A COMPARISON OF MAJOR FACTORS THAT AFFECT HOSPITAL FORMULARY DECISION-MAKING BY THREE GROUPS OF PRESCRIBERS

James M. Spence, B.S., M.S.

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APPROVED:

Ana D. Cleveland, Major Professor
Jiangping Chen, Committee Member
Oksana Zavalina, Committee Member
Wendy Heck, Committee Member
Yunfei Du, Interim Chair of the Department of Information Science
Kinshuk, Dean of the College of Information
Victor Prybutok, Dean of the Toulouse Graduate School

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The exponential growth in medical pharmaceuticals and related clinical trials have created a need to better understand the decision-making factors in the processes for developing hospital medication formularies. The purpose of the study was to identify, rank, and compare major factors impacting hospital formulary decision-making among three prescriber groups serving on a hospital's pharmacy and therapeutics (P&T) committee. Prescribers were selected from the University of Texas, MD Anderson Cancer Center which is a large, multi-facility, academic oncology hospital. Specifically, the prescriber groups studied were comprised of physicians, midlevel providers, and pharmacists. A self-administered online survey was disseminated to participants. Seven major hospital formulary decision-making factors were identified in the scientific literature. Study participants were asked to respond to questions about each of the hospital formulary decision-making factors and to rank the various formulary decision-making factors from the factor deemed most important to the factor deemed least important. There are five major conclusions drawn from the study including three similarities and two significant differences among the prescriber groups and factors. Similarities include: (1) the factor "pharmacy staff's evaluation of medical evidence including formulary recommendations" was ranked highest for all three prescriber groups; (2) "evaluation of medications by expert physicians" was ranked second for physicians and midlevel providers while pharmacists ranked it third; and (3) the factor, "financial impact of the treatment to the patient" was fifth in terms of hospital formulary

decision-making statement and ranking by all three prescriber groups. Two significant differences include: (1) for the hospital-formulary decision making statement, “I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making hospital medication formulary decisions,” midlevel providers considered this factor of significantly greater importance than did physicians; and (2) for the ranked hospital formulary decision-making factor, “financial impact of treatment to the institution,” pharmacists ranked this factor significantly higher than did physicians. This study contributes to a greater understanding of the three prescriber groups serving on a P&T committee. Also, the study contributes to the body of literature regarding decision-making processes in medicine and specifically factors impacting hospital formulary decision-making. Furthermore, this study has the potential to impact the operational guidelines for the P&T committee at the University of Texas, MD Anderson Cancer Center as well as other hospitals.

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TABLE OF CONTENTS

Page

LIST OF TABLES

Page

LIST OF FIGURES

Page

CHAPTER I

INTRODUCTION

Background

Medical knowledge is proliferating at an unprecedented rate within the United States. One example of this proliferation of knowledge is the published results of clinical trials for pharmaceutical agents. Clinical trials are the mechanism by which new or reformulated drugs are studied and deemed safe for the treatment of a wide range of health conditions. The U.S. Department of Health and Human Services, National Institutes of Health (2017) reports that in 2009 a total of 1,859 clinical trials posted results. By 2016 that number had grown to over 24,867 clinical trials with posted results. In other words, over 8 years the number of clinical trials reporting or posting results to the U.S. Food and Drug Administration has increased by greater than a factor of 13. With this rapid increase in the volume of clinical trials and the resulting reported data, it is virtually impossible for prescribers including physicians, midlevel providers, and pharmacists to critically appraise the results of clinical trial data.

Drug trials originate when drug manufacturers seek to study the safety and efficacy of a new or reformulated drug. Furthermore, drug monitoring activities routinely extend well beyond the conclusion of clinical trials to ensure long term safety. Most industrialized nations closely regulate human drug trails and have created governmental agencies responsible for overseeing these activities. In the United States, drug safety is under the purview of U.S. Department of Health and Human Services, Food and Drug Administration referred to as the FDA. According to the U.S. Department of Health and Human Services, Food and Drug Administration (2014):

> FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
>
> FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.
> (para. 1-2)

Drugs approved for routine use comprise a national drug formulary. This national drug formulary or list of approved drugs referred to as the "Orange Book":

> The publication Approved Drug Products with Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). (U.S. Department of Health and Human Services, Food and Drug Administration, 2015, para. 1)

Although the FDA is responsible for maintaining a list of approved drugs at the national level, many organizations develop medication formularies the meet the needs of their specific patient populations as well as to meet certain business objectives. Medication formularies are often tailored to an institution's healthcare delivery environment and the types of patients it serves. For the purpose of this study hospital medication formularies will be explored. These hospital medication formularies serve several purposes including to aid prescribers within the organization in medication selection, limit medication use to those deemed most effective for the hospital's patient population, and to manage medication costs. Scroccaro (2000) states the following:

> At the hospital level, the formulary is a list of available drugs meeting the medication needs of patients. The hospital formulary is often limited or

> closed by listing only those drugs judged by the institution as the current drugs of choice for given diseases or for a given therapeutic class. (p. 317S)

Hospital formularies require constant oversight and careful management. Hospital formularies are generally managed by a formal committee comprised of medical staff commonly referred to as the pharmacy and Therapeutics (P&T) committee.

P&T committees play an important role in managing the hospital formulary and more broadly the entire medication-use process. Tyler et al. (2008) state, “The P&T committee is responsible for managing the formulary system. The committee is composed of actively practicing physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers, and other health care professionals and staff who participate in the medication-use process” (p. 172). The authors further assert that the role of P&T committee is to support and state publicly the objectives of the hospital formulary system, objectively evaluate clinical data regarding new drugs or agents, review the use of these drugs in the institution, established standards, and to educate medical staff.

As stated previously, the sheer volume of reported clinical trial data is daunting. For prescribers to optimally treat their patients using drug therapies they are required to continually monitor and evaluate this daunting volume of drug data. Furthermore, P&T committees work to ensure that the hospital formulary remains current and reflects the safest and most effective drugs available. P&T committees must routinely evaluate new medical evidence and decide which agents will be added to the medication formulary. They must also decide if new medications should replace older drugs in light of new medical evidence and reported drug efficacy. A potential mechanism to assist P&T

committees in decision-making is the use of Evidence Based Medicine (EBM).

EBM is defined by Shortliffe, Perreault, Wiederhold, and Fagan (2001) as, “an approach to medical practice whereby the best possible evidence from the medical literature is incorporated in decision making” (p. 769). However, the term “best possible evidence” is problematic. For the purpose of this study, EBM taxonomy is one of the information organization constructs investigated. However, the determination of what medical evidence is considered “best possible” among individual prescribers, groups, and P&T committees is unclear. It is also unclear what additional factors affect hospital formulary decision-making.

EBM taxonomies provide a hierarchical categorization of the relative strength of medical evidence as it is presented in clinical trials. The categorization is based on clinical study characteristics as presented in the scientific literature. For example, multi-center systematic reviews are assigned a higher degree of credibility than would a single case report. The U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality (2002) concluded that over 100 various EBM taxonomies exist to aid prescribers in their evaluation of clinical trial evidence. However, it is unclear if prescribers and P&T committees accept the basic premise of EBM, if EBM taxonomies are deemed helpful, and what other factors impact hospital formulary decision-making.

Statement of the Problem

The exponential growth in medical pharmaceuticals and related clinical trials have created a need to better understand the decision-making factors in the processes

for developing hospital medication formularies. Furthermore, the degree of variability among the decision-making factors is not clearly understood among the various groups of prescribers.

Purpose of the Study

The purpose of the study was to identify, rank, and compare major factors impacting hospital formulary decision-making among three prescriber groups serving on a hospital P&T committee. Prescribers were selected from the University of Texas, MD Anderson Cancer Center which is a large, multi-facility, academic oncology hospital. Specifically, the prescriber groups studied were comprised of physicians, midlevel providers, and pharmacists. To participate in the study, prescribers must have served on the University of Texas, MD Anderson Cancer Center P&T committee and still on the medical staff of the hospital.

Definition of Terms

Antibiotic use review: Retrospective evaluation of antibiotic use. Usually quantitative and limited to identifying patterns of use. (Malone, Kier, & Stanovich, 2012, p. 706)

Blinding: A way of making sure that the people involved in a research study — participants, clinicians, or researchers — do not know which participants are assigned to each study group. Blinding usually is used in research studies that compare two or more types of treatment for an illness. Blinding is used to make sure that knowing the type of treatment does not affect a participant's response

to the treatment, a health care provider's behavior, or assessment of the treatment effects. (The U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, 2015a, para. 1)

Clinical expertise: means the ability to use clinical skills and past experience to rapidly identify each patient's unique health state and diagnosis, individual risks and benefits of potential interventions, and personal values and expectations. (U.S. Institute of Medicine, 2001, p. 147)

Cognition: 1. The mental activities associated with thinking, learning, and memory. 2. Any process whereby one acquires knowledge. (cognition, 2005, p. 305)

Decision-making: Decisions involve choosing a course of action among a set of options in order to meet a particular objective. (Patel, Kaufman, & Kannampallil, 2013, p. 165)

Drug evaluation monograph: The drug evaluation monograph provides a structured method to review the major features of a drug product. (Malone, Kier, & Stanovich, 2012, p. 706)

Drug use evaluation: see: Medication use evaluation

Drug use review: Retrospective evaluation to monitor medication use patterns. Usually quantitative and limited to trending. (Malone, Kier, & Stanovich, 2012, p. 706)

Evaluation: An evaluation reflects one's current appraisal of the stimulus, including whether it should be approached or avoided. (Cunningham & Zelazo, 2007, p. 97)

Evaluation of medications by expert physician(s): for the purpose of this study, the Evaluation of medication by one or more expert physicians and is characterized

by the opinion [or evaluation] without explicit critical appraisal, or based on physiology, bench research or first principles. (Phillips, Ball, Sackett, Badenoch, Straus, Haynes, & Dawes, 2009, Table 1 Row 5)

Evidence based medicine: The practice of evidence-based medicine (EBM) involves integrating individual clinical expertise with the best available external clinical evidence from systematic research. Development and application of clinical practice guidelines are tools used in EBM. (Malone, Kier, & Stanovich, 2012, p. 307)

Evidence based medicine taxonomy: taxonomies are used to rate the quality of an individual study and the strength of a recommendation based on a body of evidence. (Ebell, Siwek, Weiss, Woolf, Susman, Ewigman, & Bowman, 2004, p. 59)

Factor: A variable that is controlled or manipulated by the researcher. A categorical variable used to form the groupings of observations. (Hinkle, Wiersma, & Jurs, p. 735, 2003)

Formulary system: An ongoing process whereby a healthcare organization, through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population. (Tyler et al., 2008, p. 181)

Heuristics: A heuristic is a rule of thumb or mental shortcut that simplifies a decision. (Patel, Kaufman, & Kannampallil, 2013, p. 166)

Hospital formulary: At the hospital level, the formulary is a list of available drugs meeting

the medication needs of patients. The hospital formulary is often limited or closed by listing only those drugs judged by the institution as the current drugs of choice for given diseases or for a given therapeutic class. (Scroccaro, 2000, p. 317S)

Information behavior: how people need, seek, manage, give, and use information in different contexts. (Fisher, Erdelez, and McKechnie, p. xix)

Information quality: The perceived attributes of information that make it of value to a potential user in a specific context. Some components of quality include relevance, timeliness, accuracy, specificity, comprehensiveness, and authoritativeness (Case, 2008, p. 333)

Medication management process: planning, selection and procurement, storage, ordering [may include transcription], preparing and dispensing, administration, monitoring, evaluation (The Joint Commission on Hospital Accreditation, 2014, p. MM-1)

Medication use evaluation: The component of a health care organization's quality improvement program that should examine all aspects of medication use including prescribing, dispensing, administration, and monitoring of medication use. Prior to 1986, this function was commonly referred to as a drug use (or usage) evaluation (DUE). (Malone, Kier, & Stanovich, 2012, p. 1128)

Medication use process: The original definition of the medication use process included prescribing [or ordering], dispensing, administration, monitoring, and systems and management control … Currently, systems and management control is often not included within the description of the medication use process as it applies to

virtually all aspects of patient care. Medication acquisition, storage, distribution, and disposal may also be addressed if pertinent. (Malone, Kier, & Stanovich, 2012, pp. 704-705)

Midlevel provider: Midlevel providers can be grouped into two categories, advanced practice nurses (APNs) and physician's assistants (PA). Under the umbrella of APN are several specialties including the nurse practitioner (NP), clinical nurse specialist (CNS), certified nurse midwife, and certified nurse anesthetist. (Beach, Swischuk, & Smouse, pp. 329-330)

Pharmacist: One who is licensed to prepare and dispense drugs and compounds and is knowledgeable concerning their properties. (pharmacist, 2005, p. 1119)

pharmacy benefit manager: A pharmacy benefit manager (PBM) processes prescriptions for the groups that pay for drugs, usually insurance companies or corporations, and use their size to negotiate with drug makers and pharmacies. (Gryta, 2011, para. 2)

pharmacy and therapeutics committee: A P&T committee is responsible for managing the formulary system. It is composed of actively practicing physicians, other prescribers, pharmacists, nurses, administrators, quality-improvement managers, and other health care professionals and staff who participate in the medication-use process. Customarily, P&T committee member appointments are based on guidance from medical staff. (Tyler, Cole, May, Millares, Valentino, Vermeulen, & Wilson, 2008, p. 172)

Physician: A person skilled in the art of healing; *specifically*: one educated, clinically experienced, and licensed to practice medicine as usually distinguished from surgery. (physician, n.d., *merriam-webster's online dictionary*)

Randomization: A method of assigning participants in clinical trials into two or more groups randomly (by chance). One group receives the treatment or drug being researched, and one group receives either no treatment, a placebo (inactive substance), or another drug. Participants are assigned to a group by various methods. (The U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, 2015b, para. 1)

pharmacy staff evaluation of medical evidence including formulary recommendation: for the purpose of this study, a pharmacy staff evaluation of medical evidence including formulary recommendation is comprised of a Drug use review (DUR), Antibiotic use review (AUR), Drug use evaluation (DUE), Medication use evaluation (MUE), or Drug evaluation monograph accompanied by a hospital formulary recommendation prepared by pharmacy staff (Malone, Kier, and Stanovich, 2012)

Taxonomy: A classification, usually in a restricted subject field, that is arranged to show presumed natural relationships. (Taylor, 2004, p. 380)

Research Questions and Hypotheses

For the purpose of this study, a total of seven factors were identified from the scientific literature (Anagnostis, Wordell, Guharoy, Beckett, & Price, 2011; Evidence-Based Medicine Working Group, 1993; Kelly & Bender, 1983; Malone, Kier, and

Stanovich, 2012; Pedersen, Schneider, & Scheckelhoff, 2014; Segal & Pathak, 1988; U.S. Institute of Medicine, Committee on Quality of Health Care in America, 2001). Hospital formulary decision-making factors fall within three broad categories including individual, social, and environmental. All seven factors are briefly described in the following sections and are explained in greater detail in Chapter II.

The first factor is *individual evaluation of medical evidence*. Kelly and Bender (1983) contend that "the objective evaluation of clinical data regarding new drugs or agents requested for use in the hospital is the most important task of the P&T committee. Each member should have exceptional literature evaluation skills and respect this responsibility" (pp. 976-977). However, evaluation of medical literature can be subjective. In other words, how one prescriber evaluates medical evidence may differ from how another prescriber evaluates the same evidence. Such differences may lead to disagreement and affect hospital formulary decision-making. Recent efforts have been made to de-emphasize individual opinion in medical decision-making. The Evidence-Based Medicine Working Group (1993), a working group of the American Medical Association, states the following: "A new paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiological rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research" (p. 2420). However, it is unclear if the individual evaluation of prescribers remains influential in hospital formulary decision-making.

The second factor is *pharmacy staff evaluation of medical evidence including formulary recommendations*. To assist the P&T committee in their decisions, the

pharmacy staff within hospitals routinely prepare documentation. Such documents may include a drug use review (DUR), antibiotic use review (AUR), drug use evaluation (DUE), medication use evaluation (MUE), or drug evaluation monograph (Malone, Kier, and Stanovich, 2012). Furthermore, these formal documents may be accompanied by hospital formulary recommendations which are also prepared and presented by pharmacy staff. Formulary recommendations may include adding, removing, or changing the formulary status or restrictions associated with the medications being considered. These formal documents are provided and presented to P&T committee members during routine P&T committee meetings. The purpose of which is to aid P&T committee members in hospital formulary decision-making. Pedersen, Schneider, and Scheckelhoff (2014) explain:

> The most common sources used to develop materials for presentation at P&T committee meetings were drug information references, followed by pharmaceutical manufacturers, the Internet or PubMed, and therapeutic reviews obtained from the hospital's group purchasing organization. Less common sources included a formulary monograph service, a colleague at another hospital outside the health system, the health system's corporate office, Cochrane collaborative reviews, and wholesaler-provided therapeutic reviews. (p. 929)

Segal & Pathak (1988), state that in some cases a hospital's pharmacy department prepares materials for presentation to the P&T committee. It is unclear how such materials prepared by pharmacy staff for the purpose of augmenting P&T committee decision-making compare to the other decision-making factors.

The third factor explored is the *evaluation of medications by expert physicians*. In a study conducted by Segal and Pathak (1988) identifying factors that influence P&T committee drug evaluations, the authors find, " . . . more importance is attached to information collected by the hospital's own resources, such as the pharmacy

department's recommendation, comments of *key physicians* [emphasis added] in their own institution, and a review of good clinical studies" (p. 178). Although expert or key physicians are an indispensable part of frontline patient care. It is also possible that the evaluation of medical evidence by expert or key physicians is prone to bias or subjectivity. Kahneman and Klein (2009) state: "People, even experts, do not appear to be skilled in detecting patterns in the internal situation in order to identify the basis of their judgements. Therefore, reliance on subjective confidence may contribute to overconfidence" (p. 523). The influence of key or expert physicians either during interactions in the workplace or during P&T committee meeting discussions may be a factor affecting the hospital formulary decision-making process.

The fourth factor is the *number of patients affected* by adding, removing, or modifying a formulary medication. According to Kelly and Bender (1983) prescribers requesting the addition of a new drug to a hospital formulary should estimate the number of patients who will benefit from the new medication therapy. If the drug will not be used frequently or if it is difficult to procure, the P&T committee may decide not to add it to the hospital formulary. Therefore, the estimated number of patients who will benefit from a new or a change to an existing drug may also be a determining factor as P&T committees make formulary decisions.

The fifth factor is the *financial impact of the treatment for the institution*. According to Anagnostis, Wordell, Guharoy, Beckett, and Price (2011), "institutions assess a combination of factors including the cost per course of therapy against other formulary agents, well-designed clinical trials, and reimbursement from third-party payers if the drug is used in outpatient settings" (pp. 412-413). In addition to the

acquisition costs associated with medications, Chambers, Rane, and Neumann (2016) evaluated the impact of drug exclusion policies on affected patients. Such exclusions stem from policy or formulary changes made by insurers and pharmacy Benefits Managers (PBMs) and what medication costs they will or will not reimburse. The authors state:

> Decision makers should thus be mindful of the potential negative clinical and economic consequences of drug exclusion policies. Decision makers can help mitigate this risk by using formal cost-effectiveness analyses and budget impact models to account for all potential costs and benefits in their decisions. Drug exclusion policies should be transparent, with the evidence that informed the policy clearly communicated to patients and physicians, and implemented with a goal of maximizing continuity of patient care. (p. 530).

However, it is unclear how the financial impact of treatment for the institution ranks when compared to other hospital formulary decision-making factors.

The sixth factor considered in the study is the *financial impact of the treatment for the patient.* According to Deangelis (2016):

> Equally troubling are the enormous profits that pharmaceutical companies make on the sales of their drugs and how pharmaceutical executives determine the costs of those drugs, which must be paid by the public, either through their insurance companies or directly out of pocket (p. 30).

When P&T committees add or change medications on their hospital's formulary, committee members likely consider the out-of-pocket costs of medication therapies for patients and their families. The out-of-pocket costs for medications can become problematic. In addition, high drug prices result in ever increasing insurance premiums for consumers. Skyrocketing drug costs are of particular concern in oncology care. Ramsey, Lyman, and Bangs (2016) assert that "as oncology drug costs continue to rise and many patients experience financial distress in part owing to out-of-pocket drug costs, calls to reduce oncology drug prices are gaining public support and political

traction" (p. 425). In light of drug costs passed along to patients through insurance premiums and out-of-pocket expenses, P&T committees likely consider the costs incurred by patients when making formulary decisions.

The seventh and final factor is the *opportunity for new treatment options***.** Newly available drugs present new treatment options for prescribers. However, in some cases medical evidence may not exist for rare or complicated disease states. Instead prescribers must rely on clinical expertise. Clinical expertise is defined by the U.S. Institute of Medicine, Committee on Quality of Health Care in America (2001) as "the ability to use clinical skills and past experience to rapidly identify each patient's unique health state and diagnosis, individual risks and benefits of potential interventions, and personal values and expectations" (p. 147). In cases in which a dearth of medical evidence exists for a new drug therapy, do prescribers consider the novelty of a new drug and its potential for treatment outside of its approved indications as a factor when making hospital formulary decisions?

Research Questions and Hypotheses

Group 1: Physicians

Q1. What is the ranked order of factors that influence hospital formulary decision-making by physicians?

Hypothesis 1.1: For physicians, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 1.2: For physicians, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 1.3: For physicians, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 1.4: For physicians, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 1.5: For physicians, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 1.6: For physicians, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Group 2: Midlevel Providers

Q2. What is the ranked order of factors that influence hospital formulary decision-making by midlevel providers?

Hypothesis 2.1: For midlevel providers, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 2.2: For midlevel providers, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 2.3: For midlevel providers, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 2.4: For midlevel providers, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 2.5: For midlevel providers, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 2.6: For midlevel providers, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Group 3: Pharmacists

Q3. What is the ranked order of factors that influence hospital formulary decision-making by pharmacists?

Hypothesis 3.1: For pharmacists, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 3.2: For pharmacists, the evaluation of medications by expert physicians has a lower ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 3.3: For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 3.4: For pharmacists, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 3.5: For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 3.6: For pharmacists, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Significance of the Study

The number of clinical trials for medications is increasing at an unprecedented rate. As a consequence, prescribers find it increasingly difficult to stay abreast of new and constantly changing medical evidence. Furthermore, hospitals and hospital systems are under increasing pressure to reduce cost while at the same time improving

the quality of healthcare delivery and health outcomes. To address these issues, the vast majority of hospitals and hospital systems utilize a hospital formulary managed by a P&T committee. P&T committees are required to evaluate medications and determine which agents will be used to treat patients.

Overall, the study provides a greater understanding of the three prescriber groups comprised of physicians, midlevel providers, and pharmacists who routinely serve on P&T committees. Furthermore, the study identifies and ranks the major factors affecting hospital formulary decision-making. The study contributes to the body of literature regarding decision-making processes in medicine and specifically factors impacting hospital formulary decision-making. Furthermore, the results presented in the study have the potential to impact the operational guidelines for P&T committees.

Assumptions

Three major assumptions underlie this study: (1) the study participants selected are currently serving on or have served on the University of Texas, MD Anderson Cancer Center P&T committee; (2) the study participants provided truthful answers to the questions posed in the online surveys; (3) the study participants selected had computers and internet access in order to complete the online self-administered surveys.

Limitations

The limitation of this study is that it is focused on three distinct prescriber groups including physicians, midlevel providers, and pharmacists. The study does not

encompass hospital formulary decision-making that occurs outside P&T committees. Finally, the study focuses on a single large, academic, oncology hospital with more than 500 staffed inpatient beds.

Summary

The introductory chapter provides sections including the background of the study, statement of the problem, purpose of the study, definition of terms, research questions, hypotheses, significance of the study, assumptions, and limitations. The following chapter provides a review of the scientific literature relevant to the study.

CHAPTER II

LITERATURE REVIEW

Introduction

The chapter presents a synthesis of the scientific literature relevant to the study. The introduction and theoretical framework presented serve to contextualize and provide a rationale for the subject areas reviewed. Subject areas within the published literature include: hospital formularies, decision-making for hospital formularies, clinical trials, evidence based medicine (EBM) taxonomies, and aspects of pharmacy and therapeutics (P&T) committees.

Hospital Formularies

The hospital formulary is a list of drugs that a hospital deems cost effective, safe, and efficacious for treating its patients. Scroccaro (2000) states the following:

> At the hospital level, the formulary is a list of available drugs meeting the medication needs of patients. The hospital formulary is often limited or closed by listing only those drugs judged by the institution as the current drugs of choice for given diseases or for a given therapeutic class.
> (p. 317S)

The author goes on to describe additional activities involved in maintaining a hospital formulary. Such activities include continually monitoring adherence to the formulary, determining equivalent drugs, special acquisition and pricing programs, and the continual monitoring of new evidence resulting from clinical trials. The author goes on to state that an ongoing educational strategy for prescribers is important to ensure adherence to an institution's drug use policy including adherence to its medication formulary. It is difficult to pinpoint exactly when the widespread adoption of hospital

formularies and interest in their management occurred. However, such adoption appears to have begun in the early 1980s and continued into the early 1990s (Kelly & Bender, 1983; Rucker, 1982; Segal & Pathak, 1988; Sutters, 1990). The publications from this time period cover a wide swath of topics including the creation of hospital formularies, best practices for drug selection and exclusion, and methods for continuous formulary optimization.

