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Development of a model of the Pharmacy and Therapeutics Committee to predict the level of prescriber adoption of its' decisions

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DEVELOPMENT OF A MODEL OF THE PHARMACY AND THERAPEUTICS COMMITTEE TO PREDICT THE LEVEL OF PRESCRIBER ADOPTION OF ITS DECISIONS

by

Michael Thomas Andreski

An Abstract

Of a thesis submitted in partial fulfillment
of the requirements for the Doctor of
Philosophy degree in Pharmacy
(Pharmaceutical Socioeconomics)
in the Graduate College of
The University of Iowa

December 2009

Thesis Supervisor: Professor Karen B. Farris

ABSTRACT

Pharmacy and Therapeutics (P&T) Committees manage programs that provide patients with effective, safe, and financially sound medication treatments. Despite their importance, little research exists into what committee characteristics lead to adoption of its decisions by prescribers. Considered as “teams”, research from the management literature and a qualitative study identified a theoretical model of P&T Committee performance that includes five concepts and a set of four outcome measures. The study aims were to: (1) Describe the variance in P&T Committee functioning and performance in the United States, (2) Quantify drivers of performance within the P&T Committee Performance model and (3) Quantify the relationships between concepts in the P&T Committee model and the effects of these relationships on P&T Committee performance.

An on-line and paper cross-sectional survey was sent to 321 Pharmacy Directors, Hospital Administrators/Medical Staff Directors and P&T Committee Chairs at non-university non-specialty hospitals with an ASHP residency. Previously validated measures were used for two concepts, and newly created measures for three concepts. Four dependent variables were used: adoption of formulary medications, medication restrictions, Community-Acquired Pneumonia (CAP) treatment and Deep Vein Thrombosis (DVT) risk assessment protocols. Multivariate regression and path analysis were used with the dependent variables, with five primary variables of interest and five control variables.

The response rate was 17.76%. P&T Committee developed processes are successful in leading prescribers to adopting formulary medication decisions (96.02 ± 3.94%), with no differences based on hospital characteristics. They have not been as successful in developing processes for adoption of decisions on medication restrictions (77.02 ± 28.81%) and protocols (63.02 ± 32.76%, 73.02 ± 29.96%). Engaged team members were important in the adoption of all four studied P&T Committee decisions. Influential physicians and implementation activities varied in their importance depending on the decision being made. The presence of influential

physicians on the P&T Committee appeared to facilitate both implementation activities and engagement of team members. Influences outside of the committee were insignificant as predictors of decision adoption, possibly an indicator of successful efforts mitigating their influence. This research begins to address previous research gaps about factors affecting adoption of P&T Committee decisions.

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CERTIFICATE OF APPROVAL

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PH.D. THESIS

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This is to certify that the Ph.D. thesis of

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has been approved by the Examining Committee
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degree in Pharmacy (Pharmaceutical Socioeconomics)
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Greg Stewart

To my family and to all the hospital pharmacists striving to provide the best possible patient care while managing financial and personnel challenges on a daily basis.

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No educational endeavors are the product of a single person's effort, and this research is a product of the collaboration of many individuals. I would first like to acknowledge the work of Drs. Doucette, Urmie, Miller and Stewart on my dissertation committee for their insight and input into this research, without their contributions this research would not have been possible. I would like to acknowledge my fellow graduate students in Pharmaceutical Socioeconomics program, their experience and support has been there at times when I needed another perspective or a distraction. I would be remiss to not acknowledge my pharmacy and other health care colleagues throughout my practice career; their mentorship, shared experiences, and willingness to share information have left an imprint on this work.

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I owe the ability to complete this work to my family. My parents for providing support throughout my educational efforts and my children for understanding why I was often distracted over the last few years. And to my wife Melinda, without whose support and love I never would have been able to have been able to return to graduate studies or complete this research.

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CHAPTER ONE

INTRODUCTION

The clinical and financial consequences of medication therapy are a challenge for the healthcare system. At least 380,000 preventable medication errors occur in hospitals each year resulting in an additional $3.5 billion in healthcare costs (Committee on Identifying and Preventing Medication Errors 2007). These costs are in addition to the amount spent for medications which in non-federal hospitals in 2006 was $27 billion (Hoffman, J et. al. 2009). Health systems' pharmacy practitioners have developed techniques to manage medication errors and to address financial challenges of health system pharmacy practice and the most commonly used technique is the Formulary System.

The Formulary System

The Formulary System is a commonly used tool for assuring the quality of drug use and controlling its cost. According to the American Society of Health System Pharmacists (ASHP), the Formulary System is "the ongoing process through which a healthcare organization establishes policies regarding the use of drugs, therapies, and drug-related products and indentifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient populations" (ASHP 2008). However, search of Pub-Med finds that while the ASHP has the definition as stated above, the use of the terms Pharmacy and Therapeutics (P&T) Committee or Formulary are much more common within the literature. ASHP has in fact combined the prior Statements on the Pharmacy and Therapeutics Committee and Formulary System into one combined document. Further mention of "P&T Committee" will refer to the ASHP definition above.

A formulary is a document which contains lists of medications, medication use polices, and clinical practice guidelines which are the results of a deliberative process by the P&T Committee. Traditionally, a formulary has been a published book that lists the approved medications. Currently, most formularies are maintained in an electronic manner and are often incorporated as a part of the health systems' medication ordering computer system. A medication is routinely referred to as "on the formulary" or as a formulary medication if it is so listed. Only formulary medications are routinely available from the pharmacy for use in the health system.

Formularies also include medication use policies and numerous types of policies exist. For example, policies that are to be followed when medications not listed on the formulary are ordered by prescribers are found in contemporary formularies. In 2007, 88.7% of hospitals (Pederson et al. 2008) had systems in place where formulary medications were administered in place of a non-formulary medication, known as a therapeutic interchange (ACCP 1993). Some medications that are very expensive, have limited appropriate use, or require specific monitoring, also have policies that restrict their use to certain clinical situations and are called Restricted Medications. Drug Use Evaluation (DUE) programs are information gathering activities where medication patterns are analyzed and the results are reported to the P&T Committee (Bond 2000). In addition to drug-specific policies, hospitals, working in conjunction with their P&T Committees have formed multidisciplinary groups to develop policies directing medication therapies in specific disease states which are known as clinical practice guidelines or treatment protocols. Over 84% of all hospitals report using clinical practice guidelines that include medications (Pederson et al. 2008). In the 2005 survey, 96.7% of hospitals reported pharmacists were involved in the development of clinical practice guidelines; 89.1% of hospitals had pharmacists involved in guideline implementation, and pharmacists in 84.0% of hospitals were involved in monitoring clinical practice guidelines that include medications.

Development and supervision of the previously described activities are the primary activities of the P&T Committee (ASHP 2008). In a recent survey of hospital pharmacy practice, 97.6% of hospitals reported having an active P&T Committee (Pederson et al. 2005). The committee is a policy-recommending body to the medical staff and the health system administration on matters related to the therapeutic use of drugs. In most health systems, the medical staff also outlines the P&T Committees' purposes, organization, function and scope. The P&T Committee performs the evaluations of the clinical use of drugs and develops policies for managing drug use and drug administration. This committee meets regularly to review the medical and clinical literature, patient utilization and experience, economic data and provider recommendations to determine the safety and effectiveness of medications using various decision tools and models. This committee is composed of physicians, pharmacists, and other health professionals selected with the guidance of the medical staff. The mean number of P&T Committee meetings per year approaches seven per year for all hospitals, increasing to over ten per year for larger hospitals (Pederson et al. 2008). The ASHP Statement on the Pharmacy and Therapeutics committee suggests a list of ten functions (Table 1.1) as a guide for the activities of the P&T Committee (ASHP 1992).

Although the P&T Committee is usually a part of the medical staff reporting structure in healthcare organizations, the majority of responsibility for the system is held by the pharmacy department. In 2001 and 2005, Pharmacy Directors were surveyed to determine the extent of various formulary management techniques used in their hospitals. More than three-fourths used pharmacists' interventions to help monitor prescriber compliance with established medication-use policies and minimize duplication of therapeutically equivalent products. Approximately two-thirds regularly reviewed new therapeutic agents and educated prescribers about medication costs, and over half of the respondents regularly reviewed therapeutic categories and non-formulary medications.

By monitoring compliance, hospitals may raise the awareness of hospital pharmacy staff to achieve higher levels of formulary compliance.

In 2005, 29.3% of hospitals monitored formulary compliance by measuring the percentage of medication orders filled with formulary drugs. Pharmacy Directors who monitored formulary compliance were asked about the degree of formulary compliance achieved: 55.5% of hospitals achieved 90% compliance or better, 26.2% achieved 80–89% compliance, 11.6% achieved 70–79% compliance, and 6.7% achieved less than 70% compliance (Pederson et al. 2005). This is a decrease from the 2001 survey where 69% of hospitals that monitored formulary compliance reported 90% compliance or better (Pedersen 2001). Larger hospitals implement more formulary management techniques, as they have additional personnel and resources available to implement a wider range of such techniques.

The impact of the P&T Committee on hospital care is significant through effects on medication therapy. The evaluation of medications that are utilized in controlling disease is an important determinant of the quality of care that is provided by a healthcare organization (Nair 1999). Nearly every medication that is administered in a health system has at one point been evaluated through the P&T Committee. The recommended courses of medication therapy administered for many disease states have been developed through the P&T Committee as well. In terms of economic impact, 88% of teaching, 89% of nonteaching, and 100% of investor-owned hospitals reported using therapeutic interchange, with yearly savings of up to $1 million, with a median savings of between $50-100 thousand (Schachtner et al. 2002). The number of hospitals with the ability to report overall actual savings was small, approximately 25%, as most hospital information systems did not support gathering of this information. Information on cost savings from individual interchange programs is much more common. For example, one hospital decreased antibiotic costs by $150,000 by utilizing a therapeutic interchange of quinolone antibiotics (Milkovich 2001). Therapeutic interchanges are not the only means by which

P&T Committees affect hospital costs. At one hospital, a P&T Committee program of controlling access to several antibiotics among infectious disease physicians decreased yearly antimicrobial expenditures by 24.7%, saving over $1.4 million while decreasing resistance to several key pathogens. Eighty four percent of hospitals reported having DUE programs with an annual cost reduction of $7,613 per occupied bed in those hospitals (Bond 2000). Pederson found that 90.1% of hospitals performed retrospective DUE's in a 2007 survey (Pederson et al. 2008). DUE criteria are determined by the P&T Committee and included as a part of the Formulary.

In summary, P&T Committees oversee the use of medications in health systems. They accomplish this task by using the Formulary and associated medication use policies in an effort to improve or maintain patient safety, improve health and reduce costs.

Overview of Prior P&T Committee Research

While there is a small amount of research into the effectiveness of P&T Committees in terms of prescribers' use of approved formulary medications, there is little research regarding the attributes of the P&T Committee that are associated with effective performance. A search of Pub Med using the terms "formulary system effectiveness" or "formulary system efficiency" resulted in few citations. Searches using each word individually were performed and then combined. No additional citations where found from this strategy. Another search for "pharmacy and therapeutics committee effectiveness" and "pharmacy and therapeutics committee efficiency" was then performed in a similar manner, with similar results. Pub Med search for information on previously established methods of measurement of formulary effectiveness or formulary efficiency found no results. Performing the same searches in ABI inform (Proquest) had similar results. These searches resulted in identification of two specific studies of P&T Committee functionality. This small number is surprising considering the impact of the P&T Committee on medication therapy in health systems.

Searches were also performed in Pub Med and ABI inform (Proquest) that focused on the terms formulary and P&T Committees. Review of the results established that much of the existing knowledge about formularies and P&T Committees is limited in scope. For example, several studies have examined physician attitudes towards medical cost containment activities, therapeutic interchanges and acceptance of formularies (Sansgiry et al. 2003, Poole 2005). Physicians are more likely to accept formularies when they feel that cost considerations are balanced with clinical considerations (Lehmann et al. 2007). The literature is full of examples of how to manage costs and clinical concerns for specific medications or groups of medications. There are few in-depth examinations of the functionality of the P&T Committee.

This paucity of published information is not reflective of a lack of interest in the performance of P&T Committees. Personal experience, interviews of Directors of Pharmacy (Andreski 2006) and inquiry of clinical pharmacy managers through the ASHP list-serve suggests that practitioners are looking for guidance to improve their P&T Committees and formularies. Pharmacists mentioned the difficulties of focusing on evidence-based decisions, getting decisions implemented once made and achieving active participation in the decision-making process. There is an unmet need among pharmacy professionals for guidance about P&T Committees.

In one study, Nair examined P&T Committees in the context of making decisions when faced with controversial medication use issues (Nair 1999). The general objective of the study was to use a framework developed by Ancona and Caldwell to examine the relationships between external activities and group performance for P&T Committees. Specifically, four types of external activities identified by Ancona and Caldwell including ambassadorial, task coordinator, scouting and guard activities (Ancona & Caldwell 1988, 1992) were proposed as affecting the performance of P&T Committees. Ambassadorial activities persuade others to support the committee's decisions and keep the organization informed about the committee's activities, while Task Coordinator activities enable the

committee to coordinate activities across all functional departments within the organization. Scouting activities provide access to information enabling the committee to gain resources to perform its task more effectively, and Guard activities protect the committee by controlling the information and resources that outside individuals want to send or obtain from them. As the P&T Committee was posed to have high external demands placed on it, these activities were viewed as critical predictors of the committee's performance. Additionally, the nature of the external activity would determine its effect on committee performance.

Nair proposed two primary hypotheses: that P&T Committees used a variety of external activities to interact with their environments and that the nature of the external activity would determine its effect on committee performance. Results for the primary hypothesis were that the activities of the committee could be classified into two activity groups, guarding and ambassadorial/informational activities. The relationships between ambassadorial/information gathering, guard activities and committee performance were examined. Ambassadorial/information gathering activities were a significant and a positive predictor of committee performance while guard activities were not a direct predictor of P&T Committee performance. It appeared that for effective internal processes in P&T Committees there is a need for balance between ambassadorial and information gathering activities directed towards outsiders and guard activities to protect the committee from outside interference.

This research moved P&T Committee study in the direction of other team research done in the fields of psychology and management, especially in the use of Acona and Caldwell's external perspective model. It also showed that an important way to understand the performance of P&T Committees is to examine how they interact with the health system and with others outside the health system. Nair's study also provides an important starting point for further research. While Nair stated that "the effectiveness of a Formulary System is largely determined by the quality of decisions made by this

committee", the dependent variable used in the study was P&T Committee member satisfaction. The quality of decisions was not assessed in a manner that reflects formulary goals described by practicing pharmacists. Focusing on just the P&T Committee and its interactions as the driver for formulary effectiveness is most likely too limited in scope.

While there may be similarities between P&T Committees and other teams in work settings, there has not been a specific pre-existing model of team function that has been directly applied to the context of P&T Committees. There has been increasing recognition in the past thirty years that work groups and teams cannot be understood independent of their context, and knowledge pertaining to teams in one setting does not necessarily generalize to teams in other settings. Researchers have suggested that factors impacting team effectiveness are contingent on the team's context (Devine 1999). This suggests that the organizational setting of the P&T Committees and the staff involved may influence the specific functions of the formulary, differentiating the P&T Committee from previously studied teams.

When examining P&T Committees, there are suggestions in the team literature on the contexts in which to examine teams to determine the drivers of performance. One group of researchers suggests that four conceptual areas must be included when reviewing team performance. These include task/work flow interdependence, contextual creation and constraint, multi-level influence, and temporal dynamic (Kozlowski and Bell 2003). Another researcher suggests that five categories describe drivers of performance. The categories are effects of individual team member characteristics, team level characteristics, links between team-level process characteristics and performance, moderator effects on the links between team-level characteristics and performance, and the casual chain from individual team member and/or team level characteristics to team performance, with mediation of the causal chain by team process characteristics. Within each of these categories of performance drivers there are additional concepts that have been studied for their effect on the larger category (Stock 2004).

These previously used strategies for establishing a team's context within a larger organization and for determining drivers of performance can be used to create a conceptual model of the P&T Committees. This conceptual model can then be examined to determine the degree to which specific concepts act individually and in combination to produce a final outcome. Once the performance drivers are determined, interventions to increase performance of P&T Committees may be developed.

A Conceptual Model of the P&T Committee

In order to determine a conceptual model of the P&T Committees, a qualitative research study was done to answer the following research questions:

1) What are the factors that affect how decisions are made by P&T Committees and how those decisions then are adopted by prescribers?
2) What outcome measure or combination of measures effectively quantifies P&T Committee performance as reflected in the formulary?

A brief synopsis of the study is presented here and the full manuscript is available (Appendix A). The study addressed these questions, using recorded individual in-person interviews with Pharmacy Directors, P&T Committee Chairs or equivalents, and Hospital Administrators. Limited reviews of committee policies, procedures and meeting minutes were performed in those hospitals willing to provide these documents. Subjects were chosen as representatives of three key constituent groups in hospitals. Larger hospitals were chosen as potential study sites because previous research had shown that they are more likely to have active P&T Committees. An interview guide consisting of questions based on eight conceptual areas suggested by the literature was developed. Semi-structured interviews were conducted at seven hospitals in Iowa and Western Illinois.

In addressing research question one, seven different concepts were identified as are part of the P&T Committees (Figure 1.1). Six of the concepts are part of a linear

process of decision making and prescriber adoption that leads to medication therapy for patients. Concepts in the linear process were labeled Information Flow, Resource Control, Outside Influences, Decision Process, Implementation Support, and Prescriber Adoption with suggested outcome measures of Medication Therapy. The seventh and eight concepts, Physician Influence and Team Engagement, exert influence on many of the previous concepts as well as acting as a feedback mechanism to other concepts in the system. These findings will be discussed in greater detail in chapter 2.

Three areas showed important findings that may be used to improve performance of the system. First, Team Engagement and Physician Support affected many of the rest of the concepts in the system. Second, there was often some disagreement as to how influential P&T Committee members were in their respective practice settings. Finally, there was good agreement on an objective measure of performance for P&T Committees. This research expanded the previous findings by showing the effects of engagement of more professionals than physicians in the process of interacting with the practice environment in the hospital. The finding of two concepts having a large impact on system functioning might be used in the practice environment to guide selection of team members, recruiting those who would be actively engaged in the system, and directing resources to facilitate engagement, such as funding of physician time spent in the process and to support implementation activities. There was disagreement between the physicians' versus the administrators' and pharmacists' perceptions of how influential P&T Committee physicians were with their colleagues in practice settings, particularly in hospitals where pharmacists and administrators reported that their formularies were not performing well. This suggests that efforts to recruit or appoint physicians who are considered to be influential by their peers will improve the perceived acceptability of P&T Committee decisions, improving their rate of adoption. However, the extent of these effects is yet to be determined.

There was agreement regarding three outcomes of medication therapy that were perceived by all three professions as accurate reflections of the effectiveness of the committee. This is a significant departure from the previously used measures of effectiveness, namely committee member satisfaction (Nair 1999). A combination of an adjusted medication cost per day with rates of adverse reactions and medication errors could be used by practitioners to access their systems performance in delivering medication therapy that is safe, effective and economical as possible. Further development of these findings is needed.

The study supported several findings from previous P&T and team research. Among these were that P&T Committees seek outside help when making decisions, that P&T and formulary processes are in part linear Input-Process-Outcome processes, that there is a division of the decision process among the members of the committee, and that managing information and dealing with influences outside of the committee is an important part of creating an effective system.

Thus, a qualitatively-derived conceptual model of P&T Committee performance expanded the previous literature. The model may be useful in helping teams improve their performance, and it may also provide a quantifiable outcome for their performance. The first step in determining the usefulness of the model is the focus of this work.

Objectives of the Proposed Study

Formularies and P&T Committees are prevalent in hospitals, and they have a large impact on the hospital pharmacy in terms of effort required. But the current state of P&T Committee research is still rudimentary, limited to two theory-based studies, one that focused on the P&T Committee communications and another on relationships between members of the committee. Participants of the P&T Committee function as a team, and team literature provides a methodology to determine their drivers of performance.

Indentified gaps in the literature are lack of a relevant measure of performance, lack of a quantifiable model of the P&T Committee, and a lack of understanding about what variables impact P&T committee effectiveness. In order to address these gaps, the present study will address the following specific aims:

1) Describe the variance in P&T Committee functioning and performance in the United States.
2) Quantify the drivers of performance within the P&T Committee Performance model.
3) Quantify the relationships between concepts in the P&T Committee model and the effects of these relationships on P&T Committee performance.

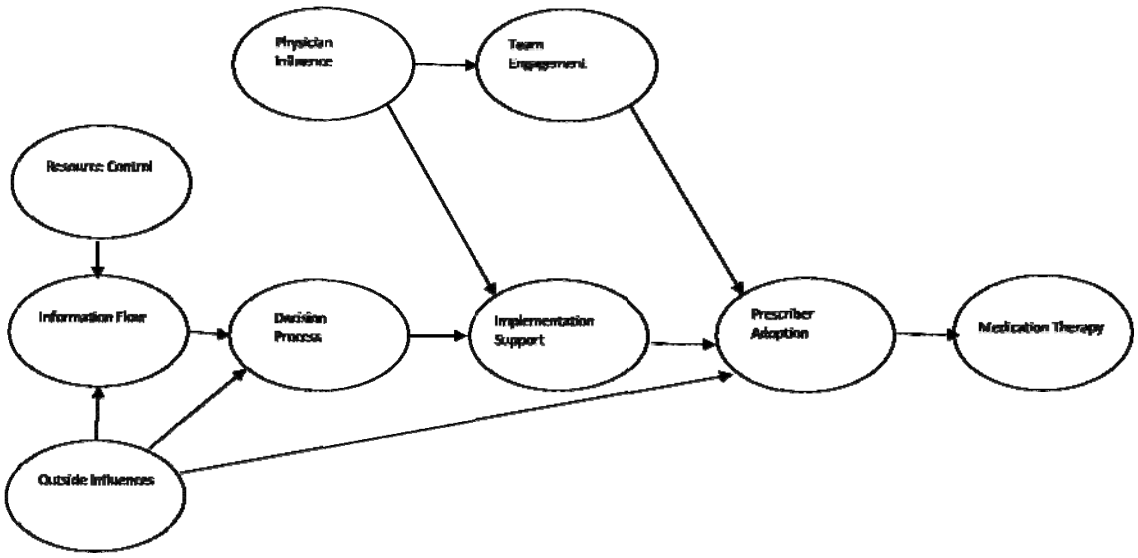
The quantitative research study methodology will be presented in chapter three.

This study was intended to expand the knowledge of how P&T Committees function within health systems and the factors and relationships within P&T Committees that lead to higher performance. One of the expected outcomes from this study was the determination of factors that healthcare professions involved with the P&T Committee may assess and manipulate to improve performance in their practice settings. This may allow health systems that have less effective systems to capture greater financial benefits for their organizations and improve clinical and financial outcomes for their patients.

Table 1.1: ASHP Statement on the Pharmacy and Therapeutics Committee: Suggested Functions of the Committee.

Serve in an evaluative, educational, and advisory capacity to the medical staff and organizational administration in all matters pertaining to the use of drugs (including investigational drugs).
Develop a formulary of drugs accepted for use in the organization and provide for its constant revision. The selection of items to be included in the formulary should be based on objective evaluation of their relative therapeutic merits, safety, and cost. The committee should minimize duplication of the same basic drug type, drug entity, or drug product.
Establish programs and procedures that help ensure safe and effective drug therapy.
Establish programs and procedures that help ensure cost-effective drug therapy.
Establish or plan suitable educational programs for the organization's professional staff on matters related to drug use.
Participate in quality-assurance activities related to distribution, administration, and use of medications.
Monitor and evaluate adverse drug (including, but not limited to, biologics and vaccines) reactions in the health-care setting and to make appropriate recommendations to prevent their occurrence.
Initiate or direct (or both) drug use evaluation programs and studies, review the results of such activities, and make appropriate recommendations to optimize drug use.
Advise the pharmacy department in the implementation of effective drug distribution and control procedures.
Disseminate information on its actions and approved recommendations to all organizational health-care staff.

Figure 1.1: P&T Committee Model



CHAPTER TWO

LITERATURE REVIEW

This chapter will review previous research that is relevant to the proposed study. This will include reviews of group and team research from business and management, other healthcare team research, and previous research by the author. The chapter will close with a summary of the pertinent findings for P&T Committee research.

Foundational Group and Team Research

The individuals who work within the P&T Committee are similar to mixed function teams which have been the subjects of research in the fields of psychology and management. In this literature (Kozlowski & Bell 2003), a work team is defined as being composed of two or more individuals who

1) Exist to perform organizationally relevant tasks,
2) Share one or more common goals,
3) Interact socially,
4) Exhibit task interdependencies such as workflow and goals,
5) Maintain and manage boundaries, and
6) Are embedded in an organizational context that sets boundaries, constrains the team, and influences exchanges with other units in the broader entity.

P&T Committees fit this definition well,

1) They perform the organizationally relevant task of overseeing the hospitals' formulary and other clinical initiatives,
2) At a minimum, share a common goal in completing these tasks as assigned by hospital management,
3) Interact socially during meetings, preparatory and implementation activities,
4) Rely on the expertise of other committee members

5) Establish boundaries limiting the activities of the committee to the tasks assigned as well as limiting input from outside of the organization, and
6) Are embedded with the health system in which they function, with specifically assigned tasks and limits dictated from the health system.

As a purpose of this research is to begin to improve P&T Committee performance, a review of the research that examines team performance and effectiveness is necessary. To examine the P&T Committee in the context of previous team research, it is necessary to review how teams have previously been studied and to identify characteristics of team research that may be utilized in by this examination.

The combined search services of ABI/Inform, Business Source Complete, EconLit, JSTOR Business, JSTOR Economics, Factiva, PsychINFO were searched for the terms “organizations”, “organizational behavior” ,”teams”, “ organizational effectiveness”, “group performance”, “work teams”, and “team effectiveness”. When the results were limited to abstracts and to publication in the years 1978 to 2008, the result was 538 citations. The abstracts of these citations were then reviewed for relevance. Two reviews, “Work Groups and Teams in Organizations” (Kozlowski & Bell 2003) and “Drivers of Team Performance: What Do We Know and What Have We Still to Learn” (Stock 2004), were especially informative. The following discussion explores characteristics that may be applicable to the study of P&T Committees.

Studies about the behavior of teams began in the 1940’s in the field of social psychology with studies of group behavior. Some of the earliest empiric research was completed by Lewin. Group research began to address issues in organizational groups in businesses and similar organizations, such as the military, as early as the late 1940’s. Until the late 1980’s the focus of research was in the field of social psychology. The focus on group research since that time has increasingly been in the fields of organizational psychology and organizational behavior. This shift also marked a change in the research focus from interpersonal attraction and interaction to group task and

technology (Bettenhausen 1991). The shift to large group research by organization researchers has also resulted in a change from the study of dysfunctional processes that lead to inefficiency to the study of synergistic processes that lead to efficiency.

In the literature there is a general consensus that work teams are composed of two or more individuals, exist to perform organizationally relevant tasks, share one or more common goals, interact socially, exhibit task interdependence and maintain and manage boundaries. Teams are also embedded in an organizational context that sets boundaries, constrains the team, and influences exchanges with other units in the broader sense of the organization (Alderfer 1977, Hackman 1987, Hollenbeck et al. 1995, Kozlowski et al. 1996a, Kozlowski et al. 1999, Salas et al. 1992).

The Input-Process-Outcome (IPO) framework developed by McGrath (1964) is the basis of most models of team effectiveness. Inputs are defined as resources that are available to the team both internally and externally at levels of the individual, team, and organization. Processes are the means by which teams members are either inhibited or enabled to combine their skills and inputs towards an outcome. Outcomes are measures of the desired endpoint(s) of the team process, and often are used to measure the effectiveness of the team. The historical reliance on the IPO model has led to a great deal of similarity across models, but there are some important differences between models as well. Small group research often uses the perspective that processes are caused by input factors and focuses on process inefficiencies that are the result of patterns of group interaction. Organizational research works from the perspective that processes are moderators that affect the input to output linkage and is interventional in nature

Ancona and Caldwell (1988, 1992) modified the basic IPO model by adding another concept to the process component of the model. Their research showed that group process has an element in addition to the internal processes of the group, the interactions of the group with outsiders. They proposed that groups are more likely to depend on non-team members for resources when performing new and unfamiliar tasks. Under these

conditions, the external activities of the group are a better predictor of group performance than the internal processes of the group. They did not test all aspects of this model but instead focused on the team's interaction with other levels of the organization or with parties outside of the organization. The authors also proposed relationships between each of these external activities and group performance, showing that ambassadorial and task coordinating activities were strongly related to group performance, while scouting and guard activities had no effects on performance.

Recent team literature has suggested that the IPO framework is insufficient for characterizing teams in at least three specific ways (Moreland 1996). First, many of the mediating factors that intervene and transmit the effect of inputs to outcomes are not truly processes. Marks et al (2001) noted that many constructs such as collective efficacy, cohesion and situational awareness are not really processes at all, but emergent states. Marks et al. defines emergent states as team properties that are dynamic in nature and vary as a function of team context, inputs, processes and outcomes, developing over the life of the team. Second, an IPO framework limits research by implying a single linear path from inputs to outcomes. Not identifying feedback loops in the IPO sequence is likely to have limited the full development of IPO focused team research. Some previous authors clearly saw the potential for feedback loops, and some explicitly recognized limits of IPO (Hackman 1987, McGrath et al. 2000). Recent research has treated traditional "outputs" like team performance as inputs to future team processes. Third, the IPO framework suggests a linear progression of main effect influences proceeding from one category to the next. Recent research has moved beyond this with interactions being documented between various inputs and processes (I x P), between various processes (P x P), and between inputs or processes and emergent states (ES) (Colquitt et al. 2002, Dirks 1999, LePine et al. 1997, Stewart & Barrick 2000).

Variables that strengthen or weaken the effects of individual and team characteristics on processes and performance are referred to as moderator variables. The

strength of the effect of these variables is mostly likely dependent on the context and function of the team. An example of this effect can be seen in a study by Jehn about the effect of the independent variable of conflict on dependent variables team member satisfaction, cohesiveness, member loyalty, productivity, efficiency and errors. The presence of the moderator variable of interdependence within the team increases the effect of the independent variable of conflict on the dependent variables (Jehn 1995). This area of research is limited by the small number of moderator variables studied using a theoretical explanation for their effects (Finkelstein et al. 1990) and that the majority of the studies focus on new product development teams. These moderator variables have been integrated into a proposed modification of the I-P-O model, although labeled as mediators.

