

**THE ADOPTION OF THE PHARMACOECONOMIC CENTER AS A
RESOURCE BY AIR FORCE MEDICAL TREATMENT FACILITIES**

by

George Emerson Jones, Jr.

Bachelor of Science
University of Kentucky, 1983

Doctor of Pharmacy
University of Kentucky, 1985

Submitted in Partial Fulfillment of the
Requirements for the Degree of Master of Science
in the College of Pharmacy
University of South Carolina

1997

College of Pharmacy
Director of Thesis

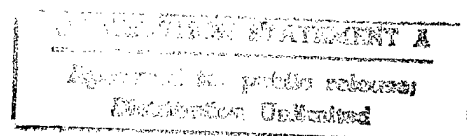
College of Pharmacy
2nd Reader

College of Pharmacy
3rd Reader

Dean of the Graduate School

DTIC QUALITY INSPECTED 2

19970625 055



REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE 18 JUN 97	3. REPORT TYPE AND DATES COVERED		
4. TITLE AND SUBTITLE THE ADOPTION OF THE PHARMACOECONOMIC CENTER AS A RESOURCE BY AIR FORCE MEDICAL TREATMENT FACILITIES			5. FUNDING NUMBERS	
6. AUTHOR(S) GEORGE EMERSON JONES, JR.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) UNIVERSITY OF SOUTH CAROLINA			8. PERFORMING ORGANIZATION REPORT NUMBER 97-065	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) DEPARTMENT OF THE AIR FORCE AFIT/CI BLDG 125 2950 P STREET WRIGHT-PATTERSON AFB OH 45433-7765			10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION AVAILABILITY STATEMENT			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 words)				
14. SUBJECT TERMS			15. NUMBER OF PAGES 97	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT	

DEDICATION

My interest in research was created by my Father and my desire for excellence nurtured by my Mother. Those many, wonderful days of going to work with Dad to “help” with experiment plots, attending Field Days, and watching you use research results to help farmers solve problems, will always be my first love. It would have been so much easier for you not to include me, but, instead you gave me more than every opportunity. I am just beginning to understand the effort and patience that took and to realize the benefit I gained. My mother never missed an opportunity to encourage. She instilled the desire to do my best and helped me see and take opportunities to improve. She helped me believe that I could accomplish whatever I set my mind to do and was there to encourage and guide every time I would try.

ACKNOWLEDGEMENTS

Special thanks go to Dr. Gene Reeder for his insight and ability to clear the “brush” and find a clear path for me to pursue; to Dr. Chris Kozma for making the analytic process make sense and his challenge to me to think outside the “statistically significant”; and to Dr. Richard Schultz who has provided feedback and direction to keep me focused and on course with the process required to accomplish the objective.

A note of thanks go to my fellow students, especially Trent and Deepa. The sharing of ideas and your critiques made this a better project.

Thanks beyond description go to my family. This entire endeavor would not have succeeded without my wonderful wife Kris. To Rachel, Mary, and Caroline my thanks for being a source of inspiration and for your patience. I am truly blessed to have you as my family.

ABSTRACT

The Department of Defense (DoD) took action to address the problem of increasing pharmaceutical expenditures by developing a TriService Pharmacoeconomic Center (PEC) in January 1993. The charge to the PEC was to develop a TriService Formulary (TSF) system to promote a consistent pharmacy benefit, educate prescribers, develop treatment guidelines, and outcome indicators.

The purpose of this study was to look at adoption of the PEC as an innovative resource for use at the treatment facility level. The overall hypothesis is that Air Force facilities have, on average, adopted the PEC as an information resource and use its recommendations in their local formulary systems. Data were collected by a survey of pharmacy directors and from prescription databases at Air Force facilities to explore this hypothesis. Pravastatin, the PEC selected HMGCoA drug of choice, is used as a surrogate to study the action taken by local facilities on a specific PEC recommendation.

We received 49 (80.3%) surveys that were usable for analysis. Responses show that PEC materials are well accepted and are being used in Air Force facilities. A significant shift to pravastatin occurred during the study period. As a quasi-experimental design, a causal link is not proposed. However, the results support describing the PEC as an innovative resource that has been adopted into local formulary systems of Air Force medical treatment facilities.