Although the promises of the hospital formulary are to contain costs, improve patient safety, and increase efficiency some disadvantages exist. By the late 1990s a fervent debate was underway regarding whether hospital formularies were achieving their intended goals. Horn (1996) states:

> While "restrictive" formularies are associated with reduced drug costs in some situations, many previously conducted studies have supported our findings. These studies found such restrictions to be linked with increased use of other services, and showed that the predominant effect of formulary restrictions was to shift costs by increasing the utilization either of non-restricted drugs or of other health care services. (p. 2204)

Another publication questioning the effects of restrictive hospital formularies was authored by Levy and Cocks (1999) and published by the National Pharmaceutical Council. This report reviewed an extensive array of published literature and included 7 chapters entitled: the economics of restricting resource allocation in healthcare, integrated pharmaceutical care, formularies in manage care plans, Medicaid formularies, physician authority curtailed by formularies, and use of formularies by hospitals and other providers. The report's executive summary states:

> The general failure of formularies and other limitations to contain total costs and improve outcomes has important implications for health care policy and the design of the health care delivery and reimbursement systems of the next millennium. The reviewed literature shows that component management, in the form of restrictions on pharmaceuticals, does not result in overall savings and

> that a system-wide, population-based approach integrating all components of heath care is needed to control health care spending and maintain quality of care. (p. VII)

Levy and Cocks make a number of compelling arguments against the use of hospital formularies. However, currently hospital formularies and pharmacy and therapeutics committees comprised of medical staff to manage them have been broadly adopted across the U.S.

Pedersen, Schneider, and Scheckelhoff (2014) conducted a study on behalf of the American Society of Health-System Pharmacists (ASHP) which included responses from 414 hospitals of varying sizes based on inpatient beds. The authors state:

> Overall, 60.4% of hospitals had limited, strict formulary with tight restriction on non-formulary medication use, and 39.6% had an open formulary, with few restrictions on prescribers … Over the past three years, 47.5% of hospitals have maintained the same type of formulary; however, 41.5% of hospitals have adopted a more limited formulary, and 11.0% of hospitals have transitioned toward a more open formulary. (p. 924)

In summary, the Pederson, Schneider, and Scheckelhoff study concluded that of the hospitals surveyed all had adopted a medication formulary. Of that total 60.4% of the hospitals use a limited or strict formulary while 39.6% use an open formulary. Furthermore, over the previous three years 41.5% of hospitals surveyed had moved to a more limited formulary while only 11.0% had moved to a more open formulary.

The hospital formulary is not a static list of drugs. Instead, the hospital formulary is a dynamic list that changes frequently and requires constant monitoring. Hospital formulary management involves complex and consensus based decision-making by medical staff. Hospital formulary decision-making is a complex process involving numerous factors. Hospital formulary decision-making impacts virtually every aspect of patient care. The scientific literature related to the decision-making process for hospital

formularies and decision-making in general is described in greater detail in the following section.

Decision-Making for Hospital Formularies

Decision-Making

For the purpose of this study, two information behavior models related to task-oriented information seeking will be examined (Hansen, 2005; Leckie, Pettigrew, & Sylvain, 1996). These models serve to illustrate how task-oriented information behaviors within professional groups including healthcare professionals involve both social and individual factors. A complimentary premise is that quality information leads to "better" decision-making (Case, 2008). Finally, relevant literature from the field of Biomedical Informatics related to medical decision-making was explored (Patel, Kaufman, & Kannampallil, 2013).

Decision-making is a primary theoretical framework of Information Science. In short, Information Science theory contends that decision-making is enhanced when decision are made with quality information which is reliable, verifiable, and trusted. Tan (2001) describes ten desirable data characteristics including: "accessibility, accuracy, appropriateness, comprehensibility, comprehensiveness, consistency, relevance, reliability, timeliness, and usefulness" (p. 57, Table 3-1). Cleveland and Cleveland (2009) state:

> Information fuels healthcare endeavors. Timely and accurate information is essential at every part of the healthcare continuum from the patient to the highest level of healthcare management. The quality of the information depends on the quality of the data that generate it. (p. 47)

Patient treatment decisions are often gleaned from various datum collected from various sources and from all forms of patient encounters. These data are analyzed, synthesized, and ultimately used to inform treatment, operational, and financial decisions. In complex healthcare environments, decision-making is likely impacted by various factors including individual, collaborative, social, and environmental factors. However, it is unclear which of these factors or combinations of factors influence decision-making and to what degree.

Paisley (1968) in the third volume of the *Annual Review of Information Science and Technology* authored a chapter entitled Information Needs and Uses. The author comments on the complex factors affecting the flow of information and the importance of conceptualizing these factors:

> Shallow conceptualization is something else again. Even small projects can demonstrate awareness of the complex systems that affect the flow of information. Shallow conceptualization implies a failure to consider these factors:
>
> 1. The full array of information sources that are available.
> 2. The uses to which the information will be put.
> 3. The background, motivation, professional orientation, and other individual characteristics of the user.
> 4. The social, political, economic, and other systems that powerfully affect the user and his work.
> 5. The consequences of information use – e.g., productivity.
>
> As a result, in many studies, it is hard to glimpse a real scientist or technologist at work, under constraints and pressures, creating products, drawing upon the elaborate communication network that connects him with sources of necessary knowledge. (p. 2)

In a much later work Patel, Kaufman, and Kannampallil (2013) explain that "decision making has been an active subject of psychological inquiry since the beginning of experimental psychology" (p. 165). The authors go on to state that "decisions involve choosing a course of action among a set of options in order to meet a

particular objective" (p. 165). P&T committees are comprised of medical professionals operating within a collaborative committee structure to make medical decisions involving the hospital formulary. Individuals serving on P&T committees are likely influenced by a complex interplay of individual, social, and collaborative decision-making factors. To explore hospital formulary decision-making within the context of these factors, literature will be reviewed as it relates to task oriented information behaviors.

For the purpose of this study, an exploration of two task oriented information seeking models were undertaken. The two models explored were authored by Hansen (2005) and Leckie, Pettigrew, and Sylvain (1996). These models illustrate the processes by which individuals within certain professions, including the healthcare professions, seek information in order to fulfill an information need. It is important to note that most information behavior models are based on individual information behaviors. Such models do not account for the additional complexities of social and collaborative interactions described by Paisley (1968) and by Patel, Kaufman, and Kannampallil (2013). The notable exception is the task-oriented information behavior model developed by Hansen (2005). This model addresses social factors that impact task oriented decision-making and studied the process in healthcare environments. Furthermore, recent literature published in the field of biomedical informatics by Patel, Kaufman, and Kannampallil (2013) acknowledges the role of social and collaborative factors in medical decision-making.

Task Oriented Information Behavior

A foundational research domain within the field of Information Science is

information behavior also commonly referred to as information seeking. Case (2006) suggests that information behavior research may be divided into four categories including: “[1] information seekers by occupation (e.g., scientists, managers), [2] information seekers by role (e.g., patient or student), [3] information seekers by demographics (e.g., by age or ethnic group), [4] theories, models, and methods used to study information seekers” (p. 295).

Information seeking for the purpose of this study most closely aligns with information seeking by occupation and is task-oriented in nature. Various scientists have developed task-oriented information seeking models based on observations from studying individuals seeking information to perform various work tasks. These models were selected from observational research conducted within work environments including healthcare settings. Two such models were developed by Hansen (2005) and Leckie, Pettigrew, and Sylvain (1996).

The first model, work task information-seeking and retrieval processes, was proposed by Hansen (2005) and may be seen in Figure 1. The author suggests, “the rationale for developing a framework for work task information seeking and retrieval is grounded in the belief that IS&R [Information Seeking and Retrieval] should not be treated in isolation, but rather as embedded in a larger task context” (p. 392). Based on Hansen’s model (see: Figure 1) information-seeking originates from a high-level organizational or social information need. An information need may also originate from a lower-level situational or individual information need. According to the model, the information need culminates in a work task comprised of one or more information seeking and information retrieval tasks. The information seeking and retrieval tasks

consist of task initiation, the task process, and task completion. The result of the completed information seeking and retrieval tasks results in the completion of the larger work task. Finally, the completed work task flows back to the situational or individual context or to the higher-level organizational or social context from which the task originated.

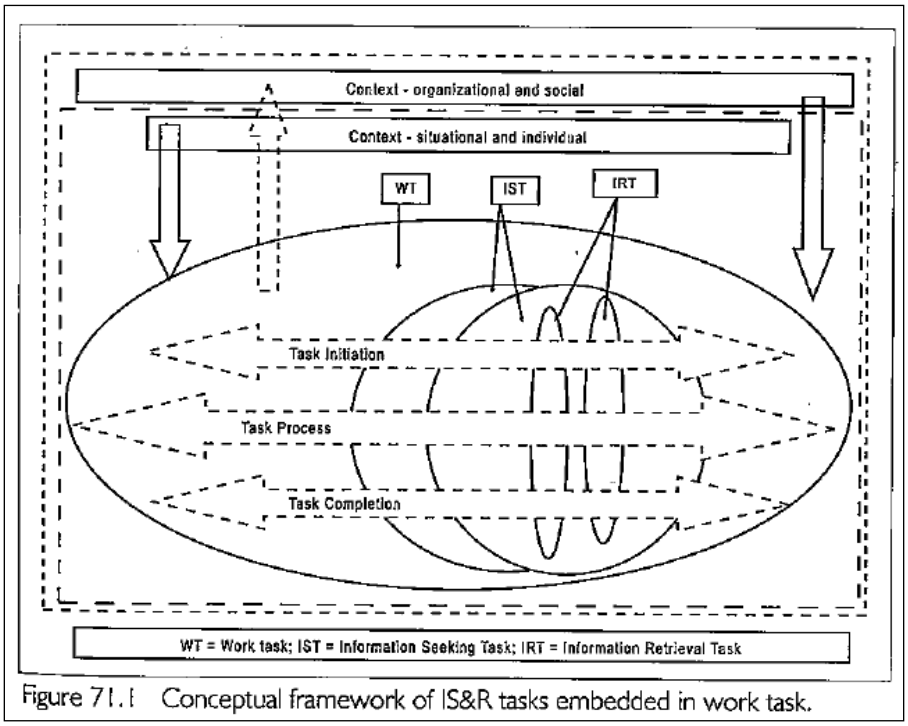

Figure 71.1 Conceptual framework of IS&R tasks embedded in work task.

Figure 1. Conceptual framework of information search and retrieval tasks embedded in work task (Hansen, 2005, p. 393).

The second and more general task oriented information seeking model is proposed by Leckie, Pettigrew, and Sylvain (1996). In this model, represented in Figure 2, information seeking tasks are associated with a specific work role. Work roles lead to a determination of what characterizes the information needed. After the characteristic of the information needed is determined the information is sought. If the outcome of the information seeking step is unsatisfactory, feedback occurs. This feedback may result

in awareness of an additional need for information with potentially different characteristics or an awareness that the required information has been obtained. Additionally, feedback may lead to additional information seeking. This cycle continues until the information acquired meets the intended outcome.

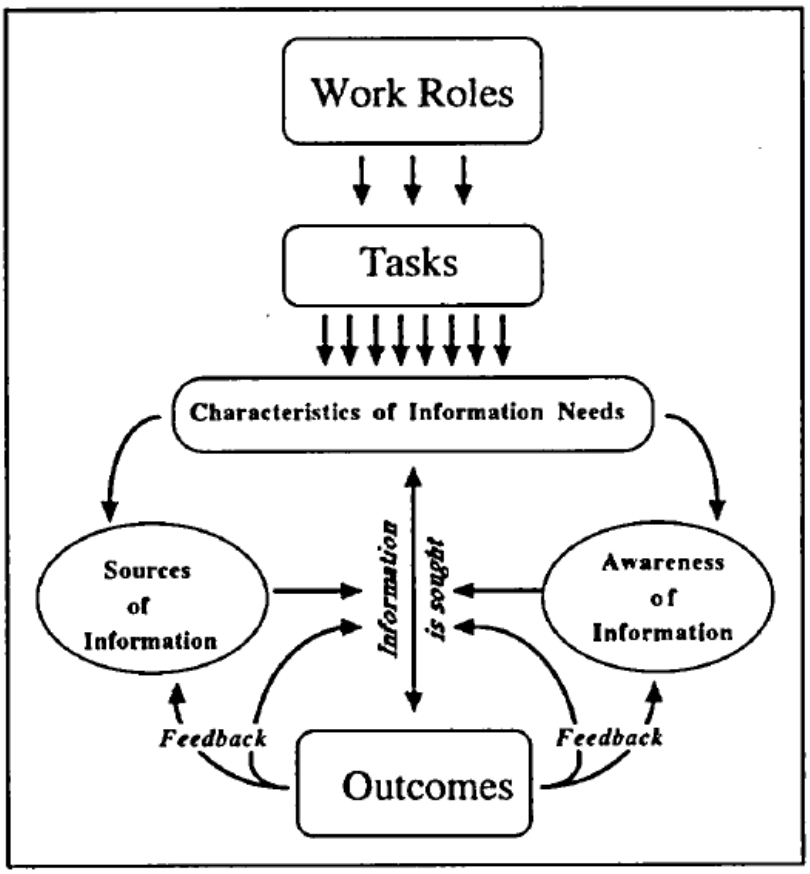

Figure 2. A model of the information seeking of professionals (Leckie, Pettigrew, & Sylvain, 1996, p. 393).

The task oriented information behavior models described provide insight into how recorded information is used to support specific tasks within a work environment. The task oriented information behavior model proposed by Hansen (2005) seems to provide the greatest degree of insight related to the task oriented decision-making activities of

P&T committees. Of the two models presented, the Hansen (2005) model accounts for the larger social context of information seeking.

Medical Decision-Making

Recent publications in the field of Biomedical Informatics expand upon the information behavior models described. Patel, Kaufman, and Kannampallil (2013) contend that traditional information-processing models may be insufficient to adequately address social and collaborative factors affecting medical decision-making. They state:

> The study of diagnostic reasoning and medical decision-making was constituted within the classical information–processing approach to cognition, which has come under criticism for its narrow focus on the rational/cognitive processes of the solitary individual. The distributed view of cognition represents a shift in the study of cognition from being the sole property of the individual to being "stretched" across groups, material artifacts and cultures … Distributed cognition has two central points of inquiry, one that emphasizes the social and collaborative nature of cognition (e.g., doctors, nurses, and other personnel jointly contributing to a decision process) and one that characterizes the mediating effects of technology or other artifacts on cognition. (p. 151)

Recent research indicates that additional social and collaborative factors are associated with medical decision-making. It seems appropriate, based on the collaborative nature of P&T committees, to expand the scope of hospital formulary decision-making research to include social and collaborative factors. In the following section, the hospital formulary is described as well as the various decisions that P&T committee members are required to make in order to appropriately manage the hospital formulary.

Hospital Formulary Management Considerations

Scroccaro (2000) states, "The hospital formulary is not simply a list of drugs; it reflects the policy of the institution with regard to the rational use of drugs" (p. 317S).

According the author, in a closed formulary system, the policy for managing the hospital formulary and for formulary decision-making should include consideration of six factors.

First, the author states that formulary considerations involve the selection of drugs that are cost-effective. This involves close examination of the efficacy of drugs in the same therapeutic class. For example, if two drugs are used to treat the same health condition and both are effective, the hospital may choose the less expensive of the two drugs for formulary inclusion. This serves to reduce the costs of drugs for both the hospital and the patient.

A second factor is to determine the benefit of drugs based also in relation to the cost of the drug. Scroccaro (2000) states:

> Many new and often more expensive drugs offer real advantages only in selected patients. For example, most newly marketed antibiotics may provide an advantage only to those patients who do not respond to the older product; also, the safety profile of a new drug may offer an advantage for those patients who do not tolerate, or may have risk factor for, the adverse events associated with the less expensive drug. (p. 318S)

As the author states, although a new or reformulated drug may be more expensive, it may prove more effective for some patients with certain conditions. Although one medication may be preferred to treat a certain condition, if the patient has an allergy to the drug, it is more desirable to use an alternative and potentially more expensive drug to avoid an allergic reaction. Additionally, P&T committees may choose to place restrictions on the use of specific drugs to ensure that they are only used under certain circumstances. For example, suppose that two drugs are available to treat the same condition and one medication is preferred and the more expensive medication is non-preferred. For a certain subset of patients meeting certain clinical criteria, the non-preferred drug is better tolerated or more effective. In these cases, it is appropriate to

treat the patient using the non-preferred and more expensive medication. In this scenario, monitoring drug use becomes important to ensure that the preferred medication is used in the majority of situations and non-preferred medication is only when certain pre-defined clinical criteria are met.

Another factor considered in hospital formulary management are drug which are considered equivalent. In this case, if two drugs are found to be equivalent in terms of "efficacy, tolerability, and compliance" (p. 319S). In these cases, the P&T committee may deem that an automatic interchange or substitution may be used. The less expensive of the equivalent drugs is chosen for addition to the formulary. In this scenario, if a medication order is written for a drug and an equivalent drug is to be substituted, an automatic substation for the preferred equivalent drug will occur.

Another consideration of P&T committees is what Scroccaro refers to as "special acquisition and pricing programs" (p. 319s). In these cases, hospitals may choose to negotiate pricing directly with a drug manufacturer or drug wholesaler. Price reductions may be warranted if a hospital uses a high volume of a particular drug and contractually agrees to only acquire that drug from a single manufacturer or wholesaler. Such agreements allow the hospital to acquire selected drugs at reduced cost.

The sixth and final consideration affecting hospital formulary management according to Scroccaro (2000) is participation in investigational drug services. The author contends "participation by the hospital pharmacy department in conducting clinical trials allows the staff to acquire a wider knowledge about the use of drugs and offers the patients an opportunity to benefit from innovative therapies" (p. 319S). The author states that participation in clinical trials through investigational drug services

reduces costs for the hospital and its patients. Investigational drugs are generally provided at no cost to hospitals or patients by the pharmaceutical company conducting the drug trial. As the author states, such investigational pharmacy services provide valuable benefits to both the hospital's patients and to its medical staff.

In addition to considering the cost of medications for hospitals, patients, and their families are affected by rising insurance premiums and out-of-pocket expenses. Deangelis (2016) states,

> equally troubling are the enormous profits that pharmaceutical companies make on the sales of their drugs and how pharmaceutical executives determine the costs of those drugs, which must be paid by the public, either through their insurance companies or directly out of pocket. (p. 30)

Chambers, Rane, and Neumann (2016) performed a study reporting how drug exclusion policies for hospitals, pharmacy benefits managers (PBMs), and governmental payers. Such drug exclusion policies affect costs including, "drug expenditures, and costs related to physician office visits, hospitalizations, laboratory tests, and so on" (p. 32). The authors conclude:

> Faced with the introduction of innovative technology and rising costs, insurers and PBMs will continue to search for ways to make their drug designs more efficient. Payers may be prepared to accept some degree of disruption to patient care. Removing drugs from formularies for which equally effective, but less expensive, alternatives are available is an attractive option. Our study suggests that, for the most part, these policies have been successful in reducing costs while minimizing the impact of patient care, although the exceptions provide room for caution. (p. 530)

For oncology care outpatient prescription medications can be quite expensive resulting in tremendous out-of-pocket expenses for patients. Ramsey, Lyman, and Bangs (2016) provide a scenario, "for example, a 50% copay for lanalidomide (Revlimid; Celgene) for myelodysplastic syndrome would translate to an out-of-pocket cost of nearly $5000 per

month, eliminating it as an option for most patients" (p. 425). If drugs selected for the hospital formulary place an excessive financial burden on patients, the patient may request less expensive treatment options or simply discontinue medication therapy altogether.

All formulary considerations described necessitate the evaluation of new drugs in terms of their associated costs for hospitals and patients. Furthermore, for new and reformulated medications the medication's efficacy must be evaluated based on the results of clinical trials. Evaluation of clinical trial data requires an in-depth understanding of the various forms of clinical trial studies and resulting data also known as medical evidence. Evaluation of medical evidence involves a complex evaluation of the reported outcomes of clinical trials. Howick et al. (2011a) explains that published clinical trial results may take many forms including: mechanistic reasoning reports, case studies, cohort studies, randomized trials, or systematic reviews. A description of the clinical trial process is presented in the subsequent section.

Clinical Trials

In most cases, new chemical or biological agents are studied in laboratory animals. Once animal studies conclude and the agent or drug is deemed appropriate for human use, it must then undergo rigorous clinical trials in humans. Hollon and Komaromy (2000) explain:

> Before a new drug, surgical procedure, or therapy becomes available to the public, it must go through a rigorous testing process and be evaluated by the US Food and Drug Administration (FDA). This testing process consists of a series of clinical trials that are designed to test the safety and usefulness of the new drug compared to the current standard treatment. (p. 1)

As stated, the clinical trial process starts by registering the drug with the FDA. The drug then enters the first of three clinical trial phases. Each clinical trial phase serves to ensure that the drug is both safe and effective. The three phases of clinical trials are described in the subsequent paragraphs.

According to Hollon and Komaromy (2000) Phase I clinical trials are designed to study the safety of a drug, examine how the drug is metabolized and excreted, and to identify potential side effects. Phase I trials usually have a small number of trial participants rarely more than 100. Healthy individuals are usually selected for participation in phase I clinical trials and are preferred since their metabolic functions are normal. The selection of healthy individuals serves to insure the trial is not affected by study participants with preexisting conditions or who have undergone previous medical treatment which may alter the metabolism of the chemical agent. Another reason for selecting healthy participants is they are more likely to recover from any unexpected side effects produced by the chemical agent.

The authors go on to state that exceptions exist for the selection of individuals for phase I trials. One such exception is for drugs used to treat cancer also known as oncology drugs. Oncology drugs are often cytotoxic. Cytotoxic drugs are known to be harmful to healthy human cells. In clinical trials involving cytotoxic drugs, testing them in healthy patients would prove harmful to the study participants due to the known cytotoxic characteristics of the chemical agent. Therefore, participant selection for phase I trials involving cytotoxic oncology drugs are often comprised of study participants who have failed to respond to previous treatment regimens. Eisenhauer, O'Dwyer, Christian, and Humphrey (2000) contend that little has changed over the past

20 years regarding the manner in which Phase I clinical trials are conducted with regard to oncology drugs. The authors state:

> Phase I trial design in cancer therapeutics has changed little in 20 years. Unlike most therapeutic areas, there are two goals in cancer trials: precise definition of an optimal (recommended phase II) dose and safe treatment of the individual patient at doses that are close to therapeutic. (p. 684)

The authors contented that oncology drugs should be studied at dose levels that are close to therapeutic levels. The authors further assert that finding an optimal methodology for dose escalation in phase I oncology trials well help ensure "new anticancer agents are not to suffer undue delays in phase I evaluation" (p. 684). After a pharmaceutical agent passes phase I, it moves on to phase II trials.

Hollon and Komaromy (2000) state, "once a drug passes the safety tests of phase I, it advances to a phase II trial with up to 200 participants" (p. 3). The authors further explain that phase II trials are used to learn more about the drug's efficacy, safety, side effects, and most importantly to optimize dosing. Another important distinction of phase II trials is that during phase II patients are studied who are suffering from the condition the drug is formulated to treat. In oncology care, Zelen (2003) states that "the goal is to determine if the therapy has any beneficial effect. The patient population in phase II trials sometimes is composed of newly diagnosed patients with advanced cancer" (para. 3). Once a drug completes phase II trials, it then progresses to phase III.

Zelen explains that that Phase III trials "are always comparative trials; one or more experimental therapies are compared with the best standard therapy or competitive therapies. They tend to have many more participants than Phase II trials, and they often require patients from many cooperating hospitals" (para. 4). Hollon and

Komaromy (2000) explain that phase III trials may consist of hundreds or even thousands of study participants. The authors assert that the main purpose of phase III trials is to make a definitive determination of a drug's efficacy and to get "an extensive look at the drug's side effects" (p. 4). There are numerous variations in the manner phase III clinical trials are designed.