An alternative model using the term IMOI (input-mediator-output-input) has been proposed. Substituting mediator (M) for process (P) reflects the broader range of variables that are important mediating influences with the ability to explain variability in team performance and viability. The extra I (Input) at the end of the model signifies the addition of possible feedback loops. It has also been suggested that causal links may not be linear or additive, but rather nonlinear or conditional (Ilgen et al. 2005).

Integrated studies go beyond one-stage relationships between constructs and examine complex models. The models studied in this category include moderator/mediator variables and indirect effects in addition to the usually studied direct effects. These studies fall into two categories, either exclusively investigating direct effects in a causal chain (Helfert 1998) or including direct and indirect effects in a single model (Ancona & Caldwell 1992; Jong et al. 2001). The findings of these models vary depending on the structure and type of team, and are difficult to generalize to dissimilar models.

Key Conceptual Issues for Team Literature Review

Kozlowski and Bell examined the nature of work teams to guide a review of work groups and team in organizations. Teams are affected by both the organizational constraints placed on their functioning and by the interaction among team members. Team members' interactions are affected by each individual's cognition, affect, and behavior. The authors suggest that four conceptual issues including 1) task/work flow interdependence, 2) contextual creation and constraint, 3) multi-level influence, and 4) temporal dynamic must be considered when reviewing team literature. These conceptual issues are found in most, if not all, teams, and any examination of the structure and function of a team should at least make sure that the team is examined with them in mind. These conceptual issues do not specifically affect performance, but must be considered holistically. For example, due to task/work flow interdependence, this concept requires an examination of how the members of the P&T Committee work together and how the performance of their tasks relies on the work of others. Each of these conceptual issues is discussed in greater detail below (Kozlowski & Bell 2003).

Task/Work flow Interdependence- The amount of task interdependence between members is an issue where team research and small group research have diverged. Team research focuses on the study of synergistic processes and group task while small group research focuses more on interpersonal attraction and interaction. The high degree of task interdependence is one of the strongest factors in defining a team, contrasting it with a generic small group. The manner in which system inputs are converted to outputs determines the work flow and degree of interdependence between members, varying with the task assigned to the team (Steiner 1972, Van De Ven et al. 1976). As P&T Committees are composed of several types of professionals, none of which are completely responsible for the inputs, processes, and outcomes of the committee and the

interdependence of the members must be assessed in any examination of P&T Committees.

Contextual creation and constraint- Teams are located in an organizational context and there is a context for members within each team. The larger organization creates contexts such as structure, leadership, and culture that constrain the teams and influences their responses. In addition to the organizational constraints, teams' responses are based on individual cognition, affect, behavior and interactions among team members. As such, team context is a product of both top-down and bottom-up influences in a dynamic process (Kozlowski and Klein 2000). The context of the P&T Committee within the larger organization and the context of the members within the P&T Committee need to be assessed in any examination of the system.

Multi-level influence- Teams are comprised of individuals and are a part of a larger multilevel organization. This necessitates that teams be studied in the context of multiple levels- individual, team, and organization (Kozlowski and Klein 2000). As P&T Committees are parts of a larger organization, the influences of the larger organization and the influences from outside the organization on the P&T Committee must be examined, in addition to characteristics of the individuals participating in the P&T Committee.

Temporal dynamic- Teams have a developmental lifecycle; they are formed, mature and evolve over time. As such, team constructs are not static, and the position of the team in its' developmental cycle must be considered in any analysis of a team (Marks et al. 2001). While there may be some turnover of members over time within P&T Committees, they can be considered mature teams for any examination of their performance.

Classification of Teams

Beyond the conceptual issues of task/work flow interdependence, contextual creation and constraint, multi-level influence and temporal dynamic, there is a wide variety in types of teams, and factors relevant to effective team functioning differ depending on the type of team. Broad classifications of team types have been suggested by several researchers based on examinations of several forms and the similarities and differences between types of teams. Sundstrom integrated several suggested classification schemes to arrive at a list of six team categories including production, service, management, project, action and performing, and advisory teams (Sundstrom et al. 2000). P&T Committees would be considered an action and performing type of team. Action and performing teams conduct complex, time-limited actions in a challenging environment with members who are expert specialists carrying out interdependent roles, which describes the P&T Committee quite accurately.

Several researchers have studied the characteristics that distinguish types of teams from each other (Sundstrom 1990, Kozlowski et al. 1999, Bell and Kozlowski 2002). Sundstrom identified three dimensions underlying typology including work team differentiation, external integration, and work cycles. Kozlowski et al focused on the dimensions of task, goals, role, process emphasis, and performance demands in determining if a team was a complex or a simple team. Kozlowski and Bell's review suggests that differences in six areas of organizational context including dynamics and degree of coupling required, team permeability and spanning, member diversity and spatial distribution, internal coupling requirements, workflow interdependence with implications for goals, roles, process and performance demands, and place in lifecycle, characterize teams (Kozlowski and Bell 2003). However, classifying teams is not an end unto itself, but understanding which factors influence effectiveness for different types of teams allows for more meaningful interventions. Unfortunately, this is a current gap in

the research according to Kozlowski and Bell. Placing P&T Committees in one of these classifications will not suggest specific performance improvement actions; rather, describing the drivers of performance for P&T Committees will contribute to filling this gap in research.

Team Characteristics Affecting Performance

Knowing the type of team does not specify performance drivers. However, knowing certain team characteristics allow application of previous research when studying a team and implementing actions to improve its performance. Different researchers have used different methodologies for examining teams. One review by Kozlowski and Bell used five conceptual areas when reviewing the aspects of creation, development, operation, and management of working teams. These concepts included 1) team composition, 2) team formation, socialization and development, 3) team leadership and motivation, 4) time continuance and decline, and 5) team processes and effectiveness (Kozlowski and Bell 2003). These five conceptual areas can be examined to determine drivers of performance in each team. In another review, Stock (2004) reviewed the literature on team performance to determine what factors were drivers of performance. She found that studies could be grouped into five categories. The first category included research into the effect of individual team member characteristics on performance and the second category the impact of team level characteristics on team performance. The third group includes studies that focus on the link between team-level process characteristics and performance, with the fourth group focusing on moderator effects on the links between team-level characteristics and performance. The fifth and final group of studies investigates the casual chain from individual team member and/or team level characteristics to team performance, with mediation of the causal chain by team process characteristics. Stocks' performance drivers will be discussed along with similar concepts from Kozlowski and Bell's review.

Team Composition and Characteristics: Moreland and Levine (1992) categorized team composition into three dimensions; size, demographic diversity, and dispositions and ability. The effect of team level characteristics is more consistent with respect to team process characteristics, suggesting a moderated indirect effect on team performance. Optimal team size depends on the task and the environment in which the team operates. While large teams may have access to more resources to facilitate difficult tasks, lack of effort due to dispersion of responsibility and coordination difficulties may hinder task performance in environments requiring prompt and decisive action. Demographic diversity and diversity in skills and expertise may have opposing effects on performance, with greater skill and expertise diversity showing higher performance over time (Watson et al. 1993, Jewel & Reitz 1981). The effects of demographic and skills diversity are inconsistent, perhaps due to presence of an inflection point at which performance begins to deteriorate with increased diversity (Barsade et al. 2000; Keller 2001; Lovelace et al. 2001; Pelled et al. 1999). Intensity of intra-team communication (Dickinson 1997), degree of cooperation (Bettencort & Brown1997), and intensity of conflicts (Janssen et al.1999) within the team are common areas of study. Increasing levels of communication and cooperation have been shown to positively affect performance, personal conflicts negatively affect performance, and certain levels of task-related conflict may improve performance, with a possible inflection point where performance begins to deteriorate with increased conflict, similar to the diversity effects.

The expertise traits of creativity (Taggar 2002) and knowledge (Denison, et al. 1996) consistently show positive effects on team performance, while experience (Ancona & Caldwell 1992) and cognitive ability (LePine et al. 1997) have not. The personality traits of conscientiousness, extroversion and team orientation are associated with improved team performance with the greatest effect seen with increased team orientation (Barrick et al. 1998, Neuman et al. 1999, Neuman & Wright 1999, Barry & Stewart 1997, Cohen et al. 1996, Isabella & Waddock 1994). Collective cognitive ability is a consistent

predictor of team effectiveness, with performance in hierarchical decision making teams improved when leader and staff are high in cognitive ability (LePine et al 1997). Increases in decision autonomy, the degree of a team's independence of external direction with respect to goals, priorities, and problem solving approaches, has been seen to effect performance both positively and negatively (Youngbae & Byungheon 1995, Liden et al. 1997).

Team Formation, Socialization and Development: Teams may be newly formed or may have membership changes that affect their character and performance. Development is the formation of a new team with no prior history in the organization. There are relatively few theories addressing team formation and development. Developmental issues affect performance more in newly formed teams or in teams that have undergone major structural changes, but research in this area is limited.

Socialization is the mechanism by which new members are brought into the culture of an existing team. Socialization has been primarily studied in the context of organizational socialization, with less work in the area of work team socialization (Chao et al 1994). Newcomers to previously stable teams are a potential challenge to existing norms, and group members work to assimilate new members to those norms (Anderson & Thomas 1996). As is the case with team formation and development, there is limited information on the effects of socialization on team performance.

Team Leadership and Motivation: There is a large amount of research on leadership focusing on leaders' traits and the amounts of activities performed by leaders. The influence of team leaders on team member behavior and on performance depends on the type of leadership. Power-building and empowered leadership have a positive impact on performance while overpowering and powerless leadership have a negative impact with passive democratic leadership style being associated with higher levels of team performance (Stewart & Manz 1995). Employee focus of leadership style has been associated with positive effects on team processes (Olson, et al. 1995).

However, there is not a large amount of research suggesting what leaders should be doing to increase team effectiveness. Team leaders have been observed to take action to improve the present functioning of the team, to exploit existing opportunities, to strengthen the teams design, or to anticipate potential problems. Two areas, development of team processes and monitoring and management of ongoing performance, have been suggested to be the roles of team leaders (Fleishman et al. 1991, Kozlowski et al. 1996b).

One intervention to improve performance would be for the team leaders to improve the team members' motivation towards team processes. There is extensive literature about individual motivation from social psychology research, but little about motivation in a team context. What research does exist is focused on individuals within the team, but not on the team as a whole. Team motivational levels are usually an extrapolation of the team members' motivations and not measures of the team as a whole, and most of the research is not in team situations as they typically exist in organizations (Weaver et al. 1997). One finding is that productivity can decline when team members feel their contributions have little value to the team, contribute little to the outcome of team processes, or are perceived as being too costly to the team member. Suggestions have been made for team leader motivational interventions for each of these situations (Sheppard 1993).

Team Continuance and Decline: Relatively little is known about long term viability of teams, though some research suggests that team performance declines over time. However, this research was conducted in teams with stable membership (Katz & Allen 1992). Teams with greater cognitive ability that are more outgoing and emotionally stable may have less decreases in performance over time (Barrick et al. 1998).

Team Effectiveness, Processes, and Enhancements: Team effectiveness is the core focus of the theory and research on teams. One review stated that there are thousands of articles addressing this subject (Kozlowski and Bell 2003). Most models of effectiveness assume that the team is mature and has completed formative development. The Input-

Process-Outcome (IPO) framework discussed earlier is the basis of most models of team effectiveness.

Team effectiveness has been defined in many different ways, often broadly, and lacks a strict conceptual construct. Measures of team effectiveness usually are reflective of the desired outcome of the process involved. In some instances, there are several measures of a team with measures specific to the internal functioning of the team, such as member satisfaction, in addition to external measures, such as productivity and output (Goodman et al. 1987). Measures of member satisfaction may not be an accurate measure of performance in certain types of task. Some research has suggested that teams make better decisions in non-routine complex tasks when there is a level of disagreement between the members (Jehn 1995). One way that team performance has been improved is by improving processes within the team.

Team Process Improvement

Determining the type of interventions that can be applied to the processes of the team in order to improve performance is the goal of much of team research. Specification of patterns of team interaction and exchange, and interventions through training, leadership, and other techniques to improve the complement between processes and task requirements is the primary focus of these efforts (Hackman 1987, Kozlowski et al. 1996a, 1996b, 1999, Tannenbaum et al. 1992). These interventions can be examined to determine further performance drivers. Three areas of constructs and mechanisms, cognitive, affective/motivational, and behavioral, are studied in order to fit team member interactions to task workflows and to describe team processes in order to improve team performance.

Cognitive constructs include team mental models, team climate, team coherence,

transactive memory and team learning. Team mental models are the team members shared organized understanding and mental model of elements of the teams' task environment (Klimoski & Mohammed 1994). These models encompass knowledge of the team's equipment and tools, tasks, members' characteristics and skills, and of what processes are considered effective within the team (Cannon-Bowers et al. 1993). When the team members have a shared understanding of these items, efficiency is improved in interdependent tasks, while it is not improved in tasks that may be completed by individual members of the team. Team climate describes shared perceptions of important contextual factors that affect group functioning and performance through mediating climate perceptions (Anderson & West 1998). Teams with a higher degree of shared climate were more effective in reaching their stated goals (Gonzalez-Roma et al. 2002). For example, a team with a shared safety climate will have better safety outcomes than a team without a shared safety climate (Hoffman & Stetzer 1996). Presence of shared team norms were positively related to team performance (Denison, et al. 1996). Team coherence is the degree to which the members of the team possess different information, but that information is compatible and in complementary forms for the use of the team (Kozlowski et al. 1996a). Teams with the ability to share information in this manner are more effective. Transactive memory is a shared system within the team for coding, storing, and retrieving information which is a combination of individual knowledge and a shared awareness of other members' knowledge (Wegner 1986). Teams with a well developed transactive memory tend to perform better than those with lesser developed transactive memory (Hollingshead 1998). Team learning refers to changes in knowledge that are shared by team members from a shared experience. Teams with a developed

sense of team learning show improved performance (Edmonson 1999).

Affective/motivational concepts include cohesion, collective mood, collective efficacy, and conflict/divisiveness. The concept of cohesion can be divided into two forms, team cohesion which is the teams' shared commitment to the teams' goals and interpersonal cohesion which is the group members liking of working with the group. Team cohesion appears to have the greatest effect on team performance, especially on additive tasks where both forms of cohesion enhance performance in disjunctive tasks (Zaccaro & Lowe 1988, Zaccaro & McCoy 1988, Kidwell et al. 1997, Neumann & Wright 1999). Collective mood is the affective tone of the team as a whole. Top down and bottom up approaches have been used in the study of collective mood (Barsade and Gibson 1998). Top down approaches study how group emotion affects individuals and bottom up approaches how individual emotional states combine at the group level to influence performance. Similarity in affective tone has been shown to improve team performance (Barsade et al. 2000). Collective efficacy is the group's shared belief in its ability to organize and implement courses of action to produce the groups shared goal (Zaccaro et al. 1995). Almost all studies of this subject have found that groups with a high level of collective efficacy are more effective (Gulley et al. 2001). Whereas group conflict/divisiveness, which are interactions within the team that evolve into the presence of factions within teams, impedes performance (Brown & Kozlowski 2000). A common cause of division is due to interpersonal conflict, which has been shown to decrease team effectiveness in teams performing both routine and non-routine tasks. The effects of task conflict may depend on the teams' task. Task conflict decreases effectiveness on routine tasks, while it may increase effectiveness in non-routine tasks (Jehn 1995).

Behavioral concepts include coordination, cooperation, and communications. Actions required for managing interdependent relationships within the team is coordination. Coordination is necessary to maximize team effectiveness, especially in situations where a large number of interactions are required to achieve a successful outcome (Zalesny et al. 1995). Teams with higher levels of measured coordination have shown better performance when individual task proficiencies were held constant (Stout et al.1995). Cooperation is the level of willful contribution to team processes, with cooperative teams usually showing higher levels of effectiveness (Wagner 1995). Cross-functional hospital teams that have higher levels of cooperation had better psychosocial and task outcomes than those with lower levels of cooperation. High cooperation teams relied on informal methods of communications (Pinto & Pinto 1990).

Communication is a means of enabling cooperation and coordination. Task work communication is the exchange of task-related information and formulating team solutions to problems and teamwork communication establishes and enhances the quality of interactions within the team (Glickman 1987, Ancona & Caldwell 1992). The effects of increased communication are mixed. One study found external communication increased effectiveness (Ancona 1990), another study found increased communication was a sign of conflict and did not increase effectiveness (Smith et al. 1994), while yet another saw no difference in performance with different amounts of communications (Campion et al 1993). Several methods of improving processes have been studied and shown to have a positive effect on performance. These then need to be applied to existing teams in order to improve their performance.

Enhancing Team Performance

Team performance is described in the literature in terms of both effectiveness and efficiency. Increasing a team's efficiency is seen as a method to increase team performance while the terms effectiveness and performance are used in a similar manner. Research to enhance team performance can be placed in three categories including decision effectiveness, team competencies and team training. Performance in terms of decision effectiveness was studied by Brehmer and Hagafors (1986). They described a model where the leader of a team divides a complex decision into several tasks and assigns team members tasks based on their backgrounds and skills in order to simplify the decision-making process. A key finding was that team leaders must have valid judgments from each subordinates assigned area to make good decisions and must be able to judge the quality of these judgments when making a final decision. Hollenbeck et al. (1995) then refined this model suggesting that external influences may affect performance through effects on the decision-making processes of teams with distributed expertise, depending on other characteristics of the team. External influences on the decision-making process were smaller in teams with highly developed decision-making skills.

Enhancing team competencies is presumed to improve performance in the IPO model. Training is the most prevalent effectiveness intervention for direct enhancement of processes (Cannon-Bowers & Salas 1997). Specifying the competencies that underlie performance and then designing and completing training that improves those competencies is required when using this strategy. Depending on the teams' context and task, internal and external linkages vary and this leads to different performance measures being appropriate for different types of teams (Goodman, et al. 1987). Due to the large variation in team type and performance measures, there are as many sets of competencies as there are types of teams, varying depending on the team members and task involved.

Once the appropriate competencies are determined, the most common technique to improve the performance is team training. The training is usually focused on goal

setting, interpersonal relations, problem solving, and role clarification. Training for goal setting focuses on skills to set and achieve goals. Interpersonal relation training focuses on skills to develop communication, supportiveness and trust. Problem solving training includes developing skills for identifying problems, generating solutions, implementation efforts, and results evaluation. Skills training intended to assist with role clarification enhances the team members understanding of other members' roles and responsibilities (Salas et al. 1999).

The past forty years has seen the development of an extensive body of literature about the structure and processes of teams in organizations. Within this literature are suggestions on how to examine teams to determine their performance drivers. Determination of performance drivers provides a method to improve outcomes of team processes. As teams are common in healthcare, how this research been applied to healthcare teams will be reviewed in the next section.

Healthcare Team Research

Much of the existing knowledge about the P&T Committee in the healthcare literature is anecdotal or limited in scope. Searches of PubMed and ABI inform found two studies specific to P&T Committee functionality and neither of these studies investigated the relationship between P&T Committee characteristics and prescribing behavior. Several other studies have examined physician attitudes towards medical cost containment activities, therapeutic interchanges and acceptance of formularies. These studies suggest that physicians are more likely to accept formularies when they feel that cost considerations are balanced with clinical considerations (Sansgiry et al 2003; Lehmann et al 2007, Poole 2005). However, an in-depth examination of the functionality of the P&T Committee is lacking.

There is activity and interest in studying team performance in healthcare settings. The majority of this research is focused on patient care teams in both acute and

ambulatory care settings. Some of these studies focus on intra-professional care teams, such as nursing teams and others include care teams with more than one profession. None of the studied teams included healthcare managers or were administrative teams (Mickan 2005; Collette 2004; Porter-OGrady 2004; Wagner 2004; Shortell et al. 2004). Most of these studies do not provide clear direction on how to create or maintain high-functioning teams, or how to apply teamwork research to improve performance of pre-existing teams. Lemieux-Charles and McGuire (2006) found that multiple research designs and methods have been used to understand different aspects of team performance, and stated that "rigorous conceptualization of team dimensions, processes and traits, and outcomes are needed in all healthcare team effectiveness research".

Several researchers remarked that the use of a single, overarching model of team performance in organizational studies should not be expected but that multiple models tailored to particular team types and work processes are most likely necessary (Devine 2002; Sundstrom et al. 2000). It was also suggested that healthcare researchers will need to adapt and modify organizational models to produce findings that will be useful to healthcare managers and teams. The need for healthcare team researchers to fill in some of the gaps by developing models of team performance specific to each type of work and care delivery setting has also been discussed, with the goal of such research to be a body of literature that decision makers can use to help improve the quality and efficiency of care (Lemieux-Charles & McGuire 2006). Given this general background, two specific studies have focused on P&T Committees.

Nair examined P&T Committee performance in the context of making decisions when faced with controversial medication use issues (Nair; 1999). The general objective of the study was to use a framework developed by Ancona and Caldwell to examine the relationship between external activities and group performance for P&T Committees. Performance in this study was measured as P&T Committee member satisfaction.

Four types of external activities identified by Ancona and Caldwell (Ancona & Caldwell; 1988, 1992) were proposed as affecting the performance of P&T Committees. These activities, ambassadorial, task coordinator, scouting and guard activities, were proposed as being used by P&T Committees to interact with their external environments. Ambassadorial activities are defined as those activities that persuade others to support the committee's decisions and keep the organization informed about the committee's activities. Task Coordinator activities are defined as those activities that enable the committee to coordinate activities across all functional departments within the organization. Scouting activities are defined as those activities that provide access to information enabling the committee to gain resources to perform its task more effectively. Guard activities are defined as those activities that protect the committee by controlling the information and resources that outside individuals want to send or obtain from them. As the P&T Committee was posed to have high external demands placed on it, these activities were posed as critical predictors of the committee's performance. Additionally, the nature of the external activity would determine its effect on committee performance. Some activities will positively predict performance while others will negatively predict performance.

Other factors were also hypothesized as influencing the relationship between external activities and committee performance. These factors were posed to be most influential when a member of the P&T Committee communicates with various constituents. Theories of interpersonal communication were used to identify the nature of these factors and their interaction effects with the committee's external activities. Three such factors were the frequency with which the committee (or a representative of the committee) interacts with the constituents, the method used to communicate with these constituents, and the overall quality of those communications.

Nair's primary hypothesis was that P&T Committees use a variety of external activities to interact with their environments. Ambassadorial activities facilitate the

team's legitimacy in the organization and promote the committee's image to outsiders. Task coordinating activities enable the committee to communicate, negotiate and obtain feedback from other committees. Scouting activities provide the team with access to information and resources thereby enabling it to increase its expertise. Guard activities control the information and resources that outsiders want to send into or obtain from the committee. The nature of the external activity will determine its effect on committee performance, with some activities positively predicting performance while others will negatively predict performance.

The results for the primary hypothesis were that the activities of the committee could be classified into two activity groups, guarding and ambassadorial/informational activities. Ambassadorial/informational activities could be further divided into four components, two types of ambassadorial activities, task coordinating, and scouting activities. One type of ambassadorial activity was persuading outsiders to support the committee's actions and the second type was providing feedback to outsiders about the committee's actions. Task coordinating activities were aimed at coordinating with other groups and individuals for information. Scouting activities were aimed at searching the committee's environment for information from the medical and pharmacy staff, searching the hospital for sources of technical expertise, and reviewing the scientific literature for information. Guarding activities were primarily directed towards hospital physicians who want to prescribe non-formulary drugs for their patients and towards manufacturers' representatives who wish to promote the inclusion of their drug products on the formulary.

The relationships between ambassadorial/information gathering, guard activities and committee performance were examined with ambassadorial/information gathering activities a significant and a positive predictor of committee performance while guard activities were not a direct predictor of P&T Committee performance. The study also found that there was no evidence for the proposed moderating effects of the frequency or

method of communication on the relationship between external activities and performance. However, the quality of these communications did appear to have some effect in improving committee performance.

Another finding was that a positive relationship existed between ambassadorial/information gathering activities and internal group processes while guard activities also showed a positive relationship with internal group processes. It appeared that for effective internal processes for P&T Committees there is a need for balance between ambassadorial and information gathering activities directed towards outsiders and guard activities to protect the committee from outside interference.

In the second study, Bagozzi, Ascione and Mannebach (2005) used the social relations model to study the relationships between pharmacists, physicians, P&T Committee Chairs, other physician members, nurses, and administrators who were members of P&T Committees at 222 research hospitals.

The two dependent variables studied were reactions of one person to another and reactions to participation in the group. The researchers measured the elicitation and reception of cooperation, influence, frustration and enjoyment between the committee members, comparing them individually and in a pair-wise manner, finding that these parameters varied considerably for the individual members, depending on their role, and that all members worked to manage intrapersonal relations with other committee members. The levels of cooperation, influence, frustration and enjoyment evoked by interactions between the members were similar for each member group.

The findings were generally consistent with past anecdotal and descriptive research suggesting that the chair and pharmacist play important roles in P&T Committee decision-making (Mannenbach et al. 1999, Palera 1984, Rucker 1992). Relatively high levels of overall influence were shown by the chair and pharmacist along with high levels of cooperation shown by all committee members. The influence demonstrated by the chair was higher in some hospitals and lower in others, the efficacy of the chair was

inconsistent across hospitals, and they were not influenced greatly by other committee members. However, the chair showed frustration with the physician, pharmacist and nurse, and they were frustrated by the chair in return.

Pharmacists showed low variability in their interactions with the other members of the committee, generally showing high levels of cooperation and moderately high levels of influence roughly equal with that of physicians and chairs. In nonhierarchical committees the physician and pharmacist showed mutuality with respect to cooperation, influence and enjoyment; the pharmacist and nurse exhibited mutuality with regard to cooperation, frustration and enjoyment; and the pharmacist and administrator displayed mutuality in terms of cooperation, influence and enjoyment. The pharmacist seems to have high degree of coordination with his/her relationships in non-formal, collegial committees. In the hierarchical committees, the pharmacist and chair experienced mutual frustration and enjoyment, perhaps reflecting the formal, authoritarian characteristics of these committees. Nurses showed high degrees of cooperation and influence in both the hierarchical and nonhierarchical committees. It appears that nurses performed important social roles in P&T Committees, as do pharmacists, with a focus on getting the committee to reach a consensus both efficiently and quickly. The role of the chair, and to a somewhat lesser extent physician and chair, was less social and more one-way.

This study shows that relationships within the P&T Committee were similar to those found in other teams, strengthening the utility of application of research in non-healthcare teams to healthcare teams. The authors suggested that further research into the effects of committee group performance on health outcomes and the effects of other groups in the hospital and outside stakeholders on the members of the P&T Committee would be useful.

Outside of Nair's application of an expanded IPO model to studying P&T Committee processes and Bagozzis' examination of relationships within the P&T Committee, there have not been systematic descriptions of the P&T Committee using

group and team research concepts. As suggested by the review of team research, until this research has been performed, it is difficult to suggest opportunities for improvement using performance enhancement techniques shown to work in other team settings. In order to begin to address that gap in the literature, the following qualitative study was performed.

Andreski Qualitative Study

A qualitative research study was performed to answer the following research questions:

1) What are the factors that affect how decisions are made by P&T Committees and how those decisions then are adopted by prescribers?
2) What outcome measure or combination of measures effectively quantifies P&T Committee performance?

The study used recorded individual in-person interviews with Pharmacy Directors, P&T Committee Chairs or equivalents, and Hospital Administrators and limited reviews of committee policies, procedures and meeting minutes from those hospitals willing to provide these documents. Subjects were chosen as representatives of three key constituent groups in hospitals. Larger hospitals were chosen as potential study sites because previous research has shown that they are more likely to have active P&T Committees. In larger hospitals, the P&T Committees are more likely to meet frequently, to have therapeutic interchange policies, regularly review new therapeutic agents, periodically review of therapeutic categories, routinely review non-formulary drugs, frequent evaluation of prescribers' adherence to medication-use policies, and require prior approval for use of certain medications.

Using previous research findings, investigators' P&T Committee experience, and consultation with pharmacy managers from a large university hospital, an initial

interview guide was developed. A list of all 33 non-specialty hospitals with an in-patient bed capacity of 90 or greater in the Iowa area codes of 515, 641, 319 and 563 as well as the Illinois area code of 309 was obtained using the American Hospital Association directory. A letter briefly describing the purpose of the study and the participation required if the hospital agreed to be included in the study was sent to the Pharmacy Directors, followed with phone calls to the Pharmacy Directors asking for participation. Policies and Procedures pertaining to the hospitals' P&T Committee and six months of P&T Committee meeting minutes, with identifying information redacted, were requested from the Pharmacy Director, allowing for collection of some of the procedural information needed.

The interviews were conducted on-site at seven hospitals and two physicians' offices with a total of ten hospitals in seven health systems included in the final sample. The average bed capacity was 394, with a range of 97 to 658 beds. After each interview was completed, the recordings were transcribed and validated. After validation, transcripts from the first five sets of interviews were deconstructed and analyzed for themes. Once the transcripts were categorized, assignment of concepts was performed. Two more sets of interviews were conducted and the validated transcripts were analyzed as before. In the latter interviews there was repetition of the concepts that were previously identified and no new concepts were recognized so saturation was reached. The final assignment of concepts was reviewed by another researcher with qualitative experience for additional validation.

Linear flow concepts

In addressing research question one, nine concepts were identified as affecting the performance of the P&T Committee. Seven of the concepts are part of a linear process of decision making and prescriber adoption that leads to medication therapy. The concepts in linear process were labeled Information Flow, Resource Control, Outside Influences,

Decision Process, Implementation Support, and Prescriber Adoption (Figure 2.1). The concepts in the linear flow were combined with suggested outcome measures of medication therapy.

Information Flow describes the flow of information into and throughout the linear portion of the system leading to the committees' decision. Resource Control describes the allocation of resources for the P&T Committee and the formulary performed primarily by management of the hospital and by the Pharmacy Department. Influences from outside of the P&T Committee such as pharmaceutical manufacturers and accreditation groups that may affect the decision making process and/or the outcomes of medication therapy are called Outside Influences. Decision Process describes decision making in the committee, including formal rules and informal processes that integrate the perspectives of committee members in order to reach decisions on P&T Committee issues. Implementation Support describes the processes that move the decisions of the P&T Committee into the practice environment and that support continued adherence to the formulary and treatment protocols. Information about the adoption of therapy and medication outcomes is gathered as a part of these activities and is used to evaluate the effectiveness of P&T Committee decisions. Prescriber Adoption measures the extent that prescribers use medication therapy that is in accordance with the committee's decisions.

The final result of the process is that patients receive medication therapy with clinical responses to the therapy. Research question two addressed the issue of formulating a set of objective measures of medication therapy in order to assess the effectiveness of the P&T Committee. None of the hospitals in the study sample had any overall measure/s for the effectiveness of the P&T Committee or their formularies, but they did mention some monitoring of costs and/or outcomes on specific initiatives taken by the committee. A list of possible measures was presented to the interview subjects to determine their utility. While there was no measure that was universally accepted or rejected, there was general agreement among the three different professions on the value

of a combination of three outcome measures including medication cost per day (possibly adjusted by DRG or for acuity level), rates of medication errors and adverse drug reactions.