TABLE OF CONTENTS

Title	i
Dedication	ii
Acknowledgements	iii
Abstract	iv
Table of Contents	v
List of Tables	vii
List of Figures	viii
Chapter	Page
I. Introduction	1
PEC Operations	3
References	5
II. Literature Review	6
Formulary Systems	6
Innovation Decision Process	9
Research Questions	12
Hypothesis	12
References	14
III. Methodology	15
Sample	16
Design	18
Survey Development	19
Prescription Data	20
Survey PreTest	21
Analysis Plan	23
References	28
IV. Results	29
Response	29
Demographics	35
Communication	39
Formulary System Operations	42
PEC Lipid Recommendations	44
Prescription Dispensing	44
Hypothesis Testing	54

V. Discussion	60
References	69
VI. Conclusion	70
Appendices	74
Bibliography	86

LIST OF TABLES

Table	Title	Page
4.1	Response Results From Survey Distribution	31
4.2	Survey Data Response Description	32
4.3	Cluster Analysis Results	34
4.4	Summary of Pharmacy Director Demographics Characteristics	35
4.5	Summary of Pharmacy Operation Results	37
4.6	Reported Provider Specialties	38
4.7	Summary of "PEC Update" Use Results	39
4.8	Additional PEC-Facility Interaction	40
4.9	Overall Rating of PEC By Responding Directors	41
4.10	Formulary System Interaction Ratings	43
4.11	PEC Hyperlipidemia Therapy Review Ratings	45
4.12	HMGCoA Marketshare Means By Observation Period	46
4.13	Pravastatin Marketshare Means By Observation Period	49
4.14	Pravastatin Marketshare Means By Complete Data Groups	50
4.15	Contrasts of Means - Hypothesis One	55
4.16	Pravastatin Marketshare By Lipid Review Usefulness Rating	57
4.17	Comparison of Means - Hypothesis Two	58

LIST OF FIGURES

Figure	Title	Page
3.1	Research Design	17
4.1	HMGCoA Mean Marketshare By Observation Period	47
4.2	Pravastatin Marketshare By Complete Data Groups	51
4.3	Pravastatin Marketshare By Observation Period - Group 2	52
4.4	Pravastatin Marketshare By Workload Grouping	53
4.5	Pravastatin Marketshare By Lipid Review Usefulness Rating	57

CHAPTER ONE

Introduction

The pressure to improve quality and contain costs is the same in the Department of Defense (DoD) health care system as in the civilian environment. The Air Force, Army, and Navy are the primary components of the DoD system. Pharmaceutical expenditures, on average, account for less than 10% of expenses in the military and civilian systems. ^(1,2) Pharmaceuticals have recently had the highest rate of increase of any medical costs and, as a result, have attracted the attention of decision makers in both systems. ⁽²⁾

The Department of Defense, through its Health Affairs (HA) section, took action to address the problem of pharmaceutical expenditure growth. A recommendation to “...establish a corporate level venture to promote cost-effective utilization of pharmaceuticals...” made by an Army process action team was adopted in January 1993 by Health Affairs. ⁽¹⁾ They directed the Air Force and Navy to work with the Army to create and staff a TriService Pharmacoeconomic Center (PEC). The PEC was to develop a TriService Formulary (TSF) system, promote a consistent pharmacy benefit, educate prescribers, develop preferred drug lists, treatment guidelines and outcome indicators, and promote medical readiness. ⁽³⁾

The Army process action team came to the conclusion that the formulary system is the avenue to use to attain rational drug therapy. This, in turn, would accomplish efficient spending of funds for pharmaceuticals. DoD facilities have in place a well structured formulary system anchored by a pharmacy and therapeutics (P&T) committee. The need, as seen by the Army team, is to improve the tools available to the local committees. In particular, they wanted to improve the type, quality, and completeness of information available at the local level. This was a first step to managing cost and the birth of the PEC.

The PEC is an innovation. It represents a unique source of information and guidance on drug selection, use, and monitoring. The PEC uses pharmacoeconomic principles as the basis to develop recommendations for optimal pharmaceutical management of specific disease states. The PEC publications and recommendations are designed to be a key resource for local formulary systems. The breadth and quality of the work are well established. However, the acceptance and use at the local level, or adoption, of PEC produced materials and recommendations have not been assessed.