One of the most common phase III trial designs is known as a double-blinded, controlled, and randomized trial. The U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality (2015a) defines blinding as:

> A way of making sure that the people involved in a research study — participants, clinicians, or researchers — do not know which participants are assigned to each study group. Blinding usually is used in research studies that compare two or more types of treatment for an illness. Blinding is used to make sure that knowing the type of treatment does not affect a participant's response to the treatment, a health care provider's behavior, or assessment of the treatment effects. (para. 1)

Another important concept related to study design is randomization. Randomization within the context of clinical trials is also defined by The U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality (2015b) as follows:

> A method of assigning participants in clinical trials into two or more groups randomly (by chance). One group receives the treatment or drug being researched, and one group receives either no treatment, a placebo (inactive substance), or another drug. Participants are assigned to a group by various methods. (para. 1)

Using the complimentary concepts of blinding and randomization together is known as a double-blinded randomized controlled clinical trial. Double-blinding means that neither the treating prescribers nor study participants know which patients are receiving the pharmaceutical agent being studied or which are receiving a placebo or inactive agent. The group receiving a placebo is referred to as the control group. Hollon and

Komaromy (2000) state a, “double-blind [clinical trial] means that neither the doctor nor the trial participant knows whether the participant is receiving the experimental treatment” (p. 5). According to the authors, this type of clinical trial design serves to eliminate study bias in two ways. First, by ensuring that study participants are unaware of their participation in a control group or the group actually receiving the medication. Secondly, “they prevent doctors from acting on preconceived notions they may have about whether or not the drug works” (p. 5). The authors go on to assert that other types of clinical trials exist including open, factorial, crossover, and orphan drug trials. However, these clinical trial designs are used less often.

Once all phases of a clinical trial end an application for approval accompanied by the clinical trial data are submitted to the FDA. If the FDA deems a drug to be both safe and effective, the drug is approved. Approval of a drug allows the pharmaceutical manufacturer to market the drug to prescribers and to the general public. If the FDA remains uncertain of a drug’s safety or efficacy, it may request additional data before making a final determination. However, if the FDA is unconvinced of the drug’s safety or efficacy based on the results of clinical trials, the application will be rejected. The reported or published results of clinical trials are referred to as medical evidence.

As stated in the introduction of Chapter I, the sheer volume of clinical trial or medical evidence being reported is daunting. It is virtually impossible for physicians, midlevel providers, and pharmacists to remain abreast of all reported medical evidence. With such a rapid increase in clinical trial volume, it is virtually impossible for prescribers such as physicians, midlevel providers, and pharmacists to critically appraise the results of clinical trials. Furthermore, a high degree of variation exists in the manner clinical

trials are conducted and the results reported in the published medical literature. In some cases, a dearth of medical evidence may exist. For example, for extremely rare health conditions limited or no medical evidence exists because the number of individuals affected by the health condition is small. In these cases, healthcare providers must rely on clinical judgment and expert opinion to treat such conditions.

It seems obvious that the evaluation of medical evidence is important in hospital formulary decision-making. However, as stated previously, it is virtually impossible for healthcare provides to evaluate the enormous volumes of medical evidence being produced by clinical trials. As a result, several evidence based medicine taxonomies have been developed by various entities. These taxonomies serve to rank and summarize medical evidence resulting from clinical trials to aid healthcare providers in their evaluation of such medical evidence. Evidence based medicine taxonomies are described in the following section.

Evidence Based Medicine (EBM) Taxonomies

The practice of using medical evidence from the scientific literature to inform patient care decisions is known as evidence-based medicine (EBM). EBM is defined by Shortliffe and Cimino (2006) as, “an approach to medical practice whereby the best possible evidence from the medical literature is incorporated in decision-making. Generally, such evidence is derived from controlled clinical trials” (p. 939). However, the phrase “the best possible evidence from the literature” is problematic. To determine “the best possible evidence” among the various reported results and among varying healthcare providers is problematic. Problems arise when individual prescribers must

evaluate vast quantities of scientific literature and determine what constitutes “the best possible evidence.”

As stated previously, medical evidence is being produced quickly and in large volumes. Furthermore, if medical evidence is to be acted upon by prescribers, it must first be critically evaluated, adopted, and subsequently translated into routine practice. Healthcare environments are notoriously complex and impacted by numerous factors which tend to slow the dissemination of medical evidence into mainstream medical practice. The U.S. Institute of Medicine, Committee on Quality of Health Care in America (2001) asserts:

> Substantial investments have been made in clinical research and development over the last 30 years, resulting in an enormous increase in the medical knowledge base and the availability of many drugs and devices. Unfortunately, Americans are not reaping the full benefit of these investments. The lag between the discovery of more efficacious forms of treatment as their incorporation into routine patient care is unnecessarily long, in the range of about 15 to 20 years. Even then, adherence of clinical practice to the evidence is highly uneven. (p. 145)

Supporting the Institute of Medicine’s assertion, Balas and Boren (2000) state, “studies suggest that it takes an average of 17 years for research evidence to reach clinical practice” (p. 66). Furthermore, clinical evidence is often unstructured and not in a form that is readily usable or actionable by healthcare providers. The authors further contend that “actionable knowledge representation is needed to make a difference in the process and outcome of patient care. Unfortunately, the current publication standards often do not provide information in the necessary structure and cannot be converted into it” (p. 68). One proposed solution to speed the rate of dissemination and adoption of medical evidence into clinical practice is to develop systems for ranking clinical evidence.

EBM taxonomies and other codification mechanisms have been developed to aid prescribers in their efforts to evaluate medical evidence. Taylor (2004) defines the term taxonomy as, “a classification, usually in a restricted subject field that is arranged to show presumed natural relationships” (p. 380). This definition certainly applies to EBM taxonomies. EBM taxonomies are restricted to the subject of published medical evidence and show presumed relationships between various forms of published medical evidence. In other words, EBM taxonomies serve to categorize medical evidence based upon certain clinical trial characteristics. In virtually all EBM taxonomies, certain types of reported medical evidence are deemed to provide a stronger or higher level of medical evidence than others. For example, study results from a multi-center controlled double-blinded randomized trial are considered a higher level of evidence than published results from a single case from a single hospital.

The U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality (2002) “summarized more than 100 sources of information on systems for assessing study quality and strength of evidence for systematic reviews and technology assessments” (p. 7). It would be impossible to describe all sources which rank medical evidence. However, two EBM taxonomies will be explored as exemplars of EBM taxonomies. The two EBM taxonomies described are the Oxford Center for Evidence Based Medicine (OCEBM) taxonomy and the strength of recommendation taxonomy (SORT). As the name suggests, the OCEBM was developed by the Oxford Center in the United Kingdom and the SORT is currently used in the U.S. to summarize medical evidence published in various family practice and primary care journals.

The OCEBM 2011 levels of evidence developed by Howick et al. (2011b) classifies the various types of medical evidence into 5 primary levels. The levels are assigned numeral values from 1 to 5. The highest or strongest level of evidence is assigned a level 1 and the lowest is assigned a level of 5. Level 1 is characterized by published systematic reviews with various forms of validation. Level 2 is characterized by an individual cross-sectional study with consistently applied reference standards, or studies that present a "dramatic effect" (column 2). Level 3 is characterized by non-randomized or studies without consistently applied reference standards. Level 4 represents case-studies or a case-series with poor or non-independent reference standards. The lowest level in the OCEBM taxonomy is Level 5, consists of "mechanism-based reasoning" (column 6).

The SORT is an EBM taxonomy used by U.S. medical journals specifically in the specialties of family practice and primary care. Ebell et al. (2004) explain that the SORT resulted from a collaboration between family medicine and primary care journal editors. The purpose was to develop a standardized manner for ranking medical evidence among the various publications. The authors state:

> Therefore, the editors of the US family medicine and primary care journals (ie, American Family physician, Family Medicine, Journal of Family Practice, Journal of the American Board of Family Practice, and BMJ-USA) and the Family Practice Inquiries Network (FPIN) came together to develop a united taxonomy for the strength of recommendations based on a body of evidence. The new taxonomy should include the following attributes: (1) be uniform in most family medicine journals and electronic databases; (2) allow authors to evaluate the strength of recommendation of a body of evidence; (3) allow authors to rate the level of evidence for an individual study; (4) be comprehensive and allow authors to evaluate studies of screening, diagnosis, therapy, prevention, and prognosis; (5) be easy to use and not too time-consuming for authors, reviewers, and editors who may be content experts but not experts in critical appraisal or clinical epidemiology; and (6) be straightforward enough that primary care physicians can readily integrate the recommendations into daily practice. (pp. 59-60).

The authors go on to explain that the SORT was designed, at least in part, for ease of use. The authors explain, “we also were committed to creating a grading scale that could be applied by authors with varying degrees of expertise in evidence-based medicine and clinical epidemiology and interpreted by physicians with little or no formal training in these areas” (p. 61).

The SORT algorithm assigns a combination of a letter “A”, “B”, or “C” (p. 62, Fig. 1) for its strength of recommendation followed by an integer value. A value of “A” is assigned for a recommendation based on consistent and good quality patient-oriented evidence, “B” is assigned for a recommendation based on inconsistent or limited quality patient-oriented evidence, and “C” is a recommendation based on consensus, usual practice, opinion, disease-oriented, evidence, and case series for studies of diagnosis, treatment, prevention, or screening. The strength of recommendation letter assignment is followed a numerical level ranking from 1 to 3 based on study quality. Level 1 studies are deemed good quality patient-oriented evidence, Level 2 is for limited quality patient-oriented evidence, and Level 3 is for other types of medical evidence.

Both the OCEBM taxonomy and SORT are attempts to standardize the manner in which medical evidence is summarized the goal of which is to assist with the assessment of the large volume and complexity of medical evidence. Although such attempts are laudable, no single EBM taxonomy or ranking system for medical evidence has emerged.

Schaafsma, Hulshof, van Dijk, and Verbeek (2004) conducted a study on behalf of the Finnish Institute of Occupational Health, to evaluate physician attitudes toward EBM. The study did not include other prescriber groups such as midlevel providers, or

pharmacists. The study used a questionnaire sent to a random sample of 144 registered physicians with an average response rate of 54%. Their conclusions related to EBM were:

> Three-quarters of the respondents indicated that they were interested in evidence-based medicine, but only one-third actually applied evidence-based medicine methods when possible … personal interest in evidence-based medicine strongly correlated with the expectation that evidence-based medicine would become more important for occupation health in the future. (p. 329)

In conclusion, EBM is an important component of medical decision-making not only as it relates to decision-making by hospital P&T committees but in many facets of patient care. However, no standardized taxonomy or method for evaluating and ranking medical evidence has emerged.

Aspects of Pharmacy and Therapeutics (P&T) Committees

P&T Committees Definition and Composition

As stated previously, the majority of large hospitals and hospital systems rely upon P&T committees to develop and manage their medication formulary as well as various aspects of the medication use process. P&T committees are usually comprised of licensed and credentialed physicians, midlevel providers, and pharmacists. P&T committees may also involve administrative staff responsible for ordering and procuring drugs and other decision-makers within the organization. In most cases, P&T committees formalize decisions by a simple majority vote representing the majority consensus of voting committee members.

Kelly and Bender (1983) define a P&T committee as a “medical staff committee … charged with maintaining the formulary system” (p. 976). A complimentary definition

is put forward by Tyler, Cole, May, Millares, Valentino, Vermeulen, and Wilson (2008) who state:

> A P&T committee is responsible for managing the formulary system. It is composed of actively practicing physicians, other prescribers, pharmacists, nurses, administrators, quality-improvement managers, and other health care professionals and staff who participate in the medication-use process. Customarily, P&T committee member appointments are based on guidance from medical staff. (p. 172)

A review of the composition of P&T committees was conducted by Duran-Garcia, Santos-Ramos, Puigventos-Latorre, and Ortega (2011). The authors analyzed publications from 1997 to 2009 from five western English and Spanish speaking countries including the U.S. The authors found that "pharmacy and therapeutics committees were present in 90% of the hospitals in four of the five countries examined" (p. 475). Individuals represented on P&T committees varied but included: physicians, midlevel providers, pharmacists, nurses, and hospital administrators. The authors further surmised that P&T committee composition variation may be attributed to differences in hospital size and organizational structure.

P&T Committees' Role

The role of P&T committees was studied by Segal and Pathak (1988). The authors conducted their study using a combination of both face-to-face interviews and surveys of P&T committee members from five hospitals located in Ohio. Each of the hospitals utilized a closed medication formulary and managed their medication formulary using a P&T committee structure. Twenty-three P&T committee members were interviewed and surveyed. The medical staff included both physicians and pharmacists. The study participants were asked to rank the perceived importance of

various drug-related information elements which they deemed important. Nine elements were identified by the physicians and pharmacists. These 9 elements were then ranked using a scale from 0 to 6 with 0 being least important and 6 being most important. Following is the ranked list of medication-related factors from the most important 1, to the least important 9:

> 1) Therapeutic advantage ... over existing drugs already on the formulary 2) pharmacokinetic features of the drug 3) profile of adverse effects compared to existing drugs 4) justification for adding the drug by the requesting physician 5) review of good clinical studies of the drug in patients similar to patients in your hospital 6) costs relative to other drugs already in the formulary 7) recommendation by the pharmacy department to either add or not add the drug to the formulary 8) the drug's acquisition cost and 9) dosage regimen advantage over existing formulary drugs.
> (p. 176, Table 2)

By closely examining the list of nine factors perceived by study participants as the most important, the item listed fifth on the list is "review of good clinical studies of the drug in patients similar to patients in your hospital" (p. 176, Table 2).

As P&T committees make medication formulary decisions, it is unclear if medical evidence or the practice of EBM is deemed important. It is also unclear if EMB taxonomies or classifications serve to ease or augment hospital formulary decision-making. Furthermore, other factors may impact medical formulary decision-making including individual professional opinion and the professional opinion of colleagues.

Theoretical Framework

According to Patel, Kaufman, and Kannampallil (2013), decision-making is impacted by individual, social, political, economic, information artifacts, and system factors. The conceptualization of these factors in research has been a long-standing

research area within the field of Information Science. A notable example can be found in the third volume of the *Annual Review of Information Science and Technology*. Paisley (1968) warns against "shallow conceptualization" of information use within complex systems:

> Shallow conceptualization is something else again. Even small projects can demonstrate awareness of the complex systems that affect the flow of information. Shallow conceptualization implies a failure to consider these factors:
>
> 1. The full array of information sources that are available.
> 2. The uses to which the information will be put.
> 3. The background, motivation, professional orientation, and other individual characteristics of the user.
> 4. The social, political, economic, and other systems that powerfully affect the user and his work.
> 5. The consequences of information use – e.g., productivity.
>
> As a result, in many studies, it is hard to glimpse a real scientist or technologist at work, under constraints and pressures, creating products, drawing upon the elaborate communication network that connects him with sources of necessary knowledge. (p. 2)

The author concludes that numerous factors must be considered to adequately conceptualize information use within broader system contexts. In addition to individual factors, research into information behavior must also consider social, political, economic, and the impact of other systems. Later research in the field of Information Science led to the development of two notable task-oriented information seeking models (Hansen, 2005; Leckie, Pettigrew, & Sylvain, 1996). These models were explained in greater detail in the section entitled Task Oriented Information Behavior. These models illustrate the processes by which individuals within certain professional groups including healthcare providers seek, retrieve, and use recorded information. Furthermore, the Hansen (2005) model represents information behavior which occurs within the broader contexts of social and collaborative environments.

Another important theoretical framework in Information Science is that decision-making is enhanced when decisions are based on reliable, verifiable, and trusted information. Various scholars have identified characteristics attributed to data and information quality. Tan (2001) describes major desirable data characteristics which include: “accessibility, accuracy, appropriateness, comprehensibility, comprehensiveness, consistency, relevance, reliability, timeliness, and usefulness” (p. 57, Table 3-1). Similarly, Case (2008) defines information quality as “the perceived attributes of information that make it of value to a potential user in a specific context. Some components of quality include relevance, timeliness, accuracy, specificity, comprehensiveness, and authoritativeness” (p. 333). Finally, Cleveland and Cleveland (2009) state, “it should be remembered that accurate, timely, and appropriate information enhances the potential of good decision making but does not guarantee it. The final decision is the responsibility of humans” (p. 48). A complementary framework proposed by Patel, Kaufman, and Kannampallil (2013) states that cognition or reasoning in collaborative environments is not relegated to individuals. This theoretical framework contends that cognition and reasoning in complex environments extends beyond the individual to groups, material artifacts, and cultures:

> The distributed view of cognition represents a shift in the study of cognition from being the sole property of the individual to being “stretched” across groups, material artifacts, and cultures. This viewpoint is gaining increase acceptance in cognitive science, HCI [Human Computer Interaction], and human factors research …Distributed cognition has two central points of inquiry, one that emphasizes the social and collaborative nature of cognition (e.g., doctors, nurses, and other personnel jointly contributing to a decision process) and one that characterizes the mediating effects of technology or other artifacts on cognition. (p. 151)

This “distributed view” of cognition recognizes that in addition to individual factors, social, collaborative, and material artifacts are also factors affecting decision-making in complex systems.

Summary

This chapter presents a review of the literature related to the study in the areas of hospital formularies, decision-making for hospital formularies, aspects of pharmacy and therapeutics (P&T) committees, medical decision-making, and a description of the theoretical framework for the study. Chapter III describes the research methodology used for this study.

CHAPTER III

METHODOLOGY

Introduction

This chapter describes the methods and procedures used to conduct the study. Specifically, this chapter includes the following sections: Introduction, Research Questions and Hypotheses, Theoretical Framework, Research Design, Methods, Validity and Reliability, Selection of Participants, Institutional Review Board (IRB) Processes, Pilot Study, Data Collection and Analysis, Online Self-Administered Survey, and the Summary.

Research Questions and Hypotheses

Group 1: Physicians

Q1. What is the ranked order of factors that influence hospital formulary decision-making by physicians?

Hypothesis 1.1: For physicians, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 1.2: For physicians, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 1.3: For physicians, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 1.4: For physicians, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 1.5: For physicians, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 1.6: For physicians, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Group 2: Midlevel Providers

Q2. What is the ranked order of factors that influence hospital formulary decision-making by midlevel providers?

Hypothesis 2.1: For midlevel providers, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 2.2: For midlevel providers, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 2.3: For midlevel providers, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 2.4: For midlevel providers, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 2.5: For midlevel providers, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 2.6: For midlevel providers, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Group 3: Pharmacists

Q3. What is the ranked order of factors that influence hospital formulary decision-making by pharmacists?

Hypothesis 3.1: For pharmacists, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 3.2: For pharmacists, the evaluation of medications by expert physicians has a lower ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 3.3: For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 3.4: For pharmacists, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 3.5: For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 3.6: For pharmacists, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Theoretical Framework

Decision-making is impacted by numerous factors including individual, social, political, economic, system, and those associated with information artifacts. Conceptualization of these factors has been a long- standing research area within the field of information science. Paisley (1968) concludes that to properly conceptualize information use within complex systems, numerous factors must be considered. Later research in the field of Information Science led to the development of two notable task-oriented information seeking models (Hansen, 2005; Leckie, Pettigrew, & Sylvain, 1996). Furthermore, these task-oriented models illustrate the complexity of information

seeking within the broader contexts of social and collaborative environments. Both models are described in detail in Chapter II.

Another important theoretical framework in information science is that the decision-making process is enhanced when decisions are based on reliable, verifiable, and trusted information. Various scholars have identified characteristics attributed to data and information quality. Tan (2001) describes major desirable data characteristics including: “accessibility, accuracy, appropriateness, comprehensibility, comprehensiveness, consistency, relevance, reliability, timeliness, and usefulness” (p. 57, Table 3-1). Similarly, Case (2008) defines information quality as “the perceived attributes of information that make it of value to a potential user in a specific context. Some components of quality include relevance, timeliness, accuracy, specificity, comprehensiveness, and authoritativeness” (p. 333). Finally, Cleveland and Cleveland (2009) state, “it should be remembered that accurate, timely, and appropriate information enhances the potential of good decision making but does not guarantee it. The final decision is the responsibility of humans” (p. 48).

A complementary and more contemporary framework proposed by Patel, Kaufman, and Kannampallil (2013) states that cognition or reasoning in collaborative environments is not relegated to individuals. This theoretical framework contends that cognition and reasoning in complex environments, such as healthcare environments, extends beyond the individual. This “distributed view” of cognition proposes that reasoning and ultimately decision-making extends beyond the individual to groups, cultures, and material artifacts.

Research Design

A survey also referred to as a questionnaire was administered to address the research questions and hypotheses stated. According to Bernard (2006), questionnaires are a form of structured interview and have been used in social science research for decades. In recent years, the use of online survey software has become more commonplace. The author describes three common methods for administering surveys to study participants including: "(1) personal, face-to-face interviews, (2) *self-administered* [emphasis added] questionnaires, and (3) telephone interviews. All three of these methods can be either assisted by, or fully automated with, computers" (p. 252). For the purpose of this study, self-administered surveys were conducted. All study participants were asked to complete an online version of the survey represented in Appendix E. An email was sent to study participants explaining the study and asking for their participation this email is represented in Appendix D. Furthermore, the email included a link or uniform resource locator (URL) which allowed the participants to access and complete the online survey. The online survey instrument represented in Appendix E was developed using Qualtics© (2017) online survey software.

Methods

As stated previously, the survey was administered using Qualtrics© (2017) online survey software. According to the Qualtrics© website, the software allows researchers to create surveys which may include over 100 question types including Likert scale questions as described by Bernard (2006). The software facilitates reporting and some functionality for online analyses of survey response and participation rates. Additionally,

the software allows the survey administrator to export survey data. Exporting data allows the researcher to perform additional statistical analyses in software such as SPSS© (2017).

One round of online surveys was conducted. Study participants were asked to complete all online survey questions as well as rank the various hospital formulary decision-making factors. The survey questions were based on the enumerated research questions and hypotheses. After participants responded to individual questions related to each of the hospital formulary decision-making factors on a 5-point Likert scale, they were also asked to rank the factors from 1 being the most important to 7 being the least important. A complete representation of the survey is included in Appendix E.

Validity and Reliability

Bernard (2006) states, "*validity* [emphasis added] refers to the accuracy and trustworthiness of instruments, data, and findings in research. Nothing in research is more important than validity" (p. 53). Subsequently, the author states that "*reliability* [emphasis added] refers to whether or not you get the same answer by using an instrument to measure something more than once" (p. 54). For the purpose of this study, an assumption is being made that the University of Texas, MD Anderson Cancer Center P&T committee members both current and past are a representative sample of hospital formulary decision-makers. It is further assumed that these licensed healthcare providers exhibit decision-making characteristics as they exist in the professional, social, and collaborative environment of a P&T committee.

Selection of Participants

The Department of Medication Management and Finance (MM&F) within the University of Texas, MD Anderson Cancer Center's Division of pharmacy is responsible for managing the composition and ongoing organizational activities of the P&T committee. MM&F departmental staff are responsible for ensuring that the committee's medical staff composition adheres to appropriate numbers of physicians, midlevel providers / advanced practice providers, and pharmacists based on the P&T committee charter. MM&F staff are responsible for various aspects of P&T committee activities including: maintaining membership rosters, preparing meeting agendas, keeping records of meeting attendance, preparing meeting minutes, keeping historical records of decisions made by the committee, and operationalizing committee decisions. Furthermore, MM&F staff ensure the hospital's electronic systems appropriately reflect the hospital's formulary, formulary restrictions, and decisions made by the P&T committee. As stated previously, the P&T committee is a medical staff committee that is physician led. The committee is both chaired and co-chaired by physicians currently on the hospital's medical staff.

The hospital's credentialing process ensures that healthcare providers serving on the medical staff at the University of Texas, MD Anderson Cancer Center are practicing with valid professional credentials and appropriate licensure. Study participants must belong to one of following licensed healthcare provider groups including: 1) physicians, 2) midlevel providers / advanced practice providers, or 3) pharmacists. Participants were identified from the University of Texas, MD Anderson Cancer Center P&T committee fiscal year rosters from 2007 to 2018. To participate in the study,

participants must currently serve or previously served as voting members of the University of Texas, MD Anderson Cancer Center P&T committee. P&T committee rosters were obtained from the division of pharmacy's department of MM&F. P&T committee service ensures participants can appropriately respond to the hospital decision-making survey questions posed to them. A total of 65 prescribers met the study criteria comprised of 50 physicians, 9 pharmacists, and 6 midlevel providers / advanced practice providers.

Selection of Physicians

Physicians asked to participate in the study were selected from both the current P&T committee roster and previous rosters. Physicians invited to participate must serve on the medical staff at the University of Texas, MD Anderson Cancer Center during the time the survey was administered. Fifty (50) physicians met the selection criteria.

Selection of Midlevel Providers

Midlevel providers asked to participate in the study were selected from both the current P&T committee roster and previous rosters. Midlevel providers invited to participate must serve on the medical staff at the University of Texas, MD Anderson Cancer Center during the time the survey was administered. Six (6) midlevel providers / advanced practice providers met the selection criteria.

Selection of Pharmacists

Pharmacists asked to participate in the study were selected from both the current

P&T committee roster and previous rosters. Pharmacists invited to participate must serve on the medical staff at the University of Texas, MD Anderson Cancer Center during the time the survey was administered. Nine (9) pharmacists met the selection criteria.

Institutional Review Board (IRB) Processes

This study followed both the University of North Texas and the University of Texas, MD Anderson Cancer Center guidelines for research. Appropriate documentation was submitted to the institutional review boards (IRBs) of both institutions. Upon formal approval by both institutions included in Appendix A and B respectively, the study was conducted. No modification requests were submitted to the IRBs for changes to the research protocol.

