from incomplete and inaccurate numbers. Bayes' Theory does not emphasize the exactness of the evidence, is time-consuming, and is unrealistic in a real clinical setting (Elstein, 2004).

Similar to Bayes' Theory, evidence-based medicine uses probabilities as statistics, to guide clinical decision-making in uncertain situations. Ashby and Smith (2000) changed Sackett and colleagues' (1996) definition of evidence-based medicine to highlight decision-making practice using evidence: "Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients', taking into account 'individual patients' predicaments, rights, and preferences [using] best evidence from clinically relevant research" (p. 3292).

Evidence-based medicine provides many benefits, but one practical use of the knowledge gained from large clinical trials is establishment of evidence-based treatment guidelines that can guide the individual patient's care plan (Lewis & Orland, 2004). These guidelines lead to the best "first step" for the disease or health issue in question. Since health care is so diverse and complex, the guides are not mandates for the decision-making unless a specific business or health care institution uses the guidelines as necessary ways for promotion of services demonstrating evidence or payment from the government or private insurance. Guidelines are not only used by decision-makers of patient care, but also by health care decision-makers in governmental and organizational

institutions as clear evidence to best evidence for patient outcomes (Ouimet, Landry, Amara, & Belkhodja, 2006).

More than 50% of United States' (U.S.) physicians use personal digital assistants (PDAs) in patient care activities (McAlearney, Schweikhart, & Medow, 2004; Skyscape, 2003). A PDA is a portable tool full of evidence-based information that can be used in health care decision-making. Dee and other researchers (2005) used a questionnaire to explore the use of PDAs in clinical decision-making by 108 attending physicians and physicians-in-training. More than 85% of the 59 frequent users acknowledged that the PDA had an impact on their clinical decision-making. Even those who occasionally used the PDA during patient encounters expressed that it had an impact on their decision-making. The PDA was a useful tool to the physicians for drug choice, interaction, dosage (79%), diagnosis or different diagnosis (6.6%), reference (11.5%), or for other reasons (3.2%). Although chi-square testing did not find a statistically significant difference between the two types of physicians, the trainees did have a slightly higher percentage of more frequent PDA use.

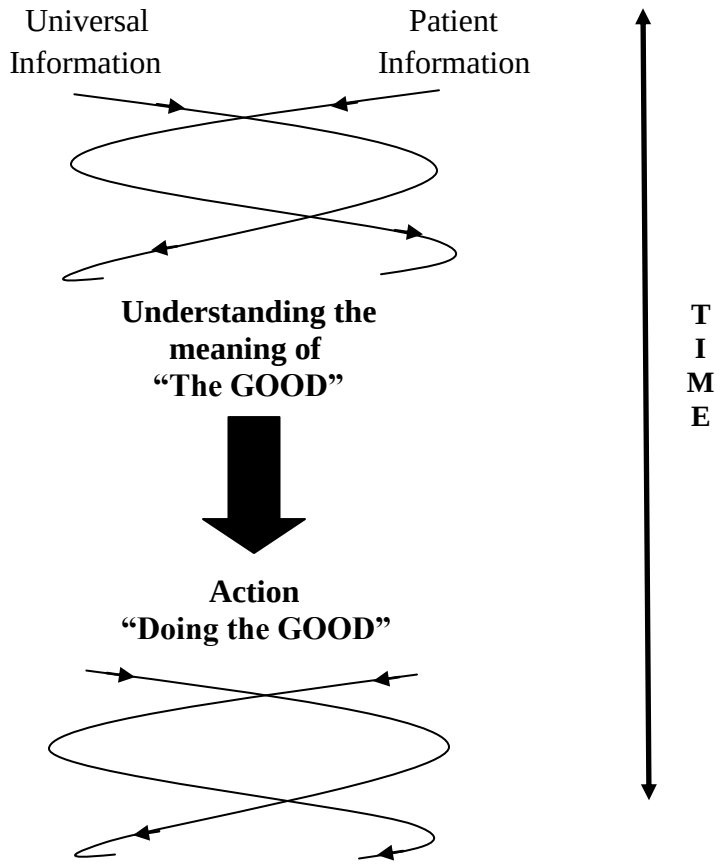
Experience-based decision-making.

Pattern recognition and intuition are two other decision-making methods, apart from the analytical Hypothetico-Deductive Reasoning Model and the quantitative, probabilistic foci of the Bayes' Theory and Decision Analysis. Pattern recognition and intuition techniques are used mostly by health professionals with more experience and who have managed similar situations in the past. Since both are lacking a clear, analytical process and/or a best evidence process, the decisions based on conscious pattern recognition and/or unconscious intuition are often ignored. However, like the analytical processes, intuition can be identified as a rational process reasonably guided by past learning, decision-making, and experience (Easen & Wilcockson, 1996).

"Intuitive judgment is the decision to act on a sudden awareness of knowledge that is related to previous experience, perceived as a whole, and difficult to articulate" (Rew, 2000, p. 95). Since complex environments in health care often require quick decisions, many experienced health professionals identify with their immediate emotional change and creative recognition, and should not be ignored. Intuition is commonly researched in the nursing profession regarding its connection to experience (King & Clark, 2002; Kosowski & Roberts, 2003; McCutcheon & Pincombe, 2001), older age, prior hospitalizations and good social support (Ruth-Sahd & Hendy, 2005), and reliability (King & Appleton, 1997; Lamond & Thompson, 2000).

Since intuition is unconscious decision-making, there is concern over one's ability to verbally recall the thought process through which the decision was made. The most realistic method of determining how an intuitive decision was made is by studying the actions promoted from the thought process. Peden Eberhart (1992) conducted pilot studies, followed by an expanded study (Peden-McAlpine, 2000), of nurse experts' early recognition of acute patient problems, to better understand how their thought processes were conducted. Although the nurses were unable to recall their thought processes during early recognition phase, they could recollect their actions in significant detail, telling a narrative plot. The expanded study by Peden-McAlpine (2000) was an evaluation of interviews based on reflection of the narrative expressions of 15 expert critical care nurses. The nurses' situational understanding constantly changed when additional patient particular information was introduced to the universal ("objective") and practical ("context-related") information. This "whole" understanding had a temporal nature which helped determine the unique patient past, present and future situations guiding complete nurse early recognition. The findings of the nurses "thinking in action" for early recognition of patient problems are illustrated in the following figure 2 demonstrating a non-linear reasoning process:

Figure 2. Thinking in Action.



Source: Peden-McAlpine, 2000

Repeated cases can create patterns of problems and experience, allowing for intuitive feelings and understanding of past occurrences, which then guide the anticipated future of pattern recognition (Offredy, 1998). Repetitive review of similar patients and health problems from other experiences will allow the health professional to quickly make inference and decisions based on experience. A person's metacognitive awareness of experience involves knowing the self as well as the background of the topic at hand (El-Koumy, 2004). So, with repeated experience of a health care situation, the health professional can reflect on prior experiences and determine what s/he needs to do in order to achieve a desired outcome. Sometimes with pattern recognition, there is incorrect

comparison of the new episode to a class prototype (the most representative type of individual), or to many exemplars, which changes the individuality of care (Buckingham & Adams, 2000b). The decision of care may then be biased on past results that incorrectly correlate with the new individual case.

Other examples of pattern recognition in clinical decision-making have been discovered in studies of experienced physiotherapists. One example from Noll and colleagues (2001) used a qualitative case study research design to demonstrate that experience does guide the forward reasoning process of pattern recognition, in order to form a working hypothesis. In each of her patient encounters, the physiotherapist with 19 years of experience depended on her organized schemata of vast knowledge and on her clinical experience of different patient symptoms to make a determined differential diagnosis. This study highlights how the human thought process, within the qualifying factor of experience, impacts clinical decision-making.

There have been further studies that identify that more than one clinical decision-making technique is evident in clinicians' decisions of a particular health issue. Hallett and colleagues (2000) did a semi-structured qualitative interview study of 62 community nurses (of various experience levels) partly regarding quality (in the particular aspect of wound care which was linked very closely with clinical decision-making in this environment). The studied nurses made dual approaches of assessment decisions in a clear and holistic manner--'correct' for each patient. They used an individualistic approach, aligned with the diagnostic decision-making. The nurses often made intuitive, quick decisions not based on a linear or definite staged process of decision-making. The nurses were able to give rationale for their sources of knowledge. Various policy guides, journals, pooled knowledge from colleagues, drug representatives, and experts helped the nurses in their decision-making. Since the nurses used both theories (intuition and diagnostic reasoning) in their decision-making for wound care, it is evident that both methods are compatible for nurses in wound care settings. To properly conduct a study,

then, on how a nurse makes decisions, the research must factor in this reality: nurses and health professionals are indeed using some of the intuitive, less quantitative, brain activities while making decisions.

Taylor (2006) determined that both physicians and nurses use all four types of decision-making (hypothetico-deductive, decision analysis, pattern matching, and intuition) in complex scenarios such as weaning patients from mechanical ventilation. Pattern matching was not commonly used, possibly owing to the individual nature of weaning. In fact, another method of decision-making--trial and error--was also apparent with mechanical settings, for example. This demonstrates that decision-making is not always a one-method process.

Other Factors Affecting Decision-Making

Decision-making models are not adequate in telling the whole story of the health professionals' decision-making processes as other contributing factors exist to influence clinical decision-making. For example, Campagna and Newlin (1997) discovered that attitudes, economic structure and reimbursement, expertise, laws and regulations, motivation, and personality influenced pharmacist drug therapy decision-making, whereas professional values, level of appointment, area of clinical practice and age affect nursing clinical decision-making (Hoffman, Donoghue, & Duffield, 2004). Experience, heuristics, task complexity, and situational context have also defined decision-making practices that establish the process of health care professional decision-making and determination of the final diagnosis or solution to a patient problem (Cone & Murray, 2002). Another study (Greenfield, Bryan, Gill, Gutridge, & Marshall, 2005) evaluated factors influencing clinicians' decisions to prescribe medication to prevent coronary heart disease and noted themes of risk and benefit of treatment, the patient's role in treatment decisions, patient characteristics, 'costs' to patients, and costs to the health services. It is

clear that there is a vast and varied collection of factors which influence each decision that a health care worker must make.

Experience.

Identifying that both analytic processing and intuitive thinking are necessary aspects of the human thinking process, Dreyfus and Dreyfus (1986) identified five stages of skill development ranging from early beginnings as a novice to the final stage as an expert. Along the skill development continuum, knowledge becomes more of an experience-based "know how" instead of simply having the "know that" facts. The five stages of a person's skill acquisition build from novice, advanced beginner, competent, proficient, to expert.

Table 5. Five Stages of Skill Acquisition.

Skill Level	Guide to Performance	Decision-Making Tools	Decision-Making Thought Process
1. Novice	Context-free and learned data	Objectively defined rules	Conscious
2. Advanced Beginner	Context-free and situational elements	RULES and real-world experience	Conscious
3. Competent	Context-free and situational elements in a goal-oriented and hierarchical organized manner	Rules and REAL-WORLD EXPERIENCE	Conscious
4. Proficient	Situational elements	Real-world experience and realization of similar situations	Conscious and Unconscious
5. Expert	Situational elements	Real world experience	Mostly unconscious

Source: Dreyfus & Dreyfus, 1986

As a person gradually progresses through the distinct stages from novice to expert, s/he uses more unstructured and complicated real-world experiences to make decisions instead of declarative, rigid, rule-based facts. Although the individual is an expert in one area in which s/he has ample skill and experience, in another context s/he is a novice with limited knowledge and expertise. Thus, the five stages of skill acquisition are fluid and contextually dependent.

A novice follows the declarative knowledge learned in the educational environment and has no coherent sense of using the facts in the real-world for the overall application to a problem. When making a decision, the novice uses objective facts to consciously determine if the answer fits with the normal situation learned in school or the typical problem solved in the literature. If the scenario is different than the story-book examples from schooling and the literature, the novice may look for advice from more experienced individuals in the same contextual environment.

With more skill and experience, the novice becomes an advanced beginner still using rules in many decisions, but gaining practical understanding of real-world applications. S/he is seeing more evidence to situations that were explained in story-book examples, but also noting various differences that identify with those examples. The advanced beginner continues to consciously demonstrate decisions based on the learned rules and on the facts of the illness (Manias, Aitken, & Dunning, 2004).

Individual competence becomes apparent as real-world examples are more complex and identified within the specific situation or context. There is a conscious organization of the decision-making task using facts and experience to guide him/her to an end result that is clearer and more attainable. Both conscious and unconscious decisions bring the competent individual to where s/he wants to end. For example, a decrease in blood pressure is desired for a man aged 55 years with comorbidities of diabetes and hypertension (high blood pressure) and history of myocardial infarction (heart attack)).

A measured blood pressure of 100/80 mmHg is marked as the patient and pharmacist goal treated by adequate exercise, diet, and drug therapy. Ample evidence of treatment options exist for an adult with diabetes and hypertension, so the pharmacist at the competence level utilizes the evidence, and her/his own professional experience of treating adults with hypertension, to determine the correct drug therapy for the unique patient.

With more situational experiences in pattern recognition and intuitive understanding, a person at the proficient skill level makes conscious decisions with unconscious feelings, guided by recognition of similar events from the past which had demonstrated unforgettable failure or success in results. She is able to work within and toward the whole picture, instead of processing information piece by piece. In the case of a pharmacist, the proficient individual has certain "ah-ha" moments when remembering similar circumstances from the past, and then decides on a particular therapy because of this realization.

An expert performs in an environment, as a united trio in conjunction with his/her context and experiences. This context and these experiences provide similarities and comfort for the expert as s/he makes decisions. Since the expert has increased understanding and participation in similar tasks, typically s/he has no conscious thought of the next step. Even though complex (health care) decisions will rarely be exactly the same with each case, a health professional who has experienced the good and the bad in numerous circumstances will make a decision based on automatic feelings instead of new analytical facts and rational reasoning with evidence. Experts are able to "see" the unexpected. They are able to anticipate the future of the whole, and not just react to the individual parts, of a case.

In nursing, Benner (1984, 1996) adapted the Dreyfus' five stages of skill acquisition (Dreyfus & Dreyfus, 1986) to distinguish nurses in the practice setting using the

conceptual model. With research she demonstrated that in complex health care settings, nurses displayed skill development in the different decision-making practices they used. Not only did she confirm the practical and medical use of the Dreyfus' stages, but she also conducted research to provide a general timeline of skill-development within each stage. Although experience is not guided by the passage of time in a certain environment, it can give a general understanding to the probable skill level: competency is noted in someone working in the same or similar contextual environment for two to three years, proficiency in approximately three to five years, and expertise in five or more years.

Even though Benner (1984, 1996) and the Dreyfus brothers (1986) concluded that experts have intuitive abilities unlike the novice or beginner, some studies come to a different conclusion. There are distinctions between the novice and expert usage of intuition, but even the novices experience unconscious realizations to guide their decision-making in patient care (Kosowski & Roberts, 2003). Even if the novice and the expert both use some intuition for their decision-making, the expert may have a more efficient and quick response time in gathering the selective questioning and testing pointed toward the possible result they have noted in their experiences (Groves, O'Rourke, & Alexander, 2003; King & Clark, 2002; Offredy, 1998).

A few studies in pharmacy focus on decision analysis in particular; however, no study pertained to *how* the pharmacy decisions were made. Rather, there was an interest in defining the role experience played in making decisions. Greer and Kirk (1988) studied 76 senior pharmacy students from four schools of pharmacy which differ regarding pharmacy degree and the extent of curricular emphasis on integration and application of specific learned pharmacy information to other courses and to external pharmacy environments. Four simulated community pharmacy clinical scenarios were developed and used with a computer decision-making instrument. Multivariate analysis of variance was used to determine that pharmacy students who had more curricular pharmacy practice experienced integration, and students with higher extracurricular pharmacy

practice experience were more focused on their information when searching for a decision. It is possible that these pharmacy students were able to hone in on the important facts necessary for the decision.

Interviewing and observing 20 nurse practitioners (NPs) working alongside a general practitioner physician, in United Kingdom primary care settings, Offredy (1998) noted a difference with respect to NP experience in the used decision-making model (hypothetico-deductive, pattern matching, intuition, and decision analysis). Many of the decisions were made with different approaches—thus demonstrating that their decision-making was not defined by one method. About 70% of the participants used early hypothesis generation leading to particular methods of assessment and data acquisition with focused questions. The more experienced NPs had earlier hypothesis generation and quicker decision-making diagnoses. They used intuition more often as a decision strategy and used pattern matching for more routine and common patient problems. Also, those NPs with barriers to decision-type, due to their role in health care, used more pattern-matching since most of the decisions were the same with similar disease states. About 65% of the participants noted that experience with a particular patient problem made the new decision easier and faster while 20% felt that a lack of knowledge made the decision more difficult.

Another study that relates decision-making to experience looks at graduate nurses' medication management (Manias, Aitken, & Dunning, 2004). The twelve graduate nurses were professionals in their first year of practice in a university teaching hospital after the three-year undergraduate nursing degree. The qualitative study of observations and interviews identified that their most common decision-making model was the analytical hypothetico-deductive reasoning model, followed by pattern recognition and then intuition. The nurses used a common examination method to identify patient problems, which provided cues needed to advance original hypotheses and then make a decision. Pattern recognition was mostly observed by nurses' decisions in specific

medical areas, such as cardiology. Decisions for medications used by patients with a similar disease presented comparable situations for other patients with the same condition. The researchers observed intuition relevant in only two of the total thirty-five graduate nurses' decisions. Similar to research by Dreyfus and Dreyfus (1986) and by Benner (1996), the graduate nurses demonstrated a competent or proficient skill level in their decision-making practices.

Bakalis and Watson (2005) concentrated on 60 individuals from three different specialties of the nursing profession: medical, surgical and critical care, using a quantitative clinical decision-making questionnaire. Although educational level of the nurses did not determine the type of decisions made, the age and length of nursing experience demonstrated an increase in speed of decisions. Nurses in the critical care environment diagnosed patient condition, managed the work environment, and acted in emergency situations more than those in the medical and surgical areas. However, the medical nurses informed patients of their prognosis more than the other types of nurses. Therefore, not only did experience guide the clinical decisions in practice, but the situated context and specific work also determined the type of nurse decision-making.

Redden and Wotton (2001) collected data from five experienced critical care nurses (CCN) and five gastrointestinal surgery nurses (GIN) using semi-structured interviews with the think-aloud protocol, as the participants analyzed two patient scenarios of third-space fluid shift. Both groups of nurses had experience with elderly patients undergoing gastrointestinal surgery, so they were assumed to be experts in this scenario type. The CCNs had a mean of 15 years experience in nursing, a mean of 6.7 years in the ward, and all had a Bachelor of Nursing degree with completed post-graduate studies; however, the GINs had a mean of 6 years in nursing and 4.4 years in their ward, and 80% had a Bachelor of Nursing degree with no post-graduate studies. Both types of nurses used the hypothetico-deductive reasoning model, but the CCNs additionally used pattern recognition in their analysis of the scenarios. The difference in experience, education,

and work environment may have guided the results in that the GINs made hypotheses with few cues and from linear reasoning like competent or proficient professionals--whereas the CCNs made more correct decisions using essential cues, knowledge, and reasoning, characteristic of experts. These results were not anticipated from the researchers, but they now draw attention to experience as a tool in decision-making.

In another study noting the role of experience, Young and colleagues (2007) supervised 11 surgery and 4 emergency medicine residents of the University of Virginia Health System in a preliminary audio recall experiment and in two clinical case scenarios. The five novice residents had ≤ 8 weeks of critical care experience, six intermediates had 8-16 weeks of experience, and four experts had > 16 weeks of critical care experience. The results were insignificant for noting the residents' recall of data; however the number of errors significantly decreased (including "buggy knowledge") and the identity of situated awareness significantly increased from novices to experts. There was also significant directionality of reasoning among the novice and expert physicians. The novice residents demonstrated more instances of backward reasoning--necessary for a differential diagnosis of assessing large amount of data and ruling in or out each independent component. Differently, the expert critical care residents used more instances of forward reasoning to quickly diagnose a clinical situation, and used fewer data points and fewer cues.

Currey and Botti (2005) observed, took notes, and interviewed 38 critical care nurses making hemodynamic clinical decisions after cardiac surgery in three critical care units in two major metropolitan hospitals in Melbourne, Australia. Expertise was defined as having three or more years of cardiac surgical intensive care (CSIC) experience and was demonstrated by 20 participants. Higher quality decision-making was observed in experienced nurses, those who received advice from the experienced CSIC nurses, or those who used evidence-based practices. The more experienced nurses, and those receiving advice from them, continuously reacted to patient salient, intermittent patient

cues, and cardiovascular parameters. However, the inexperienced nurses conducted more physical assessments--perhaps demonstrating where their expertise lay. Experienced nurses were quicker in detection and response to overall hemodynamic instability. Those inexperienced were able to treat the instability without knowledge of the underlying cause. Both types of nurses did not adhere to certain evidence-based techniques for assessing hemodynamic data accurately; some because of surgeon requests to do things a certain way apart from the guidelines, some because they were unaware of current guidelines.