The path to adoption is described as the innovation decision process.⁽⁴⁾ The innovation decision process should be assessed from the perspective of the intended user. The expected benefit of an innovation is realized through its use at that level. That is also where an effect of any decision regarding the innovation will occur. The intended users

of PEC publications and specific drug therapy recommendations are DoD medical treatment facilities.

PEC Operations

The PEC became fully staffed and operational in 1993. The PEC publishes a monthly newsletter, the "PEC Update", to communicate with the military health care facilities. The "Update" includes therapeutic class reviews, drug of choice recommendations, TSF updates, treatment guidelines, and discussion of policy issues. The PEC sends the "Update" to the Commander and Pharmacy Director of all military healthcare facilities.

The 33 issues of the "Update" published through September 1996 have included three revisions to the TSF drug list and six disease state reviews.⁽⁸⁾ A published disease state review includes a review of the selected disease, the drugs in any relevant therapeutic classes, treatment guidelines, a list of preferred drugs, and utilization review guidelines.⁽⁹⁾ The preferred drug list recommendations become the products representing that therapeutic class on the TSF drug list.

The PEC published the initial TriService Formulary (TSF) during 1993.^(1,5) The Department of Defense, through Health Affairs, has directed all Services to adopt the TriService Formulary (TSF).⁽⁶⁾ Informal assessments of compliance with this directive indicate a good deal of variance. Interpretation by facilities of the TSF directive ranges

from making the TSF products and alternative choices available, to selecting the TSF products as the drug of choice for the therapeutic class represented.⁽⁷⁾

This project describes the status of the innovation decision process applied to the PEC as a new information resource. Adoption and perceived value of the PEC are explored from the local facility perspective, including the relationship of PEC recommendations and local formulary systems. The published review on the management of hyperlipidemia and the recommendation of pravastatin for the TSF are used as examples of PEC work for this study. The setting for this project is the Air Force medical treatment facilities in the Continental United States.

REFERENCES

1. Potyk, R. et al. "Pharmacoeconomics in the Military Health Services System," Federal Practitioner, (December, 1994): 10-21.
2. Potyk, R et al. "Initial TriService formulary ready for use," American Journal of Hospital Pharmacists , 51 (Mar 11994): 588,591.
3. Operational Proponent for Department of Defense Pharmacy and Pharmacoeconomic Center (PEC) Charter. Department of Defense, Health Affairs, DoD Directive 55136.1. Washington, DC: August 29, 1995 revision.
4. Rogers EM. Communication of Innovations . New York: The Free Press, 1971.
5. "TriService Formulary and Preferred Drug List Development," PEC Update, 94(3) (January 1994): 1-2.
6. Joseph, SC. "Memorandum for Assistant Secretaries of the Army, Navy, and Air Force - Subject TriService Formulary" Washington, DC: November 10, 1993.
7. "ACP Program Update: Data Reporting," PEC Update, 96(10) (July 1996): 3.
8. "PEC Updates" Pharmacoeconomic Home Page. <http://www.ha.osd.mil/hppec2.html>. September 1996.
9. "TriService Formulary - Revision One," PEC Update, 94(9) (July 1994):1-17.

CHAPTER TWO

Literature Review

This chapter is divided into literature dealing with formulary systems and the innovation decision process. The first section addresses the theory and application of a formulary system. The second section describes the innovation diffusion process and an example of use in a pharmacy setting. Following this foundation, research questions and hypotheses are presented.

Formulary Systems

The successes and failures of formulary systems have been well documented.⁽¹⁻⁵⁾ Formulary supporters and opponents have aired their respective views at committee meetings, conferences, and in the literature for many years. The literature on formularies has predominately been from work in the inpatient setting or in Medicaid outpatient programs. However, publications from work in the managed care setting are growing.

In a recent study, Horn et al looked at consequences of cost containment strategies, including a formulary, in six managed care organizations.⁽⁶⁾ They found a “limited formulary” caused undesirable cost and utilization consequences. A shortcoming of the

Horn article and similar literature is the generalization of the results to all “formularies” from measuring effects of a specific drug list, or of some specific changes. Their conclusions are inappropriately extended to the “formulary system” when the work only addresses a particular aspect. This study has renewed the discussion in the literature of the potential effects, good or bad, of “formularies” now with a managed care perspective.