Pilot Study

A pilot study was conducted and included one physician, one midlevel provider, and one pharmacist. The purpose of the pilot study was to determine if any questions posed in the online survey required clarification and to ensure the validity and reliability of the survey. Based on feedback from the pilot study, a clarification of the prescriber role of “midlevel provider” was made to include a more contemporary and inclusive title of “advanced practice provider.” In the end, both titles were included for consistency resulting in “midlevel provider/advanced practice provider.”

Data Collection and Analysis

A single survey was sent electronically to each study participant meeting the criteria beginning on November 1, 2017. Specifically, the survey was administered and tracked using Qualtrics© (2017) online survey software. The survey is represented in table form in Appendix E. The online survey was transmitted by an email containing a URL to all physicians, midlevel providers, and pharmacists meeting the selection criteria. A number of follow up emails were sent requesting participation. After an acceptable response rate was achieved for each prescriber group the survey concluded on Monday, December 18, 2017. The time period was extended past its original two-week estimated duration to improve upon initial low response rates after two weeks.

Participants were coded when the data were exported to SPSS© (2017) software to ensure confidentiality. The results from the survey included in this work include no individually identifying data elements. Survey results were analyzed using the various reports and statistical analysis functionality available from the Qualtics© (2017) and SPSS© (2017) software. The reports were used to determine survey response rates from each provider category and to obtain certain descriptive statistics. SPSS© was also used to perform additional analyses including inferential statistics. Specifically, Kruskal-Wallis H Tests were performed to determine if statistically significant differences between the three prescriber groups from the data obtained in Parts II and III of the online survey.

Online Self-Administered Survey

Appendix E contains an exact representation of the questions asked of the

participants by way of the online self-administered survey. As stated previously, the survey was administered using the Qualtics© (2017) software. In Part I, the survey contains questions related to the background of the participants, Part II contains independent statements related to each of the identified hospital formulary decision-making factors, Part III asks participants to rank the various decision-making factors, and Part IV provides an opportunity for participants to express additional factors or other information considered when making hospital formulary decisions.

Summary

This chapter provides an overview of the qualitative research design for a comparison of major factors that affect hospital formulary decision-making by three groups of prescribers. The design of the study includes questions related to each factor impacting hospital formulary decision-making factors as well as a ranking of decision-making factors by each participant. The results are included in Chapter IV as well as summarized in the conclusion of the study provided in Chapter V.

CHAPTER IV

RESULTS

Introduction

This chapter presents the results of the study which collected data from the P&T committee of a large multi-facility oncology hospital. The chapter contains a description of the data collected from the survey and subsequently relates the results of the study to the research questions and hypotheses.

The purpose of the study was to identify, rank, and compare major factors impacting hospital formulary decision-making among three prescriber groups serving on a hospital P&T committee. Prescribers were selected from the University of Texas, MD Anderson Cancer Center which is a large, multi-facility, academic oncology hospital. Specifically, the prescriber groups studied were comprised of physicians, midlevel providers / advanced practice providers, and pharmacists. To participate in the study, prescribers must have served on the University of Texas, MD Anderson Cancer Center P&T committee and still on the medical staff of the hospital.

A total of 65 prescribers were identified who met the study criteria. The participant email, included in Appendix D, was transmitted to all 65 eligible prescribers with a link to the online survey. An initial email was sent to eligible study participants on November 1, 2017 inviting them to participate in the study. After reminder emails were sent, it was determined that collection of survey data would conclude on December 19, 2017. The 65 eligible participants were comprised of 50 physicians, 6 midlevel providers, and 9 pharmacists. Upon completion of survey data collection, 16 of 50 eligible physicians responded resulting in a 32.0% response rate for physicians. All 6

midlevel / advanced practice providers responded achieving a 100.0% response rate for this category of prescriber. Finally, 8 pharmacists of the eligible 9 participated producing an 88.9% response rate for pharmacists. In total, 30 prescribers responded of the eligible 65 resulting in a total overall response rate of 46.2%.

The online self-administered surveys comprised four parts. Part I included demographic questions regarding the participant's age, gender, months and years as a licensed healthcare provider, months and years as a licensed healthcare provider at the University of Texas, MD Anderson Cancer Center, prescribing role, current service on the P&T committee, and all previous fiscal years of service on the committee. In Part II of the survey, 7 statements were presented. Each statement applied to one of the seven identified decision-making factors. Participants were asked to rate their level of agreement or disagreement based on a 5-point Likert scale. Part III of the survey asked prescribers to rank the 7 decision-making factors in relation to one another with a "1" for the most important factor to a "7" representing the least important factor. Part IV of the survey asked participants to provide, by entering textual responses, any additional factors or information considered when making formulary decisions. Finally, participants were asked if they would like a summary of the study results. If study results were requested, the participant was asked to supply their name and email address.

The research questions and related hypotheses for each prescriber groups including physicians, midlevel providers / advanced practice providers, and pharmacists are:

Group 1: Physicians

Research Question 1: What is the ranked order of factors that influence hospital formulary decision-making by physicians?

Hypothesis 1.1: For physicians, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 1.2: For physicians, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 1.3: For physicians, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 1.4: For physicians, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 1.5: For physicians, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 1.6: For physicians, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Group 2: Midlevel Providers

Research Question 2: What is the ranked order of factors that influence hospital formulary decision-making by midlevel providers?

Hypothesis 2.1: For midlevel providers, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 2.2: For midlevel providers, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 2.3: For midlevel providers, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 2.4: For midlevel providers, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 2.5: For midlevel providers, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 2.6: For midlevel providers, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Group 3: Pharmacists

Research Question 3: What is the ranked order of factors that influence hospital formulary decision-making by pharmacists?

Hypothesis 3.1: For pharmacists, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.

Hypothesis 3.2: For pharmacists, the evaluation of medications by expert physicians has a lower ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.

Hypothesis 3.3: For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.

Hypothesis 3.4: For pharmacists, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.

Hypothesis 3.5: For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.

Hypothesis 3.6: For pharmacists, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.

Survey – Part I

In Part I of the online self-administered survey, the prescribers provided demographic information. Table 1 provides an overview of the demographics of the prescribers in terms of age, gender, years as a licensed healthcare provider, years as a licensed healthcare provider at the University of Texas, MD Anderson Cancer Center, prescribing role, current membership status on the P&T committee, and any previous years of service on the P&T committee. To summarize prescriber age range, of the 30 participants 11 prescribers range in age from 35 to 44 years and 10 from 45 to 54 years. Therefore, most of the prescribers 21 total are between the ages of 35 and 54 years. Of physicians 8 (50%) are between the ages of 35 and 44, 4 (25.0%) are between the ages of 45 and 54, 1 (6.3%) is between the ages of 55 and 64, 2 (12.5%) are between the ages of 65 and 74, and 1 (6.3%) is greater than 75 years of age. For midlevel providers, 1 (16.7%) is between the ages of 35 and 44 years, 2 (33.3%) are between the ages of 45 and 54, 2 (33.3%) are between the ages of 55 and 64, and 1 (16.7%) is between the ages of 65 and 74. For pharmacists, 2 (25.0%) are between the ages of 35 and 44, 4 (50.0%) are between the ages of 45 and 54, and 2 (25.0%) are between the ages of 55 and 64.

In terms of gender composition of physicians 11 (68.8%) were male, and 5 (31.3%) were female. For midlevel providers 2 (33.3%) were male and 4 (66.7%) were female. For pharmacists 4 (50.0%) were male, and 4 (50.0%) were female. For all providers, 17 (56.7%) males participated compared to 13 (43.3%) females.

Table 1

Demographic Characteristics Frequencies and Percentages (n=30)

Demographic Characteristic		f	%
Age	35-44	11	36.7
	45-54	10	33.3
	55-64	5	16.7
	65-74	3	10.0
	75 or older	1	3.3
Gender	Male	17	56.7
	Female	13	43.3
Years As a Licensed Healthcare Provider	5-9	3	10.0
	10-14	4	13.3
	15-19	9	30.0
	20-24	5	16.7
	25-29	2	6.7
	30-34	3	10.0
	35-39	1	3.3
	40-44	2	6.7
	45-49	1	3.3
Years As a Licensed Healthcare Provider at MD Anderson Cancer Center	0-4	3	10.0
	5-9	5	16.7
	10-14	11	36.7
	15-19	2	6.7
	20-24	2	6.7
	25-29	2	6.7
	30-34	2	6.7
	35-39	2	6.7
	40-44	1	3.3
Prescribing Role	physician	16	53.3
	midlevel provider/advanced practice provider	6	20.0
	pharmacist	8	26.7
Current Member of P&T committee	Yes	21	70.0
	No	9	30.0
Previous Years Serving on P&T committee	Fiscal Year 2017 (9/1/2016 – 8/31/2017)	20	66.7
	Fiscal Year 2016 (9/1/2015 – 8/31/2016)	20	66.7
	Fiscal Year 2015 (9/1/2014 – 8/31/2015)	21	70.0

(table continues)

Demographic Characteristic		f	%
Previous Years Serving on P&T committee *(cont.)*	Fiscal Year 2014 (9/1/2013 – 8/31/2014)	15	50.0
	Fiscal Year 2013 (9/1/2012 – 8/31/2013)	13	43.3
	Fiscal Year 2012 (9/1/2011 – 8/31/2012)	15	50.0
	Fiscal Year 2011 (9/1/2010 – 8/31/2011)	14	46.7
	Fiscal Year 2010 (9/1/2009 – 8/31/2010)	13	43.3
	Fiscal Year 2009 (9/1/2008 – 8/31/2009)	11	36.7
	Fiscal Year 2008 (9/1/2007 – 8/31/2008)	9	30.0
	Fiscal Year 2007 (9/1/2006 – 8/31/2007)	8	26.7

Note. f = frequency; % = percentage (of total).

A review of the participants' years as licensed healthcare providers was performed. These data include the timeframe from obtaining a professional license and including any subsequent residencies for all three prescribing groups studied. Refer to Table 1. For physicians 2 (12.5%) have been professionally licensed from 5 to 9 years, 3 (18.8%) for 10 to 14 years, 5 (31.3%) for 15 to 19 years, 1 (6.25%) for 20 to 24 years, 1 (6.25%) for 25 to 29 years, 1 (6.25%) from 30 to 34 years, 2 (12.5%) from 40 to 44 years, and 1 (6.25%) from 45 to 49 years. For midlevel providers, 1 (16.7%) has been professionally licensed for 5 to 9 years, 1 (16.7%) for 10 to 14 years, 1 (16.7%) for 15 to 19 years, and 3 (50.0%) for 20 to 24 years. For pharmacists, 3 (37.5%) have been licensed from 15 to 19 years, 1 (12.5%) for 20 to 24 years, 1 (12.5%) for 25 to 29 years, 2 (25.0%) from 30 to 34 years, and 1 (12.5%) for 35 to 39 years. For all prescribers (n=30) a total of 3 (10.0%) have been professionally licensed from 5 to 9 years, 4 (13.3%) for 10 to 14 years, 9 (30.0%) for 15 to 19 years, 5 (16.7%) for 20 to 24 years, 2 (6.7%) for 25 to 29 years, 3 (10.0%) from 30 to 34 years, 1 (3.3%) from 35 to 39 years, 2 (6.7%) from 40 to 44 years, and 1 (3.3%) from 45 to 49 years.

The next demographic question was to determine how long participants had served as a licensed healthcare provider at the University of Texas, MD Anderson

Cancer Center. For physicians 2 (12.5%) have been licensed healthcare providers at the University of Texas, MD Anderson Center for 0 to 4 years, 3 (18.8%) for 5 to 9 years, 6 (37.5%) for 10 to 14 years, 2 (12.5%) for 15 to 19 years, 1 (6.3%) for 30 to 34 years, 1 (6.3%) for 35 to 39 years, and 1 (6.3%) for 40 to 44 years. For midlevel providers having served as licensed healthcare providers at the University of Texas, MD Anderson Cancer Center 1 (16.7%) for 5 to 9 years, 3 (50.0%) for 10 to 14 years, 1 (16.7%) for 20 to 24 years, and 1 (16.7%) for 25 to 29 years. For pharmacists 1 (12.5%) has been a licensed healthcare provider at the University of Texas, MD Anderson Center for 0 to 4 years, 1 (12.5%) for 5 to 9 years, 2 (25.0%) for 10 to 14 years, 1 (12.5%) for 20 to 24 years, 1 (12.5%) for 25 to 29 years, 1 (12.5%) for 30 to 34 years, and 1 (12.5%) for 35 to 39 years. For all providers 3 (10.0%) have been licensed healthcare providers at the University of Texas, MD Anderson Center for 0 to 4 years, 5 (16.7%) for 5 to 9 years, 11 (36.7%) for 10 to 14 years, 2 (6.7%) for 15 to 19 years, 2 (6.7%) for 20 to 24 years, 2 (6.7%) for 25 to 29 years, 2 (6.7%) for 30 to 34 years, 2 (6.7%) for 35 to 39 years, and 1 (3.3%) for 40 to 44 years.

Next participants were asked to indicate their prescribing role at the University of Texas, MD Anderson Cancer Center. Of the 30 participants, 16 (53.3%) were physicians, 8 (26.7%) pharmacists, and 6 (20.0%) midlevel providers. Prescribing role was used in subsequent sections to address the various research questions and hypotheses and identify similarities and differences concerning the three groups of prescribers.

The final demographic question was to ascertain the current service and previous years of service on the institution's P&T committee. Participants indicating service on

the current fiscal year's (9/1/2017 to 8/31/2018) P&T committee was 21 (70%) while 9 (30%) of those who responded are not serving on the fiscal year 2018 committee. The next highest frequencies indicated by the participants on the P&T committee was for fiscal year 2015 (9/1/2014 – 8/31/2015) with 21 (70.0%), and two fiscal years with identical frequencies fiscal year 2017 (9/1/2016 – 8/31/2017) and fiscal year 2016 (9/1/2015 – 8/31/2016) both with 20 (66.7%).

Table 2 displays the average years of service by prescriber group. The prescriber group with the highest average years of service on the P&T committee was pharmacists with an average of 7.0 (SD=4.6) years, followed by midlevel providers with 4.8 (SD=2.9) years, and physicians with 4.6 (SD=3.2) years. The standard deviation among the prescriber groups regarding their years of service indicates that pharmacists had the highest standard deviation of 4.6 years, physicians with 3.2 years, and midlevel providers with 2.9 years. Across all prescriber groups the standard deviation was 3.6 years.

Table 2

Prescriber Group Years of Service Means and Standard Deviations

Prescriber Group	n	M	SD
Physician	16	4.6	3.2
Midlevel provider	6	4.8	2.9
Pharmacist	8	7.0	4.6
Total	30	5.3	3.6

Note. n = number of prescribers by group; M = mean; SD = standard deviation.

Survey – Part II

In Part II of the survey, the prescribers responded to seven statements related to each of the identified hospital formulary decision-making factors. Each of the statements were formed to illicit a level of agreement measured on a 5-point Likert scale. A response of *strongly agree* was assigned a value of 5, *agree* a value of 4, *neutral* a value of 3, *disagree* a value of 2, and *strongly disagree* a value of 1. SPSS© (2017) statistical software was used to compute the frequency, mean, and standard deviation values for each statement and the associated agreement score by prescriber group and for all prescribers in aggregate.

Table 3 presents the frequencies of responses to each of the decision-making statements by prescriber group followed by the aggregate scores for all prescribers. In response to the statement, "I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions." A total of 3 (18.8%) of physicians strongly agreed, 9 (56.3%) agreed, 2 (12.5%) were neutral, none selected disagree, and 2 (12.5%) strongly disagreed. For midlevel providers, none strongly agreed, a total of 5 (83.3%) of prescribers agreed, 1 (16.7%) was neutral, none selected disagree, and none strongly disagreed. For pharmacists, 1 (12.5%) strongly agreed, a total of 2 (25.0%) prescribers agreed, 1 (12.5%) was neutral, 3 (37.5%) selected disagree, and 1 (12.5%) strongly disagreed. For all prescribers, a total of 4 (13.3%) of prescribers strongly agreed, 16 (53.3%) agreed, 4 (13.3%) were neutral, 3 (10%) selected disagree, and 3 (10.0%) strongly disagreed.

Table 3

Prescriber Group Frequencies of Responses for Decision-Making Statements (Physicians n=*16, Midlevel Providers* n=*6, Pharmacists* n=*8, All Prescribers* n=*30)*

	5 - Strongly Agree	4-Agree	3-Neutral	2-Disagree	1-Strongly Disagree
I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions.					
Physician	3	9	2	0	2
Midlevel provider	0	5	1	0	0
Pharmacist	1	2	1	3	1
All prescribers	4	16	4	3	3
I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions.					
Physician	7	8	1	0	0
Midlevel provider	5	1	0	0	0
Pharmacist	4	3	0	0	1
All prescribers	16	12	1	0	1
I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions.					
Physician	6	8	2	0	0
Midlevel provider	0	6	0	0	0
Pharmacist	1	3	3	1	0
All prescribers	7	17	5	1	0
I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decision.					
Physician	2	9	1	4	0
Midlevel provider	3	3	0	0	0
Pharmacist	0	5	2	1	0
All prescribers	5	17	3	5	0
I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions.					
Physician	2	9	2	3	0
Midlevel provider	1	5	0	0	0
Pharmacist	4	3	1	0	0
All prescribers	7	17	3	3	0

(table continues)

	5 - Strongly Agree	4-Agree	3-Neutral	2-Disagree	1-Strongly Disagree
I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions.					
Physician	6	6	1	3	0
Midlevel provider	2	3	0	1	0
Pharmacist	3	1	0	4	0
All prescribers	11	10	1	8	0
In my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication.					
Physician	4	9	2	1	0
Midlevel provider	2	4	0	0	0
Pharmacist	3	4	1	0	0
All prescribers	9	17	3	1	0

In response to the statement, “I rely upon the pharmacy staff’s evaluation of medical evidence including formulary recommendations (e.g. drug monograph, medication use evaluation, etc.) to make hospital medication formulary decisions.” By reviewing the frequencies in Table 3, physicians indicating they strongly agreed was 7 (43.8%), those who agreed were 8 (50.0%), 1 (6.3%) was neutral, and 0 (0.0%) disagreed or strongly disagreed with this statement. Midlevel providers indicating they strongly agreed was 5 (83.3%), those who agreed was 1 (16.7%), none were neutral, none disagreed, and none strongly disagreed with this statement. By reviewing the frequencies in Table 3, pharmacists indicating they strongly agreed was 4 (50.0%), 3 (37.5%) agreed, none were neutral, none disagreed, and 1 (12.5%) strongly disagreed with this statement. Among all prescribers indicating they strongly agreed was 16 (53.3%), those who agreed were 12 (40.0%), 1 (3.3%) was neutral, and none disagreed, and 1 (3.3%) strongly disagreed with this statement.

For the hospital formulary decision-making statement, “I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions.” 6 (37.5%) physicians strongly agreed with the statement while 8 (50.0%) agreed with the statement. A total of 2 (12.5%) indicated a response of neutral and no physicians disagreed or strongly disagreed with the statement. For this hospital formulary decision-making statement, all 6 (100.0%) midlevel providers agreed with the statement. No other agreement levels were selected. For pharmacists, 1 (12.5%) pharmacist strongly agreed, 3 (37.5%) agreed, 3 (37.5%) were neutral, 1 (12.5%) agreed, and none strongly disagreed with the statement. For all prescribers 7 (23.3%) prescribers strongly agreed with the statement while 17 (56.7%) agreed with the statement. A total of 5 (16.7%) indicated a response of neutral, 1 (3.3%) prescriber disagreed, and none strongly disagreed with the statement.

In response to the statement, “I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decision.” A total of 2 (12.5%) physicians strongly agreed, 9 (56.3%) agreed, 1 (6.3%) was neutral, 4 (25.0%) disagreed, and none strongly disagreed with the statement. For midlevel providers, a total of 3 (50.0%) strongly agreed, 3 (50.0%) agreed, none were neutral, none disagreed, and none strongly disagreed with the statement. For pharmacists, 0 (0.0%) pharmacists strongly agreed with the statement, 5 (62.5%) agreed, 2 (25.0%) were neutral, 1 (12.5%) disagreed, and none strongly disagreed with the statement. Among all prescribers, A total of 5 (16.7%) prescribers strongly agreed, 17 (56.7%) agreed, 3 (10.0%) were neutral, 5 (16.7%) disagreed, and none strongly disagreed with the statement.

For the next statement, “I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions.” A total of 2 (12.5%) of physicians strongly agreed, 9 (56.3%) agreed, 2 (12.5%) were neutral, and 3 (18.8%) disagreed with the statement. For midlevel providers, a total of 1 (16.7%) strongly agreed, 5 (83.3%) agreed, none were neutral, none disagreed, and none strongly disagreed with the statement. For the pharmacists response, a total of 4 (50.0%) pharmacists strongly agreed, 3 (37.5%) agreed, 1 (12.5%) was neutral, none disagreed, and none strongly disagreed with the statement. Among all prescribers, a total of 7 (23.3%) of prescribers strongly agreed, 17 (56.7%) agreed, 3 (10.0%) were neutral, and 3 (10.0%) disagreed, and none strongly disagreed with the statement.

The next statement in Table 3 is, “I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions.” A total 6 (37.5%) physicians strongly agreed, 6 (37.5%) agreed, 1 (6.3%) was neutral, while 3 (18.8%) disagreed with the statement, and no physicians strongly disagreed. For midlevel providers, a total 2 (33.3%) strongly agreed, 3 (50.0%) agreed, 0 (0.0%) were neutral, while 1 (16.7%) disagreed, and no midlevel providers strongly disagreed. Regarding pharmacists, a total of 3 (37.5%) strongly agreed, 1 (12.5%) agreed, 0 (0.0%) were neutral, while 4 (50.0%) disagreed with the statement, and no pharmacists strongly disagreed. Among all prescribers, 11 (36.7%) prescribers strongly agreed, 10 (33.3%) agreed, 1 (3.3%) was neutral, while 8 (26.7%) disagreed with the statement, and no prescribers strongly disagreed.

For the final statement, “In my role as a medication prescriber, I consider the

opportunity for new treatment options when adding or expanding the use of a hospital formulary medication." For physicians total of 4 (25.0%) indicated strong agreement, 9 (56.3%) indicated agreement, 2 (12.5%) indicated a response of neutral, 1 (6.3%) disagreed, and none strongly disagreed. For midlevel providers, a total of 2 (33.3%) indicated strong agreement, 4 (66.7%) indicated agreement, none indicated a response of neutral, none disagreed, and none strongly disagreed. For pharmacists, a total of 3 (37.5%) indicated strong agreement, 4 (50.0%) indicated agreement, 1 (12.5%) indicated a response of neutral, none disagreed, and none strongly disagreed. Among all prescribers, a total of 9 (30.0%) indicated strong agreement, 17 (56.7%) indicated agreement, 3 (10.0%) indicated a response of neutral, 1 (3.3%) disagreed, and none strongly disagreed.

In the following sections, the research questions and hypotheses are address by the three prescriber groups studied.

Group 1: Physician

Q1: What is the ranked order of factor that influence hospital formulary decision-making?

Table 4 indicates the total number of physician participants is 16 (n=16). For physicians, the highest level of agreement with an average of 4.38 (SD=0.62) was in response to the statement, "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions." By reviewing the frequencies in Table 3, physicians indicating they strongly agreed was 7 (43.8%), those

who agreed were 8 (50.0%), 1 (6.3%) was neutral, and 0 (0.0%) disagreed or strongly disagreed with this statement.

The second highest level of agreement with an average of 4.25 (SD=0.68) was in response to the statement “I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions.” For this hospital formulary decision-making statement, 6 (37.5%) physicians strongly agreed with the statement while 8 (50.0%) agreed with the statement. Therefore, 14 (87.5%) of physicians either strongly agreed or agreed with this statement. A total of 2 (12.5%) indicated a response of neutral and no physicians disagreed or strongly disagreed with the statement.

The third highest level of agreement with a mean of 4.00 (SD=0.82) was in response to the statement, “In my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication.” A total of 4 (25.0%) indicated strong agreement, 9 (56.3%) indicated agreement, 2 (12.5%) indicated a response of neutral, 1 (6.3%) disagreed, and none strongly disagreed.

The fourth highest level of agreement with a mean of 3.94 (SD=1.12) was related to the statement “I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions.” A total 6 (37.5%) physicians strongly agreed, 6 (37.5%) agreed, 1 (6.3%) was neutral, while 3 (18.8%) disagreed with the statement, and no physicians strongly disagreed.

The fifth level of agreement with a mean of 3.69 (SD=1.20) was in response to the statement “I rely upon my individual evaluation of medical evidence to make hospital

medication formulary decisions." A total of 3 (18.8%) of prescribers strongly agreed, 9 (56.3%) agreed, 2 (12.5%) were neutral, none selected disagree, and 2 (12.5%) strongly disagreed.

The sixth level of agreement with a mean of 3.63 (SD=0.96) was to the statement "I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions." A total of 2 (12.5%) of physicians strongly agreed, 9 (56.3%) agreed, 2 (12.5%) were neutral, and 3 (18.8%) disagreed with the statement.