Heuristics and biases.

In addition to various theoretical and concrete ideas which affect the decision-making process, an individual with experience develops certain cognitive shortcuts--"rules of thumb"--that guide decisions in complex and uncertain health care settings (Hicks, Merritt, & Elstein, 2003). These shortcuts are called heuristics and biases. Similar to pattern recognition and intuition, heuristics and biases are more associated with experienced and expert health clinicians who have seen and worked with many different health conditions.

Furthermore, no analytical evidence exists that ensures appropriate use of personal heuristics and biases. Some of the heuristics, such as representativeness (making judgments based on a personal mental prototype), availability (decisions based on a recent or more salient event of patient care), overconfidence, hindsight bias, and base rate neglect, can lead to incorrect decision-making or diagnoses because of subjective probability and improper use of evidence (Brannon & Carson, 2003, Cioffi, 1997; Thompson, 2003). This subjective nature may bias the decision-maker to recall only estimates based on personal experience, individual context, and patient identity instead of noting the realistic numbers of similar cases throughout the entire world (Cioffi, 2001).

A study in the pharmacy profession (Brown, Carter, & Butler, 1995) examined different populations of participants including pharmacists in community practice, university-based researchers and clinicians, pharmacy practice residents, specialized residents, and/or post-doctoral fellows and students in their third professional year in their decision compared to a computerized decision analysis model. There were two phases in the study with typical case scenarios related to patient hypertension. Participants chose a medication and decided influential factors for their selection. After a two-week period, the same scenarios were provided to both the control and the study groups. In Phase II, the study group received probabilities for efficacy and adverse reactions with random selection for additional cost information. The study group of pharmacists changed their decisions more frequently with probabilities, unlike the students. Participants other than pharmacy students seemed to rely on biases or heuristics in their decision-making, since they changed their drug therapy suggestions more with additional information and probabilities of a better medication. It is possible that these pharmacists and other participants, apart from the students, utilized the representative and availability biases, since they worked with patients and remembered similar scenarios when making current decisions. Since students did not have much practical experience, the biases were missing from their decision-making, and they relied more on recently acquired declarative and procedural knowledge based upon lectures and learned material facts from school.

In a study of the same osteoporosis scenario used in a past study (Redelmeier & Shafir, 1995), which explored decision-making with multiple treatment alternatives, Roswarski and Murray (2006) used log-linear statistics of 192 answered surveys by residents, fellows, faculty, and staff physicians of the Indiana University School of Medicine. Those physicians supervising medical students were not influenced by multiple decision alternatives, compared to those who did not have a supervisory role and deferred the decision to others. Also, the amount of supervision was important, as those physicians who had the interaction of 11 hours or more per week were not affected in the multiple

alternative cases unlike those with 10 hours or less supervision. The less experienced physicians also deferred to others more than those with more experience. This study demonstrated that both supervision and experience can lead to less cognitive bias or heuristics in decision-making. Those physicians may teach and learn valid information which increases their understanding and their independent decision-making in patient care.

Task complexity.

The Information Processing Theory (Newell & Simon, 1972) presents that the human mind works with a limited amount of information at a specified time allotment. Thus, decision-making is affected by the degree of complexity in a patient problem and the cues relevant to the issue.

A large number of alternatives provide cognitive strain and decrease the attention given by the decision-maker (Chinburapa et al., 1993). With conflicting evidence clouding the hypotheses and thought process, decision-making is difficult for determination of the final correct diagnosis (Lewis, 1997). Likewise, task complexity of patient health problems without an analytical support system makes for difficult and less consistent decision-making (Bucknall, 2003; Hicks, Merritt, & Elstein, 2003; Hughes & Young, 1990).

Two groups of physicians (287 members of the Ontario College of Family Physicians and 352 neurologists and neurosurgeons affiliated with the North American Symptomatic Carotid Endarterectomy Trial) and one group of 41 legislators belonging to the Ontario Provincial Parliament participated in a research study (Redelmeier & Shafir, 1995) exploring medical decision-making with multiple alternatives, in a questionnaire with scenarios relevant to the participants in the three different groups. The questionnaires posed two different versions identifying with a basic two-option decision or a more

expanded version containing three options. The participants were randomly assigned to one of the two decision scenario types. In all three groups, there were significantly more default instances of doing "nothing," when a decision between a similar drug, patient, or hospital closing was apparent in the options of the expanded version. The addition of a similar type of option to the decision-making made it more difficult to clearly decide among the complex scenarios. Not only does this demonstrate that more alternatives available cause more difficulty in deciding, but with similar alternatives the decision-maker may be more prone to do "nothing" and avoid the need for making their own decision. Or they may turn to a cognitive bias, and make an intuitive decision (apart from those two similar options which might have required more thought and time).

Hicks, Merritt, and Elstein (2003) conducted a pilot study using a correlational, non-parametric approach to examine clinical decision-making consistency across decision tasks of varying complexity, among other relationships designed by the study. Consistency between intuitive and analytical decision-making was evaluated using the Decision Analytic Questionnaire (DAQ) with two clinical scenarios that might occur in the critical care unit, distinguished by number of irrelevant data, level of complexity, and number of decisions to be made. The 54 nurses had an average of 9.9 years of experience in direct patient care of the injured or critically ill in critical care areas of three private, tertiary-care, teaching, medical center hospitals in a large Midwestern city of the United States (U.S.). The nurses made both intuitive decisions of the scenarios along with probability and utility estimates similar to decision analysis. Decision-making consistency was inversely related to task complexity. Low-complexity tasks were more complete and used the nurse analytical process, compared to the high-complexity tasks which utilized more intuitive processes.

Situational context.

The work environment can also affect clinical decision-making, in a manner similar to task complexity. Researching the 6 registered nurse participants from the other study looking at cues in decision-making in Swedish medical wards, geriatric rehabilitation wards, or primary care units, Hedberg and Sätterlund Larsson (2004) analyzed the implications of environmental elements to decision-making. The two main themes of the content analysis looking at environmental elements were: interruptions and work procedures. Frequently, the nurses were interrupted from activities by other persons (patient or colleague) or noises from the phone or emergency alarms. Oftentimes, the interruptions were due to exchange of information, instructions, and assistance. The nurses had significant time pressure because of doing multiple activities, prioritizing and allocating work to others, and always working in a space that was open to others. These interruptions or difficulties of the work environment may make clinical decision-making more difficult and of lower quality. Only observations were used in this study which may have altered participant behavior. Since the methodology was performed for 4 to 6 hours, it possibly caused fatigue and/or inconsistency of results.

Different work environments allow distinct decision-making practices in any specific situational environment, guided by time and patient population (Lauri & Salanterä, 1998). As an example, Burman and fellow researchers (2002) studied nurse practitioners' (NP) decision-making with a grounded theory qualitative approach to individual interviews, using one acute and one chronic practice vignette. They sampled 36 primary care NPs with varying levels of experience--from new graduate to 26 years in different settings. The NPs did not make decisions with solely one method, but used the medical decision-making of the Hypothetico-Deductive diagnostic reasoning and nurse care planning to work with the whole patient. They wanted first to make an iterative and spiral process looking at the entire patient--including the patient's agenda and concerns--specifically noting the patient/family and community context. The NPs' level of comfort and experience also guided their decisions and their need for advice from additional

colleagues. The NPs used pattern recognition in their diagnostic reasoning of specific red flags guiding the hypotheses, and intuition to do what was best for the patient.

Insurance.

A recent article depicted the uniqueness of the United States' (U.S.) health care system, specifically their managed care and their patient insurance policies. Meyers and Colleagues (2006) of CAPRICORN (Capital Area Primary Care Research Network) sought to determine whether insurance status affected clinicians' clinical decision-making. This pilot study engaged 25 physician CAPRICORN members practicing at the Georgetown University Medical Center, in nonprofit community health centers, or at a private group practice. The participants completed a paper-card survey immediately after each patient encounter in 2 half-day patient care sessions. Of the 409 encounters, the physicians considered patients' insurance status 193 (47.2%) times and made clinical changes because of insurance issues during 99 (24.2%) encounters. Insurance decisions were mostly considered when the patient was uninsured and some changes led to patient inconvenience and possible decreased adherence. This small study may demonstrate that insurance has indeed affected clinical decision-making and therapy management in patient care.

Summary and Identifying Gaps in the Literature

Previous health profession literatures demonstrate various processes of clinical decision-making with little indication of a definite or standard method for this process. Multiple factors have been identified which affect clinical decision-making, but no single study shows an overarching facilitator or barrier to making decisions, especially relating to pharmacists' work. As mentioned before, most of the clinical decision-making studies were published in the medical and nursing professional literature with very few studies in the pharmacy literature (Brown, Carter, & Butler, 1995; Greer & Kirk, 1988; Peterson,

Kirkwood, & Hansen, 1991). Pharmacy-specific decision-making studies were conducted in the late 1980s-1990s yet are now somewhat outdated due to recent changes in Medication Therapy Management, changes in reimbursement, and changes in pharmacy educational curricula leading to a different degree in pharmacy. Also, with more collaborative practice experiences for pharmacists and prescribers, the pharmacists now are much more involved in making clinical decisions in direct patient care than in the past.

Many research studies of clinical decision-making were conducted in the acute and critical care settings (Aitken, 2003; Cone & Murray, 2002; Currey & Botti, 2006; Hicks, Merritt, & Elstein, 2003; Hughes & Young, 1990; Parker, Minick, & Kee, 1999; Peden-McAlpine, 2000; Redden & Wotton, 2001; Taylor, 2006; Young, Smith, Guerlain, & Nolley, 2007). There were very few studies that analyzed decision-making in the ambulatory, outpatient setting. In addition, many of those studies were carried out in other countries (with health care systems that are radically different from the United States' (U.S.) system) like Australia (Aitken, 2003; Currey & Botti, 2006; Hoffman, Donoghue, & Duffield, 2004; Manias, Aitken, & Dunning, 2004; McCutcheon & Pincombe, 2001; Redden & Wotton, 2001;), Finland (Lauri & Salanterä, 1998), Greece (Bakalis & Watson, 2005), Sweden (Hedberg & Sätterlund Larsson, 2003; Hedberg & Sätterlund Larsson, 2004), and England/the United Kingdom (Greenfield, Bryan, Gill, Gutridge, & Marshall, 2005; Hallett, Austin, Caress, & Luker, 2000; Offredy, 1998; Offredy, 2002; Taylor, 2006). The different contexts of those studies (being non-ambulatory, and being outside the U.S.) led to substantial divergence in the consequential formation of decision-making models for outpatient, chronic ambulatory care clinics of the U.S.. This presents a gap in relevant literature, and in policy formation for U.S.' ambulatory care pharmacists, leaving current U.S. ambulatory care pharmacists with "ill-fitting" decision-making models.

Overall, the methods, up to this point, of evaluating decision-making include clinical cases (Young, Smith, Guerlain, & Nolley, 2007), questionnaires (Bakalis & Watson, 2005; Dee, Teolis, & Todd, 2005; Greenfield, Bryan, Gill, Gutridge, & Marshall, 2005; Hicks, Merritt, & Elstein, 2003; Hoffman, Donoghue, & Duffield, 2004; Hughes & Young, 1990; Lauri & Salanterä, 1998; Ruth-Sahd & Hendy, 2005), surveys (Meyers et al., 2006; Roswarski & Murray, 2006), or written scenarios (Chinburapa et al., 1993; Offredy, 2002; Redelmeier & Shafir, 1995). Qualitative research work, on the other hand, is demonstrated in focus groups (Cone & Murray, 2002), a focus group followed by questionnaire development (McCutcheon& Pincombe, 2001), interviews led by clinical vignettes stated in person or via telephone (Burman, Stepans, Jansa, & Steiner, 2002; Redden & Wotton, 2001; Taylor, 2006), or interviews discussing actual past nurse scenarios (Hallett, Austin, Caress, & Luker, 2000; Parker, Minick, & Kee, 1999). Patient involvement, in most of the studies described in this chapter, was limited, and only occurred during a 'think aloud' clinical activity, followed by an interview (Aitken, 2003), observation (Hedberg & Sätterlund Larsson, 2004), or observation with interviews (Currey & Botti, 2006; Hedberg & Sätterlund Larsson, 2003; Manias, Aitken, & Dunning, 2004; Offredy, 1998).

Of the few research studies of pharmacist clinical decision-making, none of those studies used a qualitative methodology to understand real human (pharmacist) experiences in the clinical context of patient care. Most studies conducted in the past and in the relevant literature have been quantitative in their format and in their measurability. This study addresses some of those current gaps and provides necessary missing information, using the qualitative method of hermeneutic phenomenology, which is comprehensively described in the next chapter.

CHAPTER 3: RESEARCH DESIGN AND METHODS

Overview and Rationale

The overall research objective of this study was to analyze how experienced pharmacists, in the ambulatory care clinic setting, make clinical decisions for drug therapy. To increase the factual data for analysis, the clinical decisions and experiences of pharmacists needed to be communicated by actual pharmacists in real world situations. Qualitative research is the only methodological practice that would directly employ stories and recollections of those experienced pharmacists.

Qualitative research gives voice to people by making their stories and experiences the focus of research. It benefits a study by allowing human science to review the whole individual in his or her natural setting. Qualitative research facilitates greater understanding of the actual person because there is no reduction of the person to individual parts, but rather an analysis of the whole entity. The external appearance is not as important as the internal mystery of a person, with his or her unique experiences. The research addresses human behavior somewhat subjectively, particular to each social situation and each problem context. Unlike quantitative research, numbers are used infrequently to provide objective, mathematical results to a study. Qualitative research relies on subjective textual analyses and the interpretation of words and narrative. Denzin and Lincoln (2005) compare the qualitative researcher to a "bricoleur, quilt-maker, or assembler of montages" using various methodological practices and sequences to construct a unified final story. They also used the crystal as an analogy: just as light falls upon a crystal, there is no one "correct" telling or interpretation of any situation and the result depends on the angle and perspective of the researcher and the study context.

Understanding the philosophical underpinnings of research design provides appreciation and evidence for study analyses and findings. For instance, although one study states that it uses qualitative design and methods, it is necessary to correctly and specifically

determine the paradigms within which a specific scholarly work identifies (Dowling, 2007). Guba and Lincoln (1994) analyzed four different philosophical paradigms of research, addressing questions of ontology (form and nature of reality), epistemology (relationship between the knower and that which is studied) and methodology (how the would-be knower finds out for what s/he is looking). The four research paradigms of positivism, post-positivism, critical theory, and constructivism provide distinctive positions regarding research issues. The study of the four paradigms was repeated and updated in an article by Guba and Lincoln (2005) with the addition of the participatory/cooperative paradigm. Many of the physical and social sciences have maintained their practice and research in the positivist paradigm, while qualitative researchers often operate within a constructivist paradigm. Tables 6 and 7 differentiate between the positivist and constructivist paradigms, which are the two most contrasting paradigms.

Table 6. Basic Research Issues of the Positivist and Constructivist Paradigms.

Research Issue	Positivism	Constructivism
Ontology	Realism: "Real" reality driven by immutable natural laws and mechanisms. "The way things are" and context-free.	Relativist: "Realities" are socially constructed and may change as constructors become more informed and sophisticated.
Epistemology	Dualist/objectivist: Findings are true and through a one-way mirror.	Transactional/subjectivist: "Findings" are created with interaction.
Methodology	Experimental/manipulative: Verification of hypotheses through chiefly quantitative methods.	Hermeneutical/dialectical: Varying to constructions to distill a consensus construction.

Source: Guba & Lincoln, 1994

Guba and Lincoln (1994) also clarify below some of the important and controversial issues that are currently being debated by various researchers. Many of these issues will be described again in later segments of this chapter.

Table 7. Selected Issues Demonstrating Differences between Positivist and Constructivist Paradigms.

Research Issue	Positivism	Constructivism
Inquiry Aim	Explanation: predict and control	Understanding and reconstruction
Nature of Knowledge	Verified hypotheses established as facts or laws	Individual or collective reconstructions coalescing around consensus
Knowledge Accumulation	Accretion - "building blocks" adding to "edifice of knowledge;" generalizations and cause-effect linkages	More informed and sophisticated reconstructions; vicarious experience
Goodness or Quality Criteria	Conventional benchmarks of "rigor": internal and external validity, reliability, and objectivity	Trustworthiness and authenticity, including catalyst for action
Values	Excluded - influence denied	Included - formative
Ethics	Extrinsic: process tilts toward deception	Intrinsic: process tilts toward revelation; special problems
Voice	"Disinterested scientist" as informer of decision makers, policy makers, and change agents	"Passionate participant" as facilitator of multi-voice reconstruction
Training	Technical and quantitative; substantive theories	Resocialization; qualitative and quantitative; history, values of altruism, empowerment, and liberation
Accommodation	Commensurable	Incommensurable with Positivism
Hegemony	In control of publication, funding, promotion, and tenure	Seeking recognition and input; offering challenges to predecessor paradigms, aligned with postcolonial aspirations

Source: Guba & Lincoln, 1994

Constructivism provides the basis for this qualitative hermeneutical phenomenology research study. In this approach, context is very important, since one's experiences are dependent on the environment and may change in different situations or settings. For example, pharmacists working in an outpatient ambulatory care clinic setting, with a collaborative practice agreement, do not perform the same activities as pharmacists working in an inpatient acute care institutional setting. Also, the interaction between the researcher and the research participant (pharmacist) is crucial for gathering information about former experiences, since there needs to be social interaction and continual assistance and probing in the data collection process. Using various qualitative methods, the researcher is allowed to gather the information necessary for the final analysis. That information is evaluated in "people" and their contextual stories rather than in "numbers." Again, this supports the greater effectiveness of constructivism, rather than positivism, as the philosophical foundation of this dissertation.

As a definitive method of qualitative inquiry, this study used hermeneutic phenomenology to examine the activity of experienced pharmacist clinical decision-making in the ambulatory care clinic setting. Hermeneutic phenomenology has its beginnings in anthropology (participant observation), sociology (study of social phenomena), and philosophy of the constructivist paradigm, which dates back to the late 1800s in the United States (Boyd, 1993). Phenomenological philosophy in the constructivist paradigm emerged in the early part of the twentieth century (Todres & Holloway, 2006). Instead of collecting quantitative data, phenomenological inquiry looks into one's "lifeworld" and "lived experiences" of particular activities in a specific context. Edward Husserl is credited as being the father of phenomenology and human science research. Husserl was instrumental in the eidetic, or descriptive, approach to the philosophy involved in the epistemological (being of the world) structure. To the larger discipline of philosophy, Martin Heidegger contributed hermeneutics (the science of

interpretation), which allows researchers to go beyond just description of human experience to the study of lived experience through conscious interpretation and discovery of meaning (Cohen & Omery, 1994). Both descriptive and hermeneutical phenomenology seeks to understand human life and "being-in-the-world." Heidegger searched further, for the meaning of the human being in the context of the actual world or in experience. This sense of meaning is to be derived from background experience and culture, bringing out valuable aspects of the experience under study. Thus, participant preconceptions and understanding are important in a hermeneutic phenomenology study.

Following Heidegger's methods of hermeneutical phenomenology, the phenomenologist Max van Manen continued studying the "lifeworld." He was particularly concerned with whether the art of writing provided enough details for the reader, or enough examples, to illustrate the themes of participants' experiences. He argued that human science research is dependent upon, and practically inseparable from, the textual practice of writing. According to van Manen, "every phenomenological description is in a sense only an example, an icon that points at the 'thing' which we attempt to describe" (van Manen, 1990, p. 122). Van Manen concluded that, through textual reflection, one could understand the practical action and experience under study (Ray, 1994).

Hermeneutic phenomenology was chosen for this research project since its belief system and methods are consistent with the research objective of this study: to analyze how experienced pharmacists in the ambulatory care clinic setting make clinical decisions for drug therapy. Phenomenological methods allow descriptive understanding of the lived experiences of pharmacists in the ambulatory care clinic setting. Hermeneutics allows for interpretation of the textual descriptions of the participants, to discover the meaning of the experience of an experienced pharmacist in this setting. Phenomenology allows the current situation of pharmacists in this environment to be highlighted, but the meaning provided more understanding that will highlight any proposed implications of this research.

Participants and Setting

The participants in this research study were pharmacists engaged in clinical decision-making for patient medication therapy in Minnesota and Iowa. The researcher used a volunteer purposive type of sampling technique. This method of sampling was useful for selecting participants who met the study objectives: to understand and create meaning for the experiences of pharmacist decision-making in ambulatory care clinic settings. The literature suggests that a sample size of six to ten individuals is sufficient for a phenomenological study, since it involves the intense study of the particular (Morse, 1994; Todres & Holloway, 2006).