The position that a solid formulary system is the foundation of rational drug therapy is well supported.^(1,4,5) Pearce and Begg in a review of limited lists and formularies showed that when properly organized, the formulary concept in practice can improve health outcomes through rational drug use.⁽³⁾ This is contrary to findings such as those from the Horn article.

Schrogie and Nash have looked at the relationship of formulary management, practice guidelines, and pharmacoeconomics. They found the existence of unexplained variations in treatment selection by geographic area and provider practice setting. Their data described that there were variations in treatment selection when settings with a formulary system were compared with treatment selections made in the absence of a formulary structure. They further concluded that these treatment pattern differences led to limited incremental benefit and considerable incremental cost.⁽²⁾

Formularies are a difficult issue to generalize and evaluate. The differences among sites and management philosophies make extrapolation of results of limited value. This

makes it particularly difficult to test the value of a formulary system. Rucker noted the lack of literature looking at the application of the formulary system theory to current practice in 1990.⁽¹⁾ The literature does show, however, that an assessment of any system should include an evaluation of the process and information resources used to reach a decision. The process used for decision-making has been studied and is more easily generalizable. Key elements of a process to support a formulary system include having clear purpose, participation by all components of the delivery system, and consideration of the information resources available to the local "system".

The importance of the type and availability of resources used by decision makers has been extensively studied.^(1,4,5,7) Rucker examined the P&T process and administrative infrastructure supporting the formulary system in eight institutions ranking highest in a performance study.⁽⁸⁾ He found the decision making approach used by these optimally performing institutions stressed strong drug information resources and the interrelationship of all drug use practices.⁽⁸⁾

A literature search yielded no references that looked at the effects of having access to information generated by a centralized expert staff for use by local formulary systems. Ironically, Rucker called for creation of this type resource in the 80's.⁽⁷⁾ He described that the expected benefits of such a resource would come from the ability to use a drug-of-choice model in a more rigorous fashion. This would be made possible through access to complete and current literature and dedicated staff positions. He indicated such a

system would overcome local problems of limited staff, time, and funds. Rucker was clear, however, that the ultimate responsibility would still rest with the local P&T committee, but now with aid of comprehensive, objective information. The PEC and its intended use by local facilities fits closely to Rucker's model.

Innovation Decision Process

An innovation is defined as an idea, equipment, or information source perceived as new by an individual or organization.⁽⁹⁻¹¹⁾ Most innovations require adoption, considered as full use, before any benefit can be realized. This sets up a relationship between the source of the innovation, the actual innovation, and the intended user. The characteristics of both the intended user and the innovation, as perceived by the intended user, generally determine the timing and extent of innovation adoption.

Innovation decision research shows that characteristics of the innovation affect adoption. Some examples include relative advantage, compatibility with existing values, and complexity of the innovation compared with current activities. The testability and visibility of results from any comparisons are also key factors.⁽¹¹⁾

The characteristics of the receiver are equally important to consider. An example comes from diffusion of computers as an innovation in hospital pharmacy. Browning et al described the diffusion of computer technology in hospital pharmacy.⁽¹²⁾ They found the number of months since adopting computers had a positive correlation with the

number of beds, the number of years the pharmacy director had been practicing, pharmaceutical services offered and staff size.

The intended user must first become aware of the innovation. Diffusion is the process by which the innovation is communicated over time to members of a system.⁽¹¹⁾ The diffusion process involves interaction of the “source” of a new idea to a “receiver”. The relationship between the “source” and “receiver” has an influence on decisions made as a result of diffusion.⁽¹¹⁾ The desired outcome of diffusion is adoption. Adoption is defined as making full and regular use of the innovation.⁽⁹⁾

Kotler and others have described diffusion of innovation as a five step adoption process.⁽¹⁸⁾ He describes awareness, interest, evaluation, trial and adoption as the stages through which a user will pass before making full use of the innovation. Adoption is reached at various rates, but is the end of the process when it is reached by a given user.

However, there is not complete agreement in this body of literature on a model to represent diffusion of innovation. Rogers describes the diffusion of innovation as a four stage innovation decision process.⁽¹⁰⁾ The key difference is that Rogers describes the adoption stage as an on going decision-confirmation loop rather than an end.