Non-linear flow concepts

While the previous seven concepts primarily addressed the structure and process of decision making, two concepts, namely Physician Influence and Team Engagement, appeared ot exert influence on many of the linear flow concepts. Hospitals with high levels of Physician Influence and Team Engagement were seen to have activity outside of the committee setting and engaged in more informal information gathering and sharing than those hospitals with self described difficulties with their formularies. When Physician Influence and Team Engagement are superimposed over the linear flow concepts, the final proposed model is created (Figure 2.1).

Results of the study included three significant new findings. One was that Team Engagement and Physician Influence affect performance of much of the rest of the committee. Another was that there is often some disagreement in about how influential committee members are in their practice setting. Finally, there was agreement on an objective measure of performance for the P&T Committee.

This research expanded previous findings by showing the effects of engagement of more professionals than just physicians in the process of interacting with the practice environment in the hospital. There was disagreement between the physicians' versus the administrators and pharmacists perceptions of how influential P&T Committee physicians were with their colleagues in practice settings. These perceptions were especially different in hospitals where pharmacists and administrators reported that their formularies were not performing well. There was agreement regarding three outcomes of medication therapy that were perceived by all three professions as accurate reflections of

the effectiveness of the committee. This is a significant departure from the previously used measures of effectiveness, namely committee member satisfaction.

This study supported several findings of previous P&T and team research. Nair's findings that committees seek outside help when making decisions was repeated in hospitals with engaged members. Another repeated finding was a division of the decision process among the members of the committee. The considerable efforts by some hospitals to limit exposure of committee members to representatives of pharmaceutical manufacturer representatives repeats previous findings that managing information and dealing with influences outside of the committee is an important part of creating an effective system. The previous reports that P&T Committee and formulary processes are similar to linear Input-Process-Outcome processes was supported by the findings but the addition of the concept of Team Engagement and Physician Influence is more compatible with the IMOI model of team performance.

Summary of Findings in the Literature

Both the P&T Committee and its participants fit the conceptual definition of a team. The Andreski study found that P&T Committees were composed of several individuals including physicians, pharmacists, and other professionals, who share one or more common goals, which include safe, effective and economically sustainable medication therapy, a task relevant to the hospitals organization. Therefore, the team research discussed above provides a framework to study P&T Committee performance.

The Andreski qualitative study examined P&T Committees in a manner that addressed the need to consider task/workflow interdependence, contextual constraint, multi-level influences, and temporal dynamic in such an examination. Members of the P&T Committee interact socially in committee and other settings. They exhibit task interdependence by dividing the tasks of the P&T Committee between the members in a manner that no one individual or group can perform all of the committee's functions. The

P&T Committee is embedded in an organizational context of the hospital and medical staff, which set constraints on the functions of the P&T Committee and influences exchanges with other groups in the broader scope of the hospital. P&T Committees are a part of a larger organization, with influences of the larger organization and from outside the organization. P&T Committees can be considered mature teams for the purpose of examination as they have been in existence in most health systems for many years.

Based on the descriptions of each type of team in Sundstroms' classification system, P&T Committees most closely resemble action and performing teams which are composed of interdependent experts who engage in complex time constrained performance events. Based on another classification system (Kozlowski et al. 1999), P&T Committees could be classified as complex teams due to their externally driven structured tasks, the necessity of specific individual contributions from the several distinct professions involved, the interactive nature of those contributions and tasks, and the capacity to improve processes over time. However, neither of these classifications suggests a specific set of drivers of performance to be examined.

Examination of P&T Committee's concepts suggests that the IMOI model may better describe P&T Committees than the previously used IPO model. Information Flow and Implementation Support fit the description of emergent states in that they are dynamic in nature and vary in context to other concepts such as Team Engagement and Resource Control in each system. Finally, the model suggests that several of the concepts relate in a non-linear manner with team engagement. These findings both strengthen the evidence for the IMOI model and provide a theoretical basis for the structure of the P&T Committee Model.

The literature suggests teams should have an objective outcome measure of the desired output of the team processes (Brannick & Salas 1997). A combination of measures was suggested in the qualitative study including measures of cost, adverse reactions, and medication errors. The concept of Prescriber Adoption lends itself well to

being an objective measure as it assesses the level of acceptance of the decisions of the P&T Committee by prescribers' interaction with the Formulary System. A large percentage of hospitals monitor formulary compliance (Pederson, et al, 2007) and many also monitor compliance with medication restrictions and use of treatment protocols that include medications (Andreski 2006).

Testing a model of P&T Committee Performance

The fully specified model is shown in Figure 2.1 As suggested by previous team research, specific drivers of performance may be determined for P&T Committees. The following discussion will link the previously suggested concepts and drivers of team performance with those found in examining the P&T Committee and possible additions. The literature concepts and the qualitative study concepts for which they are most similar are shown in Table 2.1. In addition to these concepts, six other concepts identified in the qualitative study were included in the present study based primarily upon the findings of the previous qualitative study. Staffing and resource adequacy were measured for Resource Control, influences from outside of the P&T Committee for Outside influences, information quality for Information Flow, interventions performed by P&T Committee members to influence prescribers as a component of Implementation Support, and influence of physician members of the P&T Committee as Physician Influence.

Outside of Nair and Bagozzis' work, there is little from the healthcare team literature that appears to be directly applicable to P&T Committees. Two of Nair's four major activities, ambassadorial and scouting activities, were proposed as being used by P&T Committees to interact with their external environments and these activities were measured in the proposed study. Ambassadorial activities were directly measured while scouting activities were reflected in the information processes that were measured. In Bagozzi's study, the findings about the relationships between professionals who are members of the P&T Committee reinforce the findings that cooperation and influence are

important predictors of P&T Committee performance, and these were measured for Decision Process and Physician Influence

There are some concepts that have been identified as drivers of performance in previous research, but will not be included in the proposed research for the following reasons. Issues related to team formation, socialization and development were not specifically addressed in the qualitative study since each P&T Committee studied was mature. While there may be some socialization when new members are added to the team, most of their actions in the P&T Committee are defined in their job duties, particularly outside of the P&T Committee, limiting the impact of socialization. Time continuance and decline were also not assessed due to the cross-sectional nature of the study and will again not be considered for the same reason. Membership in the P&T Committee is usually stable, with limited turnover, also limiting the effects of socialization.

The team composition dimensions of size and demographic diversity do not appear to vary significantly among the P&T Committees studied previously. Creativity shows a positive effect on team performance in the literature. Creativity is defined by Taggar as being primarily composed of the traits of conscientiousness and general cognitive ability. Conscientiousness is already being measured as a separate concept and cognitive ability has not been shown to be a predictor of team performance. Knowledge also had been associated with positive effects on team performance but there is nothing to suggest that there should be a great deal of variability in P&T Committees participants considering the level of educational achievement required of their members. Direct effects from extroversion were not seen in the qualitative study so a measure of extroversion will not be included. In previous studies extroversion resulted in increased flow of information, which is being measured. Decision autonomy has mixed effects on performance, and autonomy is limited in P&T Committees due to institutional and professional constraints placed on their activities and as such will not be measured.

The cognitive concepts of Transactive memory and Team learning, which address sharing information within the team, are reflected in the reaching of consensus on decisions and sharing of information through Implementation Support activities, and so these two concepts will not be measured. The affective concepts of Collective mood, Collective efficacy, and Group conflict will not be directly measured in the proposed study. There was nothing in the qualitative study to suggest that Collective mood and Collective efficacy would affect P&T Committee performance. The evidence in the literature for these concepts affecting performance in this situation is not compelling enough to warrant their direct measurement. The effects of Group conflict are most likely reflected in the amount of consensus and cohesion in the team which are going to be measured in the proposed study. The behavioral concept Communication will not be measured as defined in the literature but was measured as the amount and quality of information as suggested in the qualitative study.

The literature also suggests investigation of moderator effects on the links between team-level characteristics and performance. Links between team-level characteristics such as Team Engagement and the moderator of Physicians Influence and the effects of that link on adoption of P&T Committee decisions were investigated in the proposed study. As suggested by another group of studies in the literature, the casual chain from individual team member and/or team level characteristics to team performance, with mediation of the causal chain by team process characteristics should also be examined. These links have been suggested in the qualitative study and a holistic model has been created and the strengths of these relationships were determined in the proposed study.

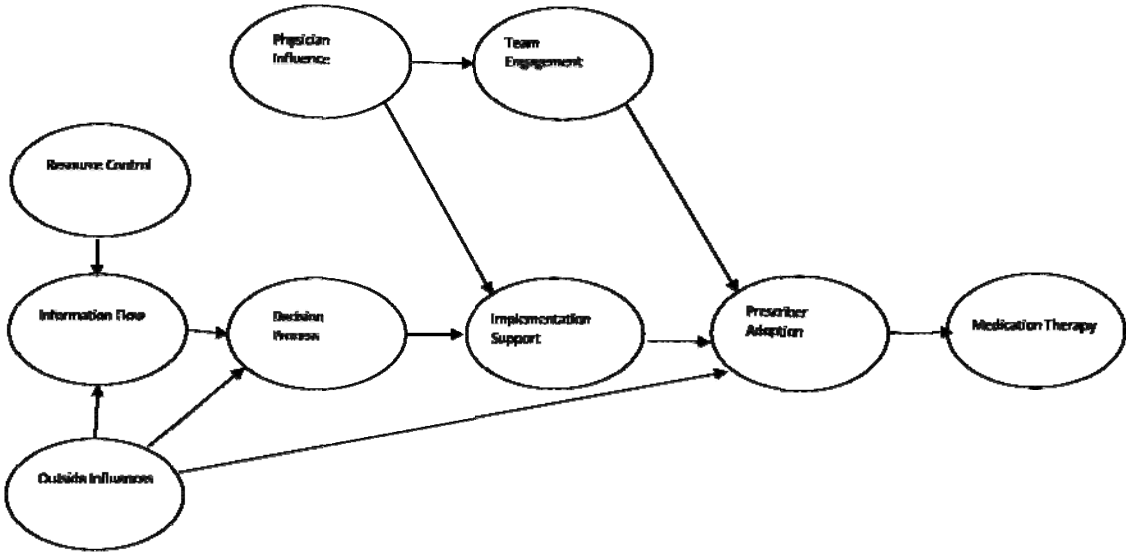
In conclusion, findings from prior small group and team research, findings from healthcare teams and of P&T Committees, as well as the previous qualitative research provided a framework for study of P&T Committees to determine the factors that

determine their performance. The next chapter proposes a methodology to perform such an examination.

Table 2.1: Concepts included in the study

Qualitative Study Concept	Concept from Literature
Information Flow	Intensity of intra-team communication, Scouting Activities
Decision Process	Consensus
Team Engagement	Team orientation/Team Mental Model/Team Climate
Implementation Support	Ambassadorial Activities
Outside Influences	Guard Activities
Physician Influence	Team leadership and motivation
Resource Control	Multi-level influence

Figure 2.1: Model of P&T Committee Performance



CHAPTER THREE

METHODS

This chapter presents the methodology that was used in this study. This section includes the study aims, design, subjects, data collection methods, development of new measures of P&T Committee model concepts, other measures that were used, and the plan for the analysis of the data.

The specific aims are to:

1) Describe the variance in P&T Committee functioning and performance in the United States.

2) Quantify the drivers of performance within the P&T Committee Performance model.

3) Quantify the relationships between concepts in the P&T Committee model and the effects of these relationships on P&T Committee performance.

Study design

The study was cross-sectional in design. A cross-sectional design was selected as the research intended to describe the current state of P&T Committees, comparing levels of performance between health systems, with the intent of determining associations between conceptual measures and performance. As well, this was the first study gathering quantitative data about the model, and this design is appropriate for this endeavor. Subject completed surveys were used to collect information for this study as they are relatively inexpensive and easy to administer. This study was approved by the University of Iowa Investigational Review Board (IRB).

Subjects

The studied population was Hospital Pharmacists, Hospital Administrators or Medical Directors, and P&T Committee Chairpersons. These subjects were practicing at hospitals with the following inclusion criteria:

1) Non-university non-specialty hospital,
2) An inpatient bed capacity of greater than ninety nine beds,
3) A currently functioning P&T Committee.
4) A P&T Committee that managed the Formulary and treatment protocols.
5) Pharmacists participate in the P&T Committee and Formulary, and
6) An ASHP residency program.

The rationale for these criteria follows. For criterion one, the majority of hospital care is provided in community hospitals that are non-university, non-specialty hospitals. For criterion two, Pedersen showed that hospitals with at least 100 beds were more likely to have a more active Formulary System than smaller hospitals, meeting more frequently and including more services such as Medication Use Evaluation and evaluation of treatment protocols (Pederson 2008). Criteria three and four excluded the few hospitals of this size and type who do not have a formulary that is managed by a P&T Committee, as presence of both criteria are necessary for the hospital to have any information for the study aims. Criterion five assured that there would be a Pharmacy Director to distribute surveys, while criterion six allowed for personalization of the surveys to the Pharmacy Director.

The study population was hospitals from the ASHP residency directory based on the first two inclusion criteria regarding type and size of hospital. The surveys were sent to the Pharmacy Directors who were asked to complete a Pharmacy survey or to give the survey to a pharmacist whose responsibilities include active participation in the P&T

Committee. The survey instrument included questions to indicate the position of the person completing the survey. The remaining three inclusion criteria were asked as the first questions in the survey. If the criteria were not met, the survey directed subjects to end the survey and return it to the researcher. It was intended that characteristics from these excluded hospitals would be used to determine if the characteristics of these hospitals were different than those of the subject hospitals, but no hospitals ended up being in that category.

The Pharmacy Director forwarded an administrators' survey to either the Hospital Administrator with responsibility for the pharmacy or to the hospitals' Medical Staff Director, whomever the Pharmacy Director determined was involved in the P&T Committee to a degree where they would have the required information to complete the survey. The Pharmacy Director also forwarded a short survey to the P&T Chair, possibly in coordination with a P&T Committee meeting.

Completed surveys from at least two respondents were required for results from a hospital to be included in the analysis. Requiring two respondents was intended to decrease response bias that might be introduced due to one individual representing an entire organization. Sending surveys to three respondents was done in the hope that at least two of the three subjects would complete the study. Management team literature usually counts the number of responding teams, not individuals towards the required "N" (Mehta et. al. 2009, Payne et. al. 2009, Woolley 2009, Lambe et.al. 2009). The desired sample size for the study was 110 hospitals. The sample size calculation is based on three assumptions. For Aim one, an analysis of the outcome variable Prescriber Adoption was conducted by comparing hospitals by number of beds in the hospital, by ownership types, and by Medicare Areas. Using an assumption of a mean of 90% and a standard deviation of 10%, a sample size of 63 would be needed to have an 80% chance of finding a 5% difference on the outcome measure (power = 0.8) with a 5% chance of finding an effect when in actuality there is no effect (alpha of 0.05). For Aims two and three,

multiple regression analysis was used to test the model for relationships between concepts, and the initial model tested had 4 independent variables. Tabachnick and Fidell suggest a rule of thumb for testing regression coefficients where the sample size should be greater than or equal to 104 + m, with m the number of independent variables (Tabachnick & Fidell 2001). Using this formula, the desired sample size is at least 108 hospitals. In order to achieve the desired sample size, assuming a 40% response rate seen in similar surveys of Pharmacy Directors (Pederson 2003, 2005, 2008), 270 hospitals would be required. The initially planned number of hospitals to which surveys were sent was 150 to compensate for partially completed surveys and to provide a margin if a lower than expected response rate was seen. Due to the low response rate in the pilot study (13.33%), surveys were sent to all 321 hospitals that met the inclusion criteria for having an ASHP residency and being a non-specialty non-university hospital.

Survey Testing

The newly constructed indexes initially were reviewed for face validity by two hospital pharmacists who participated in P&T Committees and were familiar with P&T Committee activities. The survey instrument was then reviewed by three pharmacists who participated in the qualitative study for comments on clarity of the instructions and items and finally the survey was pilot tested.

The surveys were pre-tested in a pilot study in a sample of 75 health systems stratified by CMS regions. A traditional mail survey instrument was delivered to the first 51 subjects, and they were also given the opportunity to complete a content identical version via the internet using WebSurveyor. The Pharmacy Director and Hospital Administrator/Medical Director survey instruments in the pre-test each had 57 items and the P&T Chair survey instrument had 13 items. An initial mailing contained a pre-notice to the Pharmacy Director informing them of the upcoming survey. The second mailing contained the three survey instruments, cover letters on University of Iowa College of

Pharmacy stationary, and pre-paid return envelopes. Access instructions for the on-line version of the survey were included on the first page of each survey. One week after this mailing, a reminder card was sent to all subjects. A second full mailing containing survey instruments, second cover letters, and return envelopes, were sent two weeks after the first mailing to all hospitals without two responses.

Of the 51 hospitals in the pre-test, a response was received from 16 hospitals with two choosing to not participate. Of the 14 positive responses, six hospitals had at least two respondents for a total of 17 respondents. The Directors of Pharmacy at the seven hospitals with only one response were then contacted by phone to encourage participation by the hospital. This added one additional hospital with two respondents, increasing the total to seven hospitals and 18 respondents. At least one response was received from 27% of the hospitals, with 13.3% of the contacted hospitals having two or more responses.

Due to the poor response rate, four weeks after the first mailing, it was decided to test an internet only survey. The surveys used in the second round of pilot testing were also shorter, but there were no new questions and the wording of the remaining questions was not changed. After IRB approval of the change, survey invitations were sent by e-mail to another 25 hospitals, again selected by stratified random sampling. E-mails with links were sent to the Pharmacy Directors at those hospitals. Of those 25 hospitals, responses were received from eight, with one of the eight choosing to not participate. Of the seven positive responses, two completed surveys were received from three hospitals. At least one response was received from 28% of the hospitals, with 12% of the contacted hospitals having two or more responses. The results from the second round of pilot testing were similar to the first 51 responses. In the entire pilot testing, at least one response was received from 28% of the hospitals, with 13.3% of the contacted hospitals having two or more responses. Due to the low response rate, it was decided to move to an internet only survey and to contact all 321 eligible hospitals. The 321 hospitals is a small subset of the 5,010 hospitals in the United States, 2635 which have more than one

hundred beds. 213 of these hospitals are federal government hospitals, primarily Veterans Administration hospitals (AHA 2009).

All analysis was performed using SPSS® version 17. The Cronbach's alpha of each index was calculated to determine reliability. For indices with low Cronbach's alpha, both item analysis and factor analysis was performed to determine if exclusion of any questions increases validity or if more than one concept was being measured by the index. After the analysis of the pilot testing, no indexes were changed due to small sample size of 20 hospitals that were analyzed. Some concepts were removed from the study to shorten the length of the survey in order to increase response rate.

Data collection

The final data collection was performed using two collection methods. The majority of information was collected using an internet survey administered through WebSurveyor. After pre-testing, the pharmacy survey instrument had 41 items, the Hospital Administrator/Medical Director survey instruments had 32 items and the P&T Chair survey instrument had 13 items. The data collected was coded and entered into Microsoft Excel 2007 for use in the statistical analysis software SPSS version 17 and AMOS version 5.

Survey mailings and follow-up procedures followed Dillman's Total Design Method (Dillman 2007). The Pharmacy Directors were contacted up to four times. The first three contacts were done by e-mail and the fourth by phone. The initial e-mail explained the purpose of the study, a brief overview of the procedures, internet links, usernames and passwords to the three surveys. Once the subject accessed the survey via the provided link, informed consent information and instructions were contained on the first page of the survey. One week after the initial e-mail, a reminder e-mail was sent to all hospitals without two responses. Two weeks after the first reminder e-mail, another reminder e-mail was sent to all hospitals without two responses. Two weeks after the

second reminder e-mail, another reminder e-mail was sent to all hospitals without two responses. The fourth contact by phone was done if one completed survey from the hospital had been received, in an effort to obtain a second completed survey so that the information from the hospital was included in the study. No incentives were used as accepting gifts of any kind are increasingly being banned by healthcare organizations.

P&T Committee Performance Models

This section will discuss the models of the P&T Committee which were used in the study. The P&T Committee model discussed Chapter Two was modified as discussed below. For each of the models, a line with an arrow represents an effect on the concept to which the arrow points from the concept where the line originates.

The full conceptual model of the P&T Committee Performance Model (Figure 3.1) includes the concept of Medication Therapy, with three measures of outcomes of medication therapy. The concept of medication therapy was not included in this study. A concern with using this measure in the current study is that financial, adverse drug reaction and medication errors rates would be difficult to obtain in a survey of Pharmacy Directors due to their sensitive nature. The continued development of this measure is a significant project in its own right and is reserved for future work. As Medication Therapy was not feasible as the dependent variable in the current study, the dependent variable used was Prescriber Adoption (Figure 3.2). This concept is the acceptance by prescribers of the decisions of the P&T Committee. This model was the basis for the models used in Aims One and Two.

To shorten the surveys and increase response rate, the concepts of Resource Control, Decision Process, and Information Flow were removed from the model after the pilot study. None of these concepts were thought to act directly on the dependent variable, and brief preliminary analysis suggested that the indirect variables of contributed little to the models' predictive capability. Thus, the final model contained

five concepts (Figure 3.3). For the measurement model to be tested in Aim Two, each concept was operationalized with one measure as described in the next section.

The analysis in Aim Two was a least squares regression of independent variables that were proposed to affect P&T Committee performance. The dependent variable of Prescriber Adoption measured how much prescribers adopted the decisions made by the P&T Committee. The model (Figure 3.4) represents the net effect of each independent variable as well as control variables upon the dependent variable of Prescriber Adoption.

There may also be significant relationships between concepts within the larger model. These relationships were examined in Aim Three as components of path analyses. Aim Three examined direct effects on Prescriber Adoption, Implementation Support, and Team Engagement using path analysis, a type of structural equation modeling analysis. The direct effects were:

1) Implementation Support, Team Engagement, and Outside Influence on Prescriber Adoption,
2) Physician Influence and Outside Influences on Implementation Support, and
3) Physician Influence on Team Engagement.

Once the direct effects were determined, indirect effects were determined for Outside Influences and Physician Influence on Prescriber Adoption. These effects are contained in Figure 3.3.

Measurement

The measurement of concepts was accomplished using previously validated measures of similar concepts found in the literature, by modification of previously used measures, and by development of new measures specific to this model. Selection of measures was performed by review of the transcripts and definitions of the concepts determined in the qualitative study with each concept described by at least two measures.

Table 3.1 summarizes the concepts, operationalized concepts, and the measures being used, and a discussion of each measure follows.

Prescriber Adoption

Prescriber Adoption was the intended dependent variable for the study, measuring the extent that prescribers used medication therapy that was in accordance with the P&T Committee's decisions. The measure as planned was an index of four items representing outcomes of the P&T Committee activities including dispensing of formulary medications, compliance with medication restrictions, use of treatment protocols for Community Acquired Pneumonia (CAP), and use of treatment protocols for Deep Vein Thrombosis (DVT). The means of these four items was the intended dependent variable in the, planned analysis.

The results from previous studies by Pederson (Pedersen 2005, 2008), showed a high level of adoption of formulary medication decisions with low variation. Of the 29.3% of hospitals that monitored formulary compliance, 55.5% of hospitals achieved 90% compliance or better, 26.2% achieved 80–89% compliance, 11.6% achieved 70–79% compliance, and 6.7% achieved less than 70% compliance. These rates were self reported by Pharmacy Directors, and the report did not include any data besides the frequency distributions (Pedersen 2005, 2008).

This high performance level, with low variation between hospitals would lead to difficulties in the determination of the degree to which independent variables would affect the dependent variable if only the adoption of formulary medications was included in the study. In an effort to increase variation, three other decisions that the P&T Committee makes were added to the percentage of medication orders that were filled with formulary medications to construct an index measuring prescriber adoption. Decisions to restrict medications are made in the course of P&T Committee reviews for medications for possible formulary addition, so a measure of the adoption of these

decisions was added to the index. As mentioned earlier, P&T Committees are also responsible for the approval of evidence based treatment protocols. In several of the hospitals in the qualitative study, the P&T Committee initiated development of protocols, established sub-committees to develop the protocols or reviewed and modified previously developed protocols, with final approval from the P&T Committee necessary before use in the hospitals.

In the study, respondents were asked to report the percentage of medication orders that were filled with formulary medications in the six months prior to completing the survey. The result could have a range of 0 to 100, with an expected range of 60 to 95, according to earlier findings by Pedersen.

The respondents were also asked to estimate the percentage of orders for restricted medications that met the approved usage criteria in the six months prior to completing the survey. The result ranged from 0 to 100. Restricted medications are the result of a type of decision made by the P&T committee in the review of a medication for possible inclusion on the hospitals formulary. They are medications that for clinical or economic reasons are deemed appropriate for use in only specified situations, instead of for all patients with an appropriate indication. When prescribed for a patient who's situation does not match the criteria established by the P&T Committee, the medication is considered to be a non-formulary medication and is addressed by the pharmacy staff in the manner usually performed for non-formulary medication orders. An example of this type of medication would be an antibiotic that, while possessing activity against a number of organisms, also is uniquely active against an organism. Due other treatments being available for other organisms, the antibiotic would then be restricted for use in treating the organism for which is has unique activity. Respondents were also asked to estimate compliance in the six months prior to completing the survey with two P&T Committee approved treatment protocols. The result ranged from 0 to 100. Respondents were asked to report the percent of qualifying patients who were treated with a protocol or care path

for CAP. They were also asked to report the percentage of qualifying patients assessed for DVT risk using a protocol or care path. If the respondent's hospital did not utilize either protocol, the respondents were asked to provide the percentage of qualifying patients who were treated by a protocol or care path utilized in their hospitals. In no instance did a hospital add a protocol when given this opportunity.

As a first step in the analysis, the Prescriber Adoption index was examined for reliability. The Cronbach's alpha was 0.433, which was unacceptably low. A principle components factor analysis of the items of the Prescriber Adoption Index suggested that this concept consisted of two latent concepts (Table 3.2). However, separation of the components into two indexes, one consisting of the percentage of medication orders filled with formulary medications and the percentage of orders for restricted medications that met the approved usage criteria, and the other consisting of adherence to the two treatment protocols, also resulted in unacceptably low values of Cronbach's alpha, 0.105, and 0.222, respectively. The results of the factor analysis suggest similarities within medication prescribing and similarities using the protocols, but the similarities were not large enough to be measuring the same thought process.

Given these data, four separate analyses were performed using each of the four measures as the dependent variable. This was determined to be the best course for several reasons. Each of the outcomes proposed in the original measure of Prescriber Adoption is a measure of a different aspect of prescribing. Each of these measures pertains to prescribers adopting a decision of the P&T Committee, but from a prescriber's perspective each decision could be viewed somewhat differently. For example, the decision to prescribe a medication or not, based on the formulary status, is evaluating the committees' decision on the merits of the entire medication. That evaluation is measured by the percentage of medication dispensed using formulary medications.

Deciding to prescribe a medication in concordance with a restriction is evaluating the committee's decision to limit the use of a medication. A medication may be indicated

for several diseases states, is not the preferred treatment for most of those diseases due to cost or adverse effects, but for one indication it is the preferred treatment. This is unlike a formulary decision where either the medication will be used or it will not be used at all. This is measured by the percentage of use of restricted medications in accordance with the restriction criteria.

The decision to use a CAP Protocol is deciding on a series of treatments for a disease, which is different than the decision process for a single medication. Deciding to use a DVT assessment protocol is deciding about performing a risk assessment and not necessarily starting a treatment sequence, and this too represents a different type of decision. In light of these findings, four dependent variables were used in this study.

Outside Influences

This concept describes influences from outside of the P&T Committee that affect the decision making and adoption processes. Part of the effect is due to groups and individuals outside of the health system, with the pharmaceutical industry and accreditation agencies mentioned most frequently by all interviewees. This concept was operationalized by use of an index that is a new measure of influence on P&T Committee tasks and outcomes.

The *Non-Hospital Influences Index* was a new index, and a seven point Likert-type scale was used, with response scale of from "1" (not at all) to "7" (a great deal). Mean response was used in analyses.

The questions used were:

1) How much do Pharmaceutical Industry Representatives affect P&T Committee member decisions?

2) How influential are Pharmaceutical Industry Representatives in getting drugs considered by P&T Committees for formulary inclusion?

3) How much do Pharmaceutical Industry Representatives affect the medications prescribed in the hospital?

4) How much do JCAHO standards and initiatives effect drug use policies developed by the P&T Committee?

5) How much do JCAHO standards and initiatives effect how medications are used in the hospital?

6) How influential are insurers in getting medications considered by the P&T Committee for formulary inclusion?

This index was intended to measure the overall level of influence by three groups influencing the processes of the P&T Committee and prescribing (Table 3.3). The Cronbach's alpha was 0.337, which was not completely unexpected as there is more than one group influencing the P&T Committee and medication use processes. A principle components factor analysis of the Outside Influences Index suggested that the concept as measured consisted of two latent concepts (Table 3.4). Separation of the items into two indexes, the Pharmaceutical Industry Influence Index and the Accreditation Organization Influence Index, resulted in acceptable values of Cronbach's alpha for the indexes, 0.721 and 0.835, respectively. One response regarding insurers influence was omitted due to unacceptable values for either index: that is, it did not fit conceptually with either of the new indexes, and did not affect the models' predictive ability. Varimax rotation was used in these factor analyses. Varimax rotation creates an orthogonal or uncorrelated rotation that maximizes the variance between factors defined during the analysis. The low amount of correlation between the four outcome variables supports using this method. The opposite effects expected from the two components of the outside influences also suggest a low level of correlation between the factors, again suggesting varimax rotation.

The Pharmaceutical Industry Influences Index consisted of the following items:

1) How much do pharmaceutical industry representatives affect P&T Committee member decisions?

2) How influential are Pharmaceutical Industry Representatives in getting drugs considered by P&T Committees for formulary inclusion?

3) How much do Pharmaceutical Industry Representatives affect the medications prescribed in the hospital?

The Accreditation Organization Influences Index consisted of the following items:

1) How much do JCAHO standards and initiatives effect drug use policies developed by the P&T Committee?

2) How much do JCAHO standards and initiatives effect how medications are used in the hospital?