A letter of invitation (See APPENDIX A) was sent to nine pharmacists from a list of licensed pharmacists obtained from the Minnesota Pharmacist Association (MPhA) Medication Therapy Management Academy. Of the nine pharmacists, six interested pharmacists met the inclusion criteria and were recruited into the study. Additionally, faculty and the Executive Vice President of the MPhA provided two experienced pharmacist contacts for potential participation. One of the pharmacists fit the inclusion criteria and chose to participate in the study. University of Iowa faculty provided names of seven pharmacists for potential inclusion in the study. One of these pharmacists reported interest. Since he fit the inclusion criteria, he was asked to participate in the study. Thus, the total sample size was 2 experienced pharmacists in the pilot study, and 6 in the main study.

Inclusion/Exclusion Criteria and Rationale

Inclusion Criteria.

- Pharmacist with an active state license to practice pharmacy in Iowa (IA) and/or Minnesota (MN)
- Work full-time in the ambulatory care clinic setting

- Practice in an ambulatory care clinic setting for ≥ 5 years
- Have an established interprofessional relationship
- Use clinical decision-making in patient work to identify and prevent drug therapy problems
- Able and willing to reflect on and express personal experience of clinical decision-making
- English speaker and writer

Exclusion Criteria.

- Pharmacist working in a disease-state specific ambulatory care setting
- Work in an ambulatory care community facility

The researcher chose Minnesota and Iowa for the study of experienced pharmacist clinical decision-making since the two states have a prominent and advanced practice in pharmacist delivery of patient care with similar pharmacy practices. Pharmacists worked full-time in the ambulatory care clinic setting for correct contextual clinical decision-making, producing context-specific analysis and results. According to research noted in Chapter 2 of this thesis (Benner, 1996), five years of experience in a particular setting provides experience and expertise in the practice context. Thus, the pharmacists participating in this research study had five or more years of clinical decision-making experience in the ambulatory care clinic setting. Pharmacists with an interprofessional relationship with a prescriber often have established collaborative practice agreements, allowing them to perform clinical decision-making for some chronic disease states requiring continual time commitment and medication adjustment. All participants spoke English, so the researcher and transcriptionists could conduct the research and analysis with clear speech understanding. Additionally, the pharmacists had to read and write the English language to complete the demographic form.

Generalist pharmacists were chosen since the experienced pharmacist needs to care for the whole patient, not one with a particular disease state. Finally, the community pharmacy setting was not chosen since pharmacists in this environment with adequate experience, sufficient consultation space, and available patient information were difficult to find.

Ethical Considerations

Approval for this study was obtained from the University of Minnesota (U of MN) Institutional Review Board (IRB) (See APPENDIX B). Additional human subject research approval was necessary from the Minneapolis and the St. Cloud Veterans Affairs (VA) locations (See APPENDICES C-D). Although the U of MN did not require informed consent from participant pharmacists or patients, the VA settings required this participation consent (See APPENDICES E-F) as well as the authorization for audiotaping (See APPENDICES G-H). The information and informed consent forms noted confidentiality and anonymity for the participants.

To facilitate protection of anonymity and confidentiality for the experienced pharmacist participants, participants selected pseudonyms before beginning the study. No patient, physician, or clinic names were used in this study, but substitute names were used if necessary. Information from the participant observations, interviews, and audiotaped reflective narratives were unchanged except for the removal of participant names, correction of poor grammar, and clarification of medication information (Morse, 1998). Information from the audiotapes were recorded to a password-protected computer upon receipt and then sent to a password-protected medical transcription site in Georgia. Data collected from the VA was personally transcribed as requested by the IRB at that site. The transcripts were uniquely coded for each participant and locked in the researcher's office.

Pilot Study

Pilot study participants.

Table 8. Pilot Study Self-Reported Demographic Information.

Name*	Age	Degree(s)	Pharmacy Education	Additional Education / Training	Yrs. in Amb. Care	Yrs. of Therapy DM**	Ave # pts/day	% job DM**
Julia	38	BS PharmD	PA	Residency, Certification	13	13	6	65
Shannon	33	BS	MN	Certification	6	5	5	60

- * Fictitious name chosen by participants
- ** DM = decision making

A pilot study of two recruited pharmacists working in different ambulatory care clinic settings in the Minneapolis-St. Paul area was conducted December 2006 to March 2007.

Pilot study rationale.

This pilot informed the final research methods used in the main study. Specifically, the pilot study was carried out to:

- Determine the average time of participant interview.
- Test the appropriateness of the semi-structured interview questions.
- Ascertain if the three data collection methods of individual pharmacist participant observation, participant interview, and pharmacist personal audiotaping and narrative reflection were valid for quality data of experienced pharmacist decision-making in the ambulatory care clinic setting.
- Evaluate if experienced pharmacist personal audiotaping would provide the appropriate data for analysis.

- Conclude if the phenomenological hermeneutic approach for analysis would answer the research objective.
- Discover the types of decision-making occurring in the ambulatory care clinic context.

Pilot study observation.

The researcher recorded and observed one patient interaction for each of the two pilot study pharmacist participants. During each observation, the researcher took field notes that provided written data about each interaction. These notes were used to develop the questions used in the researcher interview with each experienced pharmacist.

Average time of participant interview.

Each of the two pilot study interviews with the individual experienced pharmacist participant took about 30 minutes. These interviews demonstrated the necessity of conducting the interview immediately after the observation of the pharmacist-patient interaction and clinical decision-making. This allowed the researcher to ask sufficiently probing questions regarding recent clinical decisions, and it gave the experienced pharmacists a greater understanding of the research objective and aims.

Appropriateness of the semi-structured interview questions.

During the pilot study, the experienced pharmacists were again provided with the objective and aims of the research study. These were originally presented in their invitation e-mail and in the reminder e-mail sent one week before the observation and interview. The pharmacists were also reacquainted with the definitions of clinical decision-making. The participants were questioned regarding their understanding, and were told that the researcher would participate in the interview only as a listener asking probing questions needed to clarify the clinical decision-making.

Using the audio-recorder to document the session, the researcher listened to each pharmacist while adding clarification when needed. The researcher emphasized "how" questions because the pharmacists wanted to tell brief stories similar to the normal medical structure of a SOAP (subjective, objective, assessment, and plan) note. Examples of probing statements and questions used by the researcher in the pilot study included: "Tell me more.," "How did you decide to start them on that drug?," "How did you know when to decrease the person's metformin dose?," and "Tell me about one of those episodes."

Since the interviews progressed well and the participants demonstrated understanding of the meaning of clinical decision-making, the semi-structured questions and probes in the interview method were deemed appropriate. However, remembering correct prior patient lab values and medication dosages was difficult and the pilot pharmacists discussed possible correction for the future. The pilot study helped to determine that a pre-interview reflection upon at least three clinical decision making experiences would help pharmacists prepare for the actual interview session. This prior organization would allow the pharmacist participant to have easier retrieval of discussion points with correct patient information.

After the interviews, the pharmacist participants stated they were comfortable with conducting personal audio-taping and narrative reflection upon their clinical decision-making for the upcoming two weeks.

Pilot study data collection.

The three data collection methods generated adequate data: 107 clinical decisions from the two pilot study experienced pharmacists. Direct observation of pharmacist clinical decision-making generated field notes that helped develop additional probing questions about decision-making in later interviews. The interviews helped guide the experienced

pharmacist participant to always ask how clinical decisions were made. Also, the pilot study interview methodology showed the researcher that good interviews needed to be conducted in a quiet area away from major distractions and noise. The two week audio-tapes guaranteed more episodes of pharmacist decision-making to include in the analysis of experienced pharmacist clinical decision-making. The pharmacist participants seemed to enjoy the reflective exercise of audio-taping because it was easily done at any time throughout the work day. Thus, each data collection method was deemed important and provided quality data that was necessary in complete understanding of experienced pharmacist clinical decision-making in the ambulatory care clinic setting.

Pilot study suitable data for analysis.

When each pharmacist participant returned the two weeks of audiotaped clinical decisions, the researcher transcribed the data from the audiotapes into written text. For the main study, external medical transcriptionists were used to allow quicker transfer of the data into text to facilitate data analysis.

The pilot study pharmacists reviewed the transcription data for accuracy before any preliminary analysis was conducted. The data were then read entirely to inform the researcher of pharmacist clinical decision-making. The researcher managed the grammatical errors of word repetition and stutters before reading the whole data again. Each example of pharmacist decision-making was highlighted. Gathering the highlighted clinical decision sections in another reading demonstrated that pharmacists were using two different types of information for clinical decision-making: static information of known facts and additional information provided from each patient experience. These data information types were labeled with two main themes: “Objective” and “Context related.”

Pharmacist use of these two types of information was contemplated and presented in Table 9. The specific kinds of "Objective" and "Context-related" information were further highlighted and each specific area was determined to be a sub-theme of the two main themes. Drug and disease information, evidence-based guidelines, alternatives to drug therapy, cost, and teaching involved in health education were "objective" information types guiding clinical decisions. Patient-specific information such as motivational factors and living conditions were examples of "context-related" information used in decision-making. Finally, the specific percentages of use in clinical decision-making by the two pharmacists are included in the table 8 below.

The two main themes, Objective information and Context-related information, were only a part of the clinical decision-making process. The pharmacists used the information together and modified both as necessary in each unique patient interaction. This modification step was necessary for complete understanding between the pharmacist and patient. With this understanding, a therapeutic clinical decision was made, and follow-up decisions were considered before the pharmacist-patient interaction was complete.

The specific approach for phenomenological hermeneutic analysis was refined in the pilot study and will be discussed in the main study section.

Table 9. Summary of Pilot Participant Themes and Sub-Themes of 107 Decisions in Ambulatory Care Clinic Setting.

THEME	Objective (82.2%)	Context-Related (17.8%)
SUB-THEME 1	Drug/Disease Info (68.2%)	Patient Specific (73.7%)
SUB-THEME 2	Evidence-Based (12.5%)	
SUB-THEME 3	Alternative to Drug Therapy (8.0%)	

SUB-THEME 4	Cost (5.7%)	
SUB-THEME 5	Health Education (5.7%)	

Pilot study demonstrated methodology.

The data demonstrated that experienced pharmacists are involved in daily clinical decision-making. The pharmacist participants made many clinical decisions without having to visibly "think" or provide reasoning and understanding to others. The pharmacists may never have evaluated their clinical decision-making processes. Textual data from the experienced pharmacists provided the researcher with many examples of clinical decision-making, but the actual data needed to be carefully contemplated using the hermeneutical approach before determining "how" experienced pharmacists make clinical decisions in the ambulatory care clinic setting.

Pilot study types of clinical decision-making.

Analysis of pharmacist clinical decision-making in the pilot study provided a glimpse at experienced pharmacist activities in the ambulatory care clinic setting. As noticed in this Chapter 2, prior research in other health professions established various models regarding clinical decision-making. The analysis in this pilot study demonstrated that the pharmacists' decision-making did not clearly align with one single method.

Finally, in addition to planned reasons for conducting the pilot study, it was discovered that experienced pharmacists equate "years working in ambulatory care" with the "number of years making clinical decisions for drug therapy". Thus, the former section was removed from the main study demographic questionnaire.

Main Study

Preparation for data collection.

One week prior to the participant observations and interview, the researcher communicated with each pharmacist participant via email in preparation for the observations and interview. In that communication, the researcher asked the participant to think about clinical decision-making in his or her work setting, to reflect on at least three personal experiences, and to organize their thoughts in a narrative manner from beginning to end. Research has demonstrated that this guidance not only allows the participants to prepare for the interview and to organize their thoughts, but also engenders a greater breadth of information (Peden-McAlpine, 2000). Two definitions of clinical decision-making were provided, for the participants' understanding: "what is the best next thing for *this* patient at *this* time?" and "a problem-solving process in which the solution is in the form of a decision, typically leading to an action" (Weiner, 2004, p. 81; Kushniruk, 2001, p. 367). The participants chose a formal time and place, in a relatively quiet setting, for the observations and interview so they would be comfortable sharing personal experiences. On the chosen day, the researcher and the pharmacist participant gathered before the observation to reiterate the purpose of the study, answer any questions regarding the research study, and to complete the demographic questionnaire and consent forms.

Observation sessions and field notes.

The beginning part of the data collection was the observation and audiotaping by the researcher during patient/pharmacist interactions. The researcher observed between two and eight examples of each main study pharmacist conducting patient clinical decision-making in their specific ambulatory care clinic setting. Each observation lasted between 15 to 60 minutes.

During the observation, the researcher did not participate in the pharmacist-patient interaction, but documented (as field notes) each clinical decision, generating further questions regarding *how* the decisions were made. The field notes were used to supplement and probe for more information during the interview, reminding the pharmacists of actions they had performed during the patient interaction. Also, the notes provided recent examples of clinical decisions needing the *why* and *how* questions answered. Ultimately, the observation field notes and questions reminded the pharmacist participants of the study objectives and clarified what was meant by *how* a decision was made.

In-depth interviews.

The pharmacist interview was conducted after all their patient observations were completed. Each interview was audio-taped and was 30 to 90 minutes in duration. The researcher asked open-ended questions, beginning with the general research question necessary to obtain a rich and deep understanding of the clinical decision-making phenomenon:

- Tell me about some of the more complex decision-making cases you had and how you made those decisions. Describe each of these instances, in detail, from beginning to end.

When the pharmacist discussed a clinical decision, the researcher asked additional questions to guide the interview and to help determine *how* the decision was made. For example, the researcher asked:

- Tell me more.
- How did you know that?
- Why did you decide on that dose level?
- How did you decide on that insulin?
- Why did you decide on that medication?

At the end of the interview, the pharmacist participant was allowed to ask the researcher any questions pertaining to the study since complete participant understanding was necessary.

Pharmacist narrative reflections.

After the interview, each pharmacist participant was given a pre-addressed and stamped envelope containing a personal audio-recorder, batteries, and extra tapes. The pharmacist participant was encouraged to provide a narrative reflection on how s/he made clinical decisions each day, for a period of two weeks (10 business days). The audio recorders provided an avenue for the pharmacists to record current clinical decision-making episodes, record any forgotten information from the interview, and have more privacy and time to reflect on clinical decisions. One week after the observation and interview, the researcher e-mailed each participant pharmacist a follow-up reminder, to answer any questions, and to ensure he was audiotaping his narrative reflections of each clinical decision.

Transcription.

Upon receipt of the envelope containing two weeks of each pharmacist participant's narrative reflections, the researcher listened to the recordings and downloaded the information for transfer to the external medical transcriptionists. After complete transcription of each recording was completed, the researcher compared the textual data with the original recording for accuracy. As noted before, the pilot study and main study audiotapes of the observations, interviews, and two-week reflective sessions were transcribed verbatim by either the researcher or a medical transcription service. Any comprehension difficulties were corrected by the researcher, together with the pharmacist participant, before continuing with the analysis.

At completion of the observations, interview, and the two-week audio taping of narrative reflections, each pharmacist participant was provided with $300 in compensation. Financial support for this work was provided by an educational grant from Novo Nordisk Inc.

Data management and analysis.

The text of the field notes, interviews, and personal narrative reflections were grouped together for each of the six experienced pharmacist participants. The data were grammatically corrected to ensure sentence flow. Once edited, the entire text was read together to get a sense of the clinical decision making process as a whole (van Manen, 1997).

After reading all data for each experienced pharmacist's clinical decision-making, the data were read in a more detailed approach. Specific clinical decisions became the unit of analysis. Detailed line-by-line reading highlighted more of the actual decisions made in the pharmacist-patient interactions. During this analysis, each decision was numbered and separated from the overall text. Once divided, the researcher looked at *how* each decision was made and designed codes for each of the specific decisions.

After analyzing and interpreting the coded material as a whole, it became apparent that the pharmacists relied upon two main types of information in all clinical decision making. On the one hand, the experienced pharmacists were guided by more objective information common to all patients. On the other hand, they listened to each patient discuss his particular context and circumstances, which highlighted each patient as a more unique source of clinical information. Further going deeper and understanding these two information types produced the major themes identified in this study: the Objective information theme and the Context-related information theme.

Looking again at the highlighted and coded clinical decisions, the detailed line-by-line reading demonstrated that at least half of the pharmacist participants in the main study repeated the Objective and Context-related themes, giving necessary data saturation. The specific coded clinical decisions and common ideas were titled according to the information necessary for making a clinical decision. These titled codes become subthemes of the two main themes. For example, under the Objective information theme, subthemes of drug/disease information, alternatives to drug therapy, continued learning, evidence-based, insurance/drug cost, and teaching for health education emerged. Likewise, Context-related subthemes included the specific patient choice of treatment, patient specific experiences and behavior, and patient trends in disease-state and drug therapy.

Sifting through the textual data for evidence of clinical decision-making with saturation and repetition, the researcher had to disregard certain content. Conclusions could not be drawn about *how* each clinical decision was made unless there was saturation. When only minor repetition occurred, the ideas were highlighted but not included in the major findings of themes or subthemes for overall pharmacist decision-making in that setting. Instead, those decisions may have been particular to the individual pharmacist and the ambulatory care clinic setting in which s/he worked.

Isolating the two general types of information (Objective and Context-related) did not sufficiently illustrate the process of clinical decision-making by the experienced pharmacists. At the point where sufficient knowledge and patient-derived information existed, it was apparent that the pharmacists conducted a modification step. The experienced pharmacists continually modified, combined and interpreted objective and context-related information to make each unique patient situation more understandable.

Once both types of information were personalized for each patient in the modification step, the pharmacist had a situational understanding of each particular patient's scenario

and context. The experienced pharmacist's situational understanding then guided the clinical decisions they made for every patient. Of course this situational understanding was different for the same patient coming to the ambulatory care clinic setting at different times. Complete situational understanding was important for clinical decision-making so it became the necessary step after modification.

Since information from the two main theme areas (Objective and Context-related) was necessary for making each clinical decision, an absence in either or both types of information provided inadequate resources necessary for modification and situational understanding. Thus, no clinical decision could be made regarding patient drug therapy. At that point, there was a break in the common decision-making pathway.

The experienced pharmacists in this study all made clinical decisions for disease states included in their collaborative practice agreement(s) with the prescribing health care professional. They repeatedly discussed many of the same disease states (e.g. diabetes, coagulation disorders, and asthma) during the recollection process. Often, the pharmacists made their clinical decisions without having to interact with the prescribing physicians. On some occasions, it was necessary for the pharmacists to communicate with the prescriber because of inadequate information.

Because no existing decision-making model identified closely with the observed process of pharmacist clinical decision-making in the ambulatory care clinic setting, the researcher introduced a new decision-making model, Experienced Decision-Making Model, which is further discussed and illustrated in Chapter IV.

Considerations of Rigor

Assessments of the quality and legitimacy of a research study, with all of its findings and conclusions, are determined by the rigor of the actual study methods producing

meaningful results. Since qualitative studies are different from quantitative research, the assumptions and judgment of rigor must be determined using different language than that used in quantitative research. Beck (1993) determined a checklist for gauging the rigor of qualitative research studies. His checklist is echoed by other literatures (de Witt & Ploeg, 2006; Guba & Lincoln, 2005; Shenton, 2004) and is described below.

Auditability and dependability.

While quantitative researchers discuss reliability, qualitative investigators search for auditability and dependability in a research study. It demonstrates a consistency of results over repeated testing periods. In this research study, the three data collection methods provided method triangulation with similar results and demonstrated like conclusions. Also, experienced pharmacist participant validation of the analysis and findings increased the accuracy of the data. Participant pharmacists verified that the results were correct and in accordance with their actual clinical decision-making in the ambulatory care clinic context. The researcher had little opportunity to change data according to her study purposes, since the tape recordings were transcribed verbatim. The researcher also hopes to provide a detailed report and necessary guidance for repetition of a similar study of experienced pharmacist decision-making. Finally, Dr. Peden-McAlpine in an expert in qualitative phenomenological studies and is part of the dissertation committee. Thus, resolving her changes and gaining her acceptance of this research study allow a more dependable and credible qualitative project.

Credibility and trustworthiness.

Similar to internal validity in quantitative research, credibility and trustworthiness in qualitative research assess how vivid and faithful the description of the phenomenon actually is. In this research study, the three different data collection methods--participant observations, semi-structured interview, and two-week personal audiotaping--provided

multiple sources of data. This formed a sufficient method for comparison (Patton, 1999) and credibility (Beck, 1993), since the data were derived at different times with varied qualitative methods. The participant observations served as a current "snap-shot" verification of the pharmacist's clinical decision-making. As previously mentioned, the observation portion of the interview revealed visible actions that the pharmacist participant made, but did not disclose the "hermeneutical phenomenology," or inner workings of the mind at that moment. As the researcher and the experienced pharmacist participant reviewed the researcher's observation field notes, they were able to visibly note factual actions. Nonetheless, the transcribed information and findings were shared with participants of the study for validation and affirmation of authenticity. Rich excerpts and actual experienced pharmacist participant texts will be shared in this thesis presentation. The observation field notes were extremely useful as they gave the researcher and the pharmacist participant something to peruse, analyze, and discuss at the interview.