The seventh statement with the lowest level of agreement at 3.56 (SD=1.03) was to the statement, "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decision." A total of 2 (12.5%) physicians strongly agreed, 9 (56.3%) agreed, 1 (6.3%) was neutral, 4 (25.0%) disagreed, and none strongly disagreed with the statement.

Physician Hypotheses

> Hypothesis 1.1: "For physicians, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians."

By reviewing of the mean value order presented in Table 4, the statement "I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions" was fifth in terms of agreement score with a mean of 3.69 (SD=1.20). In response to the statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions," this statement was

ranked second based on the Likert scale with a mean of 4.25 (SD=0.68). Therefore, this hypothesis is accepted.

> Hypothesis 1.2: "The evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations."

By reviewing of the sorted mean values in Table 4, the statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions," this statement was ranked second based on the Likert scale with a mean of 4.25 (SD=0.68). However, in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," this statement was first in terms of agreement score with a mean of 4.38 (SD=0.62). This hypothesis for physicians is rejected.

> Hypothesis 1.3: "For physicians, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected."

By reviewing the sorted mean scores in Table 4, in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," this statement was first in terms of agreement score with a mean of 4.38 (SD=0.62). The statement "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making hospital medication formulary decisions" was ranked last or seventh with a mean score of 3.26 (SD=1.03). Consequently, this hypothesis is accepted.

Hypothesis 1.4: "For physicians, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution."

Upon evaluation of the sorted mean scores in Table 4, in response to the statement, "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," for physicians this statement was first in terms of agreement score with a mean of 4.38 (SD=0.62). For the corresponding statement, "I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions," the statement was ranked sixth with a mean agreement score of 3.63 (SD=0.96). As a result, this hypothesis is accepted.

Hypothesis 1.5: "For physicians, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient."

The sorted mean scores in Table 4, indicate in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," this statement was first in terms of agreement score with a mean of 4.38 (SD=0.62). The statement "I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions" has a ranking of fourth with a mean of 3.94 (SD=1.12). Therefore, this hypothesis is accepted.

Hypothesis 1.6: “For physicians, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.”

By reviewing of the mean value order presented in Table 4, the statement “I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions” was fifth in terms of agreement score with a mean of 3.69 (SD=1.20). In response to the statement, “in my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication,” this statement was ranked third based on the Likert scale with a mean of 4.00 (SD=0.82). Therefore, this hypothesis is rejected for physicians.

Group 2: Midlevel Provider

Q2: What is the ranked order of factors that influence hospital formulary decision-making by midlevel providers?”

For midlevel providers (n=6) as seen in Table 4, indicates the highest level of agreement with an average of 4.83 (SD=0.41) was in response to the statement, “I rely upon the pharmacy staff’s evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions.” By reviewing the frequencies in Table 3, midlevel providers indicating they strongly agreed was 5 (83.3%), those who agreed was 1 (16.7%), none were neutral, and none disagreed or strongly disagreed with this statement.

The statement with the second highest level of agreement at 4.50 (SD=0.55) was to the statement, “I consider the number of patients affected by adding, removing, or

modifying a drug on the formulary when making a hospital medication formulary decision." A total of 3 (50.0%) of midlevel providers strongly agreed, 3 (50.0%) agreed, none were neutral, none disagreed, and none strongly disagreed with the statement.

The third highest level of agreement 4.33 (SD=0.52) was with the statement, "In my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication." A total of 2 (33.3%) indicated strong agreement, 4 (66.7%) indicated agreement, none indicated a response of neutral, none disagreed, and none strongly disagreed.

The fourth level of agreement with a mean of 4.17 (SD=0.41) was to the statement "I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions." A total of 1 (16.7%) midlevel provider strongly agreed, 5 (83.3%) agreed, none were neutral, none disagreed, and none strongly disagreed with the statement.

The fifth level of agreement with an average of 4.00 (SD=0.00) was in response to the statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions." For this hospital formulary decision-making statement, all 6 (100.0%) agreed with the statement. No other agreement levels were selected.

The sixth level of agreement is tied with a mean of 4.00 (SD=1.10) to the previous statement. This mean value is related to the statement "I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions." A total 2 (33.3%) midlevel

providers strongly agreed, 3 (50.0%) agreed, 0 (0.0%) were neutral, while 1 (16.7%) disagreed, and no midlevel providers strongly disagreed.

The seventh and lowest level of agreement for midlevel providers with a mean of 3.83 (SD=0.41) was in response to the statement "I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions." For this statement, none strongly agreed, a total of 5 (83.3%) of prescribers agreed, 1 (16.7%) was neutral, none selected disagree, and none strongly disagreed.

Midlevel Provider Hypotheses

> Hypothesis 2.1: "For midlevel providers, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians."

By reviewing of the mean value order presented in Table 4, the statement "I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions" was last or seventh in terms of agreement score with a mean of 3.83 (SD=0.41). In response to the statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions," this statement was ranked fifth based on the Likert scale with a mean of 4.00 (SD=0.00). Therefore, this hypothesis is accepted for midlevel providers.

> Hypothesis 2.2: "For midlevel providers, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations."

By reviewing of the sorted mean values in Table 4, the statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions," this statement was ranked fifth based on the Likert scale with a mean of 4.00

(SD=0.00). However, in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," this statement was first in terms of agreement score with a mean of 4.83 (SD=0.41). This hypothesis for midlevel providers is rejected.

> Hypothesis 2.3: "For midlevel providers, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected."

By reviewing the sorted mean scores in Table 4, in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," this statement was first in terms of agreement score with a mean of 4.83 (SD=0.41). The statement "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decision" was ranked second with a mean score of 4.50 (SD=0.55). Consequently, this hypothesis is accepted.

> Hypothesis 2.4: "For midlevel providers, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution."

Upon evaluation of the sorted mean scores in Table 4, in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," for physicians this statement was first in terms of agreement score with a mean of 4.83 (SD=0.41). For the corresponding

statement, “I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions,” the statement was ranked fourth with a mean agreement score of 4.17 (SD=0.41). As a result, this hypothesis is accepted.

> Hypothesis 2.5: “For midlevel providers, a pharmacy staff’s evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.”

The sorted mean scores in Table 4, indicate in response to “I rely upon the pharmacy staff’s evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions”, this statement was first in terms of agreement score with a mean of 4.83 (SD=0.41). The statement “I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions” has a ranking of sixth with a mean of 4.00 (SD=1.10). Therefore, this hypothesis is accepted for midlevel providers.

> Hypothesis 2.6: “For midlevel providers, “individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.”

By reviewing of the mean value order presented in Table 4, the statement “I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions” was seventh or last in terms of agreement score with a mean of 3.83 (SD=0.41). In response to the statement, “in my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication,” this statement was ranked third based on the Likert

scale with a mean of 4.33 (SD=0.52). Therefore, this hypothesis is rejected for midlevel providers.

Group 3: Pharmacist

> Q3: "What is the ranked order of factors that influence hospital formulary decision-making by pharmacists?"

For pharmacists (n=8) referring to Table 4 indicates the highest level of agreement with an average of 4.38 (SD=0.74) was in response to the statement, "I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions." A total of 4 (50.0%) pharmacists strongly agreed, 3 (37.5%) agreed, 1 (12.5%) was neutral, none disagreed, and none strongly disagreed with the statement.

The second highest level of agreement 4.25 (SD=0.71) was with the statement, "In my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication." A total of 3 (37.5%) indicated strong agreement, 4 (50.0%) indicated agreement, 1 (12.5%) indicated a response of neutral, none disagreed, and none strongly disagreed.

The third factor in terms of pharmacists' level of agreement with a mean of 4.13 (SD=1.36) was to the statement, "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions." By reviewing the frequencies in Table 3, pharmacists indicating they strongly agreed was 4 (50.0%), 3 (37.5%) agreed, none were neutral, none disagreed, and 1 (12.5%) strongly disagreed with this statement.

The fourth level of agreement with an average of 3.50 (SD=0.93) was in response to the statement “I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions.” For this hospital formulary decision-making statement, 1 (12.5%) pharmacist strongly agreed, 3 (37.5%) agreed, 3 (37.5%) were neutral, 1 (12.5%) agreed, and none strongly disagreed with the statement.

The fifth level of agreement is tied with the fourth with an average of 3.50 (SD=0.76) was in response to the statement, “I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decision.” For this hospital formulary decision-making statement, 0 (0.0%) pharmacists strongly agreed with the statement, 5 (62.5%) agreed, 2 (25.0%) were neutral, 1 (12.5%) disagreed, and none strongly disagreed with the statement.

The next to last, or sixth level of agreement, with a mean of 3.38 (SD=1.51) was related to the statement “I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions.” A total 3 (37.5%) pharmacists strongly agreed, 1 (12.5%) agreed, 0 (0.0%) were neutral, while 4 (50.0%) disagreed with the statement, and no pharmacists strongly disagreed.

The seventh and lowest level of agreement for pharmacists with a mean of 2.88 (SD=1.36) was in response to the statement “I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions.” For this statement, 1 (12.5%) strongly agreed, a total of 2 (25.0%) of prescribers agreed, 1 (12.5%) was neutral, 3 (37.5%) selected disagree, and 1 (12.5%) strongly disagreed.

Pharmacist Hypotheses

> Hypothesis 3.1: “For pharmacists, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.”

By reviewing of the mean value order presented in Table 4, the statement “I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions” was last or seventh in terms of agreement score with a mean of 2.88 (SD=1.36). In response to the statement “I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions,” this statement was ranked fourth based on the Likert scale with a mean of 3.50 (SD=0.93). Therefore, this hypothesis is accepted for pharmacists.

> Hypothesis 3.2: “For pharmacists the evaluation of medications by expert physicians has a lower ranking of influence on hospital formulary decision-making than does the pharmacy staff’s evaluation of medical evidence including formulary recommendations.”

By reviewing of the sorted mean values in Table 4, the statement “I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions,” this statement was ranked fourth based on the Likert scale with a mean of 3.50 (SD=0.93). However, in response to the statement “I rely upon the pharmacy staff’s evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions,” this statement was third in terms of agreement score with a mean of 4.13 (SD=1.36). This hypothesis for pharmacists is accepted.

> Hypothesis 3.3: “For pharmacists, a pharmacy staff’s evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.”

By reviewing the sorted mean scores in Table 4, in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," this statement was third in terms of agreement score with a mean of 4.13 (SD=1.36). The statement "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making hospital medication formulary decisions" was tied for the fourth position with a mean score of 3.50 (SD=0.76). Consequently, this hypothesis is accepted.

> Hypothesis 3.4: "For pharmacists, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution."

Upon evaluation of the sorted mean scores in Table 4, in response to the statement "I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions," for pharmacists this statement was third in terms of agreement score with a mean of 4.13 (SD=1.36). For the corresponding statement, "I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions," the statement was ranked first with a mean agreement score of 4.38 (SD=0.74). As a result, this hypothesis is rejected.

> Hypothesis 3.5: "For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient."

The sorted mean scores in Table 4, indicate in response to the statement “I rely upon the pharmacy staff’s evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions,” this statement was third in terms of agreement score with a mean of 4.13 (SD=1.36). The statement “I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions” has a ranking of sixth with a mean of 3.38 (SD=1.51). Therefore, this hypothesis is accepted for pharmacists.

> Hypothesis 3.6: “For pharmacists, “individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.”

By reviewing of the mean value order presented in Table 4, the statement “I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions” was seventh or last in terms of agreement score with a mean of 2.88 (SD=1.36). In response to the statement, “in my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication,” this statement was ranked second based on the Likert scale with a mean of 4.25 (SD=0.71). Therefore, this hypothesis is rejected for pharmacists.

All Prescribers

Although no research questions or hypotheses were stated for all prescribers irrespective of provider type, the following results provide the ranked order of the decision-making statements across all prescriber groups. This provides insight into the

factors with the highest to the lowest agreement level across all three prescriber groups and for the P&T committee analyzed in its entirety.

For all prescribers surveyed comprised of physicians, midlevel providers, and pharmacists (n=30) Table 4 indicates the highest level of agreement with an average of 4.40 (SD=0.86) in response to the statement, “I rely upon the pharmacy staff’s evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions.” By reviewing the frequencies in Table 3, prescribers indicating they strongly agreed was 16 (53.3%), those who agreed were 12 (40.0%), 1 (3.3%) was neutral, and none disagreed, and 1 (3.3%) strongly disagreed with this statement.

The second highest level of agreement 4.13 (SD=0.73) was with the statement, “In my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication.” A total of 9 (30.0%) indicated strong agreement, 17 (56.7%) indicated agreement, 3 (10.0%) indicated a response of neutral, 1 (3.3%) disagreed, and none strongly disagreed.

The third highest level of agreement with an average of 4.13 (SD=0.73) was in response to the statement “I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions.” For this hospital formulary decision-making statement, 7 (23.3%) prescribers strongly agreed with the statement while 17 (56.7%) agreed with the statement. A total of 5 (16.7%) indicated a response of neutral, 1 (3.3%) prescriber disagreed, and none strongly disagreed with the statement.

The fourth level of agreement with a mean of 3.93 (SD=0.87) was to the statement “I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions.” A total of 7 (23.3%) of prescribers strongly agreed, 17 (56.7%) agreed, 3 (10.0%) were neutral, and 3 (10.0%) disagreed, and none strongly disagreed with the statement.

The fifth highest level of agreement with a mean of 3.80 (SD=1.21) was related to the statement “I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions.” A total 11 (36.7%) prescribers strongly agreed, 10 (33.3%) agreed, 1 (3.3%) was neutral, while 8 (26.7%) disagreed with the statement, and no prescribers strongly disagreed.

The sixth statement with a mean level of agreement at 3.73 (SD=0.94) was to the statement, “I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decision.” A total of 5 (16.7%) prescribers strongly agreed, 17 (56.7%) agreed, 3 (10.0%) were neutral, 5 (16.7%) disagreed, and none strongly disagreed with the statement.

The seventh and lowest level of agreement with a mean of 3.50 (SD=1.17) was in response to the statement “I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions.” A total of 4 (13.3%) of prescribers strongly agreed, 16 (53.3%) agreed, 4 (13.3%) were neutral, 3 (10%) selected disagree, and 3 (10.0%) strongly disagreed.

Table 4

Prescriber Group Means and Standard Deviations for Decision-Making Factor Statements (Physician n=*16, Midlevel Provider* n=*6, Pharmacist* n=*8, All Prescribers* n=*30)*

	M	SD
Physician		
1) pharmacy staff's evaluation of medical evidence including formulary recommendations	4.38	0.62
2) evaluation of medications by expert physicians	4.25	0.68
3) opportunity for new treatment options	4.00	0.82
4) financial impact of the treatment to the patient	3.94	1.12
5) individual evaluation of medical evidence	3.69	1.20
6) financial impact of the treatment to the institution	3.63	0.96
7) number of patients affected	3.56	1.03
Midlevel Provider		
1) pharmacy staff's evaluation of medical evidence including formulary recommendations	4.83	0.41
2) number of patients affected	4.50	0.55
3) opportunity for new treatment options	4.33	0.52
4) financial impact of the treatment to the institution	4.17	0.41
5) evaluation of medications by expert physicians	4.00	0.00
5) financial impact of the treatment to the patient	4.00	1.10
6) individual evaluation of medical evidence	3.83	0.41
Pharmacist		
1) financial impact of the treatment to the institution	4.38	0.74
2) opportunity for new treatment options	4.25	0.71
3) pharmacy staff's evaluation of medical evidence including formulary recommendations	4.13	1.36
4) evaluation of medications by expert physicians	3.50	0.93
4) number of patients affected	3.50	0.76
5) financial impact of the treatment to the patient	3.38	1.51
6) individual evaluation of medical evidence	2.88	1.36

(table continues)

	M	SD
All Prescribers		
1) pharmacy staff's evaluation of medical evidence including formulary recommendations	4.40	0.86
2) opportunity for new treatment options	4.13	0.73
3) evaluation of medications by expert physicians	4.00	0.74
4) financial impact of the treatment to the institution	3.93	0.87
5) financial impact of the treatment to the patient	3.80	1.21
6) number of patients affected	3.73	0.94
7) individual evaluation of medical evidence	3.50	1.17

Note. M = mean; SD = standard deviation. For midlevel providers, two factors are ranked fifth with identical mean values of 4.00. For pharmacists, two factors are ranked fourth with identical mean values of 3.50.

Statistical Tests

In addition to the descriptive statistical analyses performed previously, inferential statistics were performed using data obtained from Part II of the online survey. These analyses were performed to determine if statistically significant differences exist between the prescriber groups and the seven decision-making factors identified from the literature. As stated previously, Part II of the survey posed independent questions to the prescribers with level of agreement responses measured on a 5-point Likert scale.

The data for this study have several characteristics that must be understood in order to select the most appropriate statistical tests. Most importantly, the study data are not normally distributed. Normal distribution of the data was tested using SPSS© (2017) statistical software to produce values using the Kolmogorov-Shmirnov and Shapiro-Wilk tests for normality (Lund Research Ltd., Laerd Statistics , 2013c). For all independent variables associated with the seven decision-making factors in both Part II

and Part III of the survey, the Kolmogorov-Shmirnov and Shapiro-Wilk tests for normality indicate values less than 0.05, in most cases 0.00, indicating that the data are not normally distributed. The next consideration is that the sample size for this study is small. The data are comprised of only 30 participants made up of 16 physicians, 6 midlevel providers, and 8 pharmacists. Furthermore, the dependent variable is categorical while the independent variables for the decision-making factors are ordinal for Part II and Part III of the survey. Specifically, the data collected for both Part II is measured on a 5-point ordinal Likert scale while Part III was measured on a 7-point ordinal ranking scale.

According to Laerd Statistics (Lund Research Ltd., Laerd Statistics, 2013b) traditional analysis of variance statistical tests such as ANOVA tolerate some violations of normality. However, the normality issue is exacerbated when combined with a small sample size. Therefore, since the study data are not normally distributed and the sample size is small, traditional ANOVA statistical tests were not appropriate.

Nonparametric statistical methods provide an alternative as they do not require the normality assumption to be met. Furthermore, certain nonparametric tests are also appropriate for small data sets. Upon review of the various nonparametric statistical tests, it was determined that the most appropriate statistical tests considering the characteristics of the study data is the Kruskal-Wallace H Test, also known as a one-way analysis of variance for ranking (Lund Research Ltd., Laerd Statistics, 2013a; Hinkle, Wiersma, & Jurs, 2003).

Hinkle, Wiersma, and Jurs (2003), indicate that the Kruskal-Wallis test is appropriate for ordinal data with K-Sample cases. As stated previously, the dependent

variable or K-Sample cases for this study is categorical consisting of physicians, midlevel providers, and pharmacists. According to Lund Research Ltd., Laerd Statistics (2013a), the Kruskal-Wallis H test is appropriate if four assumptions are met: 1) the dependent variable should be measured at the ordinal or continuous level, 2) the independent variable should consist of two or more categorical, independent groups, 3) independence of observations, which means there is no relationship between the observations in each group, and 4) the distribution of scores for each group of the independent variable should have the same shape (which means the same variability). For these study data, all four of these assumptions are met. A statistical test was performed to determine if assumption of homogeneity of variance was met. To determine if the homogeneity of variance assumption is met, SPSS was used to compute the Levene Statistic (Lund Research Ltd., Laerd Statistics, 2013a; Hinkle, Wiersma, & Jurs, 2003). The Levene statistic may be used to determine the Homogeneity of Variance for the various independent variables.

Table 5 provides the results of Levene's test for homogeneity of variance. Upon review of the data in Table 5, one variable does not meet the homogeneity of variance requirement. For the decision-making statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions," the Levene p value is 0.002 which is < 0.05. Therefore, the null hypothesis for the Levene test is rejected for this decision-making statement and the assumption of homogeneity of variance is not met. Therefore, this independent variable will be ignored should a Kruskal-Wallis H test determine that a statistically significant difference exist between the prescriber groups.

Table 5

Levene's Homogeneity of Variance Test for Decision-Making Factor Statements

Decision-making Factor Statement	Levene Statistic	df1	df2	p
I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions	2.574	2	27	0.095
I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions	2.107	2	27	0.141
I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions	8.100	2	27	0.002
I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decisions	1.657	2	27	0.209
I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions	2.554	2	27	0.096
I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions	2.446	2	27	0.106
In my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication	0.093	2	27	0.912

Note. df = degrees of freedom; p = p statistic for Levene's test. For the decision-making statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions," the Levene p value is 0.002 which is < 0.05. Therefore, the null hypothesis for the Levene test is rejected for this statement and the assumption of homogeneity of variance is not met.

Table 6 provides the results of the independent samples Kruskal-Wallis H test obtained by running the test using SPSS© (2017) statistical software. Upon review of Table 6, one of the variables indicates a statistically significant difference between the three groups of providers. For the hospital formulary decision-making factor, "I consider

the number of patients affected by adding, removing, or modifying a drug on the formulary when making hospital medication formulary decisions," a Kruskal-Wallis H test indicated a statistically significant difference in mean agreement score between the prescriber groups $\alpha = 0.05$, $X^2 = 6.055$, $p = 0.048$. The mean rank agreement score for is 14.25 for physicians, 22.50 for midlevel providers, and 12.75 for pharmacists. No other decision-making factors for Part II of the survey indicate a statistically significant difference in agreement scores between the prescriber groups based on the results of the Kruskal-Wallis H test.

Table 6

Kruskal-Wallis H Test Results for Hospital Formulary Decision-making Statements

Hospital Formulary Decision-making Statement	X^2	df	p
I rely upon my individual evaluation of medical evidence to make hospital medication formulary decisions	2.846	2	0.241
I rely upon the pharmacy staff's evaluation of medical evidence including formulary recommendations (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions	2.695	2	0.260
I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions	4.859	2	0.088
I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decisions	6.055	2	0.048
I consider the financial impact of the treatment to the institution in terms of drug cost and potential reimbursement when making hospital medication formulary decisions	4.389	2	0.111
I consider the financial impact of the treatment to the patient in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions	0.669	2	0.716
In my role as a medication prescriber, I consider the opportunity for new treatment options when adding or expanding the use of a hospital formulary medication	0.902	2	0.637

Note. X^2 = chi square, df = degrees of freedom; p = p statistic for Kruskal-Wallis H test. For the decision-making statement "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making hospital medication formulary decisions", the p value is 0.048 which is < 0.050. Therefore, the null hypothesis for the Kruskal-Wallis H test is rejected for this statement.

Survey – Part III

In Part III of the survey, prescribers were asked to rank each of the seven hospital formulary decision-making factors in relationship to each other. The ranking used a 7-point scale with a value of 1 assigned for the most important factor to 7 for the least important factor. SPSS© (2017) statistical software was used to compute frequencies, means, and standard deviations values for each response. The responses where then categorized by prescriber group. The associated ordered ranking for each prescriber group was determined by sorting the mean values for each group from the lowest mean to the highest mean. This ranked order was then used to address the research questions and hypotheses for each of the three prescriber groups.

Table 7 presents the frequencies of responses to the ranking of each of the decision-making factors by each prescriber group followed by the aggregate frequencies for all prescribers. For the factor, “Individual evaluation of medical evidence,” a total of 6 (37.5%) physicians ranked this as the most important factor, 1 (6.3%) ranked it second, 3 (18.8%) ranked it third. Physicians raking it fourth was 1 (6.3%), fifth 2 (12.5%), none ranked it sixth, and 3 (18.8%) ranked it least important or seventh. A total of 0 (0.0%) midlevel providers ranked this as the most important factor, 1 (16.7%) ranked it second, 2 (33.3%) ranked it third. Midlevel providers raking it fourth was 0 (0.0%), fifth 0 (0.0%), while 2 (33.3%) ranked it sixth, and 1 (16.7%) ranked it least important or seventh. For all prescribers, 7 (23.3%) prescribers ranked this factor as most important while 4 (13.3%) ranked the factor second. A total of 6 (20.0%) ranked it third, 2 (6.7%) ranked it fourth, 3 (10.0%) ranked it fifth, 2 (6.7%) ranked it sixth, and 6 (20.0%) of prescribers ranked it seventh or last.

For the factor, “pharmacy staff’s evaluation of medical evidence including formulary recommendations” the following were the frequencies for physicians. By reviewing the frequencies in Table 7, 5 (31.3%) ranked it first, those who ranked it as the second most important was 6 (37.5%), and 3 (18.8%) ranked the factor third. The number of physicians ranking it fourth was 1 (6.3%), fifth most important was 1 (6.3%), 0 (0.0%) ranked it sixth, and 0 (0.0%) ranked it last or least important. The number of midlevel providers who deemed this as the most important factor was 4 (66.7%), those who ranked it as the second most important was 1 (16.7%), and 0 (0.0%) ranked the factor third. The number of midlevel providers ranking it fourth was 1 (16.7%), none 0 (0.0%) ranked it fifth, sixth, or seventh. The number of pharmacists who deemed this as the most important factor was 5 (62.5%), those who ranked it as the second most important was 2 (25.0%), and 1 (12.5%) ranked the factor third. The number of pharmacists ranking it fourth, fifth, sixth, or last was 0 (0.0%). For all prescribers, those ranking this factor first was 14 (46.67%), second were 9 (30.0%), and third were 4 (13.3%). A total of 2 (6.7%) ranked the factor fourth, 1 (3.3%) ranked it fifth, and 0 (0.0%) ranked it sixth or seventh.