Implementation Support

The concept of implementation support describes the processes that move the decisions of the P&T Committee into the practice environment and promotes continued adherence to the formulary. While most of these efforts are performed by the pharmacy, in some organizations there is some physician support. After decisions are made, prescribers are usually notified of changes to the formulary or other items, either individually or in a group. Often decisions of the committee are put into effect with specific actions taken by the pharmacy when orders for non-formulary medications are received. Therapeutic interchanges and calls to physicians to request an alternative medication are two methods mentioned frequently. This concept was operationalized by construction of a new index called the Intervention Intensity Index.

The Intervention Intensity Index was intended to measure how aggressively a hospital implemented interventions to change orders for non-formulary medications to formulary medications, enforce medication restriction, and encourage adherence to treatment protocols. All eight items were used for models with formulary adherence and restricted medications used in accordance with restriction as the dependent variable. The first four items in the index apply only to formulary adherence and restricted medications

used in accordance with restriction. These four items were not used when the index predicted the percentage of time protocols were used when appropriate. In those models the index consisted of items five through eight.

A seven point Likert-type scale was used, with response scale from "1" (never) to "7" (almost always). Mean response was the scoring method. The Intervention Intensity Index was composed of the following items:

1) How often does your P&T Committee approve therapeutic interchanges for medications that are not listed on the Formulary?

2) How often are approved therapeutic interchanges performed by the pharmacy staff when a non-formulary medication is ordered?

3) How often does pharmacy staff call physicians to obtain a medication order change from a non-formulary medication to a formulary medication?

4) How often does a physician from the P&T Committee contact physicians to obtain a medication order change from a non-formulary medication to a formulary medication?

5) How often does your hospital publish printed communications (newsletters, memos, etc.) when a change is made to the Formulary?

6) How often does your hospital provide electronic communications (E-mails, on-line newsletters, etc) when a change is made to the Formulary?

7) How often does your hospital have a member of the P&T Committee communicate personally to individual or groups of prescribers when changes are made to the Formulary?

8) How often is information on changes to the Formulary included as part of the order entry process?

Team Engagement

Team Engagement is the level of participation, coherence, cohesion and conscientiousness in the group. This concept affects many of the other concepts. The

team literature also suggests the presence of these traits is a predictor of higher levels of commitment to an organization and its processes.

The Organizational Commitment Questionnaire is frequently used in the team literature as either a predictor variable or as an outcome measure. This measure was selected for this concept due to the suggestions in the literature that a team member with a commitment to the P&T Committee result from increased levels cohesion, coherence and conscientiousness. This measure was developed by Mowday et al (1979), and the reliability of the items is Cronbach's alpha of 0.82 to 0.93 depending on the type of working being assessed. In one study of healthcare workers, the Cronbach's alpha was 0.88 (Steers 1977). The nine items that compose the index have a response scale from "1" (strongly disagree) to "7" (strongly agree). Mean response was the scoring method. The questions have been modified in context to the research. The items used were:

1) People involved in the P&T Committee are willing to put a great deal of effort beyond that normally expected in order to help it be successful.

2) People involved in the P&T Committee talk it up to peers as a great part of the organization.

3) People involved in the P&T Committee would accept almost any other job assignment in order to keep working with the P&T Committee

4) People involved in the P&T Committee find their values and the goals of the P&T Committee are very compatible.

5) The P&T Committee really inspires the very best in those involved in the P&T Committee in terms of job performance.

6) People involved in the P&T Committee are glad that they chose to work in the P&T Committee over other responsibilities they could have chosen.

7) People involved in the P&T Committee are proud to tell others that they are involved in the P&T Committee.

8) People involved in the P&T Committee really care about the fate of the P&T Committee.

9) People involved in the P&T Committee feel that it is the best possible area to be involved with.

Physician Influence

This concept was measured with the Physician Influence Index. This index was adapted from a previously validated measure called the Staff Influence on Decision Making Scale (Kruzich & Powell 1995). The index was validated for measuring the influence of social workers on decisions made in nursing homes. The 22 item scale was a modification of another measure, the Employee Influence Scale (Buffum & Holland 1980), a measure of different staff members' influence on nine items, using a Likert-type scale with responses ranging from 1 (no influence) to 5 (a great deal of influence). The Cronbach's alpha of the initial scale was 0.74 to 0.83, depending on the staff member being assessed, which was repeated in the scale adapted specifically to Social Workers. Three of the nine items on the Staff Influence on Decision Making Scale involved staffing levels decisions, and these will not be used. The level of influence of physician members of the P&T Committee on six items was measured. A seven point Likert-type scale was used, with response scale of from "1" (Not much influence) to "5" (A great deal of influence). Mean response was the scoring method. The items used were:

1) How influential are P&T member physicians on the prescribing of physicians not in their specialty?

2) How influential are P&T member physicians on convincing other physicians to prescribe formulary medications?

3) How influential are P&T member physicians on agenda decisions on reviewing medications for possible addition to the Formulary?

4) How influential are P&T member physicians on the amount of communication regarding P&T Committee issues?

5) How influential are P&T member physicians on the prescribing of physicians in their specialty?

6) How influential are P&T member physicians on the gathering of information for committee decisions?

Analysis

Statistical analysis was performed using SPSS® version 17 for Aims One and Two and Amos version 3 for Aim Three. The unit of analysis for the study was the hospital. The mean of two responses for each item was used for each item in the calculated indexes. This is the accepted methodology in the management team research literature (Mehta et. al. 2009, Payne et. al. 2009, Woolley 2009, Lambe et.al. 2009).

Respondent Characteristics: The initial analyses were calculation of the response rate and a description of the respondents. The response rate was calculated as a percentage of completed surveys received where the hospital fits the inclusion criteria. The respondents were described in terms of number of beds, ownership, and location of the hospitals.

Independent variable characterization: The amount of correlation between the independent variables was calculated using partial correlation. The analysis was controlled for the effects of the number of pharmacists, number of P&T Subcommittees, number of non-pharmacist P&T Committee members, ease of obtaining Non-formulary medications, and formulary constrictiveness. The control variables were the same items used during multivariate regression.

Variation by type of respondent: The amount of variation between the pharmacist and non-pharmacist respondents for the independent and dependent variables was determined. The mean response for each group was calculated for each of the independent variables and then compared using two-tailed independent samples t-testing. The Variance Inflation Factor was also calculated during regression testing to examine possible multicollinearity in the data.

In addition to the variation of the overall means, the intra-hospital variation of the independent and independent variables was determined. The difference between the pharmacists and non-pharmacist respondents on each measure was calculated, and then the mean intra-hospital variation was determined.

Factor Analysis: Factor analysis was performed on the measures for each concept to determine if the data were one-dimensional or multi-dimensional. Common factor analysis was used for the purpose of identifying underlying latent variables. Each index used as a measure was examined to determine if the index was measuring one or more factors.

Control Variables: In addition to the conceptual measures, five control variables were also used. These are factors that may influence Prescriber Adoption but are not considered part of the P&T Committee model. All control variables were included in the surveys completed by the Pharmacy Directors, while items 4 and 5 were also included in the surveys for P&T Committee Chairs.

1) The number of pharmacists who participate in P&T Committee meetings
2) The total number of members of the P&T Committee
3) The number of subcommittees of the P&T Committee
4) Perception of the ease of obtaining non-formulary medications.
5) Perception of formulary constrictiveness.

Aim One Analysis

Due to reliability analyses for the Prescriber Adoption Index, there were four dependent variables for Aim One. The four dependent variables were (1) percentage of medication orders that were filled with formulary medications, (2) percentage of orders for restricted medications that met the approved usage criteria, (3) percentage of qualifying patients who were treated with a protocol for CAP, and (4) percentage of qualifying patients assessed for DVT risk using a protocol. The overall means and standard deviation were calculated for each variable. The relationship between levels of each independent variable and the four dependent variables was examined. The median value of each independent variable was determined and categorical variables were

created and compared for the hospitals larger and smaller than the median size, by ownership type and by Medicare Areas. These means were compared using t-tests and ANOVA testing at an alpha level of 0.05 to determine differences.

Aim Two Analysis

The analysis for Aim Two used multivariate regression, and again the four measures from Aim One were used as the dependent variables. All of the independent variables were initially included in the analysis.

One example of a complete regression model that was tested was:

Percentage of medication orders that were filled with formulary medications = β_0 + β_1 Non-hospital Influence + β_2 Implementation Support + β_3 Team Engagement + β_4 Physician Influence + β_5 Number of P&T Committee Pharmacists + β_6 Number of P&T Subcommittees + β_7 Number of Non-Pharmacist P&T Committee Members + β_8 Ease of Obtaining Non-formulary Medications + β_9 Formulary Breadth + E.

This analysis was then repeated for percentage of orders for restricted medications that met the approved usage criteria.

For the two treatment protocols, the regression equation was modified with the removal of measures of Ease of obtaining non-formulary medications and Formulary Breadth, as these two control variables would not logically effect the adoption of protocols. The Implementation Support Index for the two models was the reduced index removing references to formularies.

One example of a complete regression model for a protocol that was tested was:

Percentage of qualifying patients assessed for DVT risk using a protocol = β_0 + β_1 Non-hospital Influence + β_2 Implementation Support + β_3 Team Engagement + β_4 Physician Influence + β_5 Number of P&T Committee Pharmacists + β_6 Number of P&T Subcommittees + β_7 Number of Non-Pharmacist P&T Committee Members + E.

This analysis was then repeated for percentage of qualifying patients who were treated with a protocol for CAP.

The first analysis was the overall F-test to evaluate the null hypothesis that all independent variables considered together do not explain a significant amount of the variation in the dependent variable. If prob. (F) < .05, then the model is considered significantly better than would be expected by chance and the null hypothesis of no linear relationship between the dependent variable and independent variables can be rejected. The R^2 value and regression coefficient values of the models were estimated. R^2 is the percent of the variance in the dependent explained by the independent variables. An increasing value of R^2 indicates a better fitting model. The goodness of fit of a statistical model describes how well it fits a set of observations. The regression coefficient is the average amount the dependent variable changes when the independent variable increases one unit and other independent variables are held constant.

When the overall F-test test was significant, the data and regression results were then examined to ensure that the regression assumptions had been met. To satisfy the assumption of linearity, the plot of observed versus predicted values were inspected for linearity. To satisfy the assumption of independence, the autocorrelation plot of the residual was inspected and the Durbin Watson statistic was calculated. To satisfy the assumption of normality, the results for each measure were tested for normality by visually inspecting plots of the data as well as analyzing the results of each measure for skew and kurtosis. To satisfy the assumption of homoscedasticity of errors, the plot of actual versus predicted residuals was visually inspected for increasing residuals over the span of the data. Plots comparing observed data and predicted data were constructed for each of the four dependent variables. Each of the responding hospitals was included in these plots. The plots included the best fit line for the data as well as the 95 percent confidence intervals for the best fit lines.

There was evidence in the qualitative study that levels of some concepts may be dependent on levels of other concepts which are interactions in regression analysis. In some hospitals, the commitment to the P&T Committee and its processes appeared to be

dependent on the influence of the committees' physician members. Often the efforts to move P&T Committee decisions into practice were dependent on how committed the committee members were to the activities of the P&T Committee. The interactions between Physician Influence and Team Engagement and Team Engagement and Implementation support were evaluated in the regression analyses.

When the overall F-test was not significant, reduction of the models was performed to determine if a reduced model would be significant. Concepts that did not add to the predictive capability of the model were removed. One strategy was to remove concepts whose effects were primarily indirect, such as Physician Influence. Another strategy used was to examine the concepts to determine if there was support in the results of the qualitative study for such a removal.

Aim Three Analysis

The analysis for Aim 3 consisted of path analysis within the model. AMOS version 5 was used to determine both direct and indirect effects on the four independent variables and Implementation Support. The direct effects regressions depended on the model being analyzed. The direct effect regressions that were part of the path analysis for the model with percentage of orders filled with formulary medications as the dependent variable were:

1) Percentage of orders filled with formulary medications = $\beta_0 + \beta_1$ Implementation Support + β_2 Team Engagement + β_3 Pharmaceutical Industry Influences + E.

2) Implementation Support = $\beta_0 + \beta_1$ Pharmaceutical Industry Influences + E. (In the model with Percentage of orders filled with formulary medications as the dependent variable.)

The direct effect regressions that were part of the path analysis for the model with Percentage of restricted medications used in accordance with restriction as the dependent variable were:

3) Percentage of restricted medications used in accordance with restriction = β_0 + β_1 Implementation Support + β_2 Team Engagement + β_3 Pharmaceutical Industry Influences + β_4 Accreditation Organization Influences + E.

4) Implementation Support = β_0 + β_1 Pharmaceutical Industry Influences + β_2 Accreditation Organization Influences + β_3 Physician Influence + E.

5) Team Engagement = β_0 + β_1 Physician Influence + E

The direct effect regressions that were part of the path analysis for the model with percentage of qualifying patients who were treated with a protocol for CAP were:

6) Percentage of qualifying patients who were treated with a protocol for CAP = β_0 + β_1 Implementation Support + β_2 Team Engagement + β_3 Pharmaceutical Industry Influences + E.

7) Implementation Support = β_0 + β_1 Pharmaceutical Industry Influences + β_2 Physician Influence + E.

8) Team Engagement = β_0 + β_1 Physician Influence + E

The direct effect regressions that were part of the path analysis for the model with percentage of time community DVT risk assessment protocol was used when use would have been appropriate were:

9) Percentage of time community DVT risk assessment protocol was used when use would have been appropriate = β_0 + β_1 Implementation Support + β_2 Team Engagement + β_3 Pharmaceutical Industry Influences + β_4 Accreditation Organization Influences + E.

10) Implementation Support = β_0 + β_1 Pharmaceutical Industry Influences + β_2 Accreditation Organization Influences + β_3 Physician Influence + E.

11) Team Engagement = β_0 + β_1 Physician Influence + E

The indirect effects were also calculated using AMOS 5.0. These again varied with the model being tested. For example, the indirect effect of Pharmaceutical Industry Influences on Percentage of orders filled with formulary medications was calculated by

first determining the coefficient for the total effect of Pharmaceutical Industry Influences on Percentage of orders filled with formulary medications by directly regressing Pharmaceutical Industry Influences alone on Percentage of orders filled with formulary medications, and then subtracting the coefficient for Pharmaceutical Industry Influences that was determined during the overall regression. The other indirect effects analyzed were:

1) Pharmaceutical Industry Influences, Accreditation Organization Influences, and Physician Influences on Percentage of restricted medications used in accordance with restriction

2) Pharmaceutical Industry Influences and Physician Influences on Percentage of qualifying patients who were treated with a protocol for CAP

3) Pharmaceutical Industry Influences, Accreditation Organization Influences, and Physician Influences on Percentage of time community DVT risk assessment protocol was used when use would have been appropriate

The data collection and analysis described in this chapter addressed the three specific aims of this study. Upon completion of the analysis, descriptions of the perceived levels of prescriber adoption of decisions of hospital P&T Committees were determined, the factors that affect the levels of prescriber adoption, and the relationships between those factors were also determined.

Table 3.1: Measures of Concepts

Concept	Operationalized Concept	Measure	Description	Used in analysis
Pharmaceutical Industry Influences	Perception of influence of pharmaceutical industry on behaviors of system	Pharmaceutical Industry Influences Index	3 items with 1 = Not at all and 7 = A great deal	Mean
Accreditation Organization Influences	Perception of influence of accreditation organizations on behaviors of system	Accreditation Organization Influences Index	2 items with 1 = Not at all and 7 = A great deal	Mean
Implementation Support	Interventions for non-formulary medication orders. Educational Efforts	Intervention Intensity Index	8 items with 1 = Never and 7 = Always	Mean
Team Engagement	Commitment to the P&T Committee and its processes	Organizational Commitment Questionnaire	9 items with 1 = Strongly Disagree and 7 = Strongly Agree	Mean
Physician Influence	Perception of Physician Influence	Physician Influence Scale	6 items with 1 = Not much Influence and 5 = A great deal of influence	Mean
Prescriber Adoption	Adoption of P&T Committee Decisions	Four Specific Outcomes	Percentage, ranging from 0 to 100.	Result

Table 3.2: Exploratory factor analysis of items originally in Prescriber Adoption Index (N = 57) [a]

	Factor 1 (Medications)	Factor 2 (Protocols)	Cronbach's Alpha
Percentage of orders filled with formulary medications	0.827		0.105
Percentage of restricted medications used in accordance with restriction.	0.711		
Percentage of time community acquired pneumonia protocol was used when use would have been appropriate.		0.817	0.222
Percentage of time community DVT risk assessment protocol was used when use would have been appropriate.		0.747	

[a] Factor analysis performed using principle component analysis with Varimax rotation.

N = 57

Table 3.3: Outside Influences Index Results (N=57)

	Mean [a]	Range	Cronbach Alpha
Outside Influences Index	3.38 ± 0.44	2.5 – 4.42	0.377
How much do Pharmaceutical Industry Representatives affect P&T Committee members' decisions?	2.03 ± 0.75	1.0 – 3.5	--
How influential are Pharmaceutical Industry Representatives in getting medications considered by the P&T Committee for formulary inclusion?	2.61 ± 0.98	1.0 – 5. 0	--
How much do Pharmaceutical Industry Representatives affect what medications are prescribed in the hospital?	2.84 ± 0.97	1.0 – 5.0	--
How much do JCAHO standards and initiatives affect drug use policies developed by the P&T Committee?	5.47 ± 0.78	3.0 – 6.5	--
How much do JCAHO standards and initiatives effect how medications are prescribed in the hospital?	5.13 ± 0.92	2.0 – 6.5	--
How influential are insurers in getting medications considered by the P&T Committee for formulary inclusion?	2.22 ± 1.15	1.0 – 5.5	--

[a] Items measured with a 7 point Likert-type scale ranging from "Not at all" (1) to "A great deal" (7).

Table 3.4: Exploratory factor analysis of items originally in Outside Influences Index (N=57) [a]

	Factor 1 (Industry)	**Factor 2 (Accreditation)**
Industry influence on committee member decisions	0.873	
Industry influence on formulary consideration	0.567	
Industry influence on prescribing	0.791	
JCAHO influence on policies		0.861
JCAHO influence on prescribing		0.915
Insurers influence on formulary consideration	0.485	0.295

[a] Factor analysis performed using principle component analysis with Varimax rotation

Figure 3.1: Model of P&T Committee Performance

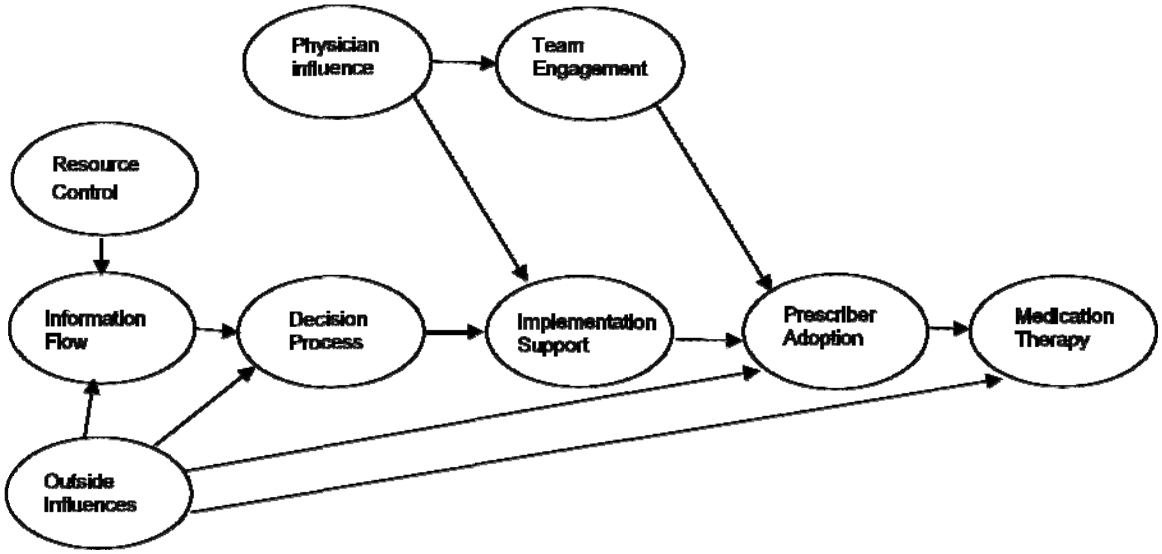


Figure 3.2: Model of P&T Committee Performance for Current Study

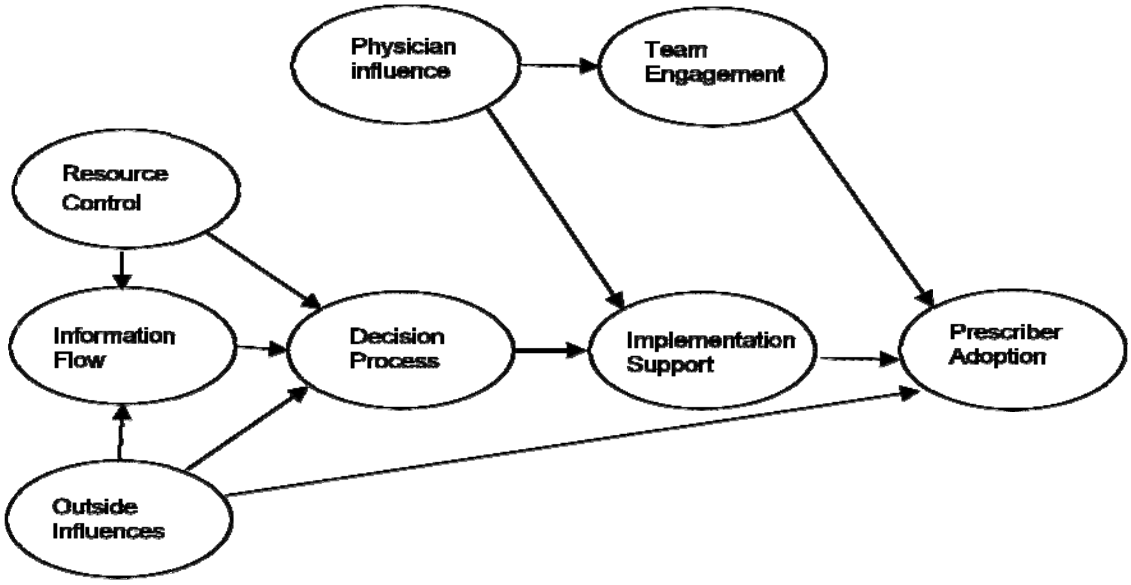


Figure 3.3: Final Conceptual Model of P&T Committee Performance

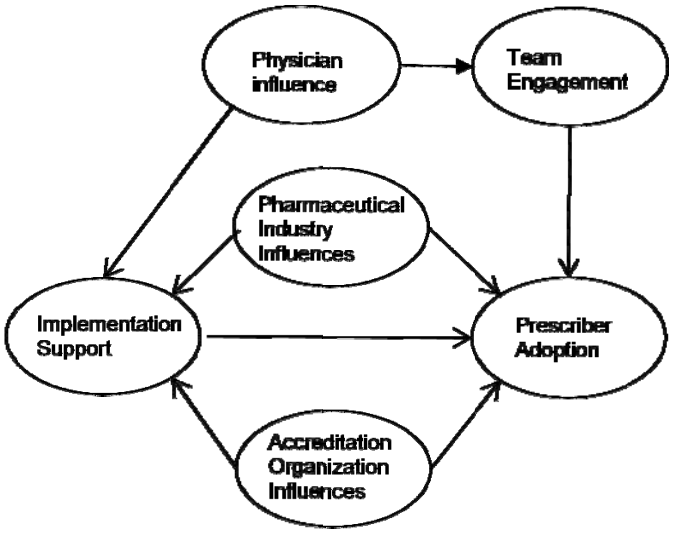
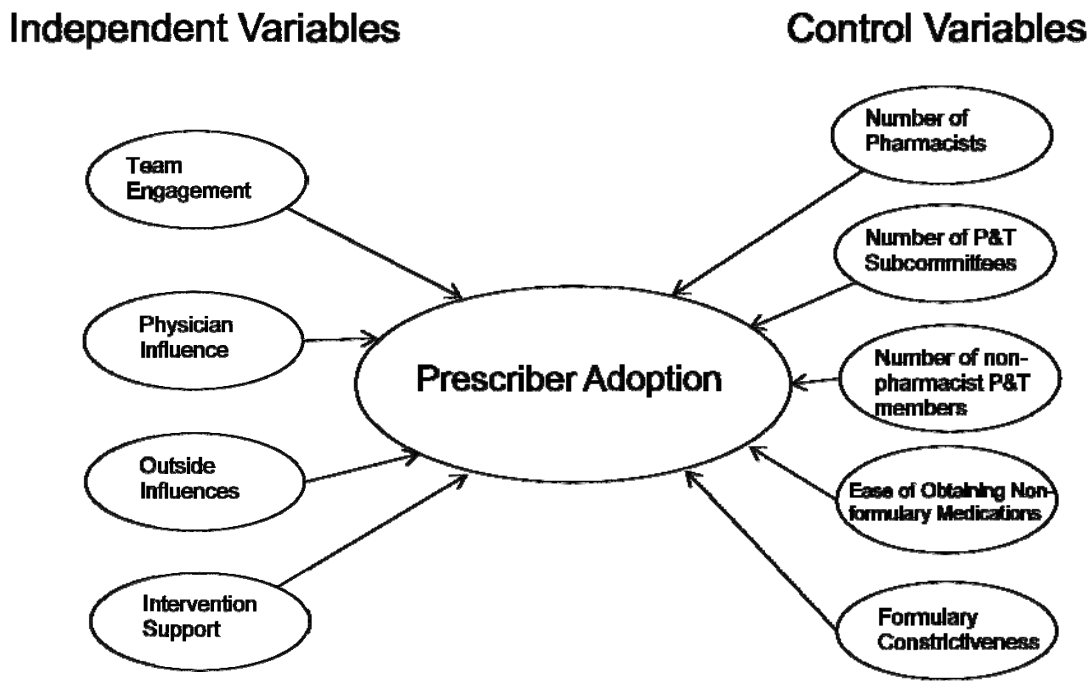


Figure 3.4: P&T Committee Performance Model



CHAPTER FOUR

RESULTS

This chapter contains the results from the analysis of the data gathered for the study. The first part of the chapter contains respondent characteristics, while the second part presents the results of the analysis for the three aims of the study. All result tables are at the end of this chapter.

Respondent Characteristics

An initial 51 surveys were mailed for survey testing on March 23, 2009. After survey modifications, e-mail invitations to an additional 270 hospital were sent beginning April 27, with data collection ending on August 13, 2009. A total of 321 hospitals were asked to participate, and at least one response was received from 86 hospitals, a response rate of 26.79% (Table 4.1). Eighty six Pharmacy Directors or a pharmacist designated by the Pharmacy Director, 27 Hospital Administrators or Medical Directors, and 44 P&T Committee Chairs completed a survey, resulting in response rates of 26.79%, 8.41%, and 13.71%, respectively. Completed surveys from at least two respondents were required for a hospitals' information to be included in the analyses. There were 57 hospitals that had two responses, so 17.76% of hospitals sent surveys qualified for inclusion in the study analysis. Responses were received from another 30 hospitals, but did not fit the inclusion criteria of two respondents per hospital. The hospitals included in the analysis were located throughout the United States (Table 4.2). These hospitals were predominantly owned by non-profit organizations and were large in size. The mix of ownership of the respondent hospitals was slightly skewed toward not-for-profit and away from for-profit when compared to the national distribution. Almost 74 percent of responding hospitals were not-for-profit compared to 58 percent nationally, while seven percent of responding hospitals were for-profit compared to almost 20 percent nationally. Key participants in

the P&T Committees at these hospitals were experienced and the committees had broad representation from many health professions.

Formulary Characteristics

The perceived difficulty of obtaining non-formulary medications and the perceived constrictiveness of the formularies at the surveyed hospitals were measured as control variables, with responses from Pharmacy Directors and P&T Chairs (Table 4.3). On average, the formularies of qualifying hospitals were somewhat constrictive with the ability to obtain non-formulary medications perceived as easy or neutral.

Model Measures

Dependent Variables

The means and standard deviations were calculated for the four dependent variables (Table 4.4). Hospitals were very successful in getting formulary medications administered to patients with little variation between hospitals (96.02 ± 3.94). They have less success in having physicians follow medication restrictions (77.02 ± 28.81) and follow protocols treating Community Acquired Pneumonia (CAP) (63.02 ± 32.76) or for assessing Deep Vein Thrombosis (DVT) risk (73.02 ± 29.94). There is significant variation between hospitals in the latter three measures.

Independent Variables

Pharmaceutical Industry Influences: Industry influences were measured using new items intended to measure the overall level of influence by the pharmaceutical industry on the processes of the P&T Committee and prescribing (Table 4.5). The Cronbach's alpha of was good (0.721), the mean showed moderately low influence (2.49 ± 0.72) with a range of 1.17 to 4.0. Of the three items measured, the Pharmaceutical Industry had the greatest influence on affecting what medications were prescribed in the hospital (2.84 ± 0.97).

Accreditation Organization Influences: This concept was measured using new items. This index was intended to measure the overall level of influence by the accrediting organization influencing the processes of the P&T Committee and prescribing (Table 4.6). The Cronbach's alpha was very good (0.835) and the average showed a moderately high level of influence of accreditation organizations on the P&T Committee (5.30 ± 0.78) with a range of 2.5 to 6.25. Of the two items measured, JCAHO had a larger influence on affecting drug use police developed by the P&T Committee (5.47 ± 0.78).

Implementation Support: This concept was measured using new items, the Implementations Support Index. This index was intended to measure the level of effort to support the movement of decisions of the P&T Committee into the practice environment and reflected in prescribing changes (Table 4.7). The Cronbach's alpha of this measure was good (0.644) and the mean showed a moderately high level of interventions being performed to implement decisions of the committee (4.75 ± 0.85) with a range of 2.38 to 6.38. Of the eight items measured, performing interchanges and sending a printed communication after formulary changes were the most common efforts to support the movement of decisions of the P&T Committee into the practice environment. Interventions by physicians were less likely to be performed than those by pharmacists.

When this variable was used in predicting adherence to treatment protocols, only three items that measured educational efforts to support implementation of protocols were used in the calculation of the index value. The Cronbach's alpha of this measure was low (0.571) and the mean showed a moderately high level of educational efforts being performed to support implementation of protocols (5.13 ± 1.21) with a range of 2.33 to 7.00.

Team Engagement: This concept was measured using a previously validated instrument, the Organizational Commitment Questionnaire (Table 4.8). This index intended to measure the overall level of commitment of the member of the P&T Committee to the functioning of the committee and to the processes that the committee

reviews and approves. The Cronbach's alpha of this measure was very good (0.906) and the mean showed moderately strong commitment to the P&T Committee (4.81 ± 0.95) with a range of 3.0 to 6.67. Of the nine items measured, the items that asked about members caring about the P&T Committee and that the goals of the P&T Committee and their goals were compatible had the highest scores indicating the greatest agreement with the items.