Fittingness.

Fittingness in qualitative research is similar to external validity in quantitative studies of generalizability to other populations. However, the purpose of a qualitative inquiry like this is not for generalizability or for transfer to others not included in the research study. It is hoped that other experienced ambulatory care clinic pharmacists will agree with many of the findings of this study. The strong participant selection inclusion and exclusion criteria will also give a good sense of fittingness to other pharmacists in similar ambulatory care clinic settings.

The true value of fittingness will not be seen until these findings are presented to pharmacists not included in this study. However, the experienced pharmacists included in this research study seemed to "fit" because of the repetition in data themes and the results of their clinical decision-making in the ambulatory care clinic setting. Another

test of the fittingness of this study is the degree to which the results compare to other similar studies, especially those of experienced clinical decision-making. The only problem with this approach as it relates to this study is that there are currently no other known clinical decision-making qualitative studies for the pharmacy profession. Essentially, the fittingness of this research project will be measured by its usefulness to current and future pharmacists as they consider decision-making techniques in the ambulatory care clinic setting.

Preconceptions and bracketing.

According to Heidegger, preconceptions are important in research understanding and meaning, since each person has past experiences making up his horizon and way of "being," from which he is unable to depart (Ray, 1994). Van Manen agreed, stating that since these understandings and presuppositions may persistently creep back into our study, it is better to make them explicit up front (van Manen, 1997). As Gadamer determined, the horizon or background of the researcher and the studied phenomenon are continually combined together in a sort of dialogue (Dowling, 2007).

Although correct timing of noting presuppositions and bracketing potential bias is debated (Tufford & Newman, 2010), from the conception of this study and throughout the research endeavor, the researcher continually managed potential research bias in the experienced pharmacist participant responses and in their narrative reflections. The researcher consistently carried the disposition of an open-minded inquirer. With the exact transcription and the clear outline of study findings, bias in results was diminished. The researcher is a community pharmacist who graduated from the University of Minnesota College of Pharmacy with an emphasis on Pharmaceutical Care. This is one reason the researcher needed to be wary of bias. The researcher also has prior student or professional relationships with some of the participants in this study. This made it even more crucial that she provided an atmosphere of an open-minded and impartial inquirer.

A researcher must face many nuances and choices about how to approach a unique research study. This study is informed by deep science behind how the human mind works, and also by the various philosophies about how to capture, revisit, and analyze how different people in different settings will use their minds. Chapter 3 has outlined how this particular study should be approached (a qualitative method), and why. Also, this chapter has highlighted some of the findings of this particular research endeavor which will be further described and illustrated in Chapter 4. Results of this study could have innovative implications for the pharmacy profession, and could improve the experience of pharmacist clinical decision-making for those in the ambulatory care clinic setting. This qualitative research was a personal learning experience, bridging gaps in theoretical or philosophical foundations that may not be based on real-world applications.

CHAPTER 4: RESULTS

The findings of this study illustrate how experienced pharmacists in the outpatient ambulatory care clinic setting make clinical decisions for drug therapy. The results are presented in two sections. The first section of this chapter reports the results of the main study, and begins with descriptive information about the participants.

The rest of the first section describes the results of the hermeneutical analysis of the textual data. The analysis provided the highlighted main themes of knowledge (Objective and Context-Related), modification, and situational understanding needed to make a final, patient-unique clinical decision for drug therapy in the ambulatory care clinic setting. As discussed in Chapter 3, the coded, specific reasons for clinical decisions made by pharmacist participants became the sub-themes if saturation by at least three of the six participants was evident. These sub-themes were supported by providing direct quotations from participant personal reflective narratives (edited for grammar).

The chosen narratives illustrate the context related to the themes and sub-themes and describe the scenario's background.

Finally, the themes were reinterpreted for final construction of a new decision-making model for experienced pharmacists since known models did not include the context of their clinical decision-making. This new model is presented later in this chapter to illustrate experienced decision-making discovered in this research study.

The last section lists the specific enabling factors and barriers to the participants' clinical decision-making in the pilot and main studies. These factors will assist in the discussion and conclusion by addressing future changes to the ambulatory care clinic setting, which may allow improved pharmacist clinical decision-making.

SECTION 1: Main Study Findings

Demographic information of experienced pharmacists.

Four male and two female experienced pharmacists participated in the main part of the research study. Their ages ranged from 30 to 42 years old. One pharmacist holds a BS degree alone, four have the entry-level PharmD degree, and one holds both a BS degree and a secondary PharmD degree received at the University of Minnesota. All participants have completed a residency and/or a certification of additional professional learning in health care. Four pharmacists reported making clinical decisions for seven years, with the two others having either five or twelve years of experience. Pharmacists saw an average of five to thirteen patients every day, spending 50-90% of their time making drug therapy decisions. The pharmacist seeing the highest average number of patients in a day (13) spent the most time in his workday making clinical decisions and thus spent much "outside" time reading and updating his clinical understanding. Two participants practice in greater or rural Minnesota, three in the Minneapolis/St. Paul area, and one in Iowa.

Table 10. Main Study Self-Reported Demographic Information.

Name*	Age	Degree	Pharmacy Education	Additional Education / Training	Yrs. of Therapy DM**	Ave # pts/day	% job Making Decisions
Wilbert	37	PharmD	MN	Residency Certification	7	8	70
Lilly	31	PharmD	MN	Certification	7	5	50
Dr. Brown	42	BS PharmD	IA/MN	Certification	12	6	60
Sophia	30	PharmD	MN	Residency	5	8	70
Butch	35	PharmD	MN	Residency Certification	7	13	90
Bobby	40	BS	MN	Certification	7	5	75

* Fictitious names used to maintain anonymity (suggested by participants)
** DM = decision-making

The six main study participant pharmacists reported 333 clinical decisions during the study period. As the unit of analysis, the pharmacists' decisions were grouped into two different knowledge themes ("Objective" and "Context-related"), which were then divided into sub-themes for emphasis.

Each pharmacist made different numbers of actual drug therapy decisions. It is worth noting that some of the drug therapy decisions were not for medicines, but were still considered therapy decisions. The results in this study demonstrate that even pharmacists do not always choose drug therapy for every medical issue when patients or objective knowledge, including laboratory values and guidelines, prefer a non-drug therapy.

Table 11. Summary of 333 Pharmacist Participant Clinical Decisions in Study.

Participant	Number of Drug Therapy Decisions
1. Wilbert	27 (8.1%)
2. Lilly	29 (8.7%)
3. Dr. Brown	59 (17.7%)
4. Sophia	31 (9.3%)
5. Butch	87 (26.1%)
6. Bobby	100 (30.0%)

Theme one: objective knowledge.

Pharmacists' formal education added to their frequent recall and prior knowledge of text-book or objective knowledge of disease states, drugs, guidelines, protocols, laboratory values, health education, medication and insurance costs, and over-the-counter therapies and techniques. Thus, the pharmacists made clinical decisions using various types of this static knowledge. Pharmacist participants rarely needed to search for external direction in making decisions because of their many years of practice working with patients having common disease states and familiar laboratory values. The majority of this objective knowledge remains unchanged unless there is a new scientific finding or an update in evidence. Knowledge of this factual information provides a solid base for clinical decision-making.

Sub-theme one: drug/disease information.

Much of an experienced pharmacist's knowledge of drug and disease data is gained in primary or higher education curriculum, is specific to a medication or disease state, and is exact or theoretical in response to common situations and diseases. These data are necessary for learning a particular "trade" and are helpful in expert decision-making. In addition, some of the information is collected from colleague knowledge, patient use, or personal experience. Such factual information is necessary for correct clinical decisions,

but these types of data are often insufficient for advanced analysis and experienced pharmacist clinical decision-making.

One study pharmacist was seeing a 67 year old male for an International Normalized Ratio (INR) follow-up for his warfarin- (Coumadin) managed atrial fibrillation, Factor-5 Leiden Disorder, and past deep vein thromboses (DVT). His INR goal range was 2-3. A little over one month earlier, he had quit smoking. After two high INR levels of 5.2 and 3.7 with warfarin dose reductions, his current INR was 3.7. The pharmacist had to consider a new clinical decision.

> He was ruled out for all the typical questions. He's on a dose of 45 mg weekly. I made the decision that his INR is high based on his smoking cessation. What that does is it affects his warfarin metabolism and also decreases clotting factor production. So, you have two reasons why an INR might increase. So, I made the decision to reduce his warfarin dose again by 10%, by about 5 mg a week. I made that decision based on my understanding of warfarin kinetics and how tobacco and smoking affect INRs.

Sub-theme two: alternative to drug therapy.

Pharmacists are generally well known for their drug therapy knowledge regarding prescription medicines. The alternative to drug therapy sub-theme demonstrates that pharmacists are also aware of non–prescription medication solutions for health care management. The majority of these decisions display the pharmacists' desire to treat the disease or condition with no medication, rather with laboratory values and numbers, adherence tools, diet, exercise, and over-the-counter alternatives.

One experienced pharmacist participant was seeing a 51-year-old female with type 2 diabetes, high cholesterol, high blood pressure, and depression. The pharmacist had a continual relationship with the patient since she was originally referred for care almost

one year prior to this visit. The patient's depression had worsened after her primary physician decreased her Cymbalta, an anti-depressant, because of her insomnia complaint. With that change, she had stopped caring about herself, lost motivation, and began to eat all she wanted. The pharmacist recently increased her Cymbalta dose to the original dose, since the adjustment had done nothing for her insomnia. At the current visit with the pharmacist, she was 8.8 pounds heavier than six weeks earlier, had a high blood pressure value, but had no problems with cholesterol and diabetes.

> We had to get into all of the depression which was fueling the weight gain. She needed to get back to doing something that I'm an advocate of, weighing yourself every day for negative or positive reinforcement. It depends how you look at it. She's taking her medicine, but I remembered she is a salt craver, salting foods like crazy when her depression was fueling. So, I printed her off something about working with Mrs. Dash's spices. She'd have to knock out all the table salt, rather than add another drug treatment. Sometimes you have to look at what are the non-drug things we can do. When you go online, you will see all these old multiple product arrangements that say, no sodium. You're using no salt and replacing it with a lot of potassium and that gets you up another electrolyte. Now that her weight has gone up almost nine pounds, she's getting closer to losing sugar control at some point. Then she knows I'm going to have to put her back on another one or two meds that she used to be on. She is to keep a food log for two weeks and to check her blood sugar. It's always an evolving thing with the relationship. But, I thought, let's have her buckle down for two weeks.

Sub-theme three: continued learning.

The next sub-theme guiding experienced pharmacist decision-making is continued learning, which can be acquired during a residency or fellowship, from reviewing the literature, verbal presentations, or research providing relevant knowledge of medicines. Similar to other health professionals, pharmacists must continually learn health related topics after primary pharmacy degree education in order to stay abreast of current

knowledge. Again, in this study, this information was known and not newly searched while making current patient drug therapy decisions.

The pharmacists in this study highlighted the need for additional learning to support clinical decision-making in their practice. Having collaborative practice agreements in certain disease states requires the pharmacist to continually learn the most recent medications as well as unique twists on understanding drug therapy and physiology of the disease state. Most experienced pharmacists routinely go beyond the regular 30 hours every two years of required continuing education credits in order to learn the latest health information.

The following example demonstrates how experienced pharmacists apply knowledge from continuing education in making drug therapy clinical decisions.

A female patient suffering from type 2 diabetes recently injured her back and had a bulging disk in the L4, L5 region. This caused much pain and restricted her normal activity level. She smokes half to three-quarters of a cigarette pack daily. This patient has a great, trusting relationship with the experienced pharmacist participant, and listens to most of his recommendations.

> I previously had a doctor from the pain clinic come and talk to my group of practitioners. I asked, "what do you do with chronic pain that we could learn here at primary care?" He immediately said, "all the pain patients that are smokers, you have to tell them it decreases the healing time of the disks in the back by 80%." I filed that one away.
>
> So her smoking has increased. I then told her, "your healing of your back could take 80% longer. You don't really know what kind of timeframe that is to heal." She seemed to buy into that. We offered her a couple of more boxes of Commit lozenges and she said this was it for her today.

> She wasn't going to buy a carton of cigarettes. She was going to stop smoking.

Sub-theme four: evidence-based.

In each health care setting or business context, there are rules to follow in order to further the mission of the business. Ambulatory care clinic settings follow clinic-specific protocols, national guidelines, and evidence-based practice in the health field. Many pharmacists are aware of current evidence-based guidelines since they are related to common diseases in the pharmacists' practices, and because they are included in collaborative practice agreements requiring pharmacist competence with the most recent information. In addition, protocols, guidelines, and evidence-based material for disease states outside of the collaborative practice agreements are useful when discussing medications with prescribers when a clinical decision cannot be made because of inadequate information or knowledge.

One study pharmacist was discussing therapy options for a patient possibly having surgery after the weekend. The patient was currently on Coumadin and the pharmacist had to determine appropriate medication therapy for the patient's upcoming surgery.

> I'll be seeing him Friday for an INR because he's on Coumadin. He will need to be off Coumadin, usually for about 3 days before the procedure. He has atrial fibrillation, and per guidelines we do not need to bridge with medication such as Lovenox. So, my decision was to stop his Coumadin for 3 days prior to the surgery, and then restart the Coumadin afterwards.

Sub-theme five: cost.

Pharmacists need to consider patients' ability to pay for medicine before actually making drug therapy decisions. Patient inability to pay for the medication might mean that he would not follow through on the treatment plan. Pharmacists in the ambulatory care

clinic setting are familiar with issues in the outpatient clinics such as insurance offerings and drug therapy costs. With this understanding, the pharmacist can make appropriate clinical decisions using the least expensive effective drug therapy or lab testing for the patient.

One pharmacist participant was given a referral for a 43-year-old male patient with type 2 diabetes, high cholesterol, high blood pressure, and bipolar disorder. He had been laid off work for months and had no income other than unemployment. The patient had significant cost issues. The patient said his clinic visits generally last about five minutes, and end with the doctor providing him a handful of sample medications such as Coreg CR, Avandia, Januvia, Lantus, and Humalog. The doctor told him to take the meds and to see him the following month. The patient's cholesterol level was too high to check the glycated hemoglobin (HbA1c) and the pharmacist believed the patient had not tested his blood sugar in a while. The patient had an opened bottle of Humalog for more than 28 days and was using the insulin only when his sugars were obviously high. For his blood pressure and past history of a cardiac bypass, he was taking lisinopril, which was stopped when he lost his job and had insurance issues. The patient did admit to poor compliance with medications in the past, but was working on his diet instead, even if he regularly has a sweet tooth. He had not seen the psychiatrist in over one year or taken his Abilify because of cost issues. His brother has complications of Type 1 diabetes and is having a few toes amputated. The patient feels desperate and needs the pharmacist's clinical decision making for drug therapy.

> My clinical decision-making today was kind of radical. I generally don't make too many changes at once, but I wasn't sure if I'm going to see the patient back again. I felt I had to get rid of his expensive samples, drugs that he's not going to be able to afford. The Avandia, Januvia, and Coreg CR are fine medications for him, except that's probably $500 a month he doesn't have. I did talk about him either having to go to Wal-Mart or Target. I happened to have a Wal-Mart list in front of me for the $4 prescription drugs. Their new one they've added is generic carvedilol,

> which he can take the 12.5mg twice a day. Also, for his blood pressure and kidney protection, he needs to be on an ACE inhibitor. I picked lisinopril since it's generic, cheaper, and I have lots of experience with it. As far as the diabetes, I want him on a 50/50 ratio, just based on experience of insulin dosing. I'm cutting his evening Lantus out entirely and just having him do the 50 units every morning. I'm going to have him inject 10 units of novolog 3 times a day, before each meal. He was given samples, a good month's supply of both insulins today. I also printed him off a patients assistance program form from Sanofi-Aventis so he could get Lantus and Apidra (to replace to novolog). I'm going to keep him on Vytorin 10/40 and he does have some generic gemfibrozil tablets for about a month. I made him a lab appointment today for fasting labs, so we can get a picture if we can even measure his cholesterol and A1C. We're not going to do anything different right now with respect to his lipids, although I did mention to him we do have a patient assistance program for the Vytorin if we feel that's a better way for him to go. I did mention to him that if that wasn't an option, we could go with a generic statin off the $4 list at Wal-Mart. He was on 2500mg of metformin in the past, and for some reason he discontinued that too. When I looked at the $4 prescription drugs today, I can get him metformin 850mg tablets. So, we are going to have him start that medication since he was agreeable to that today.
>
> I'm probably going to try and talk him into coming for a short 15-minute follow-up visit with his sugar monitor after we have lipid values, so I can verify how he's doing. It was a great 1-hour visit today, and it was real interesting to see a patient such as this when he feels that he's lost. There's nowhere to go. I was willing and able to take the time with him.

The pharmacist also discussed diet, blood sugar monitoring, and bipolar disease medications with the patient, but no further cost decisions were made.

Sub-theme six: health education.

Finally, the experienced pharmacists used health education as a professional method of teaching patients about their disease, medical device, or medication. The pharmacists constantly portrayed information to each patient using certain teaching methods that were learned through experience.

One pharmacist participant saw a 52-year-old female patient for the first time, one week after she was seen by other health professionals in the clinic. At that time, she had leg pain treated by an antibiotic for presumed cellulitis. The pain continued after treatment, so she was referred to the pharmacist from her primary doctor after a doppler ultrasound revealed a deep vein thrombosis (DVT) in her right leg. The pharmacist was asked to help initiate Lovenox and warfarin, rather than sending her to the emergency room.

> So, I spent over an hour with the patient going through Lovenox teaching and warfarin management. Since the physician did not know the true diagnosis when she met with the patient in the morning, there was a number of questions the patient had for me regarding treatment of a DVT and how to manage it at home. After education, I helped determine the starting dose of Lovenox and the warfarin.

Theme two: context-related knowledge.

The second theme highlights how pharmacists use context-related knowledge specific to individual patient situations – including the patient's past use of certain medications, individual motivation, and other health trends – in making decisions. The specific unique patient information took precedence in making the clinical decision. While some of this context-related knowledge is gleaned from prior experience with similar patients, it cannot be duplicated since each patient has unique contextual experiences, home environments, and genetic composition.

Sub-theme one: patient choice.

Since patients make the final decision of how to perform their own health care, some pharmacist decisions are part of a shared decision-making process. Patients have a personal choice when given different drug options from the pharmacist. Often, the patient makes a choice specifically fitted to her own life circumstance, knowing her own individual context and reasoning for the decision.

An example of this sub-theme was seen when an experienced pharmacist saw a 72-year old female who had a recent cholesterol panel causing the physician to refer her to the pharmacist for further medication analysis. She had been on multiple medications in the past, like Pravachol, Zocor, Zetia, and gemfibrozil which all caused intolerance and different patient complaints, such as itching, stomach upset, or myopathy.

> Currently, she's taking Questran, one packet or one scoop a day. And as far as I recall, she is my only patient here in the clinic that is on Questran. She mainly takes it for her Crohn's Disease, where she has diarrhea, and it has done a good job of controlling her symptoms. Because of her drug intolerance (to many medications), once again, I had to think through do we consider adding a new medication, one that she's never been on before, or do we try to maximize her current therapy. Because Questran can be dosed up to 24 grams a day, I did talk to her about the option of bumping up the dose and going with 4 grams twice a day. I talked her through the other options. Decided on Questran because she had tolerated this medication and was intolerant to many other medications. She helped in the decision process too. I gave her the option of starting different medicine versus increasing Questran. She requested the Questran approach.

Sub-theme two: patient specific.

In addition to individual lab values, patient specific scenarios and different disease states influence many clinical decisions. Individual motivation, compliance, and adherence guided many specific pharmacist decisions as well. These patient behaviors required personal attention apart from a common, standard plan.

A pharmacist participant was seeing a 65-year-old male patient for a follow-up for type 2 diabetes currently treated only by diet and exercise. The patient's glycated hemoglobin (HbA1c) level had just increased and his physician wanted the patient to bring in his blood sugars and discuss treatment in term of starting a new medication. The patient also had other multiple health problems related to his metabolic syndrome: significant hypertension requiring four different mediations and a poor cholesterol requiring a statin medication.

> I met with him and talked through different medication choices. Some of the issues that required me to think through which medication to choose were complicated partly because of three main things. The first is that his creatinine was slightly elevated last week at 1.4, which was up from a previous check last year of 1.0. The second thing would be a previous history of noncompliance. He is a minimizer in that he doesn't like taking medications and tries his best to hold off in starting new medications. I had that previous history having worked with him before regarding his metabolic syndrome issues. The third thing would be that he works by himself. He's self-employed, and even though he has Medicare insurance that helps pay for his medications, I know that cost issues in the past have been a concern. So, I weighed all of those different things to make a recommendation to start a sulfonylurea, even though it's usually not my first-line drug for a metabolic syndrome person. It seems like the best fit for him because of the low cost, low side effect profile, and with his renal insufficiency, I thought it would be the safest drug for him. He was not totally excited about starting a new drug, but after talking through what his sugars were and our goals, he was agreeable to start the medication.