A combination of Rogers and Kotler seems useful to describe the relationship of the PEC and healthcare facilities. From Kotler, defining adoption as making full use in

the final step of consideration can describe the overall relationship. The PEC as a resource innovation must be adopted by local facilities before specific recommendations can be considered. The part of interest from Rogers is that adoption is part of an ongoing decision-confirmation loop. Consideration of specific recommendations made by the PEC occur monthly. A local facility can be at various stages of adoption regarding a specific recommendation within the overall adoption of the PEC as a resource. The cumulative results of the specific monthly decisions will, over time, affect the overall PEC innovation adoption decision.

An example of a specific recommendation is the HMGC_oA drug of choice selection made by the PEC. The "Management of Hyperlipidemia" disease state review published in the October 1995 issue of "PEC Update" included the recommendation of pravastatin as the optimal choice in the class of HMGC_oA drugs. Pravastatin was, by this recommendation, included on the TriService Formulary. The changes in lipid therapy, specifically the HMGC_oA's, are used to evaluate local facility response to a specific PEC action. Research questions and hypotheses are based in part around the October 1995 PEC publication.

Research Questions

This project describes the relationship between the PEC and Air Force medical treatment facilities from the facility perspective. The following three research questions are the basis for this purpose:

- 1) What is the perceived value of the PEC as an information resource?
- 2) Has there been a change in lipid therapy dispensing patterns?
- 3) Has the PEC had an effect on lipid therapy dispensing patterns?

To answer these questions, we will explore PEC-Facility communications, facility characteristics, the PEC role in local formulary systems and the perceived value of the PEC. We will collect data via a survey to describe characteristics of the source-receiver relationship between the PEC and Air Force healthcare facilities. Dispensing patterns of HMGCoA drugs will be investigated as a measure of the effect of a specific PEC recommendation.

Hypothesis

The overall research hypothesis is that Air Force medical treatment facilities have, on average, adopted the PEC as an information resource for the local formulary system. It is expected that the survey results will show regular use of PEC publications and a perception of useful and significant influence of PEC recommendations. It is further hypothesized that a shift in marketshare of the HMGCoA class of drugs occurred at Air Force treatment facilities during the study period.

The following are specific hypotheses:

H1: Pravastatin will have a greater marketshare of HMGC_oA drugs in the period after distribution of the PEC lipid therapy review when compared to the period before distribution of the review.

The number of prescriptions dispensed by month for each FDA approved HMGC_oA drug product was requested from each facility for 1 year before and 1 year after the PEC lipid therapy review distribution. The proportion, or marketshare, accounted for by pravastatin will be compared over time.

H2: Facilities rating the PEC lipid therapy review and recommendations as useful will have a larger increase in pravastatin marketshare than facilities giving a neutral or not useful rating.

Facilities will be classified based on survey responses regarding the PEC lipid therapy review and recommendations. The change in the marketshare of pravastatin before and after distribution will be compared for the two groups.

REFERENCES

1. Rucker, DT et al. "Drug Formularies: Myths In Formation," Medical Care, 28(10) (1990): 928-37.
2. Schrogie JJ et al. "Relationship Between Practice Guidelines, Formulary Management, and Pharmacoeconomic Studies,." Topics Hospital Pharm Management 13(4) (1994):38-46.
3. Pearce MJ et al. "A Review of Limited Lists and Formularies," PharmacoEconomics 1(3) (1992):191-202.
4. Green JA et al. "Evaluating A Restrictive Formulary System By Assessing Nonformulary-drug Requests," American Journal of Hospital Pharmacists 42(7) (1985):1537-41.
5. Sloan, FA et al. "Hospital Drug Formularies and Use of Hospital Services," Medical Care, 31(10) (1993):851-67.
6. Horn, SD et al. "Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," American Journal of Managed Care, 2(3) (1996):253-64.
7. Rucker, TD. "Effective Formulary Development- Which Direction?," Topics Hospital Pharm Management, 1 (1981):29-45.
8. Rucker, TD. "Superior Hospital Formularies: A Critical Analysis," Hospital Pharmacy, 17(9) (1982):465-524.
9. Kotler, P and Armstrong G. Marketing: An Introduction. Englewood Cliffs, NJ: Prentice-Hall, Inc., 1987.
10. Rogers EM. Communication of Innovations. New York: The Free Press, 1971.
11. Romano, CA. "Diffusion of technology innovation," Advances In Nursing Science 13(2) (1990):11-21.
12. Browning, WC et al. "Diffusion of innovation: Computer technology in hospital pharmacy," American Journal of Hospital Pharmacy, 41(11) (1984):2343-2347.