Physician Influence: This concept was measured using a previously validated instrument, the Staff Influence on Decision Making Scale. This index was intended to measure the overall level of influence of the physician members of the P&T Committee in the practice environment (Table 4.9). The Cronbach's alpha of this measure was acceptable (0.697) and the mean showed that the physicians on the P&T Committee were moderately influential (2.98 ± 0.49) with a range of 2.0 to 4.2. Of the five items measured, physician members of the P&T Committee have the most influence on physicians of the same specialty and influence on setting the P&T agenda.

The effects of different levels of each independent variable on the dependent variable were examined (Table 4.10). The median of each independent variable was determined and two groups were created for these variables. Then, the means of the dependent variables were compared using independent sample t-testing. Higher levels of Physician Influence were associated with significantly higher levels of use of CAP protocols. Higher levels of Team Engagement were associated with higher levels of all of the dependent variables except use of CAP treatment protocols. Lower levels of Pharmaceutical Industry Influences were associated with higher use of Formulary Medications and DVT risk assessment protocols.

Correlations between the independent variables were also determined controlling for Number of Pharmacists, Number of P&T Subcommittees, Number of non-Pharmacist P&T Committee members, Ease of obtaining Non-formulary medications, and Formulary Constrictiveness (Table 4.11). Team Engagement was significantly correlated with both

Implementation Support and Physician Influence. No other correlations between independent variables were significantly correlated.

The difference in mean responses and the intra-hospital variation for dependent and independent variables between pharmacists and non-pharmacists were examined (Table 4.12). Pharmacist responses were higher for all independent variables except for Physician Influence. The mean difference between pharmacists and non-pharmacists were significant for Physician Influence and Pharmaceutical Industry Influences, but the magnitude of these differences was small, in the range of 0.35 on a scale of 1 to 7. Due to the low levels of variation between respondents, the analysis was performed using the mean value of the responses from a hospital to calculate the results of the five indexes and for the four dependent variables.

Aim One

The first aim of the study was to describe the variance in P&T Committee performance in the United States. The degree of adoption of four types of P&T Committee decisions were used as dependent variables in three analyses comparing the results of the measures based on hospital size, ownership, and geographic location.

Performance by Hospital Size

The performance of P&T Committee was examined by size of hospitals. Size of hospitals was categorized as large or small based on the median bed size of 477 beds. Comparisons were performed using t-tests (Table 4.13). There were no differences detected between hospitals above or below the median on any of the four outcomes.

Performance by Ownership Type

The performance of P&T Committee was examined by the ownership type of the hospital as reported in the AHA directory. Eleven hospitals were owned by government, 42 owned by not-for-profit corporations or organizations, and 4 owned by for-profit

corporations (Table 4.13). Comparisons were performed using ANOVA. There was a statistically significant difference between not-for-profit hospitals and both government and for-profit hospitals on the use of CAP protocol, with a higher usage rate in not-for-profit hospitals. No other significant differences based on ownership type were detected.

Performance by Geographic Region

The performance of hospitals was also examined based on the location of the hospital as defined by Medicare Region. Thirty two hospitals were located in Regions I-V, and 25 hospitals were located in Regions VI-X. The division of the regions corresponds with Regions I-V being east of the Mississippi river and Regions VI-X west of it. Comparisons were performed using t-tests (Table 4.13). There was a statistically significant difference between the two groups on the DVT assessment protocol usage, with hospitals in regions I through V using the protocol significantly more often. No other significant differences based on geographic region were detected on any other outcomes.

Aim 1 Results Summary

The results of the Aim 1 analysis showed little differences between hospitals based on hospital size, ownership, and geographic location. There was statistically significantly higher usage of CAP protocols in not-for-profit hospitals and DVT risk assessment protocols in hospitals in the eastern United States.

Aim Two

The second aim of the study was to quantify predictors of performance within the P&T Committee model. This was accomplished by performing four linear least squares regression using percentage of medication orders filled with formulary medications, percentage of restricted medications used in accordance with the restriction criteria, percentage of eligible patients treated with a CAP protocol, and percentage of qualifying

patients assessed with a DVT prophylaxis protocol as the dependent variables, assessing the effects of five model concepts and five control variables on the dependent variables.

Medication orders filled with formulary medications

With all measures included, the model was not significant with an F value of 1.632 and a p value of 0.128 (Table 4.14) and no predictors reached the level of statistical significance. The likely reason for the failure of the model to reach significance was the small size of the sample with the number of independent variables in the model and the small amount of variation in the dependent variable.

A reduced model was then analyzed. With such a small amount of variation present in the dependent variable, it was important that independent variables not be retained in the model if their contribution to the dependent variable could be due to random chance, which is the case with a non-significant regression equation. After reviewing information gathered for the qualitative study, the effects of the variable Physician Influence were thought to be found on the implementation efforts done after a decision and not directly on the dependent variable. Results of a partial F-test reinforced this possibility, and the variable of Physician Influence was removed from the regression equation and path analysis. A similar review of qualitative results and a review of the activities of accreditation organizations such as the JCAHO suggested that this variable would not directly affect the adoption of formulary medication decisions. This also was confirmed though partial F-testing. The variable Accreditation Organization Influences was removed due to these findings. Based on comments in the qualitative study, an interaction between Team Engagement and Implementation Support was evaluated, but this term was not significant ($p = 0.469$) and did not affect other variables or increase the models explanation of variance (R^2 increase of 0.013).

The model then was significant with an F value of 2.11 and a p value of 0.053 (Table 4.15). Goodness of fit statistics showed an R squared of 0.260. Team engagement

was significant (p = 0.045) with a one standard deviation increase in Team Engagement associated with a 0.305 standard deviation increase in the percentage of orders dispensed with formulary medications. This suggests that hospitals with a P&T Committee that is committed to the duties of the committee and to the process of the Formulary are more likely to have a higher rate of adoption of the committee's decisions by prescribers. The control variable of Number of P&T Subcommittees also was significant, with a one standard deviation increase in the number of subcommittees associated with a decrease of 0.281 standard deviation decrease in the percentage of orders dispensed with formulary medications. This suggests that the more the focus of the committee is split among subcommittees, the less likely prescribers are to adopt the committees' formulary decisions. Proposed interactions between Team Engagement and Implementation Support and between Team Engagement and Physician Influence were evaluated but not added to the final model due to negligible impact on R squared and no improvement on the overall F-test.

Restricted medications used in accordance with the restriction criteria

With all measures included, the model was significant with an F value of 2.81 and a p value of 0.010 (Table 4.16). Goodness of fit statistics showed an R squared of 0.407. Team Engagement (p = 0.032) and Implementation Support (p = 0.013) reached significance. A one standard deviation increase in Team Engagement was associated with a 0.390 standard deviation increase, and a one standard deviation increase in Implementation Support was associated with a 0.388 standard deviation increase in the percentage of restricted medications used in accordance with the restriction criteria.

Information in the qualitative study suggested that there could be interactions between Team Engagement and both Implementation Support and Physician Influence. With these interactions included, the model was significant with an F value of 2.76 and a

p value of 0.008 (Table 4.17). Goodness of fit statistics showed an R squared of 0.466. Implementation Support ($p = 0.013$) and the interaction between Team Engagement and Implementation Support ($p = 0.05$) were significant. The significant interaction term suggests that levels of Implementation Support vary with changing levels of Team Engagement, and as such the direct effects of Team Engagement and Implementation Support are not directly interpretable. The combination of affects from an engaged committee and more aggressive implementation efforts showed an association with a decrease in the percentage of restricted medications used in accordance with the restriction criteria ($\beta = -2.21$). This suggests that there may be a decrease in adoption of medication restrictions when the implementation efforts become more of an irritant to the prescribers, perhaps due to implementation fatigue.

The control variable of Formulary Constrictiveness was significant ($p=0.024$) with a one standard deviation increase associated with a 0.33 standard deviation increase in the percentage of restricted medications used in accordance with the restriction criteria. This suggests that prescribers are more likely to prescribe according to P&T Committee approved criteria if they perceive the formulary as being more limiting as to their choices of medications to prescribe.

An examination of the effect of the interaction can be demonstrated by holding all terms not included in the interaction constant, and then calculating the predicted percentage of restricted medications used in accordance with the restriction criteria using the maximum and minimum results for the interacting variables. Using the mean values for all non-interacting variables, and then using the ends of the observed ranges for the interacting variables, the following results were calculated:

Implementation Support	Team Engagement	Restricted Med %
2.38	3	32.71 %
2.38	6.67	60.70 %
6.38	3	145.06 %
6.38	6.67	41.24 %

These results suggest that changes in levels of Implementation Support are most effective in improving performance when levels of Team Engagement are low, but that similar increases in Team Engagement in the opposite situation are not as effective for improving team performance.

Qualifying patients treated with Community Acquired Pneumonia Protocol

For this dependent variable, the control variables for formulary constrictiveness and difficulty of obtaining non-formulary medications were not included, as they would not be expected to affect usage of disease treatment protocols. With all measures included, the model was not significant with an F value of 1.515 and a p value of 0.178 (Table 4.18). Goodness of fit statistics showed an R squared of 0.209.

A reduced model was then analyzed. It was important that independent variables not be retained in the model if their contribution to the dependent variable could be due to random chance, which is the case with a non-significant regression equation. After reviewing information gathered for the qualitative study, it appears that the consideration of CAP protocols by the P&T Committee are usually not the result of the activities of an accreditation organization, but due to recommendations from practice organizations such as the American Thoracic Society (Niederman et al 2001). Results of a partial F-test reinforced this possibility, and the variable of Accreditation Organization Influences was removed from the regression equation and path analysis. Both interactions proposed to be present were analyzed, and the interaction between Team Engagement and Physician Influence was retained in the final model. With the interaction included and Accreditation Organization Influences removed, the model was not significant (F value of 1.804 and a p value of.0.095) (Table 4.19). Goodness of fit statistics showed an R squared of 0.274. Team Engagement ($p = 0.043$) was significant. Due to the small sample sizes often seen

in team research, there is consideration being given to accepting overall F-tests with a p value of 0.10 as being significant. This model will be interpreted accepting this level of significance. An engaged P&T committee where the members are committed to the goal is associated with a decrease in the qualifying patients being treated with a Community Acquired Pneumonia protocol (β = -1.483). This may suggest that hospitals where the team members are actively engaged in the process of creation and implementation of this protocol may decrease adoption of CAP treatment protocols. But this finding should be examined in the context of an interaction between Team Engagement and Physician Influence (p=0.06) that would most likely be significant with a larger sample size. That interaction would result in an increase in adoption of CAP treatment protocols.

Percentage of qualifying patients assessed with a DVT prophylaxis protocol

For this dependent variable, the control variables for formulary constrictiveness and difficulty of obtaining non-formulary medications were not included, as they would not be expected to affect usage of disease assessment protocols. With all measures included, the model was not significant with an F value of 1.776 and a p value of 0.108 (Table 4.20). Goodness of fit statistics showed an R squared of 0.244. Pharmaceutical Industry Influences was significant (p = 0.039) but was not interpreted due to the non-significant overall F-test.

Interactions between Team Engagement and Implementation Support and between Team Engagement and Physician Influence were evaluated. The interactions were not significant, but with their addition, the overall F-test was significant with an F value of 2.483 and a p value of.0.020 (Table 4.21). Goodness of fit statistics showed an R squared of 0.383. Pharmaceutical Industry Influence (p = 0.004) was significant. A one standard deviation increase in Pharmaceutical Industry Influence was associated with a

0.451 standard deviation decrease in qualifying patients assessed with a DVT prophylaxis protocol.

Aim 2 Result Summary

The objective of Aim 2 was to quantify predictors of performance within the P&T Committee model. Examination of the proposed outcome measure found that the four types of prescribing behaviors were not similar enough to be used as index. The previously proposed model was used as a starting point for each prescribing behavior, but modifications, including deletion of one or more measures and /or addition of interactions terms, were needed to produce models that were statistically significant. Each model was also different in the degree to which specific measures affected the outcome measure. Team Engagement, or Team Engagement interacting with another concept, was significant in all four models. In three of the four models, the effect of Team Engagement, either by itself or as part of an interaction, was to increase the dependent variable. These findings are significant.

Aim Three

The third aim of the study was to quantify the relationships between concepts in the P&T Committee models and the effects of these relationships on the four measures of P&T Committee performance. This was accomplished by completion of path analysis. Direct effects and indirect effects were determined using linear least squares regression techniques.

Path Analysis

The path analyses were based upon the final reduced models.

Medication orders filled with formulary medications

All independent variables in the model (Figure 4.1) have direct effects on the outcome variable Percentage of medication orders filled with formulary medications, with Team Engagement and Pharmaceutical Industry Influence having the greatest effect (Table 4.22). The direct effect for Team Engagement was significant ($p = 0.006$). Pharmaceutical Industry Influences had a direct effect on Implementation Support with increases in Pharmaceutical Industry Influence decreasing Implementation Support, but this effect was not significant ($p = 0.323$). Pharmaceutical Industry Influences had a small indirect effect on the outcome variable in addition to its direct effects (Table 4.22).

Restricted medications used in accordance with the restriction criteria

All independent variables except Physician Influence have direct effects on the outcome variable of Percentage of restricted medications used in accordance with the restriction criteria (Figure 4.2). Implementation Support and Team Engagement have the greatest effects (Table 4.23), and both Team Engagement ($p = 0.025$) and Implementation Support ($p=0.005$) were significant. Physician Influence, Accreditation Organization Influence, and Pharmaceutical Industry Influence have indirect effects on the outcome variable. Physician Influence, which only affects the outcome variable indirectly thought Team Engagement and Implementation Support, had the largest indirect effect on the dependent variable.

Pharmaceutical Industry Influence, Accreditation Organization Influence, and Physician Influence had a direct effects on Implementation Support, with the effect of Physician Influence reaching significance ($p = 0.012$). Physician Influence also had a

direct effect on Team Engagement which reached significance (p = <0.001). This suggests that influential physicians on the P&T Committee enable implementation efforts and committee members more committed to the process. Pharmaceutical Industry Influences had an indirect effect on the outcome measure in addition to its direct effects (Table 4.23).

Community Acquired Pneumonia Protocol use in qualifying patients

All variables except Physician Influence have direct effects on the outcome variable Percentage of qualifying patients treated with Community Acquired Pneumonia protocol (Figure 4.3), with Implementation Support and Pharmaceutical Industry Influence having the greatest effects (Table 4.24). The effect of Implementation Support on the use of CAP protocols was significant (p = 0.019). Physician Influence and Pharmaceutical Industry Influence have indirect effects on the outcome variable, with Physician Influence having the largest indirect effect.

Pharmaceutical Industry Influences and Physician Influence had a direct effects on Implementation Support, with the effect of Physician Influence reaching significance (p = 0.02). Physician Influence also had a direct effect on Team Engagement which reached significance (p = <0.001). Pharmaceutical Industry Influences had an indirect effect on Prescriber Adoption in addition to its direct effects (Table 4.24). Physician Influence, which only affects the outcome variable indirectly thought Team Engagement and Implementation Support, has the largest indirect effect.

Percentage of qualifying patients assessed with a DVT prophylaxis protocol

All variables except Physician Influence have direct effects on the outcome variable Percentage of qualifying patients assessed with DVT Prophylaxis protocol (Figure 4.4), with Pharmaceutical Industry Influence having the greatest effect (Table

4.25), reaching significance (p = 0.009). Physician Influence, Accreditation Organizations Influence and Pharmaceutical Industry Influence have indirect effects on the outcome variable, with Physician Influence having the largest indirect effect on the dependent variable.

Pharmaceutical Industry Influence, Accreditation Organizations Influence and Physician Influence had a direct effects on Implementation Support, with the effect of Physician Influence reaching significance (p = 0.006). Physician Influence also had a direct effect on Team Engagement which reached significance (p = <0.001). Pharmaceutical Industry Influences had an indirect effect on Prescriber Adoption in addition to its direct effects (Table 4.25).

Aim 3 Results Summary

The third aim of the study was to quantify the relationships between concepts in the P&T Committee models and the effects of these relationships on four measures of P&T Committee performance. One finding was that the effects of each concept were different for each of the four outcome measures. Another was that Pharmaceutical Industry Influences affected both the dependent variables and other independent variables negatively in all models, while Physician Influences affected them positively.

Table 4.1 Number and Combination of Respondents

	Hospitals	Individuals
Number of hospitals sent survey	321	
Number of Hospitals with a least 1 response	87	
Hospitals Qualifying with Pharmacist, Hospital Administrator / Medical Director, and P&T Committee Chair Responding	13	
Hospitals Qualifying with Pharmacist and Hospital Administrator / Medical Director Responding	16	
Hospitals Qualifying with Pharmacist and P&T Committee Chair Responding	28	
Hospitals with only Pharmacist Respondents	30	
Hospitals with only Hospital Administrator / Medical Director Respondents	0	
Hospitals with only P&T Committee Chair Respondents	0	
Potential respondents from Hospitals with a least 1 response		261
Total respondents		156
Pharmacist Respondents		87
Pharmacy Directors		60
Pharmacy Assistant Directors		7
Pharmacy Clinical Pharmacy Coordinators		13
Pharmacy Drug Information Specialists		3
Other Pharmacists		4
Hospital Administrator / Medical Director Respondents		27

Table 4.1 Continued

Hospital Administrators	20
Medical Directors	7
P&T Committee Chair Respondents	43

[a] Includes 51 surveys sent during testing

Table 4.2: Characteristics of Hospitals Included in the Analysis (N=57)

	Frequency	%	Mean/SD
Location			
Medicare areas I-V	32	56.1	
Medicare areas VI-X	25	43.9	
Ownership			
Government	11	19.3	
Not-for-profit	42	73.7	
For profit	4	7.0	
Size			
Beds			504.39 ± 278.54
P&T Committee Characteristics			
P&T subcommittees			2.11 ± 2.14
P&T Committee members			15.89 ± 10.08
P&T Committee Pharmacists			5.84 ± 2.80
Pharmacists years of service			14.82 ± 8.33
Hospital Administrators years of service			8.42 ± 6.91
P & T Committee Participation			
Physicians	57	100	

Table 4.2: Continued

Pharmacists	57	100
Nurses	51	89.5
Hospital Administrators	33	57.9
Physician Medical Directors	25	43.9
Dietitians	25	49.9
Microbiologists/Laboratory	15	26.3
Patient Safety Officers	13	22.8
Quality Management Directors members	15	26.3
Other members [a]	13	22.8

[a] Other members included Dentists, Radiology Directors, Respiratory Therapists, ICU Directors, Infection Control Nurses, IT professionals, Medication Safety Managers, Education Department Representative, Performance Improvement Officers, Risk Management Directors, and Residents.

Table 4.3: Formulary Characteristics of Qualifying Hospitals (N=57)

	Mean/SD	Frequency	%
Perceived Non-Formulary Difficulty [a]	2.73 ± 0.89		
Very Easy		7	6.7
Easy		36	34.6
Neutral		41	39.4
Difficult		18	17.3
Very Difficult		2	1.9
Perceived Formulary Constrictiveness [b]	3.59 ± 1.05		
Not at all		2	2.0%
Very Little		14	13.7%
Average		31	30.4%
Somewhat		32	31.4%
Very		23	22.5%

Note: Frequency from all respondents at hospitals included in analysis

[a] Scale - Very Easy = 1 Easy = 2 Neutral = 3 Difficult = 4 Very Difficult = 5

[b] Scale – Not at all = 1 Very Little = 2 Average = 3 Somewhat = 4 Very = 5

Table 4.4: Outcome variables (N=57) [a]

	Mean	1st Quartile	2nd Quartile	3rd Quartile	4th Quartile
Medication Orders dispensed with Formulary Medications	96.02 ± 3.94	95	98	99	100
Restricted medications used in compliance with restriction	77.02 ± 28.81	75	90	95	100
Qualifying patients treated with Community Acquired Pneumonia protocol	63.02 ± 32.76	30	75	90	100
Qualifying patients assessed with Deep Vein Thrombosis protocol	73.02 ± 29.96	60	85	95	100

[a] All measures are percentages.

Table 4.5: Pharmaceutical Industry Influences Index Results (N=57)

	Mean [a]	Range	Cronbach Alpha
Industry Influences Index	2.49 ± 0.72	1.17 – 4.0	0.721
How much do Pharmaceutical Industry Representatives affect P&T Committee members' decisions?	2.03 ± 0.75	1.0 – 3.5	--
How influential are Pharmaceutical Industry Representatives in getting medications considered by the P&T Committee for formulary inclusion?	2.61 ± 0.98	1.0 – 5. 0	--
How much do Pharmaceutical Industry Representatives affect what medications are prescribed in the hospital?	2.84 ± 0.97	1.0 – 5.0	--

[a] Items measured with a 7 point Likert-type scale ranging from "Not at all" (1) to "A great deal" (7).

Table 4.6: Accreditation Organization Influences Index Results (N=57)

	Mean [a]	Range	Cronbach Alpha
Accreditation Influences Index	5.30 ± 0.79	2.5 – 6.25	0.835
How much do JCAHO standards and initiatives affect drug use policies developed by the P&T Committee?	5.47 ± 0.78	3.0 – 6.5	--
How much do JCAHO standards and initiatives effect how medications are prescribed in the hospital?	5.13 ± 0.92	2.0 – 6.5	--

[a] Items measured with a 7 point Likert-type scale ranging from "Not at all" (1) to "A great deal" (7).

Table 4.7: Implementation Support Index Results (N=57)

	Mean [a]	Range	Cronbach Alpha
Implementation Support Index	4.75 ± 0.85	2.38- 6.38	0.644
How often does your P&T Committee approve Therapeutic Interchanges for medications that are not listed on the Formulary?	5.45 ± 1.40	1.0-7.0	--
How often are approved Therapeutic Interchanges performed by pharmacy staff when a non-formulary medication is ordered?	5.75 ± 1.40	2.0 – 7.0	--
How often do pharmacy staff members call physicians to obtain a medication order to change a non-formulary medication to a formulary medication?	5.07 ± 1.43	2.0 –7.0	--
How often do physicians from the P&T Committee contact physicians to obtain a medication order to change a non-formulary medication to a formulary medication?	2.10 ± 1.47	1.0 – 6.0	--
When a change is made to the formulary, how often does your hospital publish printed communications (newsletters, memos, etc.)?	5.74 ± 1.51	2.0 – 7.0	--
When a change is made to the formulary how often does your hospital provide electronic communications (E-mails, on-line newsletters, etc) to prescribers?	5.25 ± 1.80	1.0 - 7.0	--
How often does your hospital have a member of the P&T Committee communicate formulary changes to individual or groups of prescribers?	4.40 ± 1.62	1.0 - 7.0	--
How often is information about formulary changes included as part of the order entry process?	4.22 ± 1.94	1.0 - 7.0	--

[a] Items in the index were measured with a Likert-type scale, ranging from "Never" (1) to "Almost Always" (7).

Table 4.8: Organizational Commitment Questionnaire Results (N=57)

	Mean [a]	Range	Cronbach Alpha
Organizational Commitment Questionnaire	4.81 ± 0.95	3.0– 6.67	0.905
People involved in the P&T Committee are willing to expend effort beyond what is normally expected to help it be successful.	4.93 ± 1.15	2 – 7	--
People involved in the P&T Committee talk it up to peers within the organization	4.24 ± 1.34	1 – 7	--
People involved in the P&T Committee would change their job assignment to keep working with P&T.	3.54 ± 1.48	1 – 7	--
People involved in the P&T Committee find their values and goals are compatible with those of the P&T Committee.	5.17 ± 1.29	0 – 7	--
The P&T Committee really inspires the very best job performance in those involved in it.	4.97 ± 1.27	2 – 7	--
People involved in the P&T Committee are glad that they chose to work with it instead of other responsibilities they could have chosen.	5.00 ± 1.05	2 – 7	--
People involved in the P&T Committee are proud to tell others that they are involved in it.	5.16 ± 1.21	2 – 7	--
People involved in the P&T Committee really care about its fate.	5.51 ± 1.17	2 – 7	--
People involved in the P&T Committee feel that it is the best committee to be involved with.	4.83 ± 1.30	2 – 7	--

[a] Items in the index were measured with a Likert-type scale, ranging from "Strongly Disagree" (1) to "Strongly Agree" (7).

Table 4.9: Physician Influence Index Results (N=57)

	Mean [a]	Range	Cronbach Alpha
Physician Influence Index	2.98 ± 0.49	2.0 - 4.2	0.697
How much influence do P&T physicians have on the prescribing of physicians in their specialty?	3.36 ± 0.53	1.5 - 4.0	--
How much influence do P&T physicians have on the prescribing of physicians not in their specialty?	2.87 ± 0.64	1.5 - 4.0	--
How much influence do P&T physicians have on setting the agenda for reviewing medications for addition to the formulary?	3.20 ± 0.77	1.5 - 5.0	--
How much influence do P&T physicians have on the amount of communication after P&T Committee decisions?	2.99 ± 0.80	1.0 - 4.5	--
How much influence do P&T physicians have on the gathering of information for committee decisions?	2.49 ± 0.87	1.0 - 4.5	--

[a] Items in the index were measured with a Likert-type scale, ranging from "Not much influence" (1) to "A great deal of influence" (7).

Table 4.10: Independent variable univariate effects on dependent variables (N=57)

	Formulary Mean/SD	Restriction Mean/SD	CAP Mean/SD	DVT Mean/SD
Implementation Support				
≤ Median	96.02 ± 4.37	72.20 ± 32.11	56.07 ± 34.54	67.02 ± 34.07
> Median	96.02 ± 3.52	81.48 ± 25.81	70.24 ± 29.73	78.80 ± 24.67
p value [a]	0.995	0.250	0.110	0.158
Physician Influence				
≤ Median	95.65 ± 4.48	71.15 ± 32.53	54.64 ± 33.57	70.85 ± 30.50
> Median	96.41 ± 3.34	83.36 ± 23.18	71.72 ± 29.84	75.27 ± 29.83
p value [a]	0.469	0.124	**0.052**	0.596
Team Engagement				
≤ Median	94.98 ± 4.44	66.35 ± 36.38	56.93 ± 35.22	60.00 ± 36.27
> Median	97.10 ± 3.08	87.69 ± 11.55	68.91 ± 29.64	85.56 ± 14.06
p value [a]	**0.042**	**0.008**	0.177	**0.002**
Pharmaceutical Industry Influences				
≤ Median	97.16 ± 3.00	79.92 ± 25.33	70.28 ± 27.41	84.46 ± 19.34
> Median	95.07 ± 4.41	74.54 ± 31.75	56.98 ± 35.97	64.25 ± 33.08
p value [a]	**0.045**	0.507	0.135	**0.009**
Accreditation Organization Influences				
≤ Median	95.71 ± 4.43	73.68 ± 32.36	58.48 ± 27.41	73.94 ± 29.28
> Median	96.39 ± 3.33	80.92 ± 24.13	68.90 ± 31.24	71.73 ± 31.55
p value [a]	0.520	0.372	0.246	0.794

[a] t-tests where p values in **BOLD** are statistically significant at $p < 0.05$

Table 4.11: Independent variable partial correlations (N=57) [a]

	Implementation Support	Physician Influence	Team Engagement	Pharmaceutical Industry Influences	Accreditation Organization Influences
Implementation Support					
Correlation	1	.237	.362	-.134	.213
p value [b]	NA	.091	**.007**	.335	.123
Physician Influence					
Correlation		1	.465	.257	.193
p value [b]		NA	**.001**	.066	.171
Team Engagement					
Correlation			1	-.047	.087
p value [b]			NA	.742	.538
Pharmaceutical Industry Influences					
Correlation				1	-.267
p value [b]				NA	.056
Accreditation Organization Influences					
Correlation [b]					1
p value					NA

[a] Controlled for Number of Pharmacists, Number of P&T Subcommittees, Number of non-Pharmacist P&T Committee members, Ease of obtaining Non-formulary medications, and Formulary Constrictiveness

[b] p values in **BOLD** are statistically significant at $p < 0.05$

Table 4.12: Comparison of variables- Pharmacist and Non-Pharmacists

	Mean/SD	Intra-team variation
Implementation Support [a]		0.22 ± 0.48
Non-pharmacists	4.66 ± 1.04	
Pharmacists	4.76 ± 0.91	
p value [b]	0.668	
Physician Influence [a]		0.64 ± 0.53
Non-pharmacists	3.12 ± 0.57	
Pharmacists	2.83 ± 0.73	
p value [b]	**0.013**	
Team Engagement [a]		0.37 ± 0.72
Non-pharmacists	4.79 ± 0.94	
Pharmacists	4.85 ± 1.07	
p value [b]	0.799	
Pharmaceutical Industry Influences [a]		1.02 ± 0.82
Non-pharmacists	2.30 ± 0.97	
Pharmacists	2.65 ± 1.01	
p value [b]	**0.047**	
Accreditation Organization Influences [a]		0.89 ± 0.84
Non-pharmacists	5.30 ± 0.99	
Pharmacists	5.33 ± 0.95	
p value [b]	0.882	
Formulary Medications [c]		2.86 ± 3.62
Non-pharmacists	92.50 ± 3.54	
Pharmacists	93.31 ± 15.03	
p value [b]	0.940	
Restricted Medications [c]		5.95 ± 4.64
Non-pharmacists	82.50 ± 3.54	
Pharmacists	82.37 ± 19.39	
p value [b]	0.993	
CAP Treatment Protocols [c]		6.19 ± 4.98
Non-pharmacists	78.75 ± 13.15	
Pharmacists	70.90 ± 27.75	
p value [b]	0.577	

Table 4.12: Continued

DVT Risk Assessment Protocols		5.95 ± 5.39
Non-pharmacists	81.25 ± 16.52	
Pharmacists	79.47 ± 18.97	
p value [b]	0.855	

[a] (Range 1-7)

[b] p values in **BOLD** are statistically significant at $p < 0.05$

[c] (Range 0-100)

Table 4.13: Outcome Variable Comparisons by Hospital Characteristic (N=57)

	Formulary Medications	Restricted Medications	CAP Protocol	DVT Protocol
Size				
Large (n=27)	95.69 ± 4.47	79.15 ± 27.46	62.08 ± 35.34	78.04 ± 21.41
Small (n= 30)	96.32 ± 3.45	74.72 ± 30.60	63.95 ± 30.70	68.54 ± 35.74
p value [a,c]	0.556	0.585	0.834	0.253
Ownership				
Government (n=11)	95.55 ± 3.83	79.80 ± 22.42	45.00 ± 38.78	64.11 ± 39.39
Not for profit (n=42)	95.99 ± 4.13	75.32 ± 31.53	70.16 ± 27.83	73.73 ± 27.58
For Profit (n=4)	97.68 ± 1.83	86.25 ± 13.00	35.00 ± 37.64	90.00 ± 0.00
p value [b, c]	0.656	0.735	**0.016**	0.418
Medicare Region				
I-V (n=32)	95.96 ± 3.74	80.00 ± 26.61	66.34 ± 32.00	83.05 ± 15.59
VI-X (n=25)	96.10 ± 4.16	72.95 ± 31.76	58.75 ± 33.92	60.90 ± 38.13
p value [a, c]	0.895	0.389	0.399	**0.006**

[a] Comparison using 2 sided independent samples t-test

[b] Comparisons using 1 way ANOVA. Differences between not-for-profit and for-profit and government were significant using Least Significant Difference, but not Tukey HSD, Scheffe, or Bonferroni post hoc tests.