Sub-theme three: patient trend.

In the ambulatory care clinic setting, pharmacists often have access to patient information or computerized histories and notes covering a long period of time. It is common that the same individual patient is cared for repetitively in the specific outpatient setting. Thus, pharmacists are able to use each patient's history to better understand that unique patient.

This patient-specific information helps the pharmacists to make customized decisions pertaining to medications and disease states, in order to develop a trend for each person that may be divergent from the common decision.

For example, one drug may be a better choice, but has been tried by that particular patient and failed. The pharmacist can proceed with the next potential medication since they can see the patient's history. Some of the pharmacists used an individual patient laboratory value trend sheet to illustrate disease and medication progress over time, which helped determine whether a decision was necessary and by what quantity the medication needed to change.

One pharmacist participant worked with a 61-year-old man with atrial fibrillation who was taking 7.5mg warfarin every day over one and one-half years for a goal International Normalized Ratio (INR) of 2-3. He has been stable and within range of the goal numbers for most of that time. However, the INR for the last two months had been 1.8, 1.9 and 1.8 on the day of his appointment.

> I made the decision to increase the dose. He was against that decision, but again that's probably based on past experience of two low INRs. We should be targeting for 2.5. Protocol would say to increase the dose by 5-20%. I increased it by 4% based on the fact that he'd been very stable on his previous dose for a while. I think a lot of practitioners might do a one-time change. But the evidence does show that the more time you spend below the INR target, the higher the risk for stroke. I wanted to increase that dose altogether. It wasn't increased last month and I had done the same thing last month and not increased it, but two months in a row is a trend. The things influencing my decision here are the CHEST guidelines setting an INR target of 2.5 and the fact that his number was remaining low despite a one-time dose adjustment last month. So, this is a trend that we need to increase the maintenance dose.

The above described qualitative explanations allow greater understanding of the main information themes and subthemes. In addition, Table 12 shows the prevalence of the Objective and Context-Related knowledge themes and their particular sub-themes observed within the clinical decisions made by participant pharmacists in this study.

Table 12. Summary of Main Study Experienced Pharmacist Themes and Sub-themes of 333 Decisions in the Ambulatory Care Clinic Setting.

THEME	Objective (80.5%)	Context-Related (19.5%)
SUB-THEME 1	Drug/Disease Info (34.7%)	Patient Choice (40.0%)
SUB-THEME 2	Alternative to Drug Therapy (21.3%)	Patient Specific (30.8%)
SUB-THEME 3	Continued Learning (16.8%)	Patient Trend (29.2%)
SUB-THEME 4	Evidence-Based (14.2%)	
SUB-THEME 5	Cost (7.8%)	
SUB-THEME 6	Health Education (5.2%)	

Theme three: modification.

Even if the objective and context-related knowledge are adequate for correct clinical decisions, these types of data are insufficient for advanced analysis and experienced pharmacist clinical decision-making. The pharmacist must combine and modify the two specific types of knowledge necessary for each clinical decision. By considering objective and context-related patient information, the pharmacist demonstrates his/her commitment to patient-centered care. This step is necessary so the final clinical decision is suitable for the specific individual patient. Since objective knowledge rarely changes because it is a generally accepted "fact," this modification step gives the pharmacist the opportunity to fit the patient-specific, context-related knowledge into the "puzzle." The

modification step is dynamic. In the ambulatory care clinic setting, the pharmacist constantly alters his/her thinking and might adjust decisions based on different objective knowledge or a patient's different contextual occurrences. In real life, regular situational changes are likewise affected by the continual advancement of time and experience.

In this study, the modification process was an active step. It was made by the experienced pharmacists based on the integration of identified objective knowledge, which served as the foundation for the pharmacists' decisions, and the contextual knowledge, which was altered according to each individual patient situation. Many times, the patient's diagnosis was previously known, but the experienced pharmacist's additional health care knowledge brought new perspectives to each individual patient's circumstances.

In this study, the pharmacists combined objective and context-related knowledge in all their clinical decisions. The objective knowledge serves as the foundation for all clinical decisions, as the pharmacists have a broad healthcare knowledge background. Thus, the pharmacist must have the particular objective knowledge of a medication and disease state before trying to modify and combine context-related and patient-specific information.

Theme four: situational understanding.

Once the pharmacist has modified the objective and standard knowledge for the exact patient context, s/he must have constant comprehension of the information required in order to meet a desired medical goal. The pharmacists in this study constantly used the objective knowledge of a diagnosed disease state as the reference point for the context-related, patient-specific information. This dual knowledge guaranteed initial situational understanding, until additional information required modification of knowledge specific

to the patient scenario. This new situational understanding was developed if a further decision was necessary.

The ambulatory care clinic setting allows continual pharmacist involvement in patient care and clinical decisions because of the numerous outpatient visits throughout time. Having the situational understanding of each patient's unique circumstances, the pharmacist is able to make the drug therapy clinical decision. This decision is based on the objective and context-related knowledge that the pharmacist has modified for the unique patient condition, leading to situated understanding of the complete scenario.

Theme five: inadequate.

Included in this new model are instances where a decision cannot be reached, due to a missing piece in the objective or context-based knowledge. Thus, the information and knowledge are insufficient for a final therapy decision. Modification and situational understanding are not permitted, since the pharmacist does not have a piece of the puzzle.

It is possible that the pharmacist does not have the factual knowledge since he does not have the full picture of the drug. For example, the medication may be newly approved or uncommon, or the pharmacist may not be confident enough in the information necessary to make the decision. This lack of factual knowledge may be the fault of the patient as well, since she may not provide necessary objective information to the pharmacist regarding past medical experience or medication name and dose from another medical facility. The pharmacist also may not have authority to make the clinical decision because the disease state or medication therapy is not included in his collaborative practice agreement. However, even if the pharmacist has the authority to make the final decision, he may recognize that there is another health professional (such as a specialist) with more advanced knowledge of the subject matter, so the pharmacist gives a referral to that health care professional.

This inadequacy may only be present for a limited time period. Once the pharmacist or patient gains or provides the adequate patient information or objective knowledge from other health professionals, a clinical decision may be made.

The following example demonstrates a lack of complete knowledge, resulting in necessary assistance from another health professional who has the additional heart disease expertise. The inadequacy was not due to a problem with the collaborative practice agreement, but the pharmacist's awareness of his own limits in objective knowledge needed to make the proper decision.

One of the study pharmacists had a follow-up visit with an 89-year-old man having dyslipidemia and hypothyroidism. With a slight decrease in his thyroid-stimulating hormone (TSH) lab value, the pharmacist had to make a decision regarding his levothyroxine dose.

> About seven weeks ago, he was on a small dose of levothyroxine 0.05 mg daily. At that time, his TSH was 9.56 and our normal range goes from 0.4 up to 5.5. Today, he showed very little improvement, coming down to 8.7. He has no signs or symptoms of hyper- or hypo- thyroidism and the only thing on his medical profile that may suggest ongoing hypothyroidism would be his dyslipidemia. He has always had high triglycerides and low HDL which can be characteristic of hypothyroidism. He is also on the lipid-lowering medicines gemfibrozil and simvastatin. I had a hard time making a decision on what to do and I did consult a review article from the *American Family Practice Journal* that I remember reading about six months ago. It states that treating subclinical hypothyroidism is of questionable value when the TSH runs between 5 and 10. So I guess the biggest question here is, since the patient thinks he feels fine, is his cholesterol abnormality significant enough for us to continue treating the TSH at this point? It's a very controversial area of practice. Therefore, I'm going to review it with his primary doctor here. The reason for my hesitancy to treat it without discussing it with the doctor is that the patient does have a history of AV heart block, and I

> guess I am unfamiliar with the intricacies of how thyroid function affects heart function, so I am a little concerned about that.

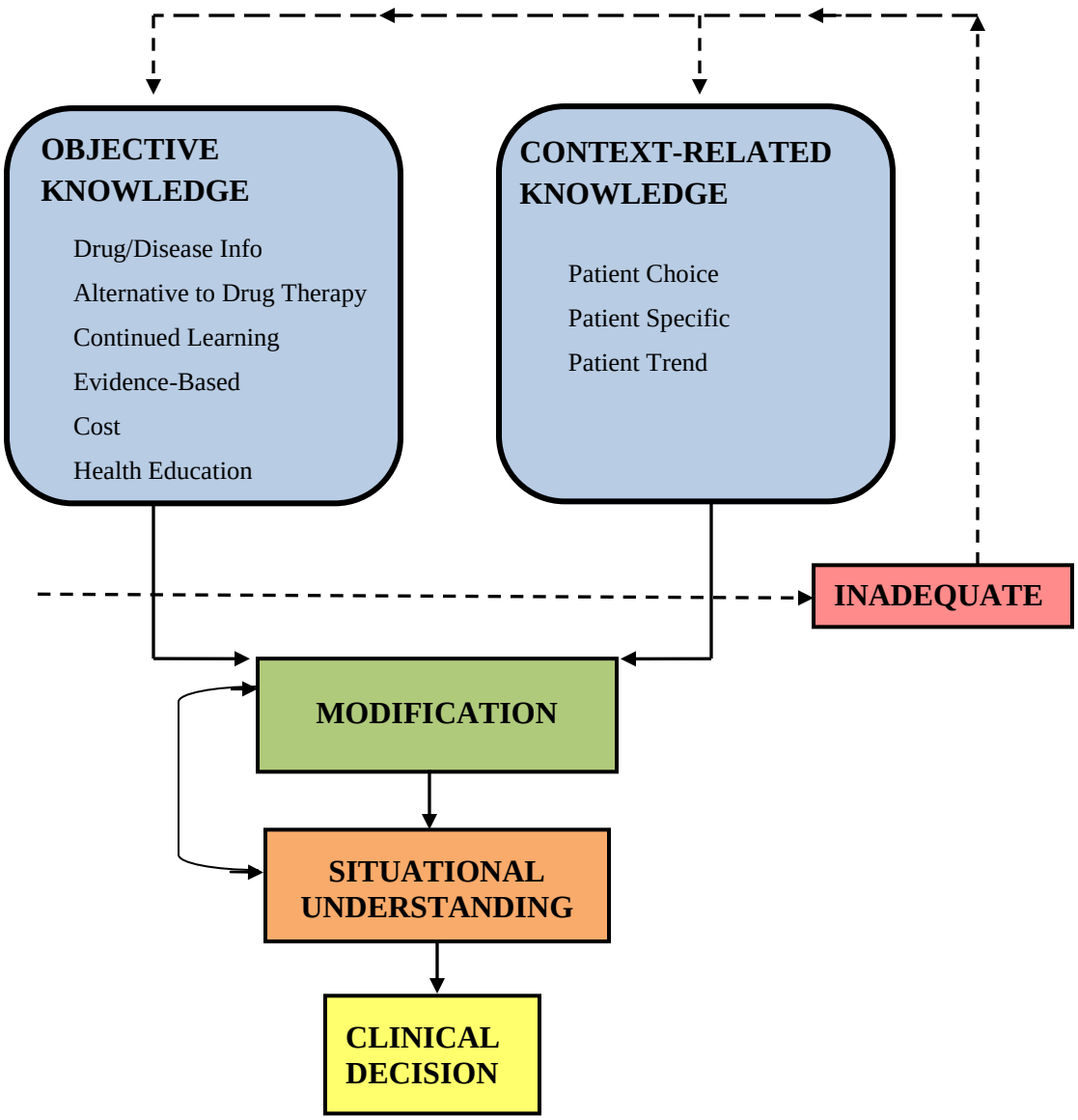
Although the pharmacist may be completely aware of the medications and physiology included for the health decision, he may not have enough context-related knowledge from the actual patient. Usually this information is necessary for documentation and causal reasoning behind a clinical decision.

Another common example of the inadequate information or knowledge needed to make a decision occurs when the decision-making authority falls outside the pharmacist's collaborative practice agreement or scope of professional practice. Sometimes patients may have a comfortable professional relationship with the pharmacist, so they may inquire about objective knowledge not within the scope of the pharmacist's clinical decision-making ability. When this occurs, pharmacists typically transfer the care to another health care professional.

Experienced pharmacist clinical decision-making model.

Since the pharmacists used knowledge of objective and context-related information to guide all clinical decisions, these two main themes are the focus of how experienced pharmacists in the ambulatory care clinic setting make clinical decisions for drug therapy. These two types of knowledge provide the foundation necessary for the modification step, and the manipulation necessary for situational understanding to occur, all leading at last to the clinical decision. Figure 3 illustrates this new model of experienced pharmacist decision-making.

Figure 3. Experienced Pharmacist Clinical Decision-Making Model.



Direct Patient Care as the Essential Theme in Pharmacist Clinical Decision-Making

Pharmacy is becoming a more patient-focused profession, especially in the ambulatory care clinic setting studied here. Without this direct patient interaction, pharmacists would be unable to individualize care in every clinical decision. They would ultimately be

unable to make clinical drug therapy decisions because context-related information would be absent. Including context-related information in every clinical decision demonstrates the unique focus experienced pharmacists in the ambulatory care clinic setting can provide to patients. Additionally, pharmacists respond to personal cues for the individual choice of drug therapy since medications needs to be matched with patient-specific reactions to medical care and situational changes. At times, clinical decisions reflect a patient's circumstance or motivation. For example, if the patient is unmotivated or prefers not to take medications, the pharmacist may decide on a once-daily therapy instead of a three times daily option.

Since pharmacists consider patients as the important piece to the drug therapy decision-making puzzle, over half of the blocking and inhibiting factors to clinical decision-making relate to patient issues. For example, the patient may not be prepared with all the information needed to make a drug therapy decision, might not think they are capable of doing the recommended therapy, do not like the cost of the recommended healthcare decision, or have a false perception of the therapy from other sources (friends, family, media). Some of these patient issues prevent the experienced pharmacist from gathering adequate information, and s/he is unable to make a clinical decision for the patient and his/her drug therapy.

SECTION 2: Enablers and Barriers

In order to identify the relevant enablers and barriers, the researcher (interviewer) asked all study participants the following two questions:

1. "What do you think enables your decision-making or makes it easier?"
2. "What do you think is a barrier to your decision-making or makes it more difficult?"

Tables 13 and 14 provide a list of all the perceived enablers and barriers to drug therapy clinical decision-making for both pilot study and main study pharmacists in the ambulatory care clinic settings.

The two pilot study participants will be marked with an "a" while the main study participants will carry a "b" after their participant identification number. There is some repetition for the main study pharmacists, so discussion of those results will appear in Chapter 5.

Table 13. Summary of Characteristics Perceived to Enable Experienced Pharmacist Decision-Making in the Ambulatory Care Clinic Setting.

PARTICIPANT	ENABLING FACTOR(S)
1a: Julia	Evidence-based resources
2a: Shannon	Collaborative Practice Agreements & Knowledge base of current literature
1b: Wilbert	Common patient situations/meds & Team environment
2b: Lilly	Time, Seeing multiple patients, & Being in clinic with other providers
3b: Dr. Brown	Blessing from doctors
4b: Sophia	Work environment, Time, Resources, & Other health-professionals
5b: Butch	Experience, Reading, Certificates, Confidence, & Communication
6b: Bobby	Experience & Common patient situations/meds

Table 14. Summary of Perceived Barriers to Experienced Pharmacist Decision-Making in the Ambulatory Care Clinic Setting.

PARTICIPANT	BLOCKING FACTOR(S)
1a: Julia	Lack of patient info & Dishonesty
2a: Shannon	Lack of patient confidence & Decision not to change
1b: Wilbert	Unpopular decision
2b: Lilly	Specialties
3b: Dr. Brown	Specific referral
4b: Sophia	Implementation, Dispensing, Time to research, & Lack of knowledge
5b: Butch	Time & Perfectionism
6b: Bobby	Patient perception, Cost, & Time

In the next chapter, discussion of the findings and results will highlight how experienced pharmacists' clinical decision-making in the ambulatory care clinic setting conforms with

the common types of decision-making and new model in the actual practice area. There also will be argument for use of these results in the pharmacy profession and other areas of health care. The study results in this chapter provide implications for further study and research in pharmacist clinical decision-making as the health care system and pharmacy profession continue to change.

CHAPTER 5: DISCUSSION AND CONCLUSIONS

In this chapter, the results of the research study of experienced pharmacist clinical decision-making in the ambulatory care clinic setting are discussed, along with implications for future research, healthcare practice and education.

Discussion of Experienced Pharmacist Clinical Decision-Making

After much textual analysis following the qualitative analysis method of van Manen (1997) and research into the various types of decision-making models, it became apparent that the experienced pharmacists participating in this study did not make all their clinical decisions according to current, well-studied decision-making models. Rather, they frequently utilized both objective and context-related knowledge in making unique clinical decisions for each patient's medical issue. Additionally, pharmacists faced inadequate knowledge and incomplete information resources such as insufficient patient medical information, inadequate laboratory data, and an absence of collaborative practice agreements. These challenges sometimes prevented pharmacists from making clinical decisions and referring the clinical decision to other health professionals. However, after time or discussion with other health professionals, there were scenarios that the experienced pharmacist was then able to receive the necessary knowledge or information necessary for a completed clinical decision.

Through education and continual study (Hanson, Bruskiewitz, & DeMuth, 2007), the experienced pharmacists gained objective knowledge needed to understand the initial patient concerns regarding a certain drug or disease state. Pharmacists know the human physiology of health issues diagnosed by other health professionals and are aware of the medication pharmacology of drugs intended to remedy patient medical problems. Combining these two objective understandings of physiology and pharmacology, pharmacists learn the effects of medications, as determined by patient-specific numerical laboratory results and patient physical consequences. Pharmacists are also aware of many non-drug treatments that are demonstrated as possible remedies for the patient health situation. Along with continual education of physiology and pharmacology, the pharmacists gain knowledge and experience in the current guidelines and evidence-based therapy choices for a given disease state, especially those commonly used under their collaborative practice agreement(s). With their experience in the medication field, pharmacists are aware of common drug therapy costs and insurance payments guiding patient acceptance of a therapy and ability to adhere with clinical recommendations. Finally, since pharmacists are often able to spend extra time with their patients, education and teaching are also necessary skills utilized in the explanation and combination of pharmacist knowledge of each physical condition and drug therapy.

Experienced pharmacists in this study used objective information to make 80.5% of their 333 clinical decisions. Although statistical significance was not the purpose of this research study, this demonstrates that pharmacists have learned a great deal of factual data from various sources, and are able to relay this to the patient in each clinical decision.

The largest amount of objective data used by these pharmacists was drug and disease state information learned in primary pharmacy education or through additional education. Pharmacists have good retention of this useful information, and relied on it in making 34.7% of their clinical decisions in this study. Pharmacists not only provide therapeutic

wisdom with prescription medications, but also have non-pharmacologic therapy knowledge (Lenz & Monaghan, 2011). The experienced pharmacists in this study utilized their knowledge of human physiology combined with non-pharmaceutical alternative therapeutic options and lifestyle modifications in 21.3% of their clinical decisions. Information gathered from continued education seminars and professional journal articles also provided useful objective knowledge for pharmacists in their clinical decision-making. The pharmacists in this study utilized this type of data in 16.8% of their clinical decisions. Continued learning is clearly a useful method of increasing current healthcare knowledge in many disease states after primary pharmacy education. Collaborative practice agreement requirements often demand that pharmacists make clinical decisions according to current disease-state guidelines and protocols that are evidence-based for "correct" outcomes. Oftentimes, experienced pharmacists use data from such guidelines to support each clinical decision. In this study, information from guidelines/protocols guided 14.2% of clinical decision-making. Pharmacists also understand that patient therapy adherence depends on agreement with the medication adjustment and ability to take the therapy as directed, and that patients who do not do so may rely on other methods of health treatment for their medical problems that may cause dangerous health results (Tu & Hargraves, 2004). Some medicines and alternative therapies are very costly and should be avoided if the patient does not have insurance or payment for the therapies. In 7.8% of the decisions using objective data, the pharmacists made clinical decisions based on patient insurance and drug therapy cost, oftentimes knowing the general price. Since the pharmacists use collaborative practice agreements for certain disease states, they commonly utilize the same drug therapies for the disease in question and quickly learn the price of such medications. Finally, the Health Education Subtheme will be discussed later in this chapter.