For the hospital formulary decision-making factor “Evaluation of medications by expert physicians,” 4 (25.0%) physicians ranked this as the most important factor while 2 (12.5%) ranked it as the second most important factor. Physicians ranking it third was 6 (37.5%), fourth was 3 (18.8%). Physicians ranking it fifth was 1 (6.3%), while none 0 (0.0%) ranked it sixth or seventh. For midlevel providers, 1 (16.7%) ranked this as the most important factor while 2 (33.3%) ranked it as the second most important factor. Midlevel providers ranking it third was 1 (16.7%), fourth was 1 (16.7%). No midlevel

providers ranked it fifth 0 (0.0%), while 1 (16.7%) ranked it sixth, and none 0 (0.0%) ranked it seventh. Pharmacists frequencies were, 1 (12.5%) ranked this as the most important factor, 1 (12.5%) ranked it second, 2 (25.0%) ranked it third. Pharmacists raking it fourth was 1 (12.5%), fifth 2 (25.0%), none ranked it sixth, and 1 (12.5%) ranked it least important or seventh. For all prescribers, a total of 6 (20.0%) ranked this factor first, 5 (16.7%) second, 9 (30.0%) third, 5 (16.7%) fourth, 3 (10.0%) fifth, 1 (3.3%) sixth, and 1 (3.3%) seventh.

For the decision-making factor “Number of patients affected by adding, removing, or modifying a formulary medication,” 1 (6.3%) physician considered this factor most important, 1 (6.3%) considered it second most important, 2 (12.5%) considered it third in importance, while 2 (12.5%) considered it fourth. Finally, 5 (31.3%) considered it fifth, 3 (18.8%) sixth, and 2 (12.5%) considered it the least most important hospital decision-making factor. For midlevel providers, those ranking it the most important factor was 0 (0.00%), those ranking it second was 0 (0.0%), and third was 2 (33.3%). This raking it fourth was 2 (33.3%), while 0 (0.0%) ranked it fifth, 0 (0.0%) ranked it sixth, and 2 (33.3%) ranked it seventh or least important. No pharmacists 0 (0.0%) ranked this factor first or most important, 0 (0.0%) ranked it second, 0 (0.0%) ranked it third, and 1 (12.5%) ranked it fourth. In the last three ranking positions, 2 (25.0%) ranked it fifth, 3 (37.5%) sixth, and 2 (25.0%) ranked it the factor they considered last. Among all prescribers, 1 (3.3%) prescriber ranked the factor first, 1 (3.3%) second, 4 (13.3%) third, 5 (16.7%) fourth. Finally, 7 (23.3%) prescribers ranked the factor fifth, 6 (20.0%) sixth, with the same number 6 (20.0%) ranked the factor seventh or last.

For the factor, “Financial impact of treatment for the institution in terms of drug costs and potential reimbursement,” no physicians 0 (0.0%) ranked this factor first or most important, 1 (6.3%) ranked it second, 1 (6.3%) ranked it third, and 2 (12.5%) ranked it fourth. In the last three ranking positions, 2 (12.5%) ranked it fifth, 6 (37.5%) sixth, and 4 (25.0%) ranked it the factor they considered last. For midlevel providers, a total of 0 (0.0%) considered this hospital formulary decision-making factor most important, 1 (16.7%) considered it second most important, 0 (0.0%) considered it third in importance, and 0 (0.0%) considered it fourth. Finally, 5 (83.3%) considered it fifth, and none 0 (0.0%) considered it as the sixth or seventh in terms of ranking the hospital decision-making factors. For pharmacists, 1 (12.5%) ranked this as the most important factor while 2 (25.0%) ranked it as the second most important factor. Pharmacists ranking it third was 1 (12.5%), fourth was 3 (37.5%), 0 (0.0%) ranked it fifth or sixth, while 1 (12.5%) ranked it seventh. For all prescribers, 1 (3.3%) ranked this factor first, 4 (13.3%) second, 2 (6.7%) third, and 5 (16.7%) ranked the factor fourth. In addition, 7 (23.3%) prescribers ranked the factor fifth, 6 (20.0%) sixth, and 5 (16.7%) ranked it seventh or last.

For the factor, “Financial impact of the treatment for the patient in terms of potential out-of-pocket expenses,” physicians raking this as the most important factor was 0 (0.00%), those ranking it second was 4 (25.0%), and third was 1 (6.3%). No physicians 0 (0.0%) ranked it fourth, while 3 (18.8%) ranked it fifth, 4 (25.0%) ranked it sixth, and 4 (25.0%) ranked it seventh or least important. According to Table 7, a total of 0 (0.0%) midlevel providers considered this hospital formulary decision-making factor most important, 1 (16.7%) considered it second most important, 0 (0.0%) considered it

third in importance, and 0 (0.0%) considered it fourth. Finally, 5 (83.3%) considered it fifth, and none 0 (0.0%) considered it as the sixth or seventh in terms of ranking the hospital decision-making factors. Pharmacists raking this as the most important factor was 0 (0.0%), those ranking it second was also 0 (0.0%), and third were 2 (25.0%). The number of pharmacists ranking it fourth was 1 (12.5%), 1 (12.5%) ranked it fifth, while 4 (50.0%) ranked it sixth, and 0 (0.0%) ranked it seventh or least important. Among all prescribers, a total of 0 (0.0%) prescribers ranked the factor first, 5 (16.7%) second, 4 (13.3%) third, and 1 (3.3%) fourth. In the last three positions, 4 (13.3%) prescribers ranked in fifth, 11 (36.7%) ranked it sixth, and 5 (16.7%) ranked it seventh.

For the decision-making factor “Opportunity for new treatment options,” no physicians 0 (0.0%) ranked it first, 1 (6.3%) ranked it second, 0 (0.0%) ranked it third, and 7 (43.8%) ranked it fourth. A total of 2 (12.5%) physicians ranked it fifth, 3 (18.8%) sixth, and 3 (18.8%) ranked it last or seventh. For midlevel providers, 1 (16.7%) ranked it first, 0 (0.0%) ranked it second, 0 (0.0%) ranked it third, and 2 (33.3%) ranked it fourth. A total of 1 (16.7%) midlevel provider ranked it fifth, 0 (0.0%) sixth, and 2 (33.3%) ranked it last or seventh. For pharmacists, 0 (0.0%) ranked it first, 1 (12.5%) ranked it second, 1 (12.5%) ranked it third, and 1 (12.5%) ranked it fourth. A total of 2 (25.0%) ranked it fifth, 1 (12.5%) sixth, and 2 (25.0%) ranked it last or seventh. For all prescribers, 1 (3.3%) prescriber ranked this factor first, 2 (6.7%) second, 1 (3.3%) third, while 10 (33.3%) ranked the factor fourth. A total of 5 (16.7%) prescribers ranked it fifth, 4 (13.3%) sixth, while 7 (23.3%) ranked it last.

Table 7

Prescriber Group Frequencies for Responses for Decision-Making Factor Ranking (Physician n=16, Midlevel Provider n=6, Pharmacist n=8, All Prescribers n=30)

	Ranking						
	1	**2**	**3**	**4**	**5**	**6**	**7**
Individual evaluation of medical evidence							
Physician	6	1	3	1	2	0	3
Midlevel provider	0	1	2	0	0	2	1
Pharmacist	1	2	1	1	1	0	2
All prescribers	7	4	6	2	3	2	6
pharmacy staff's evaluation of medical evidence including formulary recommendations							
Physician	5	6	3	1	1	0	0
Midlevel provider	4	1	0	1	0	0	0
Pharmacist	5	2	1	0	0	0	0
All prescribers	14	9	4	2	1	0	0
Evaluation of medications by expert physicians							
Physician	4	2	6	3	1	0	0
Midlevel provider	1	2	1	1	0	1	0
Pharmacist	1	1	2	1	2	0	1
All prescribers	6	5	9	5	3	1	1
Number of patients affected by adding, removing, or modifying a formulary medication							
Physician	1	1	2	2	5	3	2
Midlevel provider	0	0	2	2	0	0	2
Pharmacist	0	0	0	1	2	3	2
All prescribers	1	1	4	5	7	6	6
Financial impact of the treatment for the institution in terms of drug costs and potential reimbursement							
Physician	0	1	1	2	2	6	4
Midlevel provider	0	1	0	0	5	0	0
Pharmacist	1	2	1	3	0	0	1
All prescribers	1	4	2	5	7	6	5

(table continues)

	Ranking						
	1	2	3	4	5	6	7
Financial impact of the treatment for the patient in terms of potential out-of-pocket expenses							
Physician	0	4	1	0	3	4	4
Midlevel provider	0	1	1	0	0	3	1
Pharmacist	0	0	2	1	1	4	0
All prescribers	0	5	4	1	4	11	5
Opportunity for new treatment options							
Physician	0	1	0	7	2	3	3
Midlevel provider	1	0	0	2	1	0	2
Pharmacist	0	1	1	1	2	1	2
All prescribers	1	2	1	10	5	4	7

Table 8 presents each prescriber group's calculated average ranking and standard deviation values based on the 7-point ranking scale for each decision-making factor. For the ranking scores, 1 is assigned for the factor considered most important while 7 is assigned to the factor deemed least important. Therefore, the decision-making factors in Table 8 are sorted in ascending order for each prescriber group. In other words, the factor associated with the lowest mean ranking score and considered most important is listed first. The factor with the highest mean raking score and considered least important is listed last. Table 8 also provides the standard deviation for each factor across all prescriber groups with and the aggregate standard deviation for each factor for all prescribers. Finally, SPSS© (2017) was used to perform inferential statistics namely, a Kruskal-Wallis H test, for the hospital formulary decision-making factors ranking data.

Physician Research Question

Q1: “What is the ranked order of factors that influence hospital formulary decision-making by physicians?”

Table 8 indicates the total number of physician participants is 16 (n=16), the factor with the highest ranking with an average of 2.19 (SD=1.17) was in ranking the factor, “pharmacy staff’s evaluation of medical evidence including formulary recommendations.” By reviewing the frequencies in Table 7, the number of physicians who deemed this as the most important factor was 5 (31.3%), those who ranked it as the second most important was 6 (37.5%), and 3 (18.8%) ranked the factor third. The number of physicians ranking it fourth was 1 (6.3%), fifth most important was 1 (6.3%), 0 (0.0%) ranked it sixth, and 0 (0.0%) ranked it last or least important.

The factor with the second highest level of agreement with an average of 2.69 (SD=1.25) was in ranking the factor “evaluation of medications by expert physicians.” For this hospital formulary decision-making factor, 4 (25.0%) of physicians ranked this as the most important factor while 2 (12.5%) ranked it as the second most important factor. Physicians ranking it third was 6 (37.5%), fourth was 3 (18.8%). Physicians ranking it fifth was 1 (6.3%), while none 0 (0.0%) ranked it sixth or seventh.

The third highest ranked factor with a mean of 3.25 (SD=2.32) was in response to the factor, “Individual evaluation of medical evidence.” A total of 6 (37.5%) physicians ranked this as the most important factor, 1 (6.3%) ranked it second, 3 (18.8%) ranked it third. Physicians raking it fourth was 1 (6.3%), fifth 2 (12.5%), none ranked it sixth, and 3 (18.8%) ranked it least important or seventh.

The fourth highest factor with a mean of 4.63 (SD=1.71) was related to the factor “number of patients affected.” A total of 1 (6.3%) physicians considered this factor most

important, 1 (6.3%) considered it second most important, 2 (12.5%) considered it third in importance, while 2 (12.5%) considered it fourth. Finally, 5 (31.3%) considered it fifth, 3 (18.8%) sixth, and 2 (12.5%) considered it the least most important hospital decision-making factor.

The fifth ranked factor with a mean of 4.88 (SD=2.00) was the, “financial impact of treatment to the patient.” Physicians raking this as the most important factor was 0 (0.00%), those ranking it second was 4 (25.0%), and third was 1 (6.3%). No physician 0 (0.0%) ranked it fourth, while 3 (18.8%) ranked it fifth, 4 (25.0%) ranked it sixth, and 4 (25.0%) ranked it seventh or least important.

The factor ranked sixth for physicians with a mean of 4.94 (SD=1.44) was in response to the, “Opportunity for new treatment options.” No physicians 0 (0.0%) ranked it first, 1 (6.3%) ranked it second, 0 (0.0%) ranked it third, and 7 (43.8%) ranked it fourth. A total of 2 (12.5%) physicians ranked it fifth, 3 (18.8%) sixth, and 3 (18.8%) ranked it last or seventh.

The seventh factor ranked last with a mean of 5.44 (SD=1.50) was regarding the factor, “financial impact of treatment the treatment for the institution in terms of drug costs and potential reimbursement.” No physicians 0 (0.0%) ranked this factor first or most important, 1 (6.3%) ranked it second, 1 (6.3%) ranked it third, and 2 (12.5%) ranked it fourth. In the last three ranking positions, 2 (12.5%) ranked it fifth, 6 (37.5%) sixth, and 4 (25.0%) ranked it the factor they considered last.

Physician Hypotheses

> Hypothesis 1.1: "For physicians, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians."

By reviewing of the mean value order presented in Table 8, the factor "individual evaluation of medical evidence" was third in terms of its ranking with a mean of 3.25 (SD=2.32). In ranking the factor "evaluation of medications by expert physicians," this factor was ranked second with a mean of 2.69 (SD=1.25). Therefore, this hypothesis is accepted for physicians.

> Hypothesis 1.2: "For physicians, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations."

By reviewing of the sorted mean values in Table 4, the factor which states, "evaluation of medications by expert physicians" was ranked second based on the ranking with a mean of 2.69 (SD=1.25). However, in response to the factor "pharmacy staff's evaluation of medical evidence including formulary recommendations", this statement was first in terms of ranking with a mean of 2.19 (SD=1.17). Therefore, this hypothesis for physicians is rejected.

> Hypothesis 1.3: "For physicians, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected."

By reviewing the sorted mean scores in Table 8, by reviewing the order of the factor which states "pharmacy staff's evaluation of medical evidence including formulary recommendations", this factor was ranked first with a mean of 2.19 (SD=1.17). For the factor statement "number of patients affected" was ranked fourth with a mean ranking of 4.63 (SD=1.71). Consequently, this hypothesis is accepted.

Hypothesis 1.4: “For physicians, pharmacy staff’s evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.”

As stated previously, in response to the ranked factor “pharmacy staff’s evaluation of medical evidence including formulary recommendations,” for physicians this statement was first in terms of agreement score with a mean of 2.19 (SD=1.17). For the corresponding factor, “financial impact of the treatment to the institution,” the statement was ranked seventh or last with a mean agreement score of 5.44 (SD=1.50). As a result, this hypothesis is accepted.

Hypothesis 1.5: “For physicians, a pharmacy staff’s evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.”

The sorted mean scores in Table 8, indicate in ranking the factor “pharmacy staff’s evaluation of medical evidence including formulary recommendations,” this statement was first in terms of agreement score with a mean of 2.19 (SD=1.17). The factor “financial impact of the treatment to the patient” has a ranking of fifth with a mean of 4.88 (SD=2.00). Therefore, this hypothesis is accepted.

Hypothesis 1.6: “For physicians, individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.”

By reviewing of the mean value order presented in Table 8, the factor “individual evaluation of medical evidence” was third in terms of ranking with a mean of 3.25 (SD=2.32). In response to the factor statement, “opportunity for new treatment options” it was ranked sixth with a mean of 4.94 (SD=1.44). Therefore, this hypothesis is accepted for physicians.

Midlevel Provider Research Question

> Q2: “What is the ranked order of factors that influence hospital formulary decision-making by midlevel providers?”

The total number of midlevel providers participants is 6 (n=6) see Table 8, the factor with the highest ranking with an average of 1.67 (SD=1.21) is the factor, “pharmacy staff’s evaluation of medical evidence including formulary recommendations.” By reviewing the frequencies in Table 7, the number of midlevel providers who deemed this as the most important factor was 4 (66.7%), those who ranked it as the second most important was 1 (16.7%), and 0 (0.0%) ranked the factor third. The number of midlevel providers ranking it fourth was 1 (16.7%), none 0 (0.0%) ranked it fifth, sixth, or seventh.

The factor with the second highest level of agreement with an average of 3.00 (SD=1.79) was in ranking the factor “evaluation of medications by expert physicians.” For this hospital formulary decision-making factor, 1 (16.7%) midlevel provider ranked this as the most important factor while 2 (33.3%) ranked it as the second most important factor. Midlevel providers ranking it third was 1 (16.7%), fourth was 1 (16.7%). No midlevel providers ranked it fifth 0 (0.0%), while 1 (16.7%) ranked it sixth, and none 0 (0.0%) ranked it seventh.

The third highest ranked factor with a mean of 4.50 (SD=2.07) was in response to the factor, “Individual evaluation of medical evidence.” A total of 0 (0.0%) midlevel providers ranked this as the most important factor, 1 (16.7%) ranked it second, 2 (33.3%) ranked it third. Midlevel providers raking it fourth was 0 (0.0%), fifth 0 (0.0%), while 2 (33.3%) ranked it sixth, and 1 (16.7%) ranked it least important or seventh.

Tied for third highest factor with a mean of 4.50 (SD=1.23) was related to the factor “financial impact of the treatment to the institution.” A total of 0 (0.0%) midlevel providers considered this hospital formulary decision-making factor most important, 1 (16.7%) considered it second most important, 0 (0.0%) considered it third in importance, and 0 (0.0%) considered it fourth. Finally, 5 (83.3%) considered it fifth, and none 0 (0.0%) considered it as the sixth or seventh in terms of ranking the hospital decision-making factors.

The fourth ranked factor with a mean of 4.67 (SD=1.86) was the, “number of patients affected.” Midlevel providers raking this as the most important factor was 0 (0.00%), those ranking it second was 0 (0.0%), and third was 2 (33.3%). Two of the midlevel providers 2 (33.3%) ranked it fourth, while 0 (0.0%) ranked it fifth, 0 (0.0%) ranked it sixth, and 2 (33.3%) ranked it seventh or least important.

The factor tied for the fourth ranking for midlevel providers with a mean of 4.67 (SD=2.25) was in response to the, “Opportunity for new treatment options.” One midlevel provider 1 (16.7%) ranked it first, 0 (0.0%) ranked it second, 0 (0.0%) ranked it third, and 2 (33.3%) ranked it fourth. A total of 1 (16.7%) midlevel providers ranked it fifth, 0 (0.0%) sixth, and 2 (33.3%) ranked it last or seventh.

The last factor ranked fifth with a mean of 5.00 (SD=2.00) was regarding the factor, “financial impact of the treatment to the patient.” No midlevel provider 0 (0.0%) ranked this factor first or most important, 1 (16.7%) ranked it second, 1 (16.7%) ranked it third, and 0 (0.0%) ranked it fourth. In the last three ranking positions, 0 (0.0%) ranked it fifth, 3 (50.0%) sixth, and 1 (16.7%) ranked it the factor they considered last.

Midlevel Provider Hypotheses

> Hypothesis 2.1: "For midlevel providers, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians."

By reviewing of the mean value order presented in Table 8, the factor "individual evaluation of medical evidence" was third in terms of its ranking with a mean of 4.50 (SD=2.07). In ranking the factor "evaluation of medications by expert physicians," this factor was ranked second with a mean of 3.00 (SD=1.79). Therefore, this hypothesis is accepted for midlevel providers.

> Hypothesis 2.2: "For midlevel providers, the evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations."

By reviewing of the sorted mean values in Table 4, the factor which states, "evaluation of medications by expert physicians" was ranked second based on the ranking with a mean of 3.00 (SD=1.79). However, in response to the factor "pharmacy staff's evaluation of medical evidence including formulary recommendations", this statement was first in terms of ranking with a mean of 1.67 (SD=1.21). This hypothesis for midlevel providers is rejected.

> Hypothesis 2.3: "For midlevel providers, pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected."

By reviewing the sorted mean scores in Table 8, the factor which states "pharmacy staff's evaluation of medical evidence including formulary recommendations", was ranked first with a mean of 1.67 (SD=1.21). For the factor

statement “number of patients affected” was tied in rank for fourth with a mean ranking of 4.67 (SD=1.86). Consequently, this hypothesis is accepted.

> Hypothesis 2.4: “For midlevel providers, pharmacy staff’s evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.”

As stated previously, in response to the ranked factor “pharmacy staff’s evaluation of medical evidence including formulary recommendations,” for midlevel providers this factor was first in terms of ranking score with a mean of 1.67 (SD=1.21). For the corresponding factor, “financial impact of the treatment to the institution,” the statement was tied for third with a mean agreement score of 4.50 (SD=1.23). As a result, this hypothesis is accepted.

> Hypothesis 2.5: “For midlevel providers, pharmacy staff’s evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.”

The sorted mean scores in Table 8, indicate in ranking the factor “pharmacy staff’s evaluation of medical evidence including formulary recommendations,” this statement was first in terms of agreement score with a mean of 1.67 (SD=1.21). The factor “financial impact of the treatment to the patient” was ranked last with a mean of 5.00 (SD=2.00). Therefore, this hypothesis is accepted.

> Hypothesis 2.6: “For midlevel providers is, “individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.”

By reviewing of the mean value order presented in Table 8, the factor “individual evaluation of medical evidence” was tied for third in terms of ranking with a mean of 4.50 (SD=2.07). In response to the factor statement, “opportunity for new treatment

options" it was ranked and tied for fourth with a mean of 4.67 (SD=2.25). Therefore, this hypothesis is accepted for midlevel providers.

Pharmacist Research Question

> Q3: "What is the ranked order of factors that influence hospital formulary decision-making by pharmacists?"

Upon review of Table 8, the total number of pharmacist participants is 8 (n=8), the factor with the highest ranking with an average of 1.50 (SD=0.76) was in ranking the factor, "pharmacy staff's evaluation of medical evidence including formulary recommendations." By reviewing the frequencies in Table 7, the number of pharmacists who deemed this as the most important factor was 5 (62.5%), those who ranked it as the second most important was 2 (25.0%), and 1 (12.5%) ranked the factor third. The number of pharmacists ranking it fourth, fifth, sixth, or last was 0 (0.0%).

The factor with the second highest ranking with an average of 3.38 (SD=1.85) was in ranking the factor "financial impact of the treatment for the institution." For this hospital formulary decision-making factor, 1 (12.5%) of pharmacist ranked this as the most important factor while 2 (25.0%) ranked it as the second most important factor. Pharmacists ranking it third was 1 (12.5%), fourth was 3 (37.5%), 0 (0.0%) ranked it fifth or sixth, while 1 (12.5%) ranked it seventh.

The third highest ranked factor with a mean of 3.75 (SD=1.91) was in response to the factor, "evaluation of medications by expert physicians." A total of 1 (12.5%) pharmacist ranked this as the most important factor, 1 (12.5%) ranked it second, 2 (25.0%) ranked it third. Pharmacists raking it fourth was 1 (12.5%), fifth 2 (25.0%), none ranked it sixth, and 1 (12.5%) ranked it least important or seventh.

The fourth highest factor with a mean of 3.88 (SD=2.30) was related to the factor "individual evaluation of medical evidence." A total of 1 (12.5%) of pharmacists considered this factor most important, 2 (25.0%) considered it second most important, 1 (12.5%) considered it third in importance, and 1 (12.5%) considered it fourth. Finally, 1 (12.5%) considered it fifth, 0 (0.0%) sixth, and 2 (25.0%) considered it the least important hospital formulary decision-making factor.

The fifth ranked factor with a mean of 4.88 (SD=1.36) was the, "financial impact of treatment to the patient." Pharmacists raking this as the most important factor was 0 (0.0%), those ranking it second was also 0 (0.0%), and third were 2 (25.0%). The number of pharmacists ranking it fourth was 1 (12.5%), 1 (12.5%) ranked it fifth, while 4 (50.0%) ranked it sixth, and 0 (0.0%) ranked it seventh or least important.

The factor tied for fifth for pharmacists with a mean of 4.88 (SD=1.81) was in response to the factor, "opportunity for new treatment options." No pharmacists 0 (0.0%) ranked it first, 1 (12.5%) ranked it second, 1 (12.5%) ranked it third, and 1 (12.5%) ranked it fourth. A total of 2 (25.0%) ranked it fifth, 1 (12.5%) sixth, and 2 (25.0%) ranked it last or seventh.