[c] p values in **BOLD** are statistically significant at $p < 0.05$

Table 4.14: Regression model predicting percentage of medication orders filled with Formulary Medications- full model. [a] (N=57)

Dependent Variable- Percentage of medication orders filled with formulary medications	**B**	**Standard Error**	**Beta**	**Sig** [b]
Constant	93.25	5.71		0.000
Model Variables				
Accreditation Organization Influences	-0.194	0.72	-0.039	0.790
Implementation Support	-0.489	0.72	-0.106	0.498
Pharmaceutical Industry Influences	-0.788	0.83	-0.143	0.355
Physician Influence	-0.107	1.37	-0.013	0.938
Team Engagement	1.308	0.72	0.314	0.075
Control Variables				
Number of P&T Committee Pharmacists	-0.153	0.22	-0.109	0.486
Number of P&T Subcommittees	-0.530	0.26	-0.285	0.050
Number of non-Pharmacist P&T Committee Members	0.045	0.06	0.114	0.472
Ease of obtaining non-formulary medications	0.052	0.83	0.010	0.950
Formulary Constrictiveness	0.895	0.65	0.207	0.172

[a] Fit Statistics include R squared = 0.262; F statistic = 1.632; p-value = 0.128

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.15: Regression model predicting percentage of medication orders filled with Formulary Medications- reduced model. [a] (N=57)

Dependent Variable- Percentage of medication orders filled with formulary medications	**B**	**Standard Error**	**Beta**	**Sig** [b]
Constant	92.21	4.43		0.000
Model Variables				
Implementation Support	-0.519	0.70	-0.112	0.458
Pharmaceutical Industry Influences	-0.741	0.73	-0.136	0.314
Team Engagement	1.272	0.62	0.305	**0.045**
Control Variables				
Number of P&T Committee Pharmacists	-0.158	0.21	-0.112	0.464
Number of P&T Subcommittees	-0.523	0.26	-0.281	**0.047**
Number of non-Pharmacist P&T Committee Members	0.047	0.06	0.120	0.439
Ease of obtaining non-formulary medications	0.029	0.80	0.005	0.972
Formulary Constrictiveness	0.883	0.63	0.204	0.167

[a] Fit Statistics include R squared = 0.260; F statistic = 2.112; p-value = 0.053

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.16: Regression model predicting percentage of restricted medications used in accordance with the restriction criteria. [a] (N=57)

Dependent Variable- Percentage of restricted medications used in accordance with the restriction criteria	**B**	**Standard Error**	**Beta**	**Sig** [b]
Constant	-24.105	38.73		0.537
Model Variables				
Implementation Support	12.246	5.49	.388	**0.013**
Pharmaceutical Industry Influences	1.835	6.16	0.044	0.767
Team Engagement	11.482	5.177	0.390	**0.032**
Physician Influence	-17.885	9.58	-0.311	0.069
Accreditation Organization Influences	-0.827	5.04	-0.023	0.870
Control Variables				
Number of P&T Committee Pharmacists	-1.657	1.51	-0.163	0.280
Number of P&T Subcommittees	0.802	1.83	0.060	0.663
Number of non-Pharmacist P&T Committee Members	0.234	0.425	0.082	0.586
Ease of obtaining non-formulary medications	0.020	5.82	.000	0.997
Formulary Constrictiveness	9.384	4.48	0.297	**0.042**

[a] Fit Statistics include R squared = 0.407; F statistic = 2.810; p-value = 0.010

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.17: Regression model predicting percentage of restricted medications used in accordance with the restriction criteria with interaction terms. [a] (N=57)

Dependent Variable- Percentage of restricted medications used in accordance with the restriction criteria	**B**	**Standard Error**	**Beta**	**Sig [b]**
Constant	-118.74	38.73		0.373
Model Variables				
Implementation Support	55.026	21.04	1.498	**0.013**
Pharmaceutical Industry Influences	4.447	6.38	0.104	0.490
Team Engagement	28.996	23.95	0.985	0.234
Physician Influence	-55.475	38.43	-0.955	0.157
Accreditation Organization Influences	-0.194	4.99	-0.005	0.969
Team Engagement * Implementation Support	-8.979	4.46	-2.221	**0.051**
Team Engagement * Physician Influence	8.266	7.60	1.364	0.283
Control Variables				
Number of P&T Committee Pharmacists	-1.436	1.58	-0.141	0.368
Number of P&T Subcommittees	1.338	1.88	0.100	0.482
Number of non-Pharmacist P&T Committee Members	0.234	0.421	0.082	0.581
Ease of obtaining non-formulary medications	-0.253	6.24	-0.006	0.968
Formulary Constrictiveness	10.669	4.53	0.330	**0.024**

[a] Fit Statistics include R squared = 0.466; F statistic = 2.762; p-value = 0.008

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.18: Regression model predicting percentage of qualifying patients treated with Community Acquired Pneumonia Protocol [a] (N=57)

Dependent Variable- Percentage of qualifying patients treatment with Community Acquired Pneumonia protocol	**B**	**Standard Error**	**Beta**	**Sig [b]**
Constant	0.997	45.72		0.983
Model Variables				
Implementation Support	6.671	4.167	0.239	0.116
Pharmaceutical Industry Influences	-8.253	6.78	-0.184	0.228
Team Engagement	-4.374	5.85	-0.129	0.458
Physician Influence	13.186	11.56	0.200	0.260
Accreditation Organization Influences	5.10	6.15	0.124	.0411
Control Variables				
Number of P&T Committee Pharmacists	0.236	1.78	0.020	0.895
Number of P&T Subcommittees	2.853	2.16	0.186	0.192
Number of non-Pharmacist P&T Committee Members	-0.221	0.487	-0.068	0.652

[a] Fit Statistics include R squared = 0.209; F statistic = 1.515; p-value = 0.178

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.19: Regression model predicting percentage of qualifying patients treated with Community Acquired Pneumonia Protocol reduced model with interaction [a] (N=57)

Dependent Variable- Percentage of qualifying patients treatment with Community Acquired Pneumonia protocol	**B**	**Standard Error**	**Beta**	**Sig [b]**
Constant	232.35	125.84		0.072
Model Variables				
Implementation Support	5.839	4.14	0.209	0.166
Pharmaceutical Industry Influences	-9.988	6.90	-0.218	0.155
Team Engagement	-50.053	23.96	-1.483	**0.043**
Physician Influence	-64.256	42.07	-0.976	0.134
Physician Influence * Team Engagement Interaction	15.834	8.19	2.275	0.060
Control Variables				
Number of P&T Committee Pharmacists	0.053	1.83	0.004	0.977
Number of P&T Subcommittees	3.592	2.14	0.235	0.101
Number of non-Pharmacist P&T Committee Members	-0.316	0.486	-0.098	0.519

[a] Fit Statistics include R squared = 0.274; F statistic = 1.804; p-value = 0.095

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.20: Regression model predicting percentage of qualifying patients assessed with a DVT prophylaxis protocol [a] (N=57)

Dependent Variable- Percentage of qualifying patients assessed with DVT prophylaxis Protocol	**B**	**Standard Error**	**Beta**	**Sig [b]**
Constant	71.015	41.07		0.091
Model Variables				
Implementation Support	4.626	3.77	0.184	0.227
Pharmaceutical Industry Influences	-13.056	6.15	-0.318	**0.039**
Team Engagement	6.817	5.82	0.218	0.248
Physician Influence	-3.578	11.76	-0.059	0.762
Accreditation Organization Influence	-0.647	5.67	-0.017	0.910
Control Variables				
Number of P&T Committee Pharmacists	-0.417	1.66	-0.039	0.803
Number of P&T Subcommittees	1.337	1.94	0.096	0.495
Number of non-Pharmacist P&T Committee Members	-0.470	0.445	-0.160	0.297

[a] Fit Statistics include R squared = 0.244; F statistic = 1.776; p-value = 0.108

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.21: Regression Model predicting percentage of qualifying patients assessed with a DVT prophylaxis protocol with interaction [a] (N=57)

Dependent Variable- Percentage of qualifying patients assessed with DVT prophylaxis Protocol	**B**	**Standard Error**	**Beta**	**Sig [b]**
Constant	344.72	147.45		0.024
Model Variables				
Implementation Support	-16.155	23.63	-0.654	0.498
Pharmaceutical Industry Influences	-18.48	5.96	-0.451	**0.004**
Team Engagement	-51.693	28.27	-1.700	0.075
Physician Influence	-57.129	36.69	-0.956	0.127
Accreditation Organization Influence	1.373	5.41	0.037	0.801
Team Engagement * Implementation Support	4.407	4.93	1.306	0.377
Team Engagement * Physician Influence	11.756	7.28	1.905	0.114
Control Variables				
Number of P&T Committee Pharmacists	-1.461	1.62	-0.139	0.372
Number of P&T Subcommittees	1.58	1.82	0.117	0.391
Number of non-Pharmacist P&T Committee Members	-0.396	0.42	-0.138	0.355

[a] Fit Statistics include R squared = 0.383; F statistic = 2.438; p-value = 0.02

[b] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.22: Path Analysis: Medication orders filled with formulary medications [a] (N=57)

	Direct Effect B	Direct Effect Beta	Indirect Effect B	Indirect Effect Beta	Total B	Standard Error	Total Beta	Sig
On Medication orders filled with formulary medications								
Team Engagement	1.421	0.340	0	0	1.421	0.516	0.340	**0.006**
Implementation Support	-0.472	-0.102	0	0	-0.472	0.579	-0.102	0.415
Pharmaceutical Industry Influence	-0.890	-0.163	0.073	0.013	-0.817	0.681	-0.149	0.191
On Implementation Support								
Pharmaceutical Industry Influence	-0.154	-0.131	0	0	-0.154	0.156	-0.154	0.323

[a] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.23: Path Analysis: Restricted medications used in accordance with the restriction criteria [a] (N=57)

	Direct Effect B	Direct Effect Beta	Indirect Effect B	Indirect Effect Beta	Total B	Standard Error	Total Beta	Sig
On Outcome								
Team Engagement	8.329	0.275	0	0	8.329	3.714	0.275	**0.025**
Implementation Support	11.801	0.347	0	0	11.801	4.247	0.347	**0.005**
Pharmaceutical Industry Influence	-4.777	-0.121	-1.709	-0.043	-6.486	4.818	-0.164	0.191
Accreditation Organization Influence	-3.359	-0.092	1.579	0.043	-1.780	4.430	-0.049	0.448
Physician Influence	0	0	15.309	0.261	15.309	--	0.261	--
On Implementation Support								
Physician Influence	0.538	0.313	0	0	0.538	0.214	0.313	**0.012**
Pharmaceutical Industry Influence	-0.145	-0.125	0	0	-0.145	0.145	-0.125	0.317
Accreditation Organization Influence	0.134	0.125	0	0	0.134	0.133	0.125	0.315
On Team Engagement								
Physician Influence	1.075	0.556	0	0	1.075	0.215	0.556	**<0.01**

[a] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.24: Path Analysis: Qualifying Patients Treated with Community Acquired Pneumonia protocol [a] (N=57)

	Direct Effect B	Direct Effect Beta	Indirect Effect B	Indirect Effect Beta	Total B	Standard Error	Total Beta	Sig
On Outcome								
Team Engagement	-0.478	-0.014	0	0	-0.478	4.478	-0.014	0.164
Implementation Support	8.352	0.308	0	0	8.352	3.561	0.308	**0.019**
Pharmaceutical Industry Influence	-8.174	-0.179	-3.074	-0.067	-11.248	5.871	-0.247	0.164
Physician Influence	0	0	7.215	0.107	7.215	--	0.107	--
On Implementation Support								
Physician Influence	0.925	0.371	0	0	0.925	0.301	0.371	**0.002**
Pharmaceutical Industry Influence	-0.368	-0.218	0	0	-0.368	0.146	-0.203	0.070
On Team Engagement								
Physician Influence	1.075	0.556	0	0	1.075	0.215	0.556	**<0.01**

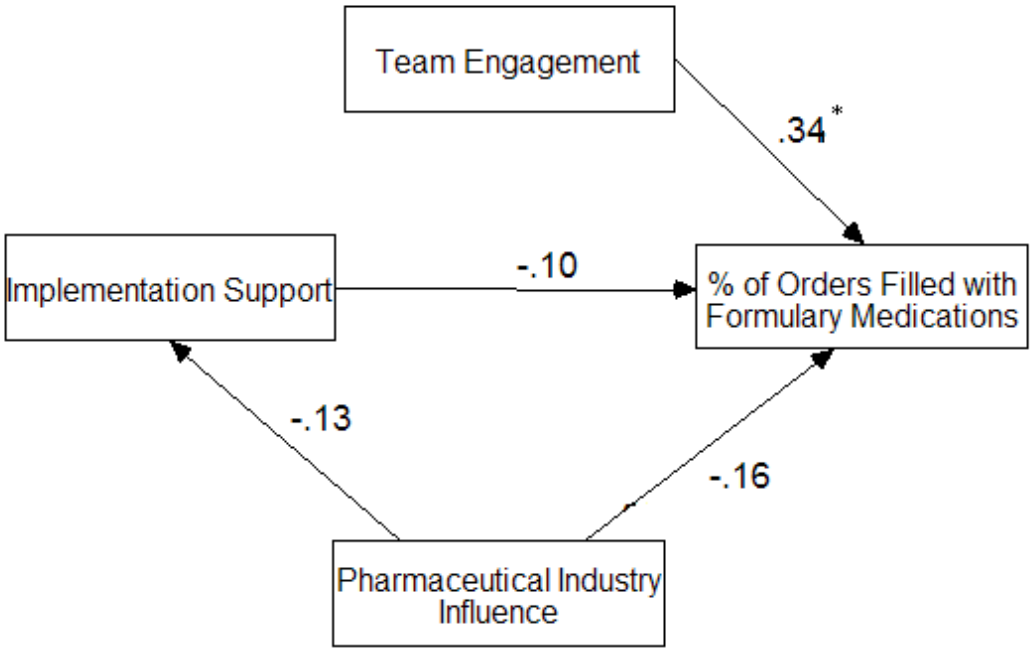
[a] Numbers in bold are significant predictors at 0.05 level of significance

Table 4.25: Path Analysis: Percentage of qualifying patients assessed with a DVT prophylaxis protocol [a] (N=57)

	Direct Effect B	Direct Effect Beta	Indirect Effect B	Indirect Effect Beta	Total B	Standard Error	Total Beta	Sig
On Outcome								
Team Engagement	5.204	0.167	0	0	5.204	3.962	0.167	0.189
Implementation Support	4.071	0.164	0	0	4.071	3.229	0.164	0.207
Pharmaceutical Industry Influence	-13.550	-0.332	-1.166	-0.029	-14.715	5.168	-0.360	**0.009**
Accreditation Organization Influence	-0.911	-0.024	0.868	0.023	-0.043	4.725	-0.001	0.847
Physician Influence	0	0	8.923	0.148	8.213	--	0.148	--
On Implementation Support								
Physician Influence	0.817	0.335	0	0	0.817	0.098	0.335	**0.006**
Pharmaceutical Industry Influence	-0.286	-0.174	0	0	-0.286	0.201	-0.174	0.155
Accreditation Organization Influence	0.213	0.141	0	0	0.213	0.185	0.141	0.249
On Team Engagement								
Physician Influence	1.075	0.556	0	0	1.075	0.215	0.556	**<0.01**

[a] Numbers in bold are significant predictors at 0.05 level of significance

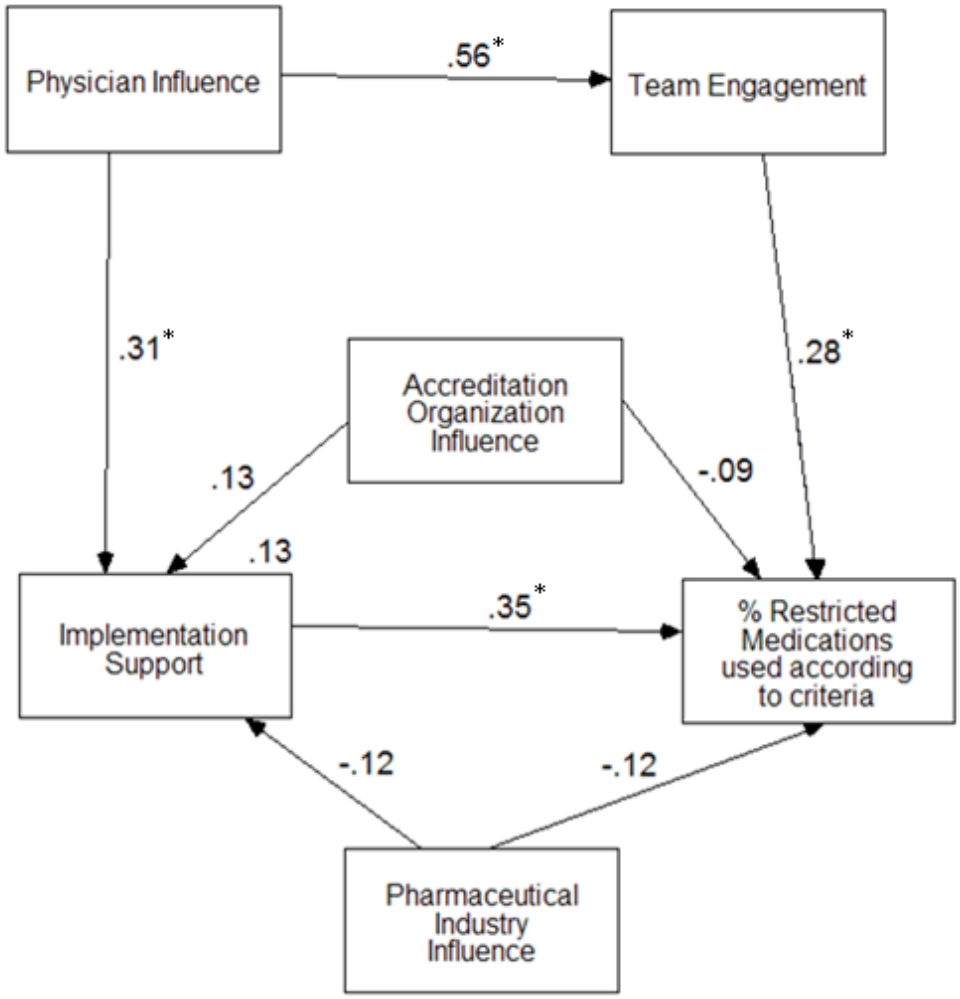
Figure 4.1: Path Analysis- Percentage of Medication Orders Filled with Formulary Medications [a,b]



[a] Numbers in the figure are Beta coefficients

[b] Numbers with a * are significant at $p < 0.05$

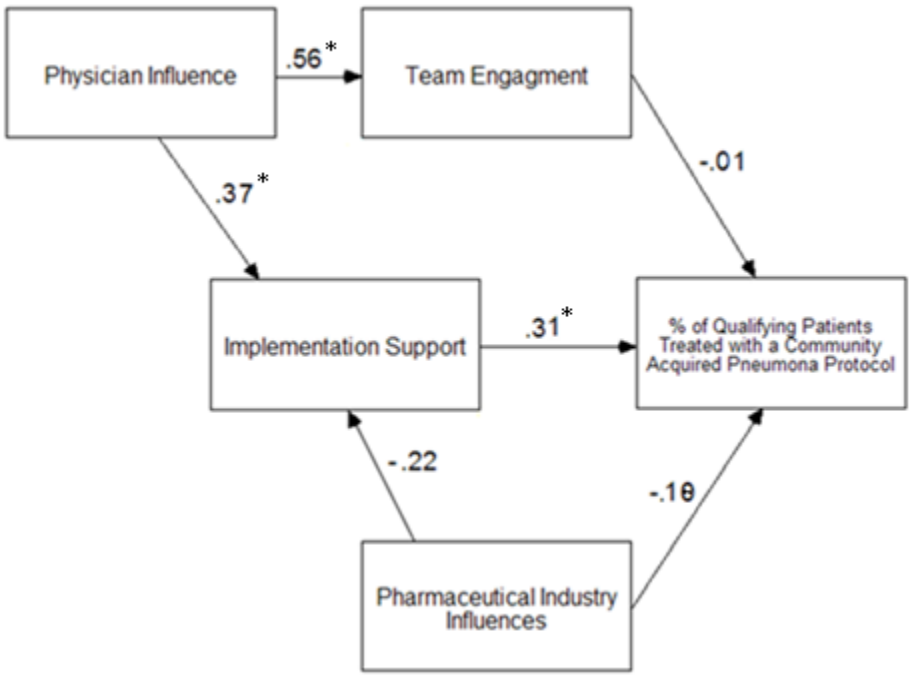
Figure 4.2: Path Analysis- Percentage of restricted medications used in accordance with restriction criteria [a,b]



[a] Numbers in the figure are Beta coefficients

[b] Numbers with a * are significant at $p < 0.05$

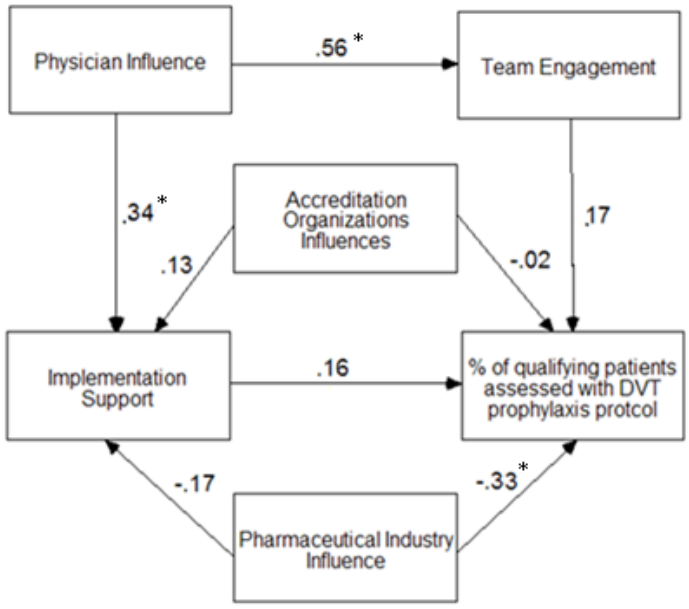
Figure 4.3: Path Analysis- Percentage of qualifying patients treated with Community Acquired Pneumonia Protocol [a,b]



[a] Numbers in the figure are Beta coefficients

[b] Numbers with a * are significant at $p < 0.05$

Figure 4.4: Path Analysis- Percentage of qualifying patients assessed with a DVT prophylaxis protocol [a, b]



[a] Numbers in the figure are Beta coefficients

[b] Numbers with a * are significant at $p < 0.05$

CHAPTER FIVE

DISCUSSION

This chapter will discuss the implications of the study results in hospital management and in the team literature. The first section will discuss the key findings and implications of these findings for pharmacy practice, the second the limitations of the study, and the third, future research into this topic suggested by the results of this study. The key findings build upon and complement each other, so the sequence of findings below is not in order of significance.

Key findings from the results

This section will discuss three main findings of the study. The first finding is that P&T Committees have developed processes that are successful in leading to prescribers to adopting decisions about formulary medications. The second finding is that P&T Committees have not been as successful in developing processes that lead to the adoption of decisions on medication restrictions and protocols. The third finding is that the adoption of P&T Committee decisions on medication restrictions, CAP treatment protocols, and DVT risk assessment protocols are unique decisions and different than those for formulary medications. The factors that influence each of these decisions are different from those of formulary medications and are unique to each type of decision.

Little variation in the adoption of P&T Committee decisions about formulary medications

The level of acceptance of formulary decisions of the P&T Committee by prescribers was high with little variance. In addition to finding very little overall variation on this measure, there were no differences based on hospital characteristics including hospital size, ownership type, or geographic region. This high level of performance of P&T Committees was expected as it had been seen in previous assessments of hospital

pharmacy practice. The lack of difference due to hospital size was also expected, as previous research of larger hospitals, defined as those with greater than 100 beds, showed they had more resources to devote to formulary activities (Pederson 2003, 2005, 2008). The findings of lack of difference based on ownership type or geographic region are new findings, not previously included in descriptions of pharmacy practice. The finding about ownership type is somewhat unexpected as it would be expected that for-profit hospitals might place a greater emphasis on formulary activities due to their focus on profits. One possible explanation is that the financial pressures for reducing costs in government and not-for-profit hospitals may result in as much emphasis on formulary activities as in for-profit hospitals. The lack of findings regarding geographic regions was expected as pharmacy practice standards and financial pressures are similar across the nation.

Hospitals and their P&T Committees have been successful in developing processes that support a high level of adoption of decisions about formulary medications. In order to determine the factors associated with the variation it was necessary to use a regression model with a reduced number of factors due to the small sample size and low variation between hospitals. In the reduced model, one model variable and one control variable were statistically significant.

Team Engagement was statistically significant in this model, in both the regression and path analyses. Increases in Team Engagement were associated with increases in the percentage of medication orders filled with formulary medications. This finding was expected and consistent with findings in the qualitative study and in the team literature. The concept of Team Engagement was described in the qualitative study and has aspects of several cognitive concepts in the literature including team orientation, team mental models, team climate, shared norms and cohesion. Higher levels of all of these traits are present in teams that are committed to the teams' successful functioning. When the team members have a shared understanding of the team's tasks, effective processes, member characteristics and skills (Cannon-Bowers et al. 1993), efficiency is improved in

interdependent tasks such as reviewing medications from a multi-disciplinary perspective. Yet, Team Engagement is distinct from these concepts, in theory, because in reviewing the net effect of the individual concepts, a case can be made that the result is a team whose members are committed to the processes because they share goals, values, and information with the other members of the team. It was critical that this concept, not the others individually, was included in the model of P&T performance because the net effect of the individual concepts was more relevant to the function of the team.

The findings in this study are similar to previous findings about team shared mental models (Klimoski & Mohammed 1994, Cannon-Bowers et al. 1993) and team climate (Anderson & West 1998, Gonzalez-Roma et al. 2002, Hoffman & Stetzer 1996, Denison, et al. 1996) where teams with shared mental models and shared team climate are likely to be more effective in their processes. Presence of shared team norms (Denison, et al. 1996) and team coherence (Kozlowski et al. 1996a) are also more likely to be effective in their processes. Team Engagement also includes the affective concept of cohesion, usually divided into team cohesion and interpersonal cohesion, which previously has been seen to have a positive effect on team performance (Zaccaro & Lowe 1988, Zaccaro & McCoy 1988, Kidwell et al. 1997, Neumann & Wright 1999) which was also repeated in this study.

Pharmaceutical Industry Influences did not have a statistically significant effect on the dependent variable in the regression and path analyses. This was unexpected as in previous studies the effects of pharmaceutical industry marketing efforts have been seen to decrease formulary compliance (Wazana 2000). The lack of effect for Pharmaceutical Industry Influences may be a result the efforts of the P&T Committee to decrease the influence of the Pharmaceutical Industry through decreasing access to prescribers and to committee members. These efforts have previously been described in the qualitative study and by Nair (1999). Implementation Support also did not have a statistically significant effect on the dependent variable. This was unexpected as a previous study of

P&T Committees found that increases in Implementation Support type activities resulted in increased committee performance through significant efforts to decrease the impact of marketing (Nair 1999). A likely explanation of this finding is there is actually little variation in Implementation Support compared to the other measures. This would seem to indicate that hospitals are doing similar levels of activity to implement P&T Committee decisions about formulary medications. The number of P&T Subcommittees was a statistically significant control variable, with increases in the number of subcommittees decreasing the percentage of medication orders filled with formulary medications. This finding was unexpected as there were suggestions in the qualitative study that including specialized subcommittees would have a positive effect on the adoption of decisions. This could be due to a decrease in the commitment to the implementation of a decision by the members of the P&T Committee who are not members of the subcommittee making the decision.

For the hospitals that were at the lower end of the range of performance on the adoption of formulary decisions, these findings may provide suggestions for direction on efforts for performance improvement. Team Engagement was measured as commitment to the processes of the P&T Committee, as suggested by previous research about cognitive and affective processes present in team behavior. Training that focuses on goal setting and achievement, develops communication, supportiveness and trust, and assists with role clarification has been previously identified as methods to increase performance in similar settings (Salas et al. 1999). These findings also suggest that efforts be made to recruit members who express an interest in the committee and its goals when replacing or adding members to the committee.

Variation in the adoption of P&T Committee decisions about medication restrictions and treatment protocols

The level of adoption of P&T Committee decisions for medication restrictions, Community Acquired Pneumonia treatment and Deep Vein Thrombosis assessment protocols were lower than decisions for formulary medications. There was significant variation between hospitals for these three measures. There were no differences due to hospital size for these three variables. No differences due to hospital characteristics were found for the adoption of medication restriction decisions.

There were two significant differences on adoption of protocol decisions based on hospital characteristics, and these are new findings. Almost twice as many patients were treated for Community Acquired Pneumonia using a protocol at not-for-profit hospitals than at either governmental or for-profit hospitals. Hospitals in Medicare Areas I to V were more likely to assess patients for Deep Vein Thrombosis risk by using a protocol than those in Medicare Areas VI to X. Medicare Areas I to V roughly corresponds to the states east the Mississippi River.

The presence of differences based on ownership type in not completely unexpected due to possible resource and priority differences between the different types of ownership groups. The team literature suggests that factors impacting team effectiveness are contingent on the team's context (Devine 1999). There may be pressure to use treatment protocols at not-for-profit hospitals that is not present at the other two types of hospitals, or physicians with a different perspective on treating conditions according to evidence-based medicine are attracted to government and for-profit hospitals. There also may be more resources available at not-for-profit hospitals for development and implementation of this protocol than at the other two types. Governmental hospitals may have limited resources due to the payment status of patients who are treated at that type of hospital, while resources may be limited due to profit motivation at for-profit hospitals. However, these differences were not seen in the other

three measures so it would be difficult to attribute the differences to any specific characteristic that would selectively effect the adoption of CAP treatment protocols.