Although some of the clinical decisions by experienced pharmacists in the collaborative practice environment required laboratory results to advance outcomes and to provide support for the final clinical decision, the pharmacists knew without hesitation which

cues were necessary in making each clinical decision. From experience, they never had to consciously decide which tests or numbers were required. For example, education teaches that the glycated hemoglobin (HbA1c) is needed for diabetes testing and the International Normalized Ratio (INR) is a necessary component for anticoagulant therapy management. Although the experienced pharmacists used these number outputs as cue acquisition and partial evidence for decisions, other facts often influenced the final decision. Often, the cue guided the pharmacist as to what "should" be done, but there were occasions when the unique patient context determined the final opposite clinical decision. Thus, more than the objective knowledge was necessary in the clinical decision, since every patient is unique with different contextual information.

In addition to objective knowledge with static data and numerical values, pharmacists also use context-related, patient-centered knowledge to guide their clinical decision-making. The pharmacist recognizes that additional information is necessary to address unique clinical situations requiring a decision. Since healthcare is no longer guided by the paternalistic model of care where there is no patient interaction and choice in clinical decisions (Mckinstry, 1992), the pharmacist listens to the patient as a direct player in each of the decisions. Patients may also make their own choices given different alternative therapy options provided by the health professional. In addition, many patient–specific values regarding life choices, past experience, motivation, and personal trends of therapy are commonly assessed in making clinical decisions specific for each patient's circumstances and experiences.

Although the context-related knowledge use is much lower (19.5%) than the use of objective knowledge, it demonstrates how pharmacists are influenced by patient input in making clinical decisions. Since the Patient Choice Sub-Theme is slightly used more frequently (40%) in the context-related knowledge, it seems that pharmacists often provide patients with the final say in the clinical decision-making process. The patient makes his/her own choice because of his/her personal context. Pharmacist decisions

within the other two sub-themes, Patient Specific (30.8%) and Patient Trend (29.2%), seem to go "against the rules" because of each patient's unique characteristics guiding the decisions. For example, patient characteristics may lead to taking the drug therapy once daily instead of three times daily, delaying the testing because of patient travel, and not altering the dose because of a patient's promise to do better next week. Each patient has unique circumstances that may complicate the usual experienced pharmacist clinical decision-making process. Additionally, pharmacists working in the outpatient ambulatory care clinic setting have the opportunity to see the same patient multiple times. Therefore, patient trends in healthcare treatment and therapeutic results occur and are documented to assist in future decision-making and to comply with legal requirements. These specific patient reactions assist the experienced pharmacists in clinical decision-making.

After the experienced pharmacist has gathered the necessary objective and context-related knowledge, they modify that information to prepare for the next step in making a clinical decision. This modification step is consistent with the research according to Schön (1987), demonstrating that there is a continual dialogue and reframing of an indeterminate problem to meet the end purpose of the clinical decision. There is constant knowing-in-action as the pharmacist demonstrates actions and makes decisions unconsciously that have, in their experience, succeeded in solving similar problems. When the pharmacist discovers a change or a different piece of information in the decision-making episode, s/he changes from the usual knowing-in-action to reflection-in-action. This reflection-in-action constitutes a change from the normal knowing-in-action, to a constant internal experimentation and reflection activity of past experiences to search for a possible new solution or clinical decision to the current unique patient scenario.

Once the modification step is completed, the pharmacist has a situated understanding of each specific individual patient's circumstances, and how they differ from the pharmacist's previous patient experiences. To this encompassing knowledge, the

experienced pharmacist adds to his/her experiences and organized memory, informing future clinical decisions.

Although experienced pharmacists in this study most often utilized an experience-based type of decision-making method (Experienced Decision-Making Model: see Figure 3) to finalize each individualized clinical decision, there was partial use of other decision-making information tools and models already described in the various literatures discussed in Chapter 2 of this thesis. These established models are the Hypothetico-Deductive Reasoning Model, probability analyses, and the experience-based methods of Intuition and Pattern Recognition.

Experienced Decision-Making Model versus the Hypothetico-Deductive Reasoning Model

Some of the less experienced pharmacists in this study occasionally used the Hypothetico-Deductive Reasoning Model, which is embodied in the pharmacy profession's Pharmaceutical Care Process, to make clinical decisions. This deductive thinking strategy requires pharmacists to use a checklist in making clinical decisions about what should be done. Some pharmacists were required to document their clinical decisions using the Pharmaceutical Care Process computer program, so their thought processes had to fit into the established format. Experienced pharmacists, when making decisions with inadequate factual information or needing to seek knowledge from other health professionals with more expertise in a particular disease state, also demonstrated the linear Hypothetic-Deductive Reasoning strategy. In doing so, the experienced pharmacists in this study echoed what a cognitive literature review noted: that experienced physicians may only use this strategy with difficult cases and that pattern recognition may be more apparent in making common clinical decisions (Elstein & Schwarz, 2002).

While experienced pharmacists making drug therapy decisions may follow the thinking process of the Hypothetico-Deductive Reasoning Model, as embodied in the Pharmaceutical Care Process, few were actually conscious of the model's language and steps when finding solutions to particular drug therapy problems. Only one of the less experienced pharmacists in this study specifically characterized the different categories of the Model as part of her decision-making process. To note, this pharmacist does use the specific computer program for documentation of all clinical decisions.

Being multifaceted in teaching clinical decision making and reasoning strategies opens pharmacists' eyes to other decision-making techniques. Prior research demonstrates that most health professionals use more than one method to make clinical decisions in real health situations, so students should be taught all models of decision-making. Rencic (2011) provided various teaching tips to help medical students better understand various techniques for complete understanding and progression to expertise in clinical reasoning. For instance, when students were empowered to be more flexible in their diagnostic strategy using both analytic (Pharmaceutical Care Process in the pharmacy profession and Bayesian Theory) and non-analytic (Pattern Recognition) approaches, greater diagnostic accuracy was achieved (Ark, Brooks, & Eva, 2007).

Experienced Decision-Making Model versus Bayesian Theory

The experienced pharmacist participants in this study used numerical and evidence-based information in many of their decisions since it was a large part of the necessary objective knowledge of collaborative practice, guided by the cost of medication and managed care formulary guidelines. But, none of the pharmacists made clear statements regarding the use of a cost-effectiveness study to guide any clinical decision. However, since the experienced pharmacists used current research evidence and guidelines in each clinical decision to find the best clinical outcome and decision, it is suggested that they utilized Bayesian Theory when making such clinical decisions. This aligns with the suggestion

that Bayesian Theory is essentially the statistical test for evidence-based medicine (Ashby & Smith, 2000; Elstein & Schwarz, 2002).

Experienced Decision-Making Model versus Pattern Recognition

During this study, participants discussed the decisions most common to their collaborative practice agreement(s) for certain disease states. This familiarity with medicines, evidence found in current research articles, and clinical guidelines enabled many of the experienced pharmacists to make clinical decisions. Study pharmacist Wilbert did discuss how he uses general guidelines and patterns of drug therapy when discussing each disease state with his residents. However, every patient has a unique context demanding varied clinical decision-making. Even when a pattern of disease state or medication was recognized, the experienced pharmacists in this study applied their pharmacist situated understanding to each unique patient's context. Therefore, the pharmacists demonstrated individualized patient care by not exclusively using pattern recognition in their clinical decision-making.

The use of pattern recognition alone is rarely seen, since some sort of patient-unique evidence is usually necessary in the final clinical decision. For example, May and others (2008) looked at expert therapists treating patients with shoulder pain. The expert clinicians used the Hypothetico-Deductive Model in their history-taking, and pattern recognition in their diagnostic reasoning. In addition to simple pattern recognition, the therapists used elements of patient-centered reasoning and the context-dependent nature of patient information. Patient uniqueness was protected, even in situations where broad pattern recognition was utilized.

Experienced Decision-Making Model versus Intuition

Another experience-based demonstration of clinical decision-making was marked by intuition and unconscious actions taken by the study pharmacists. When questioned regarding their clinical decisions, the pharmacists could provide general evidence supporting the decisions they made. This evidence often depended on the perceived patient attitude and the pharmacist's prior objective and context-related knowledge. These assumptions, made because of past history with the specific patient or prior experience with similar patients needing clinical decisions in the ambulatory care clinic setting, ultimately influenced the pharmacist's clinical decisions. Thus, it appears the experienced pharmacists demonstrated cognitive intuition in making each of their clinical decisions -- unconscious decision-making providing conscious reasons after they made the decision. The study by Lyneham and colleagues (2008), discussed below, defines this cognitive intuition that may illustrate the intuitive type demonstrated by the current research study pharmacists.

As described in Chapter 2, Benner (1984) researched and applied the Dreyfus' (1986) Model of Skill Acquisition to the nursing profession. Benner determined that after five years experience, a nurse was recognized as an "expert" and was able to use intuition in his/her decision-making. Lyneham, Parkinson, and Denholm (2008) later conducted a hermeneutic phenomenological qualitative study to help understand what makes a nurse an "expert." Fourteen emergency care nurses with 4½ to 30 years of experience demonstrated that intuition is a developmental aspect of clinical practice, and is gained by knowledge and professional experience. Although the nurses demonstrated three sequential phases of expert practice (cognitive intuition, transitional intuition, and embodied intuition), cognitive intuition seems to be more applicable to this study. Transitional intuition is purely unconscious, with unknown reasoning and personal questioning, and with confusion about why an action was performed. Embodied intuition operates at a higher level, so that the expert's professional unconscious connection with the patient allows for unquestioned activity because of the level of the professional's

expertise. Cognitive intuition, as Lyneham and colleagues (2008) determined, involves the health professional unconsciously looking at the current patient's presentation, comparing his/her activity to previous patients' situations, and then using prior stored memory, learning, and analysis which can only be consciously determined when externally questioned. Otherwise, the clinical decision-making was performed unconsciously.

The findings of this research study of experienced pharmacist clinical decision-making in the ambulatory care clinic setting are similar to the results of the expert critical care nurses' early recognition studied by Peden-McAlpine (2000). Although there were small differences in the results, the experienced pharmacists also demonstrated an unconscious inclusion of objective knowledge (universal information) and context-related knowledge (particular information) in constant modification (thinking in action) to acquire a final situated (whole) understanding necessary for a clinical decision of drug therapy.

Pharmacist Experience in the Ambulatory Care Clinic Setting

The five stages of Dreyfus' (1986) Model of Skill Acquisition and research by Benner (1984, 1996), illustrate that five or more years of experience in the same or similar practice environment are generally required before a health professional can demonstrate expertise. The experienced pharmacists in this research study all had five or more years experience making clinical decisions in the ambulatory care clinic setting. However, study pharmacist Sophia had five years of experience making clinical decisions, but demonstrated less expertise in her clinical decision-making because she frequently made conscious deductive decisions and asked more questions of other health professionals because of inadequate objective information and knowledge. Time and experience in the practice setting was not equated to expertise in her situation. Study pharmacist Butch had two more years of experience in his ambulatory care clinic setting and personally reported 20% more time on the job making clinical decisions. Even though Butch had more experience in his ambulatory care clinic setting and performed more decision-

making, conclusions regarding his expertise cannot be based solely on this research study of clinical decision-making, since there are other potential requirements necessary to achieve this high level of association.

Some others note that Benner's (1984) description of expertise is vague and incomplete because it is lacking other common determinates of expertise in addition to number of years and experience in the particular job environment. Rassafiani and colleagues (2009) used the Cochran-Weiss-Shanteau (CWS) index as a statistical method to determine clinician expertise, examining clinical decisions in relation to length of experience and type of decision-making. After addressing 110 hypothetical cases needing treatment decisions, the five-year experienced occupational therapists were divided into two different groups, depending on their consistency and ability to discriminate between cases. Rassafiani determined that the high-performing, expert group of therapists made treatment decisions with higher consistency and greater discrimination, without regard to the length of practice experience and work environment. Therefore, the CWS index may be another guideline other than years of experience for the determination of expertise in the health care professions.

In addition to actual experience in the ambulatory care clinic setting, extra years of pharmacy practice provide increased objective information and declarative knowledge leading to more memory organization. This additional information may be automatically added to knowledge because of the amount of continuing education that is required of more experienced pharmacists. Although continuing education credits are required hours, pharmacists can choose specific courses to gain knowledge necessary to their own professional practice. Increased knowledge of objective information can improve clinical decision-making and health professional collaboration in the ambulatory care clinic setting. Data and knowledge acquired in professional practice is a form of understanding that can be shared with pharmacist colleagues and other health professionals (Farrell et al., 2012; Kennie-Kaulbach et al., 2012), as well as patients (Verma et al., 2012).

Experienced pharmacists who have made more patient care and clinical decisions not only have an enhanced knowledge of objective information, but also have a higher amount of context-related understanding and memory organization that can be applied and modified in each unique clinical decision. As noted previously, the experienced pharmacists in this study who daily had more direct patient care, made more clinical decisions compared to the others with less patient interaction. This additional decision-making created more experience and expertise with patients in their collaborative practice agreement(s) disease state areas.

However, even if a pharmacist wants to increase his or her experience in a specific medical setting, the desired level of patient care may be influenced by factors outside of the pharmacist's control: the length of time of clinic service to the community, placement of clinic, number of patients with disease-state treatability by medications included in the collaborative practice agreement, comfort of physicians or other prescribers with the pharmacist, or other reasons in each ambulatory care clinic setting.

Does Additional Education Beyond Entry-Level Professional Preparation Make a Difference?

In this study, all experienced pharmacists had additional education beyond entry-level professional preparation that included added certification or residency training. Since critique of additional education was not the aim of this study, a final conclusion of the need for certification or residency is not warranted. However, this study did demonstrate that there was no one type of further training or additional learning which clearly led to a difference in clinical decision-making abilities or patient treatment outcomes. Inherent in both residencies and credentialing in various certifications, pharmacists will gain greater experience on the job doing patient care services to increase their therapy knowledge and skills beyond the minimal requirements for licensure (Council on Credentialing in Pharmacy [CCP], 2011; Fuller et al., 2012; Koski, 2008). In both post-licensure avenues, additional time doing direct patient care adds to context-related knowledge which

ultimately enhances good clinical decision-making. Additionally, if a pharmacist is able to focus his/her certification and residency experiences toward additional education and skill-building in areas specific to his/her collaborative agreement(s), s/he will likely become knowledgeable in that disease state and able to have increased interprofessional and pharmacist professional interactions.

Requiring residency training as a prerequisite for direct patient care practice as envisioned by the American College of Clinical Pharmacy (ACCP) (Murphy et al., 2006) and the American Society of Health-System Pharmacists (ASHP) (Knapp, Shah, Kim, & Tran, 2009) may not be the only method to allow pharmacists to enter into direct patient care (Bright, Adams, Black, & Powers, 2010; Nahata, 2010). As seen in this study, some experienced pharmacists with additional certification and experience instead of residency made similar and more frequent patient care clinical decisions. For example, study pharmacists Dr. Brown, Butch, and Bobby made more clinical drug therapy decisions in comparison to the other three study pharmacists. Among those three, Butch completed a residency in addition to his certification, while the other two had specific certification and were able to make direct patient care clinical decisions. In fact, pharmacist Bobby made more clinical decisions than any other experienced pharmacists within the study period. However, a more recent study is necessary which focuses on patient care since education and pharmacy practice have evolved since the beginning of this research study. Also, this research study did not evaluate the past experiences of those participating experienced pharmacists providing the direct patient care.

Study Results Compared to Other Recent Decision-Making Studies

A recent review of the clinical decision-making literature produced substantial findings similar to the results of this study. Although the process of "iterative diagnosis" is physician-based, the analytic and non-analytic reasoning of constant integration in diagnoses (Norman, Barraclough, Dolovich, & Price, 2009) is comparable to the

Experienced Decision Making Model developed in this study. Iterative diagnosis demonstrates that a clinician relies on both analytic (Hypothetico-Deductive Model and Bayes' Theorem) and non-analytical (Pattern Recognition) processes simultaneously in clinical decision-making. Depending on clinical experience and situation familiarity, the health professional may subconsciously use the analytic or non-analytical processes in different degrees to make a clinical decision. This finding is similar to the experienced pharmacist clinical decision-making process seen in this study, which demonstrates modification of both objective and context-related information for situated understanding leading to the clinical decision.

Eva (2004) described the use of analytic and non-analytic bases in expert clinician decision-making when discussing necessary education for medical students. In addition, he made the case to educators that situational and personal contexts of non-analytical sources are critical for diagnosis. Thus, examples and problem-solving in education need to represent a range of non-analytic contexts since actual practice demonstrates such variation, all of which must be analyzed with analytic information for a more complete diagnosis.

The only discussion of the iterative diagnosis pattern in the pharmacy profession was by Weiss (2011), who stated that pharmacists who are able to independently prescribe in the United Kingdom may also use iterative diagnosis when making their clinical decisions and diagnoses. However, there was no research into whether those pharmacists actually used this iterative diagnosis pattern in their diagnosis, so a final conclusion cannot be made regarding iterative diagnosis in the pharmacy profession.

Difficulties and Limitations

As with other research studies, there are times when results are unexpected and may cause errors in the study activity. Although this study provided much new information

about pharmacists in the ambulatory care clinic setting, certain difficulties and limitations need to be discussed.

For example, collection of qualitative observation data did not allow proper study of experienced pharmacist internal thinking. However, it did validate experienced pharmacist clinical decision-making in the ambulatory care clinic setting and provided additional situations for interview probing. Additionally, the observation data showed good relationships, based upon quality communication and trust, between the pharmacists and their patients. Since the medical prescribers trusted and referred the patient to the pharmacists, the patients seemed to respect the pharmacists' opinions and openly communicated personal information. As relationships grew over time between the same pharmacist and patient, there was an increased level of trust. This working relationship created additional understanding of patient social circumstances and context as well as drug therapy treatment options.

Only e-mail and internet communication were used in the early recruitment of experienced pharmacists. Without personal contact via phone or physical introduction, the pharmacists may have been more likely to decline participation in the study with less understanding of the actual study aim, objectives and requirements. Also, there may have been fear against internet solicitation from an unknown individual and researcher. Recruiting pharmacists from Iowa was more difficult than recruiting Minnesota participants, perhaps because Minnesota pharmacists were familiar with the study, College and researcher.

At the time of data collection, there were not many pharmacists conducting clinical decision-making in ambulatory care clinic settings for at least five years. Therefore, it was difficult to find a large number of pharmacists who fit all of the inclusion criteria of this research study. In addition, pharmacists belonging to different ethnic groups were not included in the study. With increased ethnic diversity in the pharmacist population

over time, any future study of experienced pharmacist clinical decision-making should allow a larger sample size and more variety of pharmacist clinicians.

The inclusion of the participant pharmacist from the Veterans Affairs (VA) location presented many difficulties and was a major delay in doing the research. However, it was important and beneficial to the study results to involve that participant in this dissertation study. The researcher had to complete a vaccination series, fulfill training and perform continual updates because of Institutional Review Board (IRB) request. All University of Minnesota consent forms had to be rewritten for patient and pharmacist approval since there was no waiver allowance at the VA. When completing the data collection, information had to be personally and physically transcribed in the Minneapolis VA setting, requiring more time in the data collection period.

Study Implications

This study provided answers to questions regarding current pharmacist activity in drug therapy decision-making in the ambulatory care clinic setting. With this new knowledge, questions regarding the future of the pharmacy profession are necessary. These include implications for future research, social pharmacy practice, pharmacy education, other healthcare provider work, general society understanding and policy initiatives.

Implications for future research.

In this study, there were common collaborative practice agreements in certain disease states of patients in the outpatient, ambulatory care clinic setting. To assist in policy decisions and education, a study could be conducted to determine what disease states are most commonly treated in direct patient care by the ambulatory care clinic pharmacist. This study could be combined with an analysis of pharmacy students' knowledge, to discover what pharmacists know upon graduation and can exercise in a collaborative

practice agreement. On the whole, more research should be completed with pharmacist collaborative practice agreements, demonstrating the continual value of pharmacist decisions, his/her assistance to other health professionals and patients, and the ongoing intensification of the pharmacy profession.

Situational context is important in all research studies, because nuances of each practice environment may result in findings that differ from those of a similar study done elsewhere. This study demonstrated experienced clinical decision-making in the ambulatory care clinic setting, but similar studies should be conducted in other areas of pharmacy, and with different levels of pharmacist (and student) experience in practice. Also, this study could be replicated in other ambulatory care clinic settings to provide results regarding experienced pharmacists practicing in varied institutions in different states or regions. If the results of future studies are similar to those of this study, more pharmacists and those outside of the profession may agree that this study demonstrates the current pharmacist clinical decision-making. Similar results would add to the credibility of this current study because auditability and dependability would be increased.

Direct patient care and patient-centered care are important in current pharmacy practice, and considerations of patient choice and specific patient context are necessary in reaching final clinical decisions. Many patients desire involvement in decision-making about their care and, when that is achieved, have increased satisfaction in subsequent clinical decisions (Glass et al., 2012). Future research in pharmacist-patient interaction and shared decision-making are important to understand the future of direct patient care in the pharmacy profession. As demonstrated in this study, the patient-centered care which pharmacists currently practice in clinical decision-making may not be the same technique as shared decision-making, in which patients participate equally in making the final clinical decision (Charles, Gafni, & Whelan, 1997; Wensing, Elwyn, Edwards, Vingerhoets, & Grol, 2002). Clarification of the level of patient care in the pharmacy

profession is important, because shared decision-making has become an important skill in many health areas and patients demand more involvement in their own health care, possibly altering current pharmacist direct patient interaction.