The factor ranked last with a mean of 5.75 (SD=1.50) was regarding the factor, "number of patients affected." No pharmacists 0 (0.0%) ranked this factor first or most important, 0 (0.0%) ranked it second, 0 (0.0%) ranked it third, and 1 (12.5%) ranked it fourth. In the last three ranking positions, 2 (25.0%) ranked it fifth, 3 (37.5%) sixth, and 2 (25.0%) ranked it the factor they considered last.

Pharmacist Hypotheses

> Hypothesis 3.1: "For pharmacists, individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians."

By reviewing of the mean value order presented in Table 8, for the factor "individual evaluation of medical evidence" was ranked fourth with a mean of 3.88 (SD=1.36). In response to the factor "evaluation of medications by expert physicians," this statement was ranked third based on the ranking scores with a mean of 3.75 (SD=1.91). Therefore, this hypothesis is accepted for pharmacists.

> Hypothesis 3.2: "For pharmacists, the evaluation of medications by expert physicians has a lower ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations."

By reviewing of the sorted mean values in Table 8, the factor "evaluation of medications by expert physicians," was ranked third based rankings with a mean of 3.75 (SD=1.91). However, in response to factor "pharmacy staff's evaluation of medical evidence," this was first in terms with a mean of 1.50 (SD=0.76). This hypothesis for pharmacists is accepted.

> Hypothesis 3.3: "For pharmacists, a pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected."

By reviewing the sorted mean scores in Table 8, in response to the factor "pharmacy staff's evaluation of medical evidence," this statement was first in terms of mean ranking score with a mean of 1.50 (SD=0.76). The factor "number of patients affected," was last with a mean score of 5.75 (SD=1.04). Consequently, this hypothesis is accepted.

Hypothesis 3.4: “For pharmacists, pharmacy staff’s evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.”

Upon evaluation of the sorted mean scores in Table 8, in response to factor “pharmacy staff’s evaluation of medical evidence including formulary recommendations,” for pharmacists this statement was first in terms of the sorted ranked factors with a mean of 1.50 (SD=0.76). For the corresponding factor, “financial impact of the treatment to the institution,” was ranked second with a mean agreement score of 3.38 (SD=1.85). As a result, this hypothesis is accepted.

Hypothesis 3.5: “For pharmacists, a pharmacy staff’s evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.”

The sorted mean scores in Table 8, indicate in response to the factor “pharmacy staff’s evaluation of medical evidence including formulary recommendations,” this factor was first with a mean of 1.50 (SD=0.76). The factor “financial impact of the treatment to the patient,” has tied for fourth with a mean of 4.88 (SD=1.36). Therefore, this hypothesis is accepted for pharmacists.

Hypothesis 3.6: “For pharmacists, “individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.”

By reviewing of the mean value order presented in Table 8, the factor “individual evaluation of medical evidence,” was fourth in terms of agreement score with a mean of 3.88 (SD=2.30). In response to the factor, “opportunity for new treatment options” the factor was tied for fifth with a mean of 4.88 (SD=1.81). Therefore, this hypothesis is accepted for pharmacists.

All Prescribers

Although no research questions or hypotheses were stated for all prescribers irrespective of provider type, the following results provide the ranked order of all prescribers. These results provide insight into the factors with the highest to the lowest ranking across all three prescriber groups. For all prescribers surveyed including physicians, midlevel providers, and pharmacists (n=30) Table 8 indicates the factor with the highest ranking with an average of 1.90 (SD=1.09). The factor, "pharmacy staff's evaluation of medical evidence including formulary recommendations" was ranked first. By reviewing the frequencies in Table 7, the number of prescribers ranking this factor first was 14 (46.67%), second were 9 (30.0%), and third were 4 (13.3%). A total of 2 (6.7%) ranked the factor fourth, 1 (3.3%) ranked it fifth, and 0 (0.0%) ranked it sixth or seventh.

The second highest level of agreement 3.03 (SD=1.56) was regarding the factor, "evaluation of medications by expert physicians." A total of 6 (20.0%) ranked this factor first, 5 (16.7%) second, 9 (30.0%) third, 5 (16.7%) fourth, 3 (10.0%) fifth, 1 (3.3%) sixth, and 1 (3.3%) seventh.

The third highest level of agreement with an average of 3.67 (SD=2.25) was in response to the factor "individual evaluation of medical evidence." For this hospital formulary decision-making factor, 7 (23.3%) prescribers ranked this factor as most important while 4 (13.3%) ranked the factor second. A total of 6 (20.0%) ranked it third, 2 (6.7%) ranked it fourth, 3 (10.0%) ranked it fifth, 2 (6.7%) ranked it sixth, and six (20.0%) of prescribers ranked it seventh or last.

The factor ranked fourth with a mean of 4.70 (SD=1.75) was regarding the factor which states “financial impact of the treatment to the institution.” A total of 1 (3.3%) of prescribers ranked this factor first, 4 (13.3%) second, 2 (6.7%) third, and 5 (16.7%) ranked the factor fourth. In addition, 7 (23.3%) prescribers ranked the factor fifth, 6 (20.0%) sixth, and 5 (16.7%) ranked it seventh or last.

The fifth highest ranking with a mean of 4.87 (SD=1.66) was related to the factor “opportunity for new treatment options.” A total of 1 (3.3%) prescriber ranked this factor first, 2 (6.7%) second, 1 (3.3%) third, while 10 (33.3%) ranked the factor fourth. A total of 5 (16.7%) prescribers ranked it fifth, 4 (13.3%) sixth, while 7 (23.3%) ranked it last.

The sixth ranked factor with a mean of 4.90 (SD=1.79) was related to the factor, “financial impact of treatment to the patient.” A total of 0 (0.0%) prescribers ranked the factor first, 5 (16.7%) second, 4 (13.3%) third, and 1 (3.3%) fourth. In the last positions, 4 (13.3%) prescribers ranked in fifth, 11 (36.7%) ranked it sixth, and 5 (16.7%) ranked it seventh.

The seventh and lowest ranking with a mean of 4.93 (SD=1.62) was in response factor “number of patients affected.” A total of 1 (3.3%) of prescribers ranked the factor first, 1 (3.3%) second, 4 (13.3%) third, 5 (16.7%) fourth. Finally, 7 (23.3%) prescribers ranked the factor fifth, 6 (20.0%) sixth, with the same number 6 (20.0%) ranking the factor seventh or last.

Table 8

Prescriber Group Means and Standard Deviations for Decision-Making Factor Ranking (Physician n=16, Midlevel Provider n=6, Pharmacist n=8, All Prescribers n=30)

	M	SD
Physician		
1) pharmacy staff's evaluation of medical evidence including formulary recommendations	2.19	1.17
2) evaluation of medications by expert physicians	2.69	1.25
3) individual evaluation of medical evidence	3.25	2.32
4) number of patients affected	4.63	1.71
5) financial impact of the treatment to the patient	4.88	2.00
6) opportunity for new treatment options	4.94	1.44
7) financial impact of the treatment to the institution	5.44	1.50
Midlevel Provider		
1) pharmacy staff's evaluation of medical evidence including formulary recommendations	1.67	1.21
2) evaluation of medications by expert physicians	3.00	1.79
3) individual evaluation of medical evidence	4.50	2.07
3) financial impact of the treatment to the institution	4.50	1.23
4) number of patients affected	4.67	1.86
4) opportunity for new treatment options	4.67	2.25
5) financial impact of the treatment to the patient	5.0	2.00
Pharmacist		
1) pharmacy staff's evaluation of medical evidence including formulary recommendations	1.50	0.76
2) financial impact of the treatment to the institution	3.38	1.85
3) evaluation of medications by expert physicians	3.75	1.91
4) individual evaluation of medical evidence	3.88	2.30
5) financial impact of the treatment to the patient	4.88	1.36
5) opportunity for new treatment options	4.88	1.81
6) number of patients affected	5.75	1.04

(table continues)

		M	SD
All Prescribers			
1)	pharmacy staff's evaluation of medical evidence including formulary recommendations	1.90	1.09
2)	evaluation of medications by expert physicians	3.03	1.56
3)	individual evaluation of medical evidence	3.67	2.25
4)	financial impact of the treatment to the institution	4.70	1.75
5)	opportunity for new treatment options	4.87	1.66
6)	financial impact of the treatment to the patient	4.90	1.79
7)	number of patients affected	4.93	1.62

Note. M = mean; SD = standard deviation. For midlevel providers, two factors are ranked third with identical mean values of 4.50 and two are ranked fourth with identical mean values of 4.67. For pharmacists, two factors are ranked fifth with an identical mean value of 4.88.

Statistical Tests

In addition to the descriptive statistical analyses performed, inferential statistics were performed. These analyses were performed to determine if statistically significant differences exist between the prescriber groups and the seven ranked means for the decision-making factors. Part III of the survey, as described previously, required the participants to rank the seven hospital formulary decision-making factors with a score of 1 being the most important to 7 being the least important. Similar descriptive and inferential statistics were performed for both Part II and Part III of the survey.

As described previously, the data for this study are not normally distributed. Furthermore, the dependent variable is categorical while the independent variables for the ranked decision-making factors are ordinal. For the rationale regarding the selection and use of the Kruskal-Wallis H test see the section entitled Survey - Part II and the subheading entitled Statistical Test Results. Table 9 provides the results of Levene's test for homogeneity of variance for the ranked decision-making factors.

Upon review of the data in Table 9, all variables meet the homogeneity of variance requirement. Therefore, the null hypothesis for Levene's test is accepted for the hospital formulary decision-making factors and the assumption of homogeneity of variance is met. Therefore, calculations using the Kruskal-Wallis test may be used determine if statistically significant differences exist between the prescriber groups.

Table 9

Levene's Homogeneity of Variance Test Results for Decision-Making Factor Ranking

Hospital Formulary Decision-making Factor	Levene Statistic	df1	df2	p
my individual evaluation of medical evidence	0.024	2	27	0.977
pharmacy staff's evaluation of medical evidence including formulary recommendations	0.466	2	27	0.632
evaluation of medications by expert physicians	0.935	2	27	0.405
number of patients affected	1.514	2	27	0.238
financial impact of the treatment to the institution	0.610	2	27	0.551
financial impact of the treatment to the patient	1.020	2	27	0.374
opportunity for new treatment options	0.587	2	27	0.563

Note. df = degrees of freedom; p = p statistic for Levene's test.

Table 10 provides the results of the independent samples Kruskal-Wallis H test as determined by running the test using SPSS© (2017) statistical software. Upon review of the table, one of the variables indicated a statistically significant difference between the three groups of prescribers. A Kruskal-Wallis H test showed for the factor, "financial impact of treatment to the institution," the following results: $\alpha = 0.05$, $X^2 = 2.720$, $p = 0.021$. For this factor, the mean rank score for physicians was 19.31, for midlevel providers 13.92, and for pharmacists 9.06. The significant difference is between Pharmacists and Physicians. Pharmacists ranked this factor significantly

higher in terms of importance than did Physicians. No other decision-making factors for Part III of the survey indicated a statistically significant difference in mean ranking scores between the prescriber groups based on the results of the Kruskal-Wallis H test.

Table 10

Kruskal-Wallis H Test for Results for Decision-Making Factor Ranking

Hospital Formulary Decision-making Factor	Chi-Square	df	p
my individual evaluation of medical evidence	1.648	2	0.439
pharmacy staff's evaluation of medical evidence including formulary recommendations	2.950	2	0.229
evaluation of medications by expert physicians	1.790	2	0.409
number of patients affected	2.720	2	0.257
financial impact of the treatment to the institution	7.716	2	0.021
financial impact of the treatment to the patient	0.143	2	0.931
opportunity for new treatment options	0.013	2	0.993

Note: df = degrees of freedom; p = p statistic for Kruskal-Wallis H Test. For the decision-making factor "financial impact of treatment to the institution", the p value is 0.021 which is < 0.050. Therefore the null hypothesis for the Kruskal-Wallis H test is rejected.

Survey – Part IV

Additional Factors

In Part IV of the survey, participants were asked to "List any additional factors you consider when making medication formulary decisions." A total of 8 (50.0%) physicians, 3 (50.0%) midlevel providers, and 3 (37.5%) pharmacists provided responses. The exact text of the responses is listed by prescriber group in Table 11.

Table 11

Prescriber Group Additional Hospital Formulary Decision-making Factors

Group	Responses
Physician	Redundancy to any current meds in formulary
	Ability to change the course of the disease ex. immunotherapy, Car T cell therapy etc.
	Existence of similar drugs in the formulary and weighing comparative efficacy
	Identification of potentials for misuse
	Prioritization of resource allocation
	Safety concerns- whether a REMS program exists
	Adverse event profile; incremental benefit over alternate options, and the cost of any perceived or real advantage.
	weight of evidence
	success of reimbursement
	We are not given out of pocket cost information for patients at the time we are making formulary decisions
	Unfortunately in my life I think about the cost/benefit of everything I do. However, at the institution cost to the institution or patient do not seem to matter. In most of the conditions we treat at MD Anderson there is only limited amount of years we can add to a patients [patient's] life and they are very costly. This is always a dilemma for me. Now that the FDA is so easy in approving any agent with a p-value the system is going to be more problematic when the national leader has set the bar so extremely low.
	man [main] consideration is the patent's [patient's] financial status and affordability
Midlevel Provider	Similar drug options already available if any.
	Adverse reactions along with frequency and severity of these reactions observed in published studies.
	Efficacy of the drug.
	Risk of harm with inappropriate use (who will be allowed to prescribe the drug, and restrictions that need to be placed on prescribing)
	Do we have a substitute on formulary to provide the patients (especially like for combo blood pressure meds-can we provide each individual medication)
	If we add drugs do we need to take some off--for things like storage
	As MDACC has an in and out patient should the drug be available only in the outpatient pharmacy (this is done with many of the oral chemo drugs)

(table continues)

Group	Responses
Midlevel Provider *(cont.)*	For the institution what is the present pay for drug by insurance company and do they have specific criteria --If they have specific criteria how do we make sure they are followed prior to prescribing or dispensing the drug
	Experience using the medication and the outcomes and safety of its use.
Pharmacist	Efficacy in comparative studies, particularly if one of the drugs being compared is already on formulary.
	Safety issues such as cost of treating side effects, severity of side effects
	I am only asked to participate in the P&T committee when it pertains to a drug I am familiar with, but it really depends on my own knowledge and experience with the disease state. If I am more familiar, I rely on my own investigation more so than if I am not familiar. If I am not familiar, I rely more on the pharmacy Med Management personnel's evaluation and/or expert testimony by physicians in the field.
	This may skew your results, but I have not officially been a member of P&T for many years. I am asked to participate ad hoc or to fill in if [name removed] is not able to attend.

Note. Items in square brackets "[ ]" indicate typographical corrections or redacted text to ensure confidentiality of study participants.

Additional Information

In Part IV of the survey participants were also asked to provide additional information considered when making hospital formulary decisions. The specific survey question was, "Please provide additional information you consider when making medication formulary decisions." A total of 3 (18.8%) physicians, 2 (33.3%) midlevel providers, and 1 (12.5%) pharmacists provided responses. The exact text of the responses by prescriber group are listed Table 12.

Finally, participants were asked if they would like a summary of the study results. Of the 30 participants, a total of 7 (23.3%) requested a summary of the study results and included their names and respective email addresses. Upon successful review and approval of this study by the work's major professor, dissertation committee, and

successful defense of the work as stipulated by the University of North Texas, Interdisciplinary Information Science PhD program, a summary will be provided to all participants who requested a summary of the study results.

Table 12

Prescriber Group Additional Hospital Formulary Decision-Making Information

Group	Responses
Physician	Receiving feedback about the monitoring/oversight of institutional use
	Is it a useful drug
	will it truly help
	is it because the company paid the researcher
	Is there a bias
	whether the prescribing will be restricted to certain services
Midlevel Provider	For the new cancer drugs--what is the TRUE benefit in quality of life or prolonged life (for prolonged do not consider 2 weeks a true benefit)
	Also if just approved by FDA--is there any other tumor types in clinical trials that would show how this drug would benefit a bigger population (if approved for a rare tumor type)
	Also look at side effect profile and can they be managed fairly easily
	Impact of the medication on cancer and infections or the disease.
Pharmacist	The cost of the medication only comes into consideration after all other factors are considered and other alternatives evaluated.

Summary

This chapter presented the analysis and findings of the data collected from the online self-administered survey. All participants have served on the University of Texas, MD Anderson Cancer Center pharmacy and Therapeutics Committee and are still on the medical staff of the institution. The survey was completed by 30 prescribers comprised of 16 physicians, 6 midlevel providers, and 8 pharmacists.

In Part II of the survey, prescribers were asked to respond to 7 statements related to each of the hospital formulary decision-making factors. Each statement was assign an agreement score associated with the 5-point Likert scale. Means were then computed for each of the 7 statements and corresponding hospital formulary decision-making factors. Subsequently, the means were sorted to ascertain the highest to lowest level of agreement for each hospital formulary decision-making factor and for each prescriber group. The primary research questions for all three prescriber groups was to determine the ranked order of the seven hospital formulary decision-making factors. These results are presented in Table 4.

For the data obtained from Part II of the survey, a Kruskal-Wallis H test was performed to determine if any statistically significant differences exist. The statistical test showed a significant difference in mean agreement score exists between prescriber groups for one hospital formulary decision-making factor. In response to the statement, "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decision." A Kruskal-Wallis H test showed there was a statistically significant difference in mean agreement score between the prescriber groups, $\alpha = 0.05$, $X^2 = 6.055$, $p = 0.048$. A mean rank agreement score of 14.25 was observed for physicians, 22.50 for midlevel providers, and 12.75 for pharmacists. No other decision-making factors for Part II of the survey, regarding the agreement statements, indicated a statistically significant difference in agreement scores between the prescriber groups.

In part III of the survey, prescribers were asked to rank the seven hospital formulary decision-making factors. For this part of the survey, a score of 1 was

assigned for the factor considered most important factor to a score of 7 for the least important factor. Means were then computed for each of the seven hospital formulary decision-making factors. These means were sorted in ascending order to ascertain the factor ranked most important to the factor ranked least important for each prescriber group. As mentioned previously, the primary research questions for all three prescriber groups was to ascertain the ranked order for the seven hospital formulary decision-making factors. These results are presented in Table 8 for each prescriber group and among all prescribers. These results were also used to address the 6 hypotheses for each provider group. These hypotheses were analyzed in detail and each hypothesis either accepted or rejected. See the sections entitled Survey – Part III, and associated subsections entitled physician hypotheses, midlevel provider hypotheses, and pharmacist hypotheses.

A Kruskal-Wallis H test was also performed for the hospital decision-making factor ranking data associated with Part III of the survey. These data revealed a statistically significant difference in mean agreement score between the prescriber groups. The difference was observed for the factor, "financial impact of treatment to the institution." The results of the Kruskal-Wallis H test were, $\alpha = 0.05$, $X^2 = 2.720$, $p = 0.02$. The mean rank score was 19.31 for physicians, 13.92 for midlevel providers, and 9.06 for pharmacists. No other decision-making factors for Part III of the survey according the Kruskal-Wallis H test indicated a statistically significant difference.

Part IV of the survey asked prescribers to provide any additional factors or information considered when making hospital formulary decisions. Additional factors provided by the participants are included in Table 11. Additional information considered

when making hospital formulary decisions are included in Table 12. These additional factors and information are discussed in greater detail in Chapter V.

The next chapter provides an overview of the study and conclusions. In addition, the significance of the study and recommendations for future research are discussed.

CHAPTER V

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Introduction

This chapter presents an overview of the study with the findings as they relate to the research questions, hypotheses, literature, and conclusions drawn from the study. In addition, the significance of the study and recommendations for future research are discussed.

Overview of the Study

The purpose of the study is to identify, rank, and compare major factors impacting hospital formulary decision-making among three prescriber groups serving on a hospital pharmacy and Therapeutics (P&T) committee. Prescribers were selected from the University of Texas, MD Anderson Cancer Center which is a large, multi-facility, academic oncology hospital. Specifically, the prescriber groups studied were physicians, midlevel providers, and pharmacists.

Upon review of the scientific literature, seven major hospital formulary decision-making factors were identified and include:

- Individual evaluation of medical evidence (Kelly & Bender, 1983)
- pharmacy staff evaluation of medical evidence including formulary recommendations (Malone, Kier, & Stanovich, 2012)
- Evaluation of medications by expert physicians (Segal & Pathak, 1988)
- Number of patients affected (Kelly & Bender, 1983)
- Financial impact of the treatment for the institution (Anagnostis, Wordell, Guharoy, Beckett, & Price, 2011)
- Financial impact of the treatment for the patient (Deangelis, 2016)

- Opportunity for new treatment options (U.S. Institute of Medicine, Committee on Quality of Health Care in America, 2001)

First, the seven identified factors were included in hospital formulary decision-making statements and scored by participants on a 5-point Likert scale indicating a level of agreement. Second, the factors we ranked by participants on a 7-point ranking scale with 1 being most import to 7 least important. The following section provides the summarized findings and addresses the stated research questions and hypotheses posed by the study.

Hospital Formulary Decision-Making Statements

The mean order based on agreement scores for hospital formulary decision-making statements is summarized in Table 13. Some factors are tied in terms of their agreement scores and appear as duplicate ranking values in the numerated lists. This order serves to address the research questions and associated hypotheses for each prescriber group:

Group 1: Physicians

Q1: What is the ranked order of factors that influence hospital formulary decision-making by physicians?

1. Pharmacy staff's evaluation of medical evidence including formulary recommendations
2. Evaluation of medications by expert physicians
3. Opportunity for new treatment options
4. Financial impact of the treatment to the patient
5. Individual evaluation of medical evidence
6. Financial impact of the treatment to the institution

7. Number of patients affected

Group 2: Midlevel Providers

Q2. What is the ranked order of factors that influence hospital formulary decision-making by midlevel providers?
pharmacy staff's evaluation of medical evidence including formulary recommendations

1. Number of patients affected
2. Opportunity for new treatment options
3. Financial impact of the treatment to the institution
4. Evaluation of medications by expert physicians
5. Financial impact of the treatment to the patient
6. Individual evaluation of medical evidence

Group 3: Pharmacists

Q3. What is the ranked order of factors that influence hospital formulary decision-making by pharmacists?

1. Financial impact of the treatment to the institution
2. Opportunity for new treatment options
3. pharmacy staff's evaluation of medical evidence including formulary recommendations
4. Number of patients affected
4. Evaluation of medications by expert physicians
5. Financial impact of the treatment to the patient
6. Individual evaluation of medical evidence

Table 13

Prescriber Group Ordered Factors for Decision-Making Factor Statements (physician n=16, midlevel provider n=6, pharmacist n=8, all prescribers n=30)

Decision-making factor	Physician	Midlevel Provider	Pharmacist
Pharmacy staff's evaluation of medical evidence including formulary recommendations	1	1	3
Evaluation of medications by expert physicians	2	5 (tie)	4 (tie)
Opportunity for new treatment options	3	3	2
Financial impact of the treatment to the patient	4	5 (tie)	5
Individual evaluation of medical evidence	5	6	6
Financial impact of the treatment to the institution	6	4	1
Number of patients affected	7	2	4 (tie)

Note. For midlevel providers, two factors are tied for the fifth position. For pharmacists, two factors are tied for fourth position.

In addition to the three research questions, six hypotheses were developed for each prescriber group. A summary of the hypotheses results based on the hospital formulary decision-making statements is presented in Table 14. Hypotheses 2 is identical for physicians and midlevel providers. However, Hypotheses 2 is stated differently for pharmacists. All other hypotheses are identical for all prescriber groups.

For physicians four hypotheses were accepted including 1, 3, 4 and 5 while two were rejected 2 and 6. Midlevel providers' hypotheses results are identical to physicians. For pharmacists, Hypotheses 1, 2, 3 and 5 were accepted while two were rejected 4 and 6.

Table 14

Prescriber Group Hypotheses Results for Decision-Making Factor Statements

Hypotheses	Physician Results	Midlevel Provider Results	Pharmacist Results
1.1, 2.1, 3.1: Individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.	accepted	accepted	accepted
1.2, 2.2: Evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.	rejected	rejected	
3.2: Evaluation of medications by expert physicians has a lower ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.			accepted
Hypothesis 1.3, 2.3, 3.3: pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.	accepted	accepted	accepted
Hypothesis 1.4, 2.4, 3.4: pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.	accepted	accepted	rejected
Hypothesis 1.5, 2.5, 3.5: pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.	accepted	accepted	accepted
Hypothesis 1.6, 2.6, 3.6: Individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.	rejected	rejected	rejected

Note. Hypothesis 2 is the same for physicians and midlevel providers, but different for pharmacists. All other hypotheses are identical among all three prescriber groups.

Hospital Formulary Decision-Making Factor Ranking

Prescribers were asked to rank the seven identified hospital formulary decision-making factors on a 7-point ranking scale. Table 15 provides a summary of the hospital formulary decision-making factors based on ranked order for each of the prescriber groups. Some ranked factors have identical means and are tied in terms of ranked order. The sorted mean values were used to address the research questions and hypotheses for each prescriber group including physicians, midlevel providers, and pharmacists:

Group 1: Physicians

Q1: What is the ranked order of factors that influence hospital formulary decision-making by physicians?