The difference between the two Medicaid areas was not expected. Due to the activities of professional associations and accreditation organizations it would be expected that practice differences between areas within the country should be minimal. There may be differences in physician attitudes toward protocols in these different regions that would account for these differences. As this difference was not present in the CAP protocol, the difference in physician attitudes may be limited to risk assessment protocols, though this would be difficult to explain. Adding to that difficulty is the lack of differences in the other two measures between the two geographic regions.

There are practice implications for hospitals with lower rates of medication restrictions and acceptance of protocols but these findings suggest that hospital characteristics that were measured in the study such as ownership type are not a key factor. Rather, the larger implications of the differences between the three outcome measures are included in the next findings.

Adoption of P&T Committee decisions are unique and factors that influence each of these decisions vary

The adoption of P&T Committee decisions on medication restrictions, CAP treatment protocols, and DVT risk assessment protocols are unique decisions and appear to be different that those for formulary medications. The factors that influence each of these decisions are different from those of formulary medications and are unique to the type of decision.

The finding that all four of these decisions were unique was unexpected. Due to the expected small variation in the percentage of medication orders dispensed with Formulary medications, an index that included four exemplary decisions of P&T Committees was proposed. One of the dependent variables, percentage of orders filled

with formulary medications, has been previously studied (Pederson et al. 2008). The other three dependent variables had not been specifically measured in previous studies. The assumption was that the processes leading to adoption of all four decisions would be similar.

The first suggestion that the prescribing decisions of the dependent variables were different was the lack of internal consistency for the measure when the four dependent variables were evaluated together as an index. Results of a factor analysis suggested that there were two groups of decisions being measured. Two of the decisions being tested, percentage of medication orders filled with formulary medications and percentage of restricted medications used in accordance with the restriction criteria, are for specific medications. The other two decisions, percentage of eligible patients treated with a CAP protocol and percentage of qualifying patients assessed with a DVT prophylaxis protocol, are for the use of an entire plan of treatment for a specific disease or patient situation. When the variables were then grouped according to the results of factor analysis, there was still a lack of internal consistency. This was unexpected as well.

There was almost no commonality between the decision to prescribe a formulary medication and the decision to use a medication in accordance with approved criteria for use. Two factors that may be affecting these measures are external to the decision processes. The first is that many hospitals do not maintain non-formulary medications in their inventory and they also have approved therapeutic interchange policies, facilitating the dispensing of formulary medications. The second is that when a restricted medication is prescribed outside of approved criteria and there is no therapeutic interchange, the medication is often dispensed. Restricted medications are maintained in the hospital pharmacy's inventory for use in patients whose situation meets the restriction criteria so the two factors that facilitate the dispensing of formulary medications are not present. Another possibility is that the two decisions are different and findings from the regression and path analyses support this statement (see next section for this discussion).

There was some commonality between the decisions to use the two protocols but not enough to justify use as an index. The differences may be due to the patient situation where the protocols would be used. The CAP protocol is used when a diagnosis has been made and a treatment is needed. The DVT protocol is used to screen patients for the risk of a potential condition, not for the treatment of an active condition. This suggests that factors that affect the decisions to use the two protocols are different. Again, the regression and path analysis also support this finding, as the concepts associated with each decision were different (see next section).

The primary implication related to the dependent variables of this study is that when these four decisions are considered by the P&T Committee they need to be viewed as separate and unique outcomes and measured individually. While unexpected, this finding is consistent with previous team research where the use of a single, overarching model of team effectiveness in organizational studies is not expected. Rather, models tailored to particular work processes are most likely necessary to fully understand teams (Devine 2002, Sundstrom et al. 2000). This is a significant finding with the potential for impact on P&T Committee processes and for hospital pharmacy practice. Earlier findings by Pederson that the P&T Committee and supporting processes are effective in getting prescribers to use formulary medications may lead to an assumption amongst practitioners that the same factors that lead to success with adoption of formulary medications would ensure success in other initiatives. These results suggest that this is only partially correct, and that hospitals need to monitor each outcome they are intending to affect through the P&T Committee, as least on a periodic basis. The factors that lead to success in P&T Committee managed initiatives, besides formulary medications, must be determined and then incorporated into practice.

Restricted medications used in accordance with the
restriction criteria

At the outset of this study, five variables were expected to influence the dependent variables, namely Implementation Support, Team Engagement, Physician Influence, Pharmaceutical Industry Influence and Accreditation Organization Influence. The next three subsections discuss the findings from the regression and path analyses for each dependent variable and explain the variables that were associated with each.

The level of acceptance of medication restriction decisions of the P&T Committee was moderately high with a good deal of variation. Over half of the hospitals surveyed had an adoption rate of ninety percent or higher. One control variable, one model variable, and one interaction between variables in the model were statistically significant. The model reached statistical significance with no model reductions and explained 47 percent of the variation. Implementation Support and the interaction between Implementation Support and Team Engagement were significant in the regression. In the path analysis, Team Engagement and Implementation Support had significant effects on the dependent variable. Physician Influence has significant effects on Implementation Support and Team Engagement. The results of the path analysis were similar to the regression results regarding the concepts that had significant effects on the dependent variable, but the direction of those effects were opposite of those in the regression analysis. The effect of Physician Influence on Team Engagement was sufficient to enable Team Engagement to have a significant effect on the dependent variable.

In the regression analysis, increases in the interaction between Team Engagement and Implementation Support were associated with a decrease in the adoption of medication restrictions. There is nothing in the literature reviewed for this study that would suggest that a team that is committed to the processes of the committee, including implementation activities, would decrease performance. This finding suggests that if the implementation activities being performed for medication restrictions are identical to

those for formulary medications that those activities do not encourage compliance in the case of medication restrictions.

The results of the path analysis are more consistent with literature findings. The significant effects of Team Engagement on the adoption of medication restrictions is most likely due to the positive effects on performance that have been previously seen in the literature due to the cognitive and affective traits that committed teams possess. The commitment to the processes of the team are due to shared mental models (Klimoski & Mohammed 1994, Cannon-Bowers et al. 1993), shared team climate (Anderson & West 1998, Gonzalez-Roma et al. 2002, Hoffman & Stetzer 1996, Denison, et al. 1996), shared team norms (Denison, et al. 1996), and team coherence (Kozlowski et al. 1996a) and cohesion (Zaccaro & Lowe 1988, Zaccaro & McCoy 1988, Kidwell et al. 1997, Neumann & Wright 1999). The significant effects of Implementation Support are also what would be expected, as the activities that were measured in this concept are intended to increase the adoption of the committee's decisions. Hospital pharmacies perform therapeutic interchanges, contact physicians when they order restricted medications for patients who do not fit the restriction criteria and provide education efforts to support medication restriction decisions (ASHP 2008, ACCP 1993). The significant effects of Physician Influence on the independent variables Team Engagement and Implementation Support are consistent with suggestions in the qualitative study. When influential physician leaders of the committee act as empowering leaders, they should have positive impact on performance which has been seen in the literature (Stewart & Manz 1995).

Qualifying Patients Treated with Community Acquired Pneumonia Protocol

The level of acceptance of a protocol for the treatment of Community Acquired Pneumonia was not very high, with a great deal of variance. About one fourth of the hospitals surveyed had an adoption rate of ninety percent or higher. No control variables,

one model variable, and one interaction between variables in the model were statistically significant. Even with a reduced model, the model for the adoption of CAP treatment protocols the overall F-test was not significant ($p = 0.106$). While a model with this p value in the overall F-test is not usually considered interpretable, some suggestions have been made in the management literature to use a p value of 0.10 as being significant (Schmidt 1996). Moving to using a p value of 0.10 increases the possibility of making a type I error, which would mean accepting a 10 percent chance that the effects of the model variables on the outcome variable are actually due to random chance. This would also increase the chance of making a type II error, increasing the chance that effects of the model variables would be interpreted as due to random chance, when in fact they are not. The model explained 25 percent of the variation of the adoption of CAP treatment protocols. Team Engagement and the interaction between Physician Influence and Team Engagement were significant in the regression. In the path analysis no independent variable had significant effects on the dependent variable. Physician Influence has significant effects on Implementation Support and Team Engagement.

As Team Engagement is part of an interaction, it should not be interpreted individually. The interaction of Physician Influence and Team Engagement had a significant positive effect on the adoption of CAP treatment protocols, which is consistent with previous literature findings regarding the effects of empowering leadership (Stewart & Manz 1995) and committed committee members on team performance (Klimoski & Mohammed 1994, Cannon-Bowers et al. 1993, Anderson & West 1998, Gonzalez-Roma et al. 2002, Hoffman & Stetzer 1996, Denison, et al. 1996, Denison, et al. 1996, Kozlowski et al. 1996a, Zaccaro & Lowe 1988, Zaccaro & McCoy 1988, Kidwell et al. 1997, Neumann & Wright 1999). The lack of significant effects of any of the independent variables on the adoption of CAP protocols is in part a confirmation of the effect of the small sample size on reaching overall model significance. The significant effects of Physician Influence on the independent variables

Team Engagement and Implementation Support in the path analysis were consistent with suggestions in the qualitative study as discussed above regarding the adoption of medication restrictions.

Qualifying patients assessed with a DVT prophylaxis protocol.

The level of acceptance of a protocol for the assessment of risk of Deep Vein Thrombosis was moderately high, with a great deal of variance. About one half of the hospitals surveyed had an adoption rate of at least eighty five percent. No control variables, one model variable, and one interaction between variables in the model were statistically significant. The model for the adoption of DVT risk assessment protocols reached statistical significance with no model reductions and explained 40 percent of the variation of the adoption of DVT risk assessment protocols. Pharmaceutical Industry Influence and the interaction between Implementation Support and Team Engagement were significant in the regression. In the path analysis Pharmaceutical Industry Influence had significant effects on the dependent variable. Physician Influence has significant effects on Implementation Support and Team Engagement. The effect of Pharmaceutical Industry Influence on the adoption of DVT risk assessment protocols in the regression is an interesting finding. One possible explanation for this effect could be that the manufacturers may think that assessing patients for the risk of DVT may decrease the number of patients treated with their medication, and work to convince physicians to not use the protocol. Pharmaceutical industry marketing efforts have been seen to decrease formulary compliance (Wazana 2000) and this finding suggests that this may be possible in regards to treatment and assessment protocols.

While each decision of the P&T Committee or dependent variables in this study appear to be unique, it is important to consider the importance of the model variables across the unique decisions.

Implications for the P&T Committee Model

The variables in model developed for describing P&T Performance performed moderately well in this study.

Team Engagement performed well as a measure of the level of commitment to the processes and outcomes of the P&T Committee. It was a significant predictor of performance in the models for the adoption of formulary medications, CAP treatment protocols as an individual measure and as part of an interaction for the adoption of medication restrictions or DVT risk assessment protocols. These findings confirm what was found in the qualitative study and in previous team literature.

Implementation Support had mixed performance as a measure of the efforts of the P&T Committee to implement its decisions. As used in the study, it was a significant predictor of adoption of decisions on restricted medications in both the regression and path analysis but not significant for the adoption of either protocol or for formulary medications. The findings of the study suggest that efforts of the committee to implement decisions should be customized to the individual decision, and this measure also should be modified for decision context.

Physician Influence performed well as a measure of the influence of physicians involved in P&T Committee Processes. Physician Influence was not statistically significant in any regression model, but this was most likely due to its effects being indirect on the dependent variables in the current model. The effects of Physician Influence on Implementation Support and Team Engagement were statistically significant in the path analyses. It was expected to be a significant predictor, as previously the expertise trait of knowledge (Denison, et al. 1996) consistently showed positive effects on team performance. The lack of significant direct effects may be due to the prescribers' perceptions of the level of influence of the physician members of the P&T Committee and the committee members' perceptions being dissimilar, decreasing the ability of the

measure to differentiate between high and low levels of influence. Future path models should include a measure of the direct effect of this variable on the dependent variables.

Pharmaceutical Industry Influences performed well once it was separated from the effects of accreditation organizations. It was a significant predictor only in the model for adoption of DVT risk assessment protocols. The effects of pharmaceutical industry marketing efforts are known to decrease formulary compliance (Wazana 2000), so it would have been expected to be a significant predictor in more instances. One improvement to the variable would be to include items measuring the extent of the efforts of the committee to counteract the effects of pharmaceutical industry marketing, as Nair (1999) found these effects to be significant. The items in the measure used in the study measured the net effect of the pharmaceutical industries efforts to influence prescribers. For example, one item asked "How much do pharmaceutical industry representatives affect P&T Committee member decisions?" An example of the type of item to be added could be "How much do hospital regulations restrict the contact of physicians with pharmaceutical sales representatives?"

Accreditation Organization Influences may not be a significant factor in the effectiveness of the P&T Committee's efforts in promoting prescribers adoption of its decisions. It was not statistically significant in the two models where it was retained, namely the adoption of medication restrictions and the adoption of DVT risk assessment protocols. The lack of a significant effect of Accreditation Organization Influences on the DVT protocol was unexpected as the assessment of DVT risk is emphasized by the Joint Commission on the Accreditation of Health Care Organizations' Surgical Care Improvement Project (JCAHO 2008). This may suggest that the variable needs to be modified for the context of the decision being implemented by the committee. The qualitative study also suggested that perhaps this variable was a more important predictor of the efficiency of the committee in the adoption of its decisions so it may be more useful in efforts to measure efficiency. P&T Committees in hospitals where Accreditation

Organization Influences are greater may spend a greater amount of their time on meeting the requirements of these organizations. Thus, they have less time to spend on other activities. This may result in a less effective committee for other activities. An example of this would be the P&T Committee taking longer to make and implement a medication restriction decision.

The interactions between Team Engagement and Implementation Support or between Physician Influence and Team Engagement were significant only in the model predicting adoption of medication restrictions. However, the inclusion of these interactions was an important factor in achieving statistical significance for the models for the two protocols and for increasing the significance and predictive ability of the model for adoption of medication restriction. These findings and those of the qualitative study suggest that future models should include these interactions in their analyses.

The only significant control variable was constrictiveness of the formulary in the model for adoption of restricted medications, with increases in the constrictiveness of the formulary increasing the percentage of restricted medications used in accordance with the restriction criteria. This may be a by-product of a strong program of support of the decision during the implementation of the decision adding to the perception of the formulary being constrictive. The lack of significance of the control variables does not suggest that they should be removed from the models at this point, as they may be significant in other types of hospitals. They may be important to control for in all such analyses.

Overall, the model performed well for an early stage of development of a model for the prediction of the adoption of P&T Committee decisions. The exclusion of three of the original variables, Information Flow, Decision Process, and Resource Control, which were suggested in the qualitative study, most likely decreased the ability of the model to predict adoption of P&T Committee Decisions. These variables were deleted to shorten the surveys and possibly improve the survey response. The exclusion of a direct effect

from Physician Influence to the dependent variables probably decreased the predictive ability of the model as well, and should be added in future studies.

The models were modified from the one originally proposed. The first substantive change was the removal of three variables that were theorized to affect the outcome variables in an indirect manner. The removal of these variables was done understanding that their removal could decrease the predictive capability of the models in lieu of any increase in survey response. Information from qualitative study suggested that these would mostly likely exert the weakest effects on the outcome variables. At least one study with these variables included is needed before consideration of permanent removal of any or all of them from the models. The second substantive change was the move from one general model to four outcome specific models. The change from one model to four models was needed due to the lack of a reliable scale for the outcome variable, and these findings were strong and indicative of the changes.. The third substantive change was the removal of additional variables from outcome specific models. The removal of variables in two of the models was performed based on information from analysis that was supported by information from the qualitative study. However, further study will be needed to confirm if these variables should be retained in or removed from these models. The small sample size of the current study did not provide enough power to give conclusive evidence for a removal from the models. The models approached statistical significance even with the small sample size of 57 hospitals, and would most likely reach significance with a marginally larger sample size.

The question of whether one model is adequate for predicting different decisions must be considered. While the factors that affected the adoptions of P&T Committee decisions varied by the specific decision, the model is at the very least an adequate baseline for determination of the factors affecting decision adoption. Until the entire model that was described in the qualitative study can be tested, including the three indirect variables and an outcome measure of clinical and financial outcomes, it would be

premature to make substantive changes to the model. The results of the study do warrant that the model be studied separately for each outcome.

Findings on Measures

In addition to the findings about the dependent variables and the model, three new measures including the Intervention Intensity Index, the Pharmaceutical Industry Influences Index, and the Accreditation Organization Influences were used in this study. Implementation Support was measured using new the Intervention Intensity Index. The complete measure performed well when used for models that were formulary related, namely predicting adoption of formulary medications and medication restrictions. Five of the items in the index measured efforts that would be used to support the implementation of the P&T Committees' decisions on formulary medications and medication restrictions. Use of all five items was not appropriate for the models pertaining to protocols, so the index was calculated using three items measuring educational efforts when used for the two protocols. The reduced measure did not perform as well as the entire index, and further development of a complete measure for measuring Implementation Support for protocols is needed. Items that measure the availability of protocols in pharmacy information systems and if the hospital approves and performs interventions when patients are indentified as candidates for protocol use might improve the performance of this measure. Further qualitative research may also be necessary.

In team research, it is important to obtain reports from different teams members and determine their similarity. If the responses are different, then specific strategies are used in analyses to account for the variation. The mean differences between pharmacist and non-pharmacist responses were statistically significant for two measures, Physician Influence and Pharmaceutical Industry Influences. The actual differences in these measures were small. The intra-hospital variations on all of the independent and dependent variables were also small. Given these small differences, the averages for the

teams were used in all analyses. However, these potential differences in responses from the different professions require further investigation before moving to pharmacist only surveys.

The influence of groups outside of the P&T Committee was intended to be measured with the Outside Influences Index but the original measure had unacceptable internal consistency. This most likely resulted from the opposing goals of the two groups, pharmaceutical corporations mostly oppose formularies and treatment protocols (Wazana 2000), while accreditation groups work to implement best practices determined through comparative research (JCAHO 2008). Neither index had items that measured the amount of effort that was needed by the committee or the hospital to either counteract or complement the effects of either of these influences. The items in both indexes also need to be placed in the context of the dependent variable. For example, the item in the current index "How much do pharmaceutical industry representatives affect P&T Committee member decisions?" would be modified to "How much do pharmaceutical industry representatives affect P&T Committee member decisions about medication restrictions?"

Implications for professional practice

Pharmacists are key participants in the P&T Committee process, often coordinating almost all activities of the committee and almost all of the implementation activities to move the decisions of the committee into clinical practice. The results of the study repeat earlier findings that health system pharmacists are performing at a high level in their efforts to have prescribers adopt the Formulary decisions of the P&T Committee. There is so little variation that it was difficult with the available sample to differentiate the factors that influence the adoption of formulary medications. Performance is at such a high level that improvements would be difficult to accomplish. There might be increases in efficiency that could be realized but the study was not designed to assess efficiency.

In the periodic reviews by Pederson (Pederson 2003, 2005, 2008), there is no mention of monitoring of rates of use of restricted medications according to the restriction criteria and no mention of monitoring the use of individual treatment protocols, so a comparison to previously reported performance on these measures is not possible. This is somewhat surprising considering that clinical practice is moving away from formulary lists to evidence-based treatment protocols that include medications.

Perhaps the most important implication for professional practice is that the P&T Committee needs to be flexible in its processes depending on the decision being made and implemented. More research will be needed to identify effective interventions for increases in both efficacy and efficiency. Addressing the same factors that significantly affect the adoption of formulary decisions will mostly likely not significantly affect the adoption of other decisions, and in fact, may cause a reverse effect in other decisions. For example, increases in Team Engagement increased adoption of formulary medications, but increases in Team Engagement decreased the adoption of CAP treatment protocols.

The results of the study begin to suggest possible performance improvement efforts. As mentioned above, increases in Team Engagement were seen to increase adoption of formulary medications. P&T Committees who wished to improve their performance on the adoption of formulary medication decisions could implement efforts to improve communication between P&T Committee members. Implementation Support activities were seen to improve the adoption of medication restrictions. P&T Committees in hospitals where an increase in the percentage of restricted medications used according to protocol is wanted could increase the number of educational programs that discuss the rationale behind the restriction. The influences of the Pharmaceutical Industry were seen to decrease the adoption of DVT risk assessment protocols. A hospital that wanted to increase the adoption of this protocol could work to decrease the impact of

pharmaceutical company marketing efforts by decreasing the access of representatives to prescribers.

Limitations of the study

As in any research, there were limitations to the study. One limitation of this study was the relatively small sample size. This caused difficulty in the analysis, especially in reaching statistically significant overall F-tests. In future research a method to increase response from non-pharmacist members of the committee is needed. The response rate for pharmacists was significantly higher than for either of the other professionals. Another potential respondent pool that could be used in future research is nurses who participate on the P&T committee, as nurses participated in almost all of the committees surveyed.

Another limitation was that the concepts of Information Flow, Decision Process, and Resource Control were removed to decrease the substantial length of the surveys. This reduced model removed assessment of significant concepts that were identified in the qualitative study. These concepts may have had substantial effects on the dependent variable and may have added to the predictive ability of the models. The removal of these variables also removed information about the factors that affect concepts that may have a direct effect on the dependent variable. This missing information limits the ability of the models to be used in efforts to increase P&T Committee performance. Knowledge of the effects of the allocation of resources, the amount and quality of information, and the degree of consensus in committee decisions on the dependent variable and on other independent variables is likely to increase the utility of the model in performance improvement efforts.

The generalizability of the results to other hospitals is another study limitation. Hospitals with an ASHP residency are more than likely unique in their practice perspective. Having the resources and commitment to education to have such a residency

is found in a specific subset of hospitals that may also have a different set of resources to devote to the Formulary and treatment protocols. They may be especially different from smaller hospitals that have much fewer resources to devote to these issues. It would also be difficult to generalize these results to large university hospitals. In addition to having health care professional students and the educational commitments, there most likely would be a different type of physician who practices in a university hospital. While these physicians may be more comfortable with adopting new treatments, they also may be involved in clinical research that may affect their ability to participate in a P&T Committee due to ethical concerns.

Another limitation was that while the survey asked the respondents specifically about the four different dependent variables, the respondents were asked to complete the survey items for the independent variables from the perspective of general P&T Committee activities. It is unlikely that the results of this study would be comparable to those in a study where the measures were completed in the context of the individual dependent variables. In this study, for example, this resulted in the direct effects of Physician Influence on Team Engagement to be identical in all of the path analyses. Future research will need to be performed placing the survey in the context of a specific P&T Committee decision.

The model used from the previous qualitative research was not developed to be decision specific. This may have contributed to the relatively low predictive value for several of the models, limiting the ability to specify the interventions to be considered when improving performance. More qualitative research may need to be conducted before further quantitative studies on each outcome are performed.

Lessons and Challenges for P&T Researchers

As noted in the above, there was not a substantial amount of previous P&T specific research from which to base this study. This presented both an opportunity and a

challenge for conducting this research. In order to hopefully assist future researchers, the following observations may be of assistance.

While there are parallels to previous team research, the P&T Committee operates in a somewhat different manner than teams in many other organizations. In a typical team setting, the team members are making a decision that will then enter the culture of the organization in which the team functions, with authority derived from the management structure of the organization. In the case of a P&T Committee, some decisions are also implemented due to similar authority, and example of which would be the performance of a therapeutic interchange by the pharmacy staff. Other decisions rely on the acceptance of a prescriber, most commonly a non-employee physician, who has the autonomy to not follow the dictates of the organization. This suggests that performance improvement efforts commonly seen in the team literature may not be effective in this case, and that a greater focus on persuasive efforts is needed.

Future researchers will need to consider using a much larger population than the limited ASHP residency listing to have a large enough sample size to allow for adequate power in the findings. This will be a challenge as there is no central source of contacts in hospital pharmacies. At this time, none of the practice, advocacy, or licensure organizations maintain a comprehensive listing of hospital pharmacy directors. Most hospitals' internet sites contain no directory information for pharmacy professionals. Due to these facts, a research wishing to study this population should plan on significant efforts in order to create their sample of pharmacies. In the same vein, efforts to contact other members of the P&T Committee than Hospital Administrators/Medical Directors could be more effective in obtaining data. Care must be taken, however, that those individuals have adequate access to information about the committee and a full understanding of the committees' processes.

The finding that different types of P&T decisions appear to have different factors that may affect their adoption suggests that researchers should consider limiting research

on one type of decision per study. Further qualitative research should be conducted that focuses on adding depth to the individual decision models before performing further quantitative research. In order for the adoption of decisions to be meaningful, some linkage to patient outcomes is needed. To focus solely on the adoption of P&T Committee decisions assumes that the committee will make optimal decisions. The lack of adoption of some decisions may be related to the prescribers' perception of the quality of the decision, and a measure of this factor would be a valuable addition to the models.

Future Research

To facilitate future research in this area, a partnership with a large group of hospitals that is willing to allow access to sensitive information and to increase participation most likely will be necessary. This may be a large regional network of hospitals or a national cooperative buying group. A network where there is considerable flexibility in the operation of individual hospitals will be needed in order to maximize variation. Once this is accomplished, there are several avenues for future research.

One direction will be to reintroduce the indirect concepts of Information Flow, Decision Process, and Resource Control that were identified in the qualitative study. Another will be to include the financial and clinical outcomes that are the result of medication therapy as the factors that affect adoption of decisions may not be the same as those that result in maximized patient outcomes.

The finding that each adoption decision is unique presents another direction for future research. The study, using either the reduced model in this study or expanded to the full model suggested by the qualitative study, could be repeated for a number of dependent variables. In each of the studies, the items in each index would be modified to the context of the decision being measured.

Another direction suggested by the research is to investigate factors that affect efficiency in the process. There are some suggestions in the results of the study that

factors that were thought to influence the effectiveness of the P&T Committee and its processes may actually be affecting efficiency of the process. For example, higher levels of Physician Influence may be increasing the efficiency of Implementation Support activities by increasing the level of credibility of interventions performed to increase adoption of the committee's decisions amongst prescribers. Some additional qualitative research may be needed to determine if additional factors affecting efficiency.

In addition to expanding the description of the processes involved in the adoption of P&T Committee decisions, future research could develop interventions intended to improve P&T Committee processes. Interventions to address the factors suggested by this study could be developed using previous research that have successfully addressed similar situations. This research could be performed on the current model, or applied to findings from some of the research suggested above. This will also require the cooperation of a number of hospitals willing to participate in the study, possibly the same hospitals recruited for further development of the models.

Conclusions

The study described the current levels of adoption of decisions of the P&T committee and determined the factors that affect the adoption of the committees' decisions by prescribers. Decisions of P&T Committees including formulary decisions, medication restriction decisions, CAP treatment protocol decisions, and DVT risk assessment protocol decisions were actually four distinct decisions and were not indicative of a single P&T decision concept. Hospital characteristics of size, ownership, and location were not predictors of adoption of decisions of the P&T Committee. The factors that influenced the adoption of the decision varied based on the type of decision that was being adopted.

Engaged team members were consistently important in the adoption of P&T Committee decisions including decisions about formulary medications, medication

restrictions, Community Acquired Pneumonia treatment protocols, and Deep Vein Thrombosis risk assessment protocols. Influential physicians and implementation activities varied in their importance depending on the decision being made. The presence of influential physicians on the P&T Committee appeared to facilitate both implementation activities and engaged team members. Influences outside of the committee were assessed and found to be insignificant as predictors of decision adoption, which may be an indicator of success of the efforts undertaken to mitigate their influence. This research has begun to address the previous gaps in research about the factors affecting the adoption of P&T Committee decisions.

APPENDIX A- A CONCEPTUAL MODEL OF THE FORMULARY SYSTEM

Background

The clinical and financial consequences of medication therapy are a challenge for acute care pharmacy practitioners. At least 380,000 preventable medication errors occur in hospitals yearly with up to $3.5 billion in costs from such errors (Committee on Identifying and Preventing Medication Errors 2007). These costs are in addition to the $27 billion spent for medications in non-federal hospitals in 2006 (Hoffman, J et. al. 2009).

The formulary system is a commonly used cost and clinical management tool. These systems are usually managed by Pharmacy and Therapeutics (P&T) Committees, with 97.6% of hospitals reporting having a P&T Committee (Pederson et al. 2005). The committee consists of physicians, pharmacists, other health professionals, and health system administrators.

Previous P&T Research

Personal experience and inquiry of clinical pharmacy managers through the ASHP List-serve suggests that practitioners are looking for guidance to improve their formulary systems and P&T Committees. Pharmacists mentioned the difficulties of focusing on evidence-based decisions, getting decisions implemented once made and achieving active participation in the decision-making process.

Much of the existing knowledge about P&T Committees is limited in scope. For example, several studies have examined physician attitudes towards medical cost containment activities, therapeutic interchanges and acceptance of formularies. We know that physicians are more likely to accept formularies when they feel that cost considerations are balanced with clinical considerations (Sansgiry et al. 2003, Lehmann

et al. 2007, Poole 2005). An in-depth examination of the functionality of the formulary system and the P&T Committee is lacking.

Searches of PubMed and ABI inform (Proquest) found 2 specific studies of P & T committee functionality. P&T Committees are also similar to mixed function teams involved in a linear process with a feedback mechanism to some level of management, about which there is research from the fields of psychology and business management.

In the first study, based on Ancona and Caldwell's teamwork research (Ancona & Caldwell 1988, 1992), there was division of the decision process among the members of the P&T Committee, and committees were generally better performers when they sought outside assistance for addressing controversial issues. Additionally, efforts to protect committee members from outside influence had no influence on performance. Nair used self-satisfaction among committee members as her outcome measure of team performance (Nair 1999).

The second study by Bagozzi, Ascione and Mannebach used the social relations model to study the relationships between physicians who were committee chairs, other physician members, pharmacists, nurses, and administrators who were members of P&T Committees. The researchers measured the elicitation and reception of cooperation, influence, and frustration and enjoyment between the committee members. These parameters varied considerably for the individual members, depending on their role, and all members worked to manage intrapersonal relations with other committee members. Further research into the effects of committee group performance on health outcomes and the effects of other groups in the hospital and outside stakeholders would be useful (Bagozzi, Ascione and Mannebach 2005).

In the team literature, Brehmer and Hagafors' described a model where the leader of a team divides a complex decision into several tasks and assigns team members tasks based on their backgrounds and skills. This process simplifies the decision-making process, but leader must also be able to judge the quality of the judgments when making a

final decision (Brehmer & Hagafors 1986). Hollenbeck et al then refined this model suggesting that external influences may affect decision-making processes of these teams, with external influences smaller in teams with highly developed decision-making skills (Hollenbeck et al. 1995). Jehn also suggested that teams make better decisions in non-routine complex tasks when there is a level of disagreement between the members (Jehn 1995). In this literature, outcomes are usually measured with an objective measure of performance rather than team satisfaction.