Implications for social pharmacy practice.

Because pharmacists provide direct patient care in diverse settings, they must be able to effectively communicate objective information both to patients with limited health knowledge and to fellow professionals with advanced medical education. While students are educated to communicate at a patient level of knowledge, more communication strategies are necessary for pharmacists in practice (Greenhill, Anderson, Avery, & Pilnick, 2011; Guirguis, 2011). This research study demonstrated that communication strategies are necessary in objective health education and direct patient care. Although this health education teaching was only used by the experienced pharmacists in making 5.2% of their 333 decisions, Butch noted that teaching and communication itself was a feature that enabled his clinical decision-making practices. A recent study of Canadian pharmacists providing direct patient care with collaborative care practices (Kennie-Kaulbach et al., 2012) also determined that communication was an important competency related to patient care delivery.

Implications for other health professionals.

The Institute of Medicine (IOM) book, Crossing the Quality Chasm: A New Health System for the 21st Century (National Research Council, 2001), established a challenge to re-design health care. Teamwork by professionals in the health care environment is crucial for caring for patients with complicated health histories (Berwick, 2002). Recently, the Interprofessional Education Collaborative (IPEC) established competencies which require study for interprofessional understanding and agreement, knowledge of

roles and responsibilities, communication and teamwork in the health professional workforce (Interprofessional Education Collaborative [IPEC] Expert Panel, 2011).

Teamwork and working with other health care professionals enabled the clinical decision-making and patient care of experienced pharmacists in this study. All professionals have different expertise, and information and knowledge from each professional can be combined to assist the patient with complete health care treatment. For example, in this study when the pharmacists had inadequate information of a disease-state or laboratory value(s), other health care professionals had helpful insight for the clinical decision-making. Overall, there may be challenges to teamwork at first, but in time, inclusion of the pharmacist in the healthcare team may provide many benefits (Legault et al., 2012; Pottie et al., 2008).

Also, as prescribers realize that pharmacists have competency and knowledge in other disease-state areas, they will consider more collaborative practice agreements (APhA Foundation, 2011). To assist in developing this larger knowledge base, pharmacists should be more engaged and learned in other disease states. They should continue to be educated, after their primary higher education ends, to become "professional" in the areas of knowledge needed to contribute to discussions with other health care leaders (Villeneuve et al., 2009). In this study, one pharmacist demonstrated that his continued learning allowed him to provide updated current information to others. This additional knowledge and information-sharing may provide him with more professional trust and credibility, along with personal job satisfaction.

Because of recent government policies, including the Medicare Part D prescription drug benefit and Medication Therapy Management (MTM) which include pharmacists in health care management, other health professionals now must know of the impact of pharmacists in patient's health care (Isetts, 2012). However, while many health

professionals may already understand how a pharmacist can benefit their health care team and patient care in general, public policy may need to support increased pharmacist inclusion in collaborative care (Lai, Smith, Stebbins, Cutler, & Lipton, 2011).

Implications for policy.

This study demonstrated the use of pharmacist collaborative practice agreements in the ambulatory care clinic setting for clinical decision-making in drug therapy. The clinical decision-making was demonstrated in disease states in which the pharmacists had collaborative agreements with the prescriber. At times, the absence of a collaborative practice agreement prevented the pharmacist from gathering adequate information necessary for clinical decision-making for a particular disease state. State governments and leaders of health organizations should establish additional collaborative practice agreements to allow greater patient care.

This study of pharmacist clinical decision-making demonstrates that pharmacists are able to perform MTM in ambulatory care clinic settings. With their direct patient care and knowledge of complete patient information, these pharmacists demonstrated how policies encouraging pharmacists to perform MTM are suitable in the ambulatory care clinic setting. Likewise, including pharmacists in direct patient care in each health care facility should be mandatory since better patient therapeutic, safety, and humanistic outcomes are seen (Chisholm-Burns et al., 2010).

Implications for pharmacy education.

Many of the implications of this research study begin in the education environment of current pharmacy students. Pharmacy education needs to produce competent pharmacist clinical decision-makers by providing correct education for successful graduates. In this study, it was apparent that many of the disease states included in collaborative practice

agreements are among the most common chronic illnesses in the United States (Centers for Disease Control and Prevention [CDC], 2012). So, to encourage increased pharmacist collaborative care of chronic illnesses, pharmacy students need to have extensive knowledge regarding diabetes mellitus, heart disease, stroke, cancer, arthritis, and other common chronic patient disorders.

Also, pharmacy students need be taught various decision-making methods even if they will not be used frequently as new pharmacists. As demonstrated in this study, with increased experience, pharmacists incorporate different decision-making models and approaches to patient care in their professional practice. Also, since other health professionals use similar decision-making methods, it is important to understand how the necessary elements of their thinking process help determine the final clinical decision (Rencic, 2011).

Interprofessional education is important as collaboration in healthcare and professional teamwork in pharmacist clinical decision-making is necessary. Realistic exposure to teamwork complexity is needed so students have a basic understanding of others' roles in the healthcare team (Legault et al., 2012; Lingard et al., 2012). Interprofessional education (especially between pharmacists and physicians) should be accomplished through a shared teaching experience at the earliest possible stages of professional education, since this interprofessional understanding in education can improve future doctor-pharmacist working relationships (Gallagher & Gallagher, 2012).

Can we guide students and newer pharmacists to bring together objective and context-based information before graduation so it does not take as much experience in the practice environment to develop expertise? The Accreditation Council for Pharmacy Education (ACPE) has implemented mandatory standards for pharmacy students to have Introductory Pharmacy Practice Experiences (IPPEs) and Advanced Pharmacy Practice Experiences (APPEs) before completing the professional education leading to the Doctor

of Pharmacy Degree (Accreditation Council for Pharmacy Education [ACPE], 2011). With these standards, pharmacy student educators must engage students in early learning experiences with other students and patients. The students are often learning from each other, teaching other students, and guiding patients regarding objective and context-related information. Although academia has long valued the patient-centered care of pharmacy student education (Haines et al., 2011), the American College of Clinical Pharmacy (ACCP) has described a further need for direct patient care experiences in the delivery of effective APPE, so pharmacy students are provided with practice and given the tools for contemporary patient-centered practice (Rathbun et al., 2012). Also, these experiences will allow students to build their organized memory schemata before becoming real, practicing pharmacists in the health care environment.

Communication education is necessary since pharmacists need to learn to be effective teachers of disease-state management and drug therapy to patients and other health professionals. Even in this study, communication was demonstrated as an enabling factor in making clinical decisions, and delivery of health education was an important objective task for pharmacists to have learned. With the continual expansion of the pharmacists' roles to fulfill better patient care in collaboration with other health professionals, communication is highly ranked as a necessary professional competency (Kennie-Kaulbach et al., 2012). Although the IPPEs and APPEs provide introductory examples of necessary communication practice, other opportunities to speak and teach about health care need to be available (Hasan, 2008). In addition, since communication between physicians and pharmacists is significant in collaborative relationships, pharmacy students should learn communication skills not only for patients and families, but also for discussion with other health professions (Hall, 2005).

Implications for society.

From this study, the public notes that pharmacists make clinical drug therapy decisions with established trust from other health professionals. Using this trust to gain collaborative practice agreements with prescribers, pharmacists are able to utilize their knowledge to make decisions to improve patient health. Spending time with a pharmacist allows patients to get the healthcare assistance they need, not only with drugs, but also with non-medical items. With the government activation of Medication Therapy Management (MTM), some third-party insurers, Medicare Part D prescription drug plans, and employers are even paying for a pharmacist to review a person's complete medication profile (Beatty et al., 2012). This study clearly showed that an experienced pharmacist in the ambulatory care clinic setting would be a great resource when patients need that complete medication review and consultation. People should be confident that clinical knowledge and evidence are behind clinical pharmacist decisions. As demonstrated in this research study, patients should have the assurance that pharmacists make clinical decisions WITH their influence, not without considering the actual person and their unique experiences.

Conclusions

This research study used a qualitative focus to demonstrate how experienced pharmacists make clinical decisions in the ambulatory care clinic setting. This dissertation is a unique report of current pharmacist practice of direct patient care in the chronic ambulatory care clinic setting. Other healthcare professions have extensive literature exploring clinical decision-making practices by professionals in their practicing locations. Recently, the pharmacy profession has begun adding literature related to decision-making. However, this is the first study demonstrating pharmacist clinical decision-making in the chronic ambulatory care clinic setting.

This study should stimulate more research regarding the topic of pharmacist clinical decision-making. It adds value to the profession by demonstrating that pharmacists in the ambulatory care clinic setting use direct patient care in making clinical decisions specifically for each individual in their unique circumstance with complex health needs. It highlights the need for collaborative practice agreements, teamwork in the health care environment, and updates in education. This research study demonstrates the current pharmacist inclusion in Medication Therapy Management as the proper policy decision which pharmacists will continue to practice.

The profession is constantly advancing toward better patient health and every emphasis of pharmacists' abilities and actual performances guarantee that the profession is necessary and that the individual pharmacy professionals are important inclusions to our health care environment. I look forward to upcoming improvements in the pharmacy profession that are stimulated from this study highlighting experienced pharmacist clinical decision-making for drug therapy in the ambulatory care clinic setting.

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Appendix A: Pharmacist Letter of Invitation

Hi (*possible pharmacist subject name*)-

My name is Christine Bartels Eid, and I am a graduate student at the College of Pharmacy at the University of Minnesota. I am in my final year of the graduate program, and am conducting a research study to help finalize my PhD. The research I am doing will discover methods of pharmacist drug therapy decision-making when choosing drugs for patients. The results will benefit the pharmacy profession now and in the future, and will influence other health professionals as well. Additionally, the results may influence patients and future drug therapy decision-making.

You have been chosen as a potential participant in this research study because of the suggestion of many people. I do ask you to be a pharmacist with an active Minnesota license and with a relationship with prescribing health professionals. Also, I request that you have made drug therapy decisions for 5 or more years and are willing to verbally express past decision-making stories in English. It is voluntary to participate in this study, so please make your own decision to participate in this endeavor after you have read this complete request letter.

If you choose to participate in this research study, please read the attached pharmacist information sheet. In addition, I will contact your pharmacy director to gain the rights to be in research with you. I will ask if there is a review committee at your place of employment that I must work with, in addition to the University of Minnesota Institutional Review Board (IRB) protecting human subjects.

Your participation in this research study includes an observation of your interaction with a patient, deciding on new medication and any changes to their drug therapy. I request observation and audio recording of at least 2 patient interactions and drug decision episodes in one day. Later that day after the observation, I will conduct a face-to-face interview with you to obtain more stories of your drug decision-making experiences of the past. I will remind you of this interview session one week prior to the observation and interview. The interview will be audio-recorded and will take about 30-45 minutes of your time. Finally, I will ask you to audio record yourself for 2 weeks describing the most complex and interesting decisions you made in the day. I will provide you with a self-addressed and postage-paid envelope for return of the tape recorder and tapes. Throughout the whole research project, I will copy the recordings exactly as you speak the information and will provide the textual information to you as a check.

You will receive a $300 check for participation in the entire research study. There are no other direct rewards. As pointed out before, the results of this study will highlight the pharmacist drug therapy decision-making processes, encourage relationships with other health professionals, and help society in future pharmacist-patient interactions of drug therapy.

There are minimal risks of participating in this study. During the observation, I will be present in your patient interaction doing audio-recording and taking brief notes. This activity may inhibit you from performing a regular interaction even if I am not participating in the actual practice. If you feel uncomfortable at any time of the research study, you can end your participation or decline answering any question.

If you have any further questions about the research study, please contact me, Christine Bartels, as the primary researcher (bart0242@umn.edu or 612-624-6105). Additionally, you can contact my graduate studies advisor, Dr. Barbara Brandt (brandt@umn.edu or 612-625-3972) or the Research Subjects' Advocate Line (612-625-1650).

Thank you for your consideration and possible working relationship,

Dr. Christine Bartels Eid

****

Christine E. Bartels Eid, Pharm.D.
Ph.D. Candidate
Social & Administrative Pharmacy Graduate Program
University of Minnesota College of Pharmacy
7-164 Weaver-Densford Hall
Phone: 612-624-6105
Fax: 612-625-9931

Appendix B: University of Minnesota IRB Approval

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Research Subjects' Protection Programs
Institutional Review Board: Human Subjects Committee (IRB)
Institutional Animal Care and Use Committee (IACUC)

Mayo Mail Code 820
D-528 Mayo Memorial Building
420 Delaware Street S.E.
Minneapolis, MN 55455
612-626-5654
Fax: 612-626-6061
irb@umn.edu
iacuc@umn.edu
http://www.research.umn.edu/subjects.htm

11/28/2006

Christine E Bartels
College of Pharmacy
5-130 WDH
Minneapolis Campus

RE: "Analysis of Experienced Pharmacist Clinical Decision-Making for Drug Therapy Management in the Ambulatory Care Setting"
IRB Code Number: **0609P92550**

Dear Dr. Bartels Christine

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study includes the consent form dated October 18, 2006 and recruitment materials received October 20, 2006.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 8 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

For your records and for grant certification purposes, the approval date for the referenced project is October 9, 2006 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal; approval will expire one year from that date. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious unexpected adverse events should be reported to the IRB as they occur. The IRB wishes you success with this research. If you have questions, please call the IRB office at (612) 626-5654.

Sincerely,

Cynthia McGill

Cynthia McGill, CIP
Research Compliance Supervisor
CM/egk
CC: Barbara Brandt

Appendix C: Minneapolis Veterans Affairs IRB Approval

VA Medical Center, Minneapolis, MN

Department of Veterans Affairs
REPORT OF INSTITUTIONAL REVIEW BOARD-A
FULL COMMITTEE INITIAL REVIEW

Project Title: #3939-A: Community Re-Integration problems and Treatment Preferences among OIF/OEF Veterans

Investigator: Melissa Atwood, PharmD

VAMC: Minneapolis **Approval Date: 7/2/07**

R & D Approval
Date 8.14.07 Signed
Ronald Bach, PhD

COMMITTEE FINDINGS:

1. The information given in the Consent form under the Description of Research by Investigator is complete, accurate and understandable to a research subject or a surrogate who possess standard reading and. comprehension skills. (YES) NO NA

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. (YES) NO NA

3. Every effort has been made to decrease risk to subject(s)? (YES) NO

4. The potential research benefits justify the risk to subject(s)? (YES) NO

5. If subject is incompetent, and surrogate consent is obtained, have all of the following conditions been met: a) research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to the subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described? YES NO (NA)

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. YES NO (NA)

7. Members of minorities and women have been included in the study population whenever possible and scientifically desirable. (YES) NO

8. Comments: **The waiver of informed consent and authorization for screening and recruiting for this protocol was approved. Use only copies of the attached approved informed consent and Protected Health Information (PHI) authorization forms. The original signed consent and authorization forms should be filed in the investigator's record, a copy should be given to the subject, a copy sent to the Research Office, and a copy scanned in the subjects' medical record (if appropriate). Any serious or unexpected adverse experience should be reported to the Institutional Review Board within 5 days. Any changes in the protocol, consent or authorization forms or personnel must receive prior approval by the Institutional Review Board. A progress report including a description of the research findings, gender and ethnicity of subjects (this must be collected) and a list of subjects' names must be submitted for the continuing review one year from the approval date. Notification of study completion/termination is required.**

RECOMMENDATION: (APPROVE) **DISAPPROVE/REVISE**

Signature of Chairman: DANIEL HANSON, MD, PhD DATE 8-28-07

VAF 10-1223 (local form revised March 2006)

Appendix D: St. Cloud Veterans Affairs IRB Approval

Department of Veterans Affairs
REPORT OF INSTITUTIONAL REVIEW BOARD-A
FULL COMMITTEE INITIAL REVIEW

Project Title: #3938-A: Community Re-Integration problems and Treatment Preferences among OIF/OEF Veterans

Investigator: Richard Stambaugh, PharmD

VAMC: Minneapolis **Approval Date: 7/2/07**

Minneapolis VAMC R & D Approval
Date 8/14/07 Signed /K Rice MA for
Ronald Bach, PhD

COMMITTEE FINDINGS:

1. The information given in the Consent form under the Description of Research by Investigator is complete, accurate and understandable to a research subject or a surrogate who possess standard reading and. comprehension skills. (YES) NO NA

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. (YES) NO NA

3. Every effort has been made to decrease risk to subject(s)? (YES) NO

4. The potential research benefits justify the risk to subject(s)? (YES) NO

5. If subject is incompetent, and surrogate consent is obtained, have all of the following conditions been met: a) research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to the subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described? YES NO (NA)

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. YES NO (NA)

7. Members of minorities and women have been included in the study population whenever possible and scientifically desirable. (YES) NO

8. Comments: **The waiver of informed consent and authorization for screening and recruiting for this protocol was approved. Use only copies of the attached approved informed consent and Protected Health Information (PHI) authorization forms. The original signed consent and authorization forms should be filed in the investigator's record, a copy should be given to the subject, a copy sent to the Research Office, and a copy scanned in the subjects' medical record (if appropriate). Any serious or unexpected adverse experience should be reported to the Institutional Review Board within 5 days. Any changes in the protocol, consent or authorization forms or personnel must receive prior approval by the Institutional Review Board. A progress report including a description of the research findings, gender and ethnicity of subjects (this must be collected) and a list of subjects' names must be submitted for the continuing review one year from the approval date. Notification of study completion/termination is required.**

RECOMMENDATION: **APPROVE** **DISAPPROVE/REVISE**

Signature of Chairman: for DANIEL HANSON, MD, PhD DATE 9-5-07

VAF 10-1223 (local form revised March 2006)

Appendix E: Minneapolis Veterans Affairs Pharmacist Consent Form

Department of Veterans Affairs **VA RESEARCH CONSENT FORM**

Protocol # 03939-A

Subject Name: **Date:**

Title of Study: Analysis of Experienced Pharmacist Clinical Decision-Making for Drug Therapy Management in the Ambulatory Care Setting

Principal Investigator: Melissa Atwood, Christine Bartels **VAMC:** Minneapolis

PHARMACIST

INTRODUCTION

It is important that you read and understand the following explanation of the proposed research study before you agree to participate. This consent form describes:

- The purpose,
- The description of the study,
- The benefits,
- The risks and/or discomforts (including any potential for pain),
- Steps taken to decrease or eliminate the risks, discomforts, or possible pain,
- Any other treatments that may be available, and
- Confidentiality and use of research results.

Whether you decide to participate or not, treatment at the VA for which you are eligible will not be affected.

This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or information unclear to you.

PURPOSE OF THE STUDY

You are being asked to voluntarily participate in a research study to determine 1) drug therapy decision-making process(es) of experienced pharmacists in the ambulatory care setting, 2) to compare and contrast pharmacist clinical decision-making with current decision-making models, and 3) to specifically identify enabling factors and barriers to clinical decision-making in the ambulatory care context. You have been asked to participate in this study because you are a pharmacist with five or more years of decision-making experience in the ambulatory care setting in the states of Minnesota or Iowa, work in a general ambulatory care setting, speak and write in English, hold an

interdisciplinary relationship, and use clinical decision-making at work. Your participation is expected to last 3 weeks, and approximately 3 people will be in the study at this site.

DESCRIPTION OF STUDY

The following information describes what will happen while you participate in the study: you will be observed and audio-recorded during at least 2 patient interactions and drug decision episodes in one day. Later that day after the observation, you will participate in a face-to-face interview with Dr. Christine Bartels (Co-PI) to obtain more stories of your drug decision-making experiences of the past. You will be reminded of this interview session one week prior to the observation and interview. The interview will be audio-recorded and will take about 1-2 hours of your time. Finally, you are asked to audio record yourself for 2 weeks describing the most complex and interesting decisions you made in the day. You will be provided with an addressed and postage-paid FedEx envelope for return of the tape recorder and tapes. Throughout the whole research project, the recordings will be copied exactly as you speak the information and the textual information will be provided to you as a check.

RISKS AND/OR DISCOMFORTS

There are minimal risks of participating in this study. During the observation, the researcher will be present in your patient interaction doing audio-recording and taking brief notes. This activity may inhibit you from performing a regular interaction even if there is no additional participation in the actual practice. If you feel uncomfortable at any time of the research study, you can end your participation or decline answering any question. In addition, there may be other unknown effects that could occur.

BENEFITS

There will be no compensation for pharmacist participation, but professional pride in participation in this research study. There may be no other direct benefits to for being in this research study. The knowledge gained from this study may benefit others in the future.