1. Pharmacy staff's evaluation of medical evidence including formulary recommendations
2. Evaluation of medications by expert physicians
3. Individual evaluation of medical evidence
4. Number of patients affected
5. Financial impact of the treatment to the patient
6. Opportunity for new treatment options
7. Financial impact of the treatment to the institution

Group 2: Midlevel Providers

Q2: What is the ranked order of factors that influence hospital formulary decision-making by midlevel providers?

1. Pharmacy staff's evaluation of medical evidence including formulary recommendations
2. Evaluation of medications by expert physicians
3. Individual evaluation of medical evidence

3. Financial impact of the treatment to the institution
4. Number of patients affected
4. Opportunity for new treatment options
5. Financial impact of the treatment to the patient

Group 3: Pharmacists

Q3: What is the ranked order of factors that influence hospital formulary decision-making by pharmacists?

1. Pharmacy staff's evaluation of medical evidence including formulary recommendations
2. Financial impact of the treatment to the institution
3. Evaluation of medications by expert physicians
4. Individual evaluation of medical evidence
5. Opportunity for new treatment options
5. Financial impact of the treatment to the patient
6. Number of patients affected

Table 15

Prescriber Group Ordered Factors for Decision-Making Factor Ranking (Physician n=16, Midlevel Provider n=6, Pharmacist n=8, All Prescribers n=30)

Decision-Making Factor	Physician	Midlevel Provider	Pharmacist
Pharmacy staff's evaluation of medical evidence including formulary recommendations	1	1	1
Evaluation of medications by expert physicians	2	2	3
Individual evaluation of medical evidence	3	3 (tie)	4
Number of patients affected	4	4 (tie)	6
Financial impact of the treatment to the patient	5	5	5 (tie)
Opportunity for new treatment options	6	4 (tie)	5 (tie)
Financial impact of the treatment to the institution	7	3 (tie)	2

Note. Factors 3 and 4 are tied in terms of ranking means for midlevel providers, and factor 5 is tied for pharmacists.

Table 16

Provider Group Hypotheses Results for Decision-Making Factor Ranking

Hypotheses	Physician Result	Midlevel Provider Result	Pharmacist Result
Hypothesis 1.1, 2.1, 3.1: Individual evaluation of medical evidence has a lower ranking of influence on hospital formulary decision-making than does the evaluation of medications by expert physicians.	accepted	accepted	accepted
Hypothesis 1.2, 2.2: Evaluation of medications by expert physicians has a higher ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.	rejected	rejected	
Hypothesis 3.2: Evaluation of medications by expert physicians has a lower ranking of influence on hospital formulary decision-making than does the pharmacy staff's evaluation of medical evidence including formulary recommendations.			accepted
Hypothesis 1.3, 2.3, 3.3: pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the number of patients affected.	accepted	accepted	accepted
Hypothesis 1.4, 2.4, 3.4: pharmacy staff's evaluation of medical evidence including formulary recommendations has a higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the institution.	accepted	accepted	accepted
Hypothesis 1.5, 2.5, 3.5: pharmacy staff's evaluation of medical evidence including formulary recommendations has higher ranking of influence on hospital formulary decision-making than does the financial impact of the treatment for the patient.	accepted	accepted	accepted
Hypothesis 1.6, 2.6, 3.6: Individual evaluation of medical evidence has a higher ranking of influence on hospital formulary decision-making than does the opportunity for new treatment options.	accepted	accepted	accepted

The summary of the hypotheses results based on hospital formulary decision-making factor ranking is presented in Table 16. Hypotheses 2 is identical for physicians

and midlevel providers. However, this hypothesis is stated differently for pharmacists. For physicians five hypotheses were accepted including 1, 3, 4, 5, and 6 while Hypothesis 2 was rejected. Results for midlevel providers are identical to physicians. For pharmacists, all six hypotheses were accepted.

Conclusions

There are five major conclusions to be drawn from the study including three similarities and two significant differences.

Similarities:

1. The factor, *pharmacy staff's evaluation of medical evidence including formulary recommendations* was ranked highest for all three prescriber groups.
2. The factor, *evaluation of medications by expert physicians* was ranked second for physicians and midlevel providers while pharmacists ranked it third.
3. The factor, *financial impact of the treatment to the patient* was fifth in terms of hospital formulary decision-making statements order and ranked fifth on average by all three prescriber groups.

The similar findings among the prescriber groups provides evidence of the following. The factor, "pharmacy staff's evaluation of medical evidence including formulary recommendations," is deemed the most important hospital formulary decision-making factor by all 3 prescriber groups and aids greatly in P&T committee hospital formulary decision-making. It is also clear that the evaluation of medications by expert physicians is an important factor. Expert physicians interject valuable clinical knowledge and expertise into the decision-making process. Finally, the financial impact of treatment to the patient was consistently ranked among the bottom three factors. This is likely due to the difficulty in ascertaining out-of-pocket costs from insurance

carriers and determining a single out-of-pocket cost estimate. Out-of-pocket expenses vary depending on a patient's insurance status or on types of insurance coverage. As a physician points out when responding to Part IV (see: Table 11) of the survey regarding additional decision-making factors, "We are not given out of pocket cost information for patients at the time we are making formulary decisions."

Significant Differences

1. For the hospital-formulary decision-making statement, "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making hospital medication formulary decisions." Midlevel providers considered this factor of significantly greater importance than did physicians or pharmacists.

2. For the ranked hospital formulary decision-making factor, "financial impact of treatment to the institution." Pharmacists ranked this factor significantly higher than did physicians.

It is unclear why a significant difference exists between midlevel providers as opposed to physicians and pharmacists when responding to the statement, "I consider the number of patients affected by adding, removing, or modifying a drug on the formulary when making a medication formulary decision." Greater insight into this difference could be ascertained by additional qualitative research. The second significant difference was between pharmacists as compared to physicians when ranking the factor "financial impact of treatment to the institution." Pharmacists indicted a significantly higher ranking of importance than did physicians. This could be attributed to the fact that the Division of pharmacy bears budgetary responsibility for both medication related acquisition expenses and the associated medication related income.

Such fiscal responsibility within the organization could explain this significantly higher ranking of importance for pharmacists serving on the P&T committee.

Additional Points

1. More variability existed between prescriber groups when responding to independent hospital formulary decision-making statements on a 5-point Likert scale than on a 7-point ranking scale.

2. Greater homogeneity emerged among the prescriber groups based on the results of ranking the factors on a 7-point ranking scale. This is especially true of physicians and midlevel providers.

3. The decision-making statement, "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions" did not pass Leven's homogeneity of variance test and was not considered during statistical analysis.

Greater variability between the hospital formulary decision-making statements versus the ranked factors is likely a result of data characteristics. For the decision-making statements a 5-point Likert scale was used versus for the factors a 7-point ranking. The ranking section of the survey required participants to arrive at a singular ranked order for each of the factors in relationship to one another. The ranking data appears to have revealed greater homogeneity among the groups than did the Likert scale statements. Homogeneity related to hospital formulary decision-making factors is especially apparent among physicians and midlevel providers. Finally, for the statement "I rely upon the evaluation of medications by expert physicians to make hospital medication formulary decisions," all six midlevel providers selected "agree" for this statement. In other words, no variance existed in the responses for the statement for among midlevel providers.

Significance of the Study

The number of clinical trials for medications is increasing at an unprecedented rate in the United States. Consequently, prescribers find it increasingly difficult to stay abreast of new and constantly changing medical evidence. Hospitals and hospital systems are under increasing pressure to reduce cost while at the same time improving the quality of healthcare delivery and outcomes. To address these issues, the majority of hospitals and hospital systems utilize a hospital formulary managed by a P&T committee comprised of its medical staff. P&T committees are required to evaluate medications and determine which agents will be used to treat patients and which are effective for treatment and most economically advantageous. How the various prescriber groups arrive at decisions related to the hospital formulary is not well understood.

This study contributes to a greater understanding of the three prescriber groups serving on a P&T committee comprised of physicians, midlevel providers, and pharmacists. Furthermore, the study identifies and ranks the major factors affecting hospital formulary decision-making. The study contributes to the body of literature regarding decision-making processes in medicine and specifically factors impacting hospital formulary decision-making. Furthermore, this study has the potential to impact the operational guidelines for the P&T committee at the University of Texas, MD Anderson Cancer Center as well as other hospitals.

Recommendations for Future Research

Replicating the study at other hospitals that manage their hospital formulary

using a P&T committee structure will serve to produce more generalizable results. A survey of various general and specialty hospitals would yield additional insights into hospital formulary decision-making which may occur outside of a specialty oncology hospital.

Additional insight into the prescriber decision-making factors could occur by conducting content analysis based on historical P&T committee meeting minutes. Content analysis could potentially correlate the various decision-making factors identified in the study with the final decisions arrived at by the P&T committee. However, the difficulty with this approach, is that only summarized meeting minutes are produced by Division of pharmacy staff. Furthermore, P&T committee meetings are not recorded nor are verbatim transcripts produced.

There is the potential to identify other hospital formulary decision-making factors that are not explicitly apparent from a review of the literature. Participants were asked to provide additional hospital formulary decision-making factors in Part IV of the survey. These additional factors are listed in Table 11 and should be considered for inclusion in future research. Furthermore, in Part IV of the survey participants were asked to state any additional information used when making decisions these responses are listed in Table 12. Determination of additional individual, collaborative, and information artifact decision-making factors (Patel, Kaufman, & Kannampallil, 2013) will require conducting focus groups or semi-structured interviews (Bernard, 2006) of P&T committee members from various types of hospitals.

Of the differences identified between the prescriber groups, it is unclear the reasons for the differences and how the differences could be addressed. A greater

understanding of the identified differences could facilitate greater collaboration and understanding among the prescriber groups and impact P&T committee decision-making and operation.

Summary

This chapter presented an overview of the study findings in relation to the major hospital formulary decision-making factors identified in the literature. It also addressed the stated research questions and hypotheses for physicians, midlevel providers, and pharmacists. Five major conclusions were drawn regarding the prescriber groups including three similarities and two differences. The significance of the study was also discussed in terms of insight gained by conducting the study. Finally, recommendations for additional research were provided.

APPENDIX A

IRB APPROVAL LETTER UNIVERSITY OF NORTH TEXAS

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EST. 1890

THE OFFICE OF RESEARCH AND INNOVATION
Research and Economic Development

October 4, 2017

Dr. Ana Cleveland
Student Investigator: James Spence
Department of Information Science
University of North Texas

RE: Human Subjects Application No. 17-347 Dear Dr. Cleveland:

In accordance with 45 CFR Part 46 Section 46.101, your study titled “A Comparison of Major Factors that affect Hospital Formulary Decision-Making by Three Groups of Prescribers” has been determined to qualify for an exemption from further review by the UNT Institutional Review Board (IRB).

Enclosed are the consent documents with stamped IRB approval. Since you are conducting an online study, **please copy the approved language and paste onto the first page of your online survey. You may also use the enclosed stamped document as the first page of your online survey.**

No changes may be made to your study’s procedures or forms without prior written approval from the UNT IRB. Please contact The Office of Research Integrity and Compliance at 940-565- 4643 if you wish to make any such changes. Any changes to your procedures or forms after 3 years will require completion of a new IRB application.

We wish you success with your study.

Sincerely,

Chad Trulson, Ph.D.
Professor
Chair, Institutional Review Board

CT:jm

APPENDIX B

IRB APPROVAL EMAIL CORRESPONDENCETHE UNIVERSITY OF TEXAS, MD ANDERSON CANCER CENTER

From: Campbell,Theresa H
Sent: Monday, October 02, 2017 7:30 AM
To: Spence,James M <JMSpence@mdanderson.org>
Subject: RE: Protocol PA17-0630 - IRB Exempt

Yes, you may now proceed with your study. IRB Exempt means you will not have an annual review as this study is considered “exempt”.

Thank you,

Theresa Campbell
Human Research Regulations Specialist
Office of Protocol Research, Unit 1637
The University of Texas MD Anderson Cancer Center
Phone: 713-563-5433 Fax: 713-794-4589

From: Spence,James M
Sent: Monday, October 02, 2017 6:46 AM
To: Campbell,Theresa H
Subject: FW: Protocol PA17-0630 - IRB Exempt

Theresa,

I received the following email after submitting an “activation memo” for Protocol PA17-0630. I’m a bit unclear as to what the email means.

Does this mean that since the study is considered “IRB Exempt” and I’ve resolved all contingencies that it is OK for me to proceed with the study?

Thanks in advance,

James M. Spence, MLIS
Manager, pharmacy Quality Improvement and Analytics
Division of pharmacy - Medication Management & Analytics
T 713-563-3674

From: Kara M. Seales [mailto:kmseales@mdanderson.org]
Sent: Friday, September 29, 2017 3:09 PM
To: Spence,James M <JMSpence@mdanderson.org>; Heck,Wendy D <WDHeck@mdanderson.org>; Campbell,Theresa H <THCampbe@mdanderson.org>; Cortez,Yadira L <ylcortez@mdanderson.org>; Tamez,Margie <mtamez@mdanderson.org>
Subject: Protocol PA17-0630 - IRB Exempt

Institutional Review Board (IRB)
Unit 1637
Phone 713-792-2933
Fax 713-794-4589
Office of Protocol Research

To: James M. Spence 09/29/2017
From: Kara M. Seales
CC: Wendy D Heck, Theresa H. Campbell, Yadira L. Cortez, Margie Tamez
MDACC Protocol ID #: PA17-0630
Protocol Title: A COMPARISON OF MAJOR FACTORS THAT AFFECT HOSPITAL FORMULARY DECISION-MAKING BY THREE GROUPS OF PRESCRIBERS
Version: 03

Subject: Protocol PA17-0630 - IRB Exempt

IRB Approval Date: 08/27/2017
IRB Activation Date: 09/29/2017

According to the Code of Federal Regulations (45CFR46) those research activities involving human subjects which qualify under specific exemption categories are not subject to the above regulations, and therefore do not require Institutional Review Board review.

The IRB Chair or designee reviewed the research and granted exemption based on the following category:

Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Any subsequent changes to the research activity should be submitted for IRB review.

In the event of any questions or concerns, please contact the sender of this message at (713) 792-2933.

Kara M. Seales 09/29/2017 03:09:03 PM

_____

This is a representation of an electronic record that was signed and dated electronically and this page is the manifestation of the electronic signature and date:

Kara M. Seales
09/29/2017 03:08:01 PM
IRB 4 Chair Designee
FWA #: 00000363
OHRP IRB Registration Number: IRB 4 IRB00005015

APPENDIX C

INFORMED CONSENT

University of North Texas
and
The University of Texas, MD Anderson Cancer Center
Institutional Review Board Informed Consent Notice

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the purpose, benefits and risks of the study and how it will be conducted.

Title of Study: A COMPARISON OF MAJOR FACTORS THAT AFFECT HOSPITAL FORMULARY DECISION-MAKING BY THREE GROUPS OF PRESCRIBERS

Student Investigator: James M. Spence, University of North Texas (UNT) Department of Information. Supervising Investigator: Ana Cleveland, PhD.

Purpose of the Study: The purpose of the study is to identify, rank, and compare major factors impacting hospital formulary decision-making among three prescriber groups serving on a hospital pharmacy and Therapeutics (P&T) committee.

Prescribers will be selected from The University of Texas, MD Anderson Cancer Center which is a large, multi-facility, academic oncology hospital. Specifically, the prescriber groups studied are comprised of physicians, midlevel providers, and pharmacists.

Study Procedures: You will be asked to respond to questions about each of the hospital formulary decision-making factors. Second, study participants will be asked to rank the various formulary decision-making factors from the factor deemed most important to the factor deemed least important. The online survey will take about 15 to 20 minutes of your time.

Foreseeable Risks: No foreseeable risks are involved in this study.

Benefits to the Subjects or Others: Overall, the study is expected to provide a greater understanding of the three prescriber groups comprised of physicians, midlevel providers, and pharmacists who routinely serve on P&T committees.

Furthermore, the study seeks to identify and rank the major factors affecting hospital formulary decision- making. The study may contribute to the body of literature regarding decision-making processes in medicine and specifically identify factors impacting hospital formulary decision-making. This study has the potential to impact the operational guidelines for the P&T committees. Study results cannot be guaranteed.

Compensation for Participants: None

Procedures for Maintaining Confidentiality of Research Records: Confidentiality will be maintained to the degree possible given the technology and practices used by the online survey company. Your participation in this online survey involves risks to confidentiality similar to a person’s everyday use of the internet. Survey data will

remain confidential and securely stored on the University of Texas, MD Anderson Cancer and UNT campuses, and any data published will be aggregated.

Questions about the Study: If you have any questions about the study, you may contact: James M. Spence at 713-563-3674 or by email jmspence@mdanderson.org, or jms0435@unt.edu, or Ana Cleveland at 940- 565-2445 or by email ana.cleveland@unt.edu

Review for the Protection of Participants: This research study has been reviewed and approved by the UNT and University of Texas, MD Anderson Cancer Center Institutional Review Boards (IRBs). The UNT IRB can be contacted at 940- 565-4643 with any questions regarding the rights of research subjects. The University of Texas, MD Anderson Cancer Center IRB can be contacted at 713- 792-2933.

Research Participants' Rights:
Your participation in the survey confirms that you have read all of the above and that you agree to all of the following:

- James M. Spence has explained the study to you and you have had an opportunity to contact him/her with any questions about the study. You have been informed of the possible benefits and the potential risks of the study.
- You understand that you do not have to take part in this study, and your refusal to participate or your decision to withdraw will involve no penalty or loss of rights or benefits. The study personnel may choose to stop your participation at any time.
- You understand why the study is being conducted and how it will be performed.
- You understand your rights as a research participant and you voluntarily consent to participate in this study.
- You understand you may print a copy of this form for your records.

I have read the description of the study, and I have decided to participate in the research project described here. I understand that I may refuse to answer any (or all) of the questions at this or any other time. I understand that there is a possibility that I might be contacted in the future about this, but that I am free to refuse any further participation if I wish.

During the course of this study, the research team at UNT and The University of Texas, MD Anderson Cancer Center will be collecting information about me that they may share with health authorities, study monitors who check the accuracy of the information, individuals who put all the study information together in report form. By answering the questions, I am providing authorization for the research team to use and share my information at any time. If I do not want to authorize the use and disclosure of my information, I may choose not to answer these questions. There is no expiration date for the use of this information as stated in this authorization.

I may withdraw my authorization at any time, in writing, for any reason as long as that information can be connected to me. I can learn more about how to withdraw my authorization by calling 713-792-2933 or by contacting the study investigators.

APPENDIX D

ELECTRONIC MAIL MESSAGE TO PARTICIPANTS

Dear current or previous pharmacy and Therapeutics Committee Member,

My name is James Spence, and I am a doctoral candidate in the Interdisciplinary Ph.D. Program in Information Science at the University of North Texas. My faculty advisor is Dr. Ana D. Cleveland.

I would like to invite you to participate in a qualitative survey-based study for my dissertation entitled “A Comparison of Major Factors That Affect Hospital Formulary Decision-Making by Three Groups of Prescribers.” The study engages physicians, midlevel providers/advanced practice providers, and pharmacists to participate, jointly but confidentially, in analyzing factors that impact hospital formulary decision-making.

Based on your record on service on The University of Texas, MD Anderson Cancer Center pharmacy and Therapeutics Committee, you have been selected as a participant for this study. Your participation is voluntary, and your input is important as we discover the factors that impact hospital formulary decision-making.

There will a single survey which will consist of a questionnaire that you will fill out electronically using Qualtrics, online survey software. It is anticipated that the survey will take approximately 15 to 20 minutes for you to complete. All information obtained will be confidential.

If you agree to participate in this study, I have included a link or URL to the online survey below. There will be no negative effects for agreeing or declining to participate in the study.

Follow this link to the Survey:
${l://SurveyLink?d=Take the Survey}

Or copy and paste the URL below into your internet browser:
${l://SurveyURL}

Follow the link to opt out of future emails:
${l://OptOutLink?d=Click here to unsubscribe}

Thank you in advance for your participation in this study! If you have any questions, feel free to contact me at jmspence@mdanderson.org, jms0435@unt.edu, or 713-563-3674.

James M. Spence, MLIS Doctoral Candidate
Interdisciplinary Ph.D. Program in Information Science University of North Texas
jms0435@unt.edu

Ana Cleveland, Ph.D. Supervising Investigator
Interdisciplinary Ph.D. Program in Information Science University of North Texas
Ana.Cleveland@unt.edu

APPENDIX E

SURVEY

Part I: Please provide the following background information:

1. What is your age (select **one** age range listed below) ?

   ☐ 18-24 years old

   ☐ 25-34 years old

   ☐ 35-44 years old

   ☐ 45-54 years old

   ☐ 55-64 years old

   ☐ 65-74 years old

   ☐ 75 years or older

2. What is your gender (select one) ?

   ☐ Male

   ☐ Female

3. How many years and months have you been a licensed healthcare provider (including any residencies)?

   Years _____

   Months _____

4. How long have you been a licensed healthcare provider at the University of Texas, MD Anderson Cancer Center (years and months) ?

   Years _____

   Months _____

5. What is your prescribing role at The University of Texas, MD Anderson Cancer Center (select one) ?

   ☐ physician

   ☐ midlevel provider/Advanced Practice Provider (e.g. physician Assistant, Advanced Practice Nurse)

   ☐ pharmacist

   ☐ None of the above

6. Are you a current member of the The University of Texas, MD Anderson Cancer Center pharmacy and Therapeutics (P&T) Committee?

   ☐ Yes

   ☐ No

   How many previous years have you served on The University of Texas, MD Anderson Cancer Center pharmacy and Therapeutics (P&T) Committee (select all previous years of service) ?

   ☐ Fiscal Year 2017 (9/1/16-8/31/17)
   ☐ Fiscal Year 2016 (9/1/15-8/31/16)
   ☐ Fiscal Year 2015 (9/1/14-8/31/15)
   ☐ Fiscal Year 2014 (9/1/13-8/31/14)
   ☐ Fiscal Year 2013 (9/1/12-8/31/13)
   ☐ Fiscal Year 2012 (9/1/11-8/31/12)
   ☐ Fiscal Year 2011 (9/1/10-8/31/11)
   ☐ Fiscal Year 2010 (9/1/09-8/31/10)
   ☐ Fiscal Year 2009 (9/1/08-8/31/09)
   ☐ Fiscal Year 2008 (9/1/07-8/31/08)
   ☐ Fiscal Year 2007 (9/1/06-8/31/07)

Part II: Using the 5-point scale, please rate your level of agreement or disagreement with the 7 P&T decision-making factor statements below:

7. I rely upon my **individual evaluation of medical evidence** to make hospital medication formulary decisions (select one).

1	2	3	4	5
Strongly Disagree	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

8. I rely upon the **pharmacy staff's evaluation of medical evidence including formulary recommendations** (e.g. Drug Monograph, Medication Use Evaluation, etc.) to make hospital medication formulary decisions (select one).

1	2	3	4	5
Strongly Disagree	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

9. I rely upon the **evaluation of medications by expert physicians** to make hospital medication formulary decisions (select one).

1	2	3	4	5
Strongly Disagree	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

10. I consider the **number of patients affected** by adding, removing, or modifying a drug on the formulary when making a hospital medication formulary decisions (select one).

1	2	3	4	5
Strongly Disagree	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

11. I consider the **financial impact of the treatment to the institution** in terms of drug cost and potential reimbursement when making hospital medication formulary decisions (select one).

1	2	3	4	5
Strongly Disagree	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

12. I consider the **financial impact of the treatment to the patient** in terms of the out-of-pocket expenses they may incur when making hospital medication formulary decisions (select one).

1	2	3	4	5
Strongly Disagree	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

13. In my role as a medication prescriber, I consider the **opportunity for new treatment options** when adding or expanding the use of a hospital formulary medication (select one).

1	2	3	4	5
Strongly Disagree	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

Part III: Please rank the decision-making factors listed below when making a hospital medication formulary decision. Indicate a "1" for the most important factor and a "7" for the least important factor:

14. Rank the Formulary Decision Making Factors. Indicate a "1" for the most important factor and "7" for the least important factor:

Assigned Rank	Decision making Factor
	My individual evaluation of medical evidence
	pharmacy staff's evaluation of medical evidence including formulary recommendations
	Evaluation of medications by expert physicians
	Number of patients affected by adding, removing, or modifying a formulary medication
	Financial impact of the treatment for the institution in terms of drug costs and potential reimbursement
	Financial impact of the treatment for the patient in terms of potential out-of-pocket expenses
	Opportunity for new treatment options

Part IV: Please provide additional information.

15. List any additional factors you consider when making medication formulary decisions:

_____

_____

Please provide additional information you consider when making medication formulary decisions:

_____

_____

16. Would you like a summary of study results upon its conclusion?

If yes, please provide your name and email address.

☐ Yes

☐ No

If yes, please provide your name and email address

Name: _____

Email address: _____

Thank you for your participation.

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