Thus, the team literature provides direction to expand previous findings. The gaps in research include a lack of a full description of Formulary System functionality and an objective outcome measure. To begin to address these gaps, the goal of this research was to fully describe both formulary systems and a P&T Committee functional model. We performed a qualitative research study to answer the following research questions:

1) What are the factors that affect how decisions are made by P&T Committees?
2) How are P&T Committee decisions adopted by prescribers?
3) What outcome measure or combination of measures effectively quantifies P&T Committee performance as reflected in the Formulary System?

Methods

Design

We performed a qualitative study using recorded individual in-person interviews with Pharmacy Directors, P&T Committee Chairs or equivalents, and Hospital Administrators. We also performed limited reviews of committee policies, procedures and meeting minutes from those hospitals willing to provide these documents.

Subjects

Subjects were chosen as representatives of three key constituent groups in hospitals. Larger hospitals were chosen as potential study sites because previous research showed they were more likely to have active Formulary Systems. A list of all 33 non-specialty hospitals with an in-patient bed capacity of 90 or greater in the Iowa area codes of 515, 641, 319 and 563 as well as the Illinois area code of 309 was obtained using the American Hospital Association directory. After obtaining approval from the Institutional Review Board, a recruitment letter describing the purpose of the study and participation was sent to the Directors of Pharmacy of a random sample of 20 these hospitals, followed with phone calls to the Pharmacy Directors asking for participation. If the director accepted, then the names of the P&T Committee Chair and Hospital Administrator whose duties included supervision of the Pharmacy were obtained. The Pharmacy Directors assisted in contacting these individuals for interview scheduling in most cases. P&T policies and procedures and six months of redacted P&T Committee meeting minutes were requested, allowing for collection of some procedural information.

Interview Guide

We proposed several factors may affect committee performance (Turben 1995, Palay 1984, Heide 1994) and we used these concepts to prepare an interview guide (Table A1). The interview guide was tested in two interviews at a large university hospital and modified based on the results of the testing.

Analysis

After each interview was completed, the recordings were manually transcribed. The transcripts were compared to the recordings and corrected to ensure accuracy. After validation, transcripts from the first five sets of interviews were deconstructed and

analyzed for themes. The transcriptions were marked with a theme designation to assist in categorization. Once the transcripts were categorized, assignment of concepts was performed. Two more sets of interviews were conducted and analyzed as before. There was repetition of the concepts that were previously identified and no new concepts were recognized so saturation was reached.

The final assignment of concepts was reviewed by another researcher with qualitative experience for additional validation.

Results

Respondent information

A total of 10 hospitals in 7 health systems were included in the final sample, 8 in Iowa and 2 in Illinois, 8 owned by a religious organization, 1 county hospital, and 1 not-for-profit corporation. The average bed capacity was 394, ranging from 97 to 658. The interviews were conducted on-site at 7 hospitals and 2 physicians' offices and were from 15 minutes to 1 hour and 48 minutes in length, recorded with a digital recorder. Recruitment was challenging as all three subjects at each hospital were required to be involved in the research. Of the non-participating hospitals, one half of the hospitals were contacted by phone numerous times with no response and the other half were unable to participate due to workplace issues.

Formulary system concepts

In addressing research questions 1 and 2 we identified 8 concepts, 1) Information Flow, 2) Resource Control, 3) Outside Influences, 4) Decision Structure, 5) Implementation Support, 6) Prescriber Adoption, 7) Medication Therapy, and 8) System Engagement that are part of the formulary system. Seven of the concepts are part of a linear process of decision making and Prescriber Adoption that leads to medication

Table A1- Concepts used to create interview guide.

Concept	Definition	Sample Question
Committee organizational structure	Location of the P&T Committee in the hospital and medical staff organizational structure.	Where does the P&T Committee fit in your hospital and medical staff organizational structures?
Membership composition, roles, and power balance	The professionals that compose the committee, their roles, and the power balance within the committee.	Tell me about how much influence each member has on the committees' decisions.
Level of influence of the members outside of the committee'	The level of influence of the members of the P&T Committee in their respective practice groups outside of the committee.	In your opinion, how does that level of influence in his/her practice affect how decisions of the committee are perceived by people who work in the hospital?
Committee governance	The manner in which members of the committee interact with each other, including formal and informal discussion rules.	How do the rules / guidelines of your committee affect how your P&T Committee makes decisions?
Degree of organizational support	The type and amount of resources that are made available to the P&T Committee by the sponsoring organization.	What research resources does your organization provide for your P&T Committee?
Ethical and other policies relating to the interactions of committee members with outside parties	Effects on the system from parties and factors outside of the formulary system.	What ethical policies are in effect for your P&T Committee members and how do these compare with those for employees and physicians who are not P&T members?
Method of communication of decisions to affected parties outside the committee.	The communications seen in each hospital.	How does your P&T Committee communicate their decisions to practitioners outside of the committee?
Outcome Measure	The method of measurement the performance of the health systems' formulary system and P&T Committee.	If you had to give a report to your administrator about the effectiveness of the P&T Committee and the formulary process that the committee manages, what would you use?

therapy. Another concept influences most of the other concepts but is not a part of the linear flow and was discussed later. Representative supporting quotations from interviewees are highlighted in italics in the presentation of each concept.

Linear process concepts

Information Flow

Similar to decision support systems seen in the medical and systems literature, Information Support describes the flow of information in the system leading to the committees' decision. Information flow is done in both structured and non-structured manners. Most of the information that is utilized in the decision-making process originates with the pharmacy department, with some non-pharmacist committee members also performing literature research. There was consensus among the three types of subjects regarding this concept. "*We do all the reviews of medications and care paths that are presented in the meeting"* –Pharmacist. "*Well, we rely on (Clinical Coordinator) to bring us the scientific information and background. Most of the physicians view that if we are discussing a request for formulary inclusion, the person who represents the specialty or area that that particular pharmacological agent impacts, is expected to hold forth and to give his or her opinion on that"* –Physician. "*I think we rely heavily on information from the clinical pharmacists. I feel again, that the clinical pharmacists have opportunity to do research and bring it back"* –Administrator.

Information Flow is accomplished formally and informally, with formulary reviews and meeting minutes being the most common formal mechanisms and with informal communication taking place in many settings. "*I am very confident that the minute I brought up that we wanted to look at aprotinin prescribing with the cardiovascular surgeon and the anesthesiologist; every anesthesiologist knew we were looking at it within a day"* –Pharmacist. Outside groups such as accreditation organizations and the pharmaceutical industry are also system information sources.

Resource Control

Resource Control describes allocation of resources for the P&T Committee and the formulary process which is performed primarily by hospital management and the Pharmacy. There is minor involvement of physicians and medical staff administrators. Resources are committed for research to support the decision process and implementation of committee decisions. Often the pharmacy is allocated the most resources. There was agreement between the administrators and pharmacists as to their roles in resource control. "*So I wouldn't say it's my full time job to work on P&T stuff, but close to it. It's extremely time consuming and I think a lot of places struggle with even attempting to have accepted processes because they don't have the resources"* –Pharmacist. "*We fund our P&T Chair (physician) for 10 hours a week so they can actively participate in all the things that go on in the process"* –Administrator. Physicians mentioned that administration and pharmacy controlled most of the system resources and physicians are sometimes not aware if there are any resources that they control. "*No, I'm not sure but I would doubt that I have any funds that I control"* –Physician.

Outside Influences

This concept describes influences from outside of the formulary system that may affect the decision making process and/or the outcomes of medication therapy. Part of the effect is due to groups and individuals outside of the health system, with the pharmaceutical industry and accreditation agencies mentioned most frequently by all interviewees. "*The sales reps don't influence decisions but they do influence the agenda when they are detailing a med heavily"* –Pharmacist.

Most hospitals have restrictions on the activities of sales representatives in the hospital, including restrictions on access to personnel and certain marketing activities. Some hospitals expend considerable effort and resources to monitor activities of sales representatives. "*They're (sales representatives) signing in, they have to pick up a special badge that says "Vendor", have to give their car keys so that's their way of getting it*

back, and knowing they're leaving, or supposedly leaving. We allow in-servicing by reps as long as pharmacy's present and we know ahead of time"–Pharmacist. Several of the health systems had ethical policies for P&T Committee members. "*All committee members have to basically sign the same statement no matter what the Medical Staff committee, and that's talking about identifying if they have relationships with vendors"* – Pharmacist.

Considerable resources are used to comply with accreditation standards. Every pharmacist and most administrators and physicians commented on how much committee time and effort was spent in ensuring compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards. "*Joint Commission runs the world. The medication management standards have applied so much pressure and created so many headaches"* –Pharmacist.

The influence of heterogeneity of patient response to medications on therapy outcomes was mentioned by physicians and pharmacists and is considered an outside influence. Both mentioned that medication therapy outcomes are not wholly dependent on the quality of the therapy, recognizing that variations in outcomes are seen between similar patients with a degree of unpredictability.

Decision Structure

This concept describes the process of committee decision making, including formal rules and informal processes that integrate committee member perspectives in order to reach decisions. The most common procedure was discussion in the committee meeting until a consensus was reached, with a formal vote sometimes being taken. *"We try to get consensus, often we don't even vote on an issue, the chair just says that it's approved"* –Pharmacist. *"There's general consensus, sometimes getting to that consensus is really what it's about"* –Physician.

Implementation Support

The concept of implementation support describes the processes that move P&T

Committee decisions into the practice environment and support continued adherence to the formulary and treatment protocols. Information about the adoption of therapy and medication outcomes is gathered as a part of these activities to evaluate the results of P&T Committee decisions. While most of these efforts are performed by pharmacy, in some organizations there is physician involvement, usually limited to meeting attendance or being a signatory on a letter to physicians. After decisions are made, prescribers are notified of changes made to the formulary and other decisions. "*Sometimes we send myself or one of the clinical staff to the medical department meetings, along with the Chair, to help explain the decision"* –Pharmacist. "W*e do a pharmacy newsletter. And we take it back to the department in question"* –Physician.

Often committee decisions are put into effect by specific actions done by the pharmacy on receipt of non-formulary medication orders. Therapeutic interchange and calls to physicians to request an alternative medication were mentioned frequently. "*Our pharmacists make calls on non-formulary orders and make therapeutic interchanges that the P&T approves"* -Pharmacist. "*If it's not on formulary they (prescribers) are called, most of the time. And then they (pharmacy) ask them (prescribers) if want them (pharmacy) to order it"* –Physician.

Prescriber Adoption

Committee decisions must be adopted by prescribers to have any impact. This concept measures the extent to which prescribers use medication therapy in accordance with the committee's decisions. Pharmacists were much more likely to have numerical information than physicians. "*We have 3 non-formulary requests a month and we fill over 3200 doses a day"* –Pharmacist. Physicians often mentioned difficulty in obtaining non-formulary drugs. "*The culture is that if it's not on the formulary, you need to be very persuasive to get somebody to go out and buy it somewhere"* –Physician. A difference between adoption of protocols and medications was mentioned, with the most common reason for using protocols being convenience. "*When all you have to do is sign an order*

sheet and it saves you, what, 15 separate orders, it makes my life easier, so I use it" - Physician.

Medication Therapy and Outcome Measures

The final result of the process is patients receiving medication therapy with a clinical response. Research question three addressed the issue of an objective measure of formulary system effectiveness. We found that none of the hospitals had any overall measure/s for the effectiveness of the formulary system or the P&T Committee. Most the hospitals did mention monitoring of costs and/or outcomes on specific committee initiatives. Administrators were more likely than physicians and pharmacists to discuss monitoring of projects and/or medication classes. "*I don't think there's anything that's specific for that (P&T effectiveness)"* –Physician. "*It's more of a process basis. There's not a regular reporting, it's just based on projects and things like that"* –Administrator.

Once it was established that a hospital did not have a measure for system performance, interview subjects were presented with a list of possible components of a measure to determine their utility. While no measure was universally accepted or rejected, there was general agreement among the study subjects on the value of a combination of three outcome measures: medication cost per day (possibly adjusted by DRG or for acuity level), medication errors rate and adverse drug reaction rate.

Non-linear flow concept

The previous seven concepts primarily addressed the structure and process of decision making, adoption of decisions by practitioners, and measures of medication therapy outcomes. The eight and last concept exerts influence on all the previous concepts and acts as an information feedback mechanism to other concepts.

System Engagement

The level of commitment of the individuals to the successful functioning of the system we describe as the concept of system engagement. Hospitals with high levels of

system engagement had activity outside of the committee setting and engaged in more informal information gathering and sharing than those hospitals with self described difficulties in the formulary process. Several committee chairs and pharmacists mentioned the importance of informal communications and collaboration in building an engaged committee. *"Some of the best talks are in parking lots and hallways and when you're getting a cup of coffee"* –Pharmacist. *"What's going to come out of there is you have to have communication with people who use the drug and then get their input"* – Physician. At one hospital, all interviewees mentioned the high level of activity that takes place in the committee as reflected by high attendance and free flow of information to and from the medical staff. *"It's a part of our culture here; physicians are expected to actively participate in committees"* –Physician.

Hospitals with high levels of system engagement also have physicians who were influential in their respective practice settings. Hospitals with low levels of system engagement had difficulties in getting physicians to be active liaisons between the P&T Committee and their peers. *"The people (physicians) that are on there (P&T), though, are well respected by their peers, are well respected by the group, because we wouldn't have wanted people that weren't well respected by the group"* –Pharmacist. *"It would be very good to have an influential member who would take it back to the committee but there's a ton of apathy out there."* -Physician.

Full Model

When System Engagement is superimposed over the linear flow concepts, the final proposed model is created. While there was little reciprocal activity between most of the concepts in the linear flow, Implementation Support has several reciprocal relationships with other concepts. System Engagement also has several reciprocal relationships, and acts with Implementation Support as a feedback mechanism for the system.

Relationships between concepts

The concepts in the linear flow interact to move information and resources, along with outside influences, to a decision point in the committee setting. Prescribers then choose whether or not to prescribe in accordance with committee decisions, with resulting medication therapy and clinical outcomes. As most of these relationships are direct and similar to other descriptions of Input-Process-Outcome (I-P-O) systems, they will not be discussed in detail. The relationship between System Engagement and Implementation Support and their affect on other concepts appears to be highly influential on the process and those relationships was discussed in greater detail.

System Engagement and Resource Control

Allocation of resources into the system increases active participation on the P&T Committee. While most hospitals rely on unpaid physicians, reimbursing for time spent on committee activities increases physician chair participation at one hospital. *"We negotiated for the P&T Chairman, and also for Dr. (Physician Name). We negotiated a set number of hours for each of them and we pay them for their time. Rather than just be appointed to be P&T Chairman (and) having their own practices that they would have to juggle to maintain … he would spend (a) certain amount of time a month to attend P&T and that has worked out well"* –Pharmacist. Conversely, lack of engagement also affects resource allocation. In several hospitals the lack of engaged committee members resulted in more resources being needed to make and implement decisions. *"They (physicians) are not attending. But we work around that, we still get the work done. We do spend more resources and there is some opportunity cost due to that"* –Pharmacist.

System Engagement and Information Flow

The pharmacy ensures that committee members have information available before meetings, which engages the other committee members. Engaged physicians members are valuable as information resources, bringing clinical practice perspective to committee decisions. *"One of the things we insist on in this hospital is that not only the agenda, but*

the background information or the application or the policy to be discussed or what have you, it's sent out seven days beforehand. So that obviously everybody can read that" – Physician. *"Most of the physicians view that if we are discussing a request for formulary inclusion, the person who represents the specialty or area that that particular pharmacological agent impacts, is expected to hold forth and to give his or her opinion"* –Physician.

System Engagement and Decision Structure

The level of engagement of the medical staff affects how P&T decisions are made, with engaged physician members leading to decisions that may be more acceptable to the medical staff. "*(A protocol) was initially discussed by the special care committee, who sent it to the medicine department, who sent it back with a recommendation to special care to send it to the Pharmacy committee. Very laborious, but it does get reviewed many times and the ultimate responsibility for setting of the order goes to the Pharmacy Committee but there is a lot of input prior to and concurrent with the discussion at the pharmacy committee and then it's accepted better*" –Physician.

System Engagement and Prescriber Adoption

Lack of engaged and influential physicians causes difficulties in getting decisions adopted by staff physicians. *"The biggest thing would be to have more physician involvement and to have physicians that would be more influential to their respective background that would come to P&T meetings and actually go disseminate information and get it talked about themselves without me having to go around to everybody and basically present to everybody, that's my biggest hindrance."* – Pharmacist

System Engagement and Implementation Support

An active P&T Chair facilitates active pharmacist participation in supporting P&T initiatives. On the other hand, unengaged pharmacists also negatively affect implementing formulary decisions. *"We identify the key areas we want to focus on, and we prioritize it and formulary is always in there. They*

(pharmacists) do a good job of supporting P&T Committee because most of them know that they have the backing of the P&T Chair. –Pharmacist. *"When a pharmacist is faced with a medication order and it (the order) may not meet the restriction and what is that pharmacist to do … If the drug's on the shelf, the path of least resistance is to dispense the drug"* –Pharmacist.

Implementation Support and Resource Control

Lack of resources can lead to difficulties in implementing P&T decisions. *"I've conveyed as strongly as I can for quite a while… that we don't have the resources to deliver the services you want including the services JCAHO is demanding"* –Pharmacist.

Implementation Support and Prescriber Adoption

Having processes in place to implement and support formulary decisions increases the rate of compliance. One hospital discussed reasons for their high level of formulary compliance. "*Probably just by a phone call saying that we don't stock that or we don't have that. Then we use something else. The interchanges really help there; it takes away that phone call"* –Pharmacist. Multiple communication methods enhance adoption of P&T decisions. *"The minutes are sent to each different department … If there are some issues that have come up (Pharmacy Director) writes letters. We put things onto FormWeb (on-line information system)"* -Physician. Hospitals gather information about the level of decision adoption during implementation. *"It's based on situations that we are seeing on a day to day basis or we've been hearing about or we are getting feedback from our pharmacists in the front line"* –Pharmacist.

Implementation Support and Information Flow

Information gathered during implementation is forwarded to be used by the P&T Committee at later time. One hospital discussed how they begin to initiate formulary reviews by using this information. *"I always have a non-formulary drug request form, we will track them and if we consistently get the same product we are getting requests for we will look and see, maybe we should*

add that to the formulary" –Pharmacist.

Discussion

This research increases understanding of formulary system functionality and develops an objective measure of formulary system performance. Three findings may be used to improve performance of the system. First, Resource Control, System Engagement and Implementation Support affect performance of much of the rest of the concepts in the system. Second, there is often some disagreement about how influential committee members are in their practice setting. Finally, there was agreement on objective measures of performance for formulary systems.

This research suggests that Resource Control, System Engagement and Implementation Support facilitate both decision making of the committee and adoption of the decisions by practitioners. These concepts act upon many of the other concepts in the system and they have the greatest impact on the success of both the P&T Committee and the formulary system. Due to effects of System Engagement on other parts of the linear flow, it is difficult to place it within the linear flow.

This research expands the previous findings by showing the effects of engagement of more professionals than just physicians in the process of interacting with the practice environment in the hospital. The finding could be used in the practice environment to guide selection of team members, recruiting those who would be actively engaged in the system, and directing resources to facilitate engagement, such as funding of physician time spent in the process, and to support implementation activities.

There was disagreement between the perceptions of physicians compared to those of the administrators and pharmacists about how influential P&T Committee physicians were with their colleagues in practice settings. These perceptions were especially different in hospitals where pharmacists and administrators reported that their formulary systems were not performing well. This suggests that efforts to recruit or appoint

physicians who are considered to be influential by their peers may improve the perceived acceptability of P&T Committee decisions, improving their rate of adoption.

There was agreement regarding three outcomes of medication therapy that were perceived by all the study subjects as accurate reflections of the effectiveness of the committee. This is a significant departure from the previously used measures of effectiveness, namely committee member satisfaction. A combination of an adjusted medication cost per day with adverse reaction rate and medication error rate could be used to assess system performance in delivering medication therapy that is as safe, effective and economical as possible.

This study supported several findings of previous P&T and team research. Nair's previous finding that committees seek outside help when making decisions was repeated in hospitals with engaged members, and that there is a division of the decision process among the members of the committee. Other repeated findings were that the P&T and formulary processes are linear Input-Process-Outcome processes, with Resource Control, Information Flow and Outside Influences as Inputs, Decision Frame, Implementation Support, System Engagement, and Prescriber Adoption as Processes, and Medication Therapy as an Outcome. The considerable efforts by some hospitals to limit exposure of committee members to representatives of pharmaceutical manufacturer representatives repeats previous findings that managing information and dealing with influences outside of the committee is an important part of creating an effective system.

One limitation of the study is self-selection bias, as the hospitals made the choice to participate. Most of the hospitals in the study described their systems as performing well and were willing to be examined in a research context, while hospitals that believed that their systems were not performing well may not have wished to be examined. Another limitation is generalizability of the findings to hospitals in other geographic areas, to teaching or specialty hospitals, or to hospitals that are different in size, ownership characteristics from those studied. There were also proportionally more

hospitals owned by religious organizations in the sample than in the population, so findings may also not apply to government or not-for-profit corporation hospitals.

The model created through this study was the basis for future studies to define and measure the concepts identified, to quantify the effects of the concepts upon each other and on the level of adoption of P&T decisions, and to further develop the outcome measures proposed by this study.

Conclusion

Seven hospital formulary systems were studied using qualitative research interviews of hospital administrators, physicians, and pharmacists. In addition to further development of the previously described Input-Process-Outcome structure of these systems, a concept describing the level of engaged participation of influential practitioners emerged as a system driver. Components of an objective measure of performance for the formulary system were also identified

APPENDIX B- SURVEY OF HOSPITAL FORMULARY SYSTEMS CHARACTERISTICS

Pharmacy

Dear Pharmacy Director,

One of the biggest challenges for health system pharmacists is working with the Pharmacy and Therapeutics (P&T) Committee to maintain the Formulary and clinical initiatives. Contributing to this challenge is the relative lack of information that can be used to improve the effectiveness of the P&T Committee by increasing the acceptance of their decisions by prescribers. We invite you and two others from your hospital staff to participate in a research study being conducted by investigators from The University of Iowa. The purpose of the study is to determine what factors affect P&T Committee performance.

We are inviting you to be in this study because your hospital is a non-specialty hospital with more than 99 beds. We obtained your name and address from the ASHP Residency directory. Approximately 300 people will take part in this study at the University of Iowa.

You are free to skip any questions that you prefer not to answer. It should take about 20 minutes to complete the survey. You will be contacted by E-mail in 2 weeks and called in 3 and 4 weeks if we do not receive returned surveys.

We will keep the information you provide confidential, however federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. The username you used to access this survey will be used to track responses to the study and to be able to include characteristics of your hospital in data analysis. The link between the ID code number and your name and the hospitals name will be destroyed after data analysis. If we write a report about this study we will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However we hope that the results from the study can contribute to better understanding the factors affecting P&T performance.

You will not have any costs for being in this research study. You will not be paid for being in this research study as we realize that compensation for helping us with this study may create an issue with your hospital's ethics policy. Taking part in this research study is completely voluntary.

If you have any questions about the research study itself, do not hesitate to contact Mr. Andreski with comments or questions via phone (319) 400-7269, fax (319) 353-5646 or email michael-andreski@uiowa.edu or Dr. Miller via email william-a-miller@uiowa.edu. If you experience a research-related injury, please contact: Mr. Andreski via phone (319) 400-7269, fax (319) 353-5646 or email michael-andreski@uiowa.edu or Dr. Miller via email william-a-miller@uiowa.edu.

If you have questions about the rights of research subjects, please contact the Human Subjects Office, 300 College of Medicine Administration Building, The University of Iowa, Iowa City, IA 52242, (319) 335-6564, or e-mail irb@uiowa.edu.

Thank you very much for your consideration of this research study. Completing the internet survey indicates your willingness to participate in the research study.

Sincerely,

Michael Andreski, RPh, MBA
PhD Candidate

William A. Miller, Pharm.D., FCCP, FASHP
Professor Emeritus
Pharmaceutical Socioeconomics
University of Iowa College of Pharmacy

For this survey, the Pharmacy and Therapeutics Committee includes the P&T Committee and its subcommittees which are involved in choosing the medications on the formulary, evaluating of the clinical use of medications (including outcomes), developing policies and quality assurance activities for medication use and administration, and evaluating and monitoring of adverse drug reactions and medication errors. Within the survey, "P&T Committee" refers to the preceding definition. In addition, think about the overall committee when you answer the questions, not a specific subcommittee.

1) Does your hospital have a P&T Committee or equivalent?
2) How many pharmacists participate on the P&T Committee?
3) How long have you been participating in P&T activities?
4) How many subcommittees of P&T are there?
5) How many physicians, nurses, hospital administrators and others are voting members of the P&T Committee?
6) Please select all who routinely participate on the P&T Committee Physicians
   Pharmacists,
   Nurses
   Hospital Administrator
   Physician Medical Director
   Dietitian
   Microbiologist/ Laboratory Representative
   Patient Safety Officer
   Quality Management Director
7) How difficult is it to obtain a non-formulary Medication in your hospital?
   Very Easy Easy Neutral Difficult Very Difficult
8) How restrictive is the formulary in the number of meds in each therapeutic category? (Ex. - ACE-Inhibitors)
   Not at all Very little Average Somewhat Very
9) In the last 6 months, about what percentage of medication orders would you estimate are filled with formulary medications?
10) In the last six months in about what percentage of qualifying patients would you estimate were treated with a protocol or care path for community acquired pneumonia?
11) In the last six months in about what percentage of qualifying patients would you estimate were assessed for DVT risk using a protocol or care path?

12) In the last six months, about what percentage of orders for restricted medications met the criteria for approved uses?
13) How much do Pharmaceutical Industry Representatives affect P&T Committee members' decisions?
    Not at all 2 3 4 5 6 A great deal
14) How influential are Pharmaceutical Industry Representatives in getting medications considered by the P&T Committee for formulary inclusion?
    Not at all 2 3 4 5 6 A great deal
15) How much do Pharmaceutical Industry Representatives affect what medications are prescribed in the hospital?
    Not at all 2 3 4 5 6 A great deal
16) How much do JCAHO standards and initiatives affect drug use policies developed by the P&T Committee?
    Not at all 2 3 4 5 6 A great deal
17) How much do JCAHO standards and initiatives effect how medications are prescribed in the hospital?
    Not at all 2 3 4 5 6 A great deal
18) People involved in the P&T Committee are willing to expend effort beyond what is normally expected to help it be successful.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
19) People involved in the P&T Committee talk it up to peers within the organization.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
20) People involved in the P&T Committee would change their job assignment to keep working with P&T.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
21) People involved in the P&T Committee find their values and goals are compatible with those of the P&T Committee.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
22) The P&T Committee really inspires the very best job performance in those involved in it.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
23) People involved in the P&T Committee are glad that they chose to work with it instead of other responsibilities they could have chosen.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
24) People involved in the P&T Committee are proud to tell others that they are involved in it.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
25) People involved in the P&T Committee really care about its fate.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
26) People involved in the P&T Committee feel that it is the best committee to be involved with.
    Strongly Disagree 2 3 4 5 6 Strongly Agree
27) How much influence do P&T physicians have on the prescribing of physicians in their specialty?
    Not much influence 2 3 4 A great deal of influence
28) How much influence do P&T physicians have on the prescribing of physicians not in their specialty?
    Not much influence 2 3 4 A great deal of influence
29) How much influence do P&T physicians have on setting the agenda for reviewing medications for addition to the formulary?
    Not much influence 2 3 4 A great deal of influence
30) How much influence do P&T physicians have on the amount of communication after P&T Committee decisions?
    Not much influence 2 3 4 A great deal of influence

31) How much influence do P&T physicians have on the gathering of information for committee decisions?
Not much influence 2 3 4 A great deal of influence
32) How often does your P&T Committee approve Therapeutic Interchanges for medications that are not listed on the Formulary?
Never 2 3 4 5 6 Almost Always
33) How often are approved Therapeutic Interchanges performed by pharmacy staff when a non-formulary medication is ordered?
Never 2 3 4 5 6 Almost Always
34) How often do pharmacy staff members call physicians to obtain a medication order to change a non-formulary medication to a formulary medication?
Never 2 3 4 5 6 Almost Always
35) How often do physicians from the P&T Committee contact physicians to obtain a medication order to change a non-formulary medication to a formulary medication?
Never 2 3 4 5 6 Almost Always
36) When a change is made to the formulary, how often does your hospital publish printed communications (newsletters, memos, etc.)?
Never 2 3 4 5 6 Almost Always
37) When a change is made to the formulary how often does your hospital provide electronic communications (E-mails, on-line newsletters, etc) to prescribers?
Never 2 3 4 5 6 Almost Always
38) How often does your hospital have a member of the P&T Committee communicate formulary changes to individual or groups of prescribers?
Never 2 3 4 5 6 Almost Always
39) How often is information about formulary changes included as part of the order entry process?
Never 2 3 4 5 6 Almost Always

APPENDIX C- IRB APPROVAL

IRB ID #: 200902755

To: Michael Andreski

From: IRB-01 DHHS Registration # IRB00000099,

Univ of Iowa, DHHS Federalwide Assurance # FWA00003007

Re: Development of A Model of the Formulary System to Predict the Level of Prescriber Adoption of Pharmacy and Therapeutics Committee Decisions

Protocol Number:
Protocol Version:
Protocol Date:
Amendment Number/Date(s):

Approval Date: 04/25/09
Next IRB Approval

Due Before: 03/16/10

Type of Application:	**Type of Application Review:**	**Approved for Populations:**
☐ New Project	☐ Full Board:	☐ Children
☐ Continuing Review	Meeting Date:	☐ Prisoners
☒ Modification	☒ Expedited	☐ Pregnant Women, Fetuses, Neonates
	☐ Exempt	

Source of Support:

Investigational New Drug/Biologic Name:

Investigational New Drug/Biologic Number:

Name of Sponsor who holds IND:

Investigational Device Name:

Investigational Device Number:

Sponsor who holds IDE:

This approval has been electronically signed by IRB Chair:

William Hubbard, MA 04/25/09 0916

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are attached. Please make copies from the attached "masters" for subjects to sign when agreeing to participate. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.) If hospital/clinic patients are being enrolled, a copy of the signed Informed Consent Document should be placed in the subject's chart, unless a Record of Consent form was approved by the IRB.

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection

of private identifiable information. Your project "expires" at 12:01 AM on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project on or before that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however the HSO will send a reminder notice approximately 60 and 30 days prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the “Investigator’s Guide to Human Subjects Research.” Research investigators are expected to comply with these policies and procedures, and to be familiar with the University’s Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.

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