CONFIDENTIALITY AND USE OF RESEARCH RESULTS

The results of this study may be published or presented but your identity and records will not be revealed unless required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accounting Office and other Federal agencies, the Research and Development Committee and/or the Institutional Review Board (IRB)/Human Studies Subcommittee of the VA Medical Center to review records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

COSTS TO YOU FOR PARTICIPATING
There is no cost to you for taking part in this study. All the study costs will be paid for by the researcher, Dr. Christine Bartels.

MEDICAL CARE IF YOU ARE INJURED
In case you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will consider payment for necessary medical care for any injury or illness directly related to your participation in this research study. If you receive this type of medical care, you must contact the Research Investigator for this study. You can find contact information in the section of this consent titled "Compensation for Any Injuries".

COMPENSATION FOR ANY INJURIES
You have not released the VA Medical Center from liability by signing this form. This includes but is not limited to: 1) free medical care other than as described in this consent form, 2) payment of lost wages, or 3) compensation for pain and suffering. Compensation for those items from the VA may be available under applicable Federal Law. You should immediately report any injuries resulting from your participation in this study at any time to Dr. Christine E. Bartels at (612) 281-7531. You may contact Dr. Melissa Atwood at (612) 467-3546 during the day.

NEW INFORMATION
You will be given any new significant information that is discovered during the course of this study which may influence your willingness to continue the study.

RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above. Christine Bartels has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study.

I understand that I do not have to take part in this study and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published but my identity and records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Christine Bartelsat (612) 281-7431 at any time and the VA operator at (612) 725-2000 after hours and ask to have the physician on call paged. I will tell the operator I am in a research study. (If I do not live in the metropolitan area, I may call the toll-free number: 1-866-414-5058.)

If any medical problems occur in connection with this study the VA will provide emergency care.

If you have any questions about the rights of a research subject, you may contact the Patient Representative at (612) 725-2106. If you wish to verify the validity of the study and its authorized contacts, you may call the patient representative, contact the IRB office at 612-467-2800.

My questions have been answered and I voluntarily consent to participate in this study. By signing this form, I have not given away any of my legal rights, which I have as a subject of this research study. I will receive a signed copy of this consent form.

_____	_____
Subject's Signature	Date
_____	_____
Signature of Investigator	Date
_____	_____
Witness to the Signature	Date

Appendix F: St. Cloud Veterans Affairs Pharmacist Consent Form

Department of Veterans Affairs **VA RESEARCH CONSENT FORM**

Protocol # 03938-A

Subject Name: **Date:**

Title of Study: Analysis of Experienced Pharmacist Clinical Decision-Making for Drug Therapy Management in the Ambulatory Care Setting

Principal Investigator: Richard Stambaugh, Christine Bartels **VAMC:** St. Cloud

PHARMACIST

INTRODUCTION

It is important that you read and understand the following explanation of the proposed research study before you agree to participate. This consent form describes:

- The purpose,
- The description of the study,
- The benefits,
- The risks and/or discomforts (including any potential for pain),
- Steps taken to decrease or eliminate the risks, discomforts, or possible pain,
- Any other treatments that may be available, and
- Confidentiality and use of research results.

Whether you decide to participate or not, treatment at the VA for which you are eligible will not be affected.

This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or information unclear to you.

PURPOSE OF THE STUDY

You are being asked to voluntarily participate in a research study to determine 1) drug therapy decision-making process(es) of experienced pharmacists in the ambulatory care setting, 2) to compare and contrast pharmacist clinical decision-making with current decision-making models, and 3) to specifically identify enabling factors and barriers to clinical decision-making in the ambulatory care context. You have been asked to participate in this study because you are a pharmacist with five or more years of decision-

making experience in the ambulatory care setting in the states of Minnesota or Iowa, work in a general ambulatory care setting, speak and write in English, hold an interdisciplinary relationship, and use clinical decision-making at work. Your participation is expected to last 3 weeks, and approximately 3 people will be in the study at this site.

DESCRIPTION OF STUDY

The following information describes what will happen while you participate in the study: you will be observed and audio-recorded during at least 2 patient interactions and drug decision episodes in one day. Later that day after the observation, you will participate in a face-to-face interview with Dr. Christine Bartels (Co-PI) to obtain more stories of your drug decision-making experiences of the past. You will be reminded of this interview session one week prior to the observation and interview. The interview will be audio-recorded and will take about 1-2 hours of your time. Finally, you are asked to audio record yourself for 2 weeks describing the most complex and interesting decisions you made in the day. You will be provided with an addressed and postage-paid FedEx envelope for return of the tape recorder and tapes. Throughout the whole research project, the recordings will be copied exactly as you speak the information and the textual information will be provided to you as a check.

RISKS AND/OR DISCOMFORTS

There are minimal risks of participating in this study. During the observation, the researcher will be present in your patient interaction doing audio-recording and taking brief notes. This activity may inhibit you from performing a regular interaction even if there is no additional participation in the actual practice. If you feel uncomfortable at any time of the research study, you can end your participation or decline answering any question. In addition, there may be other unknown effects that could occur.

BENEFITS

There will be no compensation for pharmacist participation, but professional pride in participation in this research study. There may be no other direct benefits to for being in this research study. The knowledge gained from this study may benefit others in the future.

CONFIDENTIALITY AND USE OF RESEARCH RESULTS

The results of this study may be published or presented but your identity and records will not be revealed unless required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accounting Office and other Federal agencies, the Research and Development Committee and/or the Institutional Review Board (IRB)/Human Studies Subcommittee of the VA Medical Center to review records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

COSTS TO YOU FOR PARTICIPATING
There is no cost to you for taking part in this study. All the study costs will be paid for by the researcher, Dr. Christine Bartels.

MEDICAL CARE IF YOU ARE INJURED
In case you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will consider payment for necessary medical care for any injury or illness directly related to your participation in this research study. If you receive this type of medical care, you must contact the Research Investigator for this study. You can find contact information in the section of this consent titled "Compensation for Any Injuries".

COMPENSATION FOR ANY INJURIES
You have not released the VA Medical Center from liability by signing this form. This includes but is not limited to: 1) free medical care other than as described in this consent form, 2) payment of lost wages, or 3) compensation for pain and suffering. Compensation for those items from the VA may be available under applicable Federal Law. You should immediately report any injuries resulting from your participation in this study at any time to to Dr. Christine E. Bartels at (612) 281-7531. You may contact Dr. Richard Stambaugh at (320) 255-6480 during the day.

NEW INFORMATION
You will be given any new significant information that is discovered during the course of this study which may influence your willingness to continue the study.

RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above. Christine Bartels has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study.

I understand that I do not have to take part in this study and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published but my identity and records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Christine Bartels at (612) 281-7431 at any time and the VA operator at (320) 252-1670 after hours and ask to have the physician on call paged. I will tell the operator I am in a research study. (If I do not live in the immediate area, I may call the toll-free number: 1-800-247-1739.)

If any medical problems occur in connection with this study the VA will provide emergency care.

If you have any questions about the rights of a research subject, you may contact the Patient Representative at (612) 725-2106. If you wish to verify the validity of the study and its authorized contacts, you may call the patient representative, contact the IRB office at 612-467-2800.

My questions have been answered and I voluntarily consent to participate in this study. By signing this form, I have not given away any of my legal rights, which I have as a subject of this research study. I will receive a signed copy of this consent form.

_____	_____
Subject's Signature	Date
_____	_____
Signature of Investigator	Date
_____	_____
Witness to the Signature	Date

Appendix G: Minneapolis Veterans Affairs Patient Consent Form

Department of Veterans Affairs **VA RESEARCH CONSENT FORM**

Protocol # 03939-A

Subject Name: **Date:**

Title of Study: Analysis of Experienced Pharmacist Clinical Decision-Making for Drug Therapy Management in the Ambulatory Care Setting

Principal Investigator: Melissa Atwood, Christine Bartels **VAMC:** Minneapolis

PATIENT

INTRODUCTION

It is important that you read and understand the following explanation of the proposed research study before you agree to participate. This consent form describes:

- The purpose,
- The description of the study,
- The benefits,
- The risks and/or discomforts (including any potential for pain),
- Steps taken to decrease or eliminate the risks, discomforts, or possible pain,
- Any other treatments that may be available, and
- Confidentiality and use of research results.

Whether you decide to participate or not, treatment at the VA for which you are eligible will not be affected.

This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or information unclear to you.

PURPOSE OF THE STUDY

The purpose of this study is to identify and evaluate the decision-making processes of pharmacists making drug therapy decisions with you. You were selected as a possible participant because you are working with an experienced pharmacist in Minnesota who has agreed to participate in this research study. Your participation is expected to last the total time of your visit with the pharmacist, and approximately 13 people will be in the study at this site.

DESCRIPTION OF STUDY

If you agree to participate in this observation, you will be asked to allow the researcher to be an observer to your consultation with your assigned pharmacist. The researcher will observe your interaction and pharmacist drug therapy decision-making. During the observation, the researcher will write brief notes and audio-record the interaction. You will be asked for provide study and study consent at the beginning of the interaction.

RISKS AND/OR DISCOMFORTS

Potential risks of this research study are limited to discussing your health experiences in front of an observer. This may change the normal process of talking with the pharmacist alone. If you feel uncomfortable at any time of the observation, you may voluntarily decline participation in the study and observation.

BENEFITS

There may be no direct benefits to you for participating in this study. This study is part of the researcher's graduate work and will ultimately improve pharmacist and other health professionals knowledge of drug therapy decision-making.

CONFIDENTIALITY AND USE OF RESEARCH RESULTS

The results of this study may be published or presented but your identity and records will not be revealed unless required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accounting Office and other Federal agencies, the Research and Development Committee and/or the Institutional Review Board (IRB)/Human Studies Subcommittee of the VA Medical Center to review records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

COSTS TO YOU FOR PARTICIPATING

There is no cost to you for taking part in this study. All the study costs will be paid for by the researcher, Dr. Christine Bartels.

MEDICAL CARE IF YOU ARE INJURED

In case you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will consider payment for necessary medical care for any injury or illness directly related to your participation in this research study. If you receive this type of medical care, you must contact the Research Investigator for this study. You can find contact information in the section of this consent titled "Compensation for Any Injuries".

COMPENSATION FOR ANY INJURIES

You have not released the VA Medical Center from liability by signing this form. This includes but is not limited to: 1) free medical care other than as described in this consent form, 2) payment of lost wages, or 3) compensation for pain and suffering.

Compensation for those items from the VA may be available under applicable Federal Law. You should immediately report any injuries resulting from your participation in this study at any time to Dr. Christine E. Bartels at (612) 281-7531. You may contact Dr. Melissa Atwood at (612) 467-3546 during the day.

RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above. Christine Bartels has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study.

I understand that I do not have to take part in this study and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published but my identity and records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Christine Bartels at (612) 281-7431 at any time and the VA operator at Dr. Melissa Atwood called at 612-467-3546 and the physician on call paged. Tell the operator you are in a research study. (If you do not live in the metropolitan area, you may call the toll-free number: 1-866-414-5058.)

If any medical problems occur in connection with this study the VA will provide emergency care.

If you have any questions about the rights of a research subject, you may contact the Patient Representative at (612) 725-2106. If you wish to verify the validity of the study and its authorized contacts, you may call the patient representative, contact the IRB office at 612-467-2800.

My questions have been answered and I voluntarily consent to participate in this study. By signing this form, I have not given away any of my legal rights, which I have as a subject of this research study. I will receive a signed copy of this consent form.

_____ _____

Subject's Signature Date

_____ _____

Signature of Investigator Date

_____ _____

Witness to the Signature Date

Appendix H: St. Cloud Veterans Affairs Patient Consent Form

Department of Veterans Affairs **VA RESEARCH CONSENT FORM**

Protocol # 03938-A

Subject Name: **Date:**

Title of Study: Analysis of Experienced Pharmacist Clinical Decision-Making for Drug Therapy Management in the Ambulatory Care Setting

Principal Investigator: Richard Stambaugh, Christine Bartels **VAMC:** St. Cloud

PATIENT

INTRODUCTION

It is important that you read and understand the following explanation of the proposed research study before you agree to participate. This consent form describes:

- The purpose,
- The description of the study,
- The benefits,
- The risks and/or discomforts (including any potential for pain),
- Steps taken to decrease or eliminate the risks, discomforts, or possible pain,
- Any other treatments that may be available, and
- Confidentiality and use of research results.

Whether you decide to participate or not, treatment at the VA for which you are eligible will not be affected.

This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or information unclear to you.

PURPOSE OF THE STUDY

The purpose of this study is to identify and evaluate the decision-making processes of pharmacists making drug therapy decisions with you. You were selected as a possible participant because you are working with an experienced pharmacist in Minnesota who has agreed to participate in this research study. Your participation is expected to last the total time of your visit with the pharmacist, and approximately 13 people will be in the study at this site.

DESCRIPTION OF STUDY

If you agree to participate in this observation, you will be asked to allow the researcher to be an observer to your consultation with your assigned pharmacist. The researcher will observe your interaction and pharmacist drug therapy decision-making. During the observation, the researcher will write brief notes and audio-record the interaction. You will be asked for provide study and study consent at the beginning of the interaction.

RISKS AND/OR DISCOMFORTS

Potential risks of this research study are limited to discussing your health experiences in front of an observer. This may change the normal process of talking with the pharmacist alone. If you feel uncomfortable at any time of the observation, you may voluntarily decline participation in the study and observation.

BENEFITS

There may be no direct benefits to you for participating in this study. This study is part of the researcher's graduate work and will ultimately improve pharmacist and other health professionals knowledge of drug therapy decision-making.

CONFIDENTIALITY AND USE OF RESEARCH RESULTS

The results of this study may be published or presented but your identity and records will not be revealed unless required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accounting Office and other Federal agencies, the Research and Development Committee and/or the Institutional Review Board (IRB)/Human Studies Subcommittee of the VA Medical Center to review records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

COSTS TO YOU FOR PARTICIPATING

There is no cost to you for taking part in this study. All the study costs will be paid for by the researcher, Dr. Christine Bartels.

MEDICAL CARE IF YOU ARE INJURED

In case you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will consider payment for necessary medical care for any injury or illness directly related to your participation in this research study. If you receive this type of medical care, you must contact the Research Investigator for this study. You can find contact information in the section of this consent titled "Compensation for Any Injuries".

COMPENSATION FOR ANY INJURIES

You have not released the VA Medical Center from liability by signing this form. This includes but is not limited to: 1) free medical care other than as described in this consent form, 2) payment of lost wages, or 3) compensation for pain and suffering.

Compensation for those items from the VA may be available under applicable Federal Law. You should immediately report any injuries resulting from your participation in this study at any time to Dr. Christine E. Bartels at (612) 281-7531. You may contact Dr. Richard Stambaugh at (320) 255-6480 during the day.

RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above. Christine Bartels has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study.

I understand that I do not have to take part in this study and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published but my identity and records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Christine Bartels at (612) 281-7431 at any time and the VA operator at (320) 252-1670 after hours and ask to have the physician on call paged. I will tell the operator I am in a research study. (If I do not live in the immediate area, I may call the toll-free number: 1-800-247-1739.)

If any medical problems occur in connection with this study the VA will provide emergency care.

If you have any questions about the rights of a research subject, you may contact the Patient Representative at (612) 725-2106. If you wish to verify the validity of the study and its authorized contacts, you may call the patient representative, contact the IRB office at 612-467-2800.

My questions have been answered and I voluntarily consent to participate in this study. By signing this form, I have not given away any of my legal rights, which I have as a subject of this research study. I will receive a signed copy of this consent form.

_____ _____

Subject's Signature Date

_____ _____

Signature of Investigator Date

_____ _____

Witness to the Signature Date

Appendix I: Veterans Affairs Pharmacist Audio-Taping Consent Form

Department of Veterans Affairs

VETERANS ADMINISTRATION

CONSENT FOR USE OF PICTURE AND/OR VOICE

CONSENT OF (Name)

NOTE: The information requested on this form is solicited under the authority of title 38, United States Code. The execution of this form does not authorize disclosure of the materials specified below except for the purpose(s) stated. The specified material may be used within the VA for authorized purposes, such as for education of VA personnel or for VA research activities. It may also be disclosed outside the VA as permitted by law. If the material is part of a VA system of records, it may be disclosed outside the VA as stated in the 'Routine Uses' in the "VA Privacy Act Systems of Records "published in the Federal Register. A copy of the 'Routine Uses' is available upon request to the administrative office of the VA facility involved.

You do not have to consent to have your picture or voice taken, recorded, or used. Your refusal to grant your consent will have no effect on any VA benefits to which you may be entitled.

I hereby voluntarily and without compensation authorize pictures and/or voice recording(s) to be made of me *(or of the above-named individual if the individual is legally unable to give consent)* by *(specify the name of the VA facility, newspaper, magazine, television station, etc.)*

While I am *(describe the activity, if any to be photographed or recorded)*

Audio-recorded observation, interview, personal audio-taping

I authorize disclosure of the picture and/or voice recording to *(specify name and address of the organization, agency, or individual(s) to whom the release is to be made)*

Dr. Christine E Bartels at the University of Minnesota - Twin Cities, College of Pharmacy, Social and Administrative Pharmacy Graduate Program

I understand that the said picture(s) and/or voice recording(s) is intended for the following purpose(s)

To identify and evaluate the decision-making processes of pharmacists making drug therapy decisions in routine health-care work.

I have read and understand the foregoing and I consent to the use of my picture and/or voice as specified for the above-described purpose(s). I further understand that no royalty, fee or other compensation of any character shall become payable to me by the United States for the use of my picture and/or voice

(SIGNATURE OF INDIVIDUAL OR OTHER LEGALLY AUTHORIZED PERSON) (DATE)

INTERVIEW AND PERMISSION OBTAINED BY (Name - title - address)

(SIGNATURE OF INTERVIEWER) (DATE)

PRODUCTION TITLE

PRODUCTION NO.

(PRINT PATIENT PLATE OR WRITE IN INDIVIDUAL'S NAME & ADDRESS

IMPORTANT: This form must always be completed prior to the making or using pictures and ½ or voice recording(s) of any individual. If that individual has any history of drug abuse, alcoholism or sickle cell anemia or infection with the human immunodeficiency virus, an additional VA Form 10-5345 is required prior to the release of any data to any source.

VA FORM MAY 1988 **10-3203**

Appendix J: Veterans Affairs Patient Audio-Taping Consent Form

Department of Veterans Affairs

VETERANS ADMINISTRATION

CONSENT FOR USE OF PICTURE AND/OR VOICE

CONSENT OF (Name)

NOTE: The information requested on this form is solicited under the authority of title 38, United States Code. The execution of this form does not authorize disclosure of the materials specified below except for the purpose(s) stated. The specified material may be used within the VA for authorized purposes, such as for education of VA personnel or for VA research activities. It may also be disclosed outside the VA as permitted by law. If the material is part of a VA system of records, it may be disclosed outside the VA as stated in the 'Routine Uses' in the "VA Privacy Act Systems of Records"published in the Federal Register. A copy of the 'Routine Uses' is available upon request to the administrative office of the VA facility involved.

You do not have to consent to have your picture or voice taken, recorded, or used. Your refusal to grant your consent will have no effect on any VA benefits to which you may be entitled.

I hereby voluntarily and without compensation authorize pictures and/or voice recording(s) to be made of *me (or of the above-named individual if the individual is legally unable to give consent)* by *(specify the name of the VA facility, newspaper, magazine, television station, etc.)*

While I am *(describe the activity, if any to be photographed or recorded)*

Audio-recorded observation only

I authorize disclosure of the picture and/or voice recording to *(specify name and address of the organization, agency, or individual(s) to whom the release is to be made)*

Dr. Christine E Bartels at the University of Minnesota - Twin Cities, College of Pharmacy, Social and Administrative Pharmacy Graduate Program

I understand that the said picture(s) and/or voice recording(s) is intended for the following purpose(s)

To identify and evaluate the decision-making processes of pharmacists making drug therapy decisions in routine health-care work.

I have read and understand the foregoing and I consent to the use of my picture and/or voice as specified for the above-described purpose(s). I further understand that no royalty, fee or other compensation of any character shall become payable to me by the United States for the use of my picture and/or voice

(SIGNATURE OF INDIVIDUAL OR OTHER LEGALLY AUTHORIZED PERSON) (DATE)

INTERVIEW AND PERMISSION OBTAINED BY (Name - title - address)

(SIGNATURE OF INTERVIEWER) (DATE)

PRODUCTION TITLE

PRODUCTION NO.

(PRINT PATIENT PLATE OR WRITE IN INDIVIDUAL'S NAME & ADDRESS

IMPORTANT: This form must always be completed prior to the making or using pictures and ½ or voice recording(s) of any individual. If that individual has any history of drug abuse, alcoholism or sickle cell anemia or infection with the human immunodeficiency virus, an additional VA Form 10-5345 is required prior to the release of any data to any source.

VA FORM MAY 1989 **10-3203**