CHAPTER THREE

METHODOLOGY

Research usually involves some form of experiment or test where a treatment or intervention is applied and an outcome observed. The work is often centered around some causal proposition. Experimental designs with randomization and controlled interventions offer the best platform to evaluate such propositions. However, much field research cannot be controlled to meet the constraints of true experimental methods. This is such a project. We will use a two part quasi-experimental design.

Sample

The Department of Defense medical treatment facilities can be classified under the three main branches of the Uniformed Services. This approach yields three distinct groups of facilities located worldwide and operated by the Army, Navy, and Air Force respectively. The population of interest for this project is the Air Force operated medical treatment facilities located in the Continental United States that have their own operational Pharmacy and Therapeutics (P&T) committee. A population of 61 facilities located on Air Forces bases throughout the Continental US meet this description. The size of the population makes it possible to sample the entire population.

Only Air Force facilities will be used. While the PEC is a TriService operation, the management philosophy and therefore the formulary decision process is substantially different among the Air Force, Army, and Navy. The decision to use only the Air Force facilities reduces the generalizability of any findings. However, it controls for the variation in management practices inherent across the three Services.

Design

A quasi-experimental design is used to answer the questions of interest. A survey and prescription dispensing database are the sources used for data collection. An experimental design would be preferable, however the circumstances do not permit using an experimental design. The treatment for this project is exposure to the PEC. All of the facilities in the population of interest have been exposed to the treatment. They have had the opportunity to form opinions and adopt or not adopt it as an information resource. A control group, variation in treatment exposure, and randomization are not possible.

The project divides into two parts based on the source of the data. Part A (Figure 3.1) is a post treatment observation to collect various facility characteristics. For this task, a survey of Air Force medical treatment facility pharmacy department chairpersons, or directors, are used (Appendix A). Pharmacy chairpersons are asked to complete the survey based on their opinion, experience, and knowledge of relevant demographics. Part B (Figure 3.2) collects pre and post prescription data around the distribution of the

PEC lipid therapy review. The data will be the number of prescriptions dispensed for all FDA approved HMGCoA drugs for the first month of each quarter from October 1994 through October 1996 (Figure 3.2). The facility will be asked to use their prescription database as the data source (Appendix B). Facilities will receive both instruments at the same time.

Figure 3.1

Research Design

Part A

X_1 O_1

A post intervention observation. X_1 = the distribution of the PEC lipid therapy review(15 October 1995). O_1 = survey (Appendix A)

Part B

O_1 O_2 O_3 O_4 O_5 X_1 O_6 O_7 O_8 O_9

A pre-post collection of data from the facility prescription dispensing database.
 X = distribution of the PEC lipid therapy review (15 October 1995). O = a month of data.

O_1 is October 1994	O_2 is January 1995	O_3 is April 1995
O_4 is July 1995	O_5 is October 1995	O_6 is January 1996
O_7 is April 1996	O_8 is July 1996	O_9 is October 1996

Survey Development

The survey instrument collects data on key activities that are related to adoption. These key activities are based on topic areas from the innovation diffusion literature. Data describing the PEC-Facility relationship for these activities are relevant to the research questions.⁽¹⁻²⁾ The desired information is divided into four general headings:

- 1) Facility and Staff demographics;
- 2) Communication with the PEC;
- 3) Formulary system operations;
- 4) PEC lipid therapy recommendations.

The survey is divided into these four sections. Questions under each of these headings were developed using a combination of techniques described by Dillman⁽³⁾ and Churchill.⁽⁴⁾

Demographic information includes pharmacy workload, staffing, and types of services available at the facility as described by Browning.⁽²⁾ The communication section assesses the distribution of PEC publications in the facility, use of quotes from PEC in local publications, and perceived value of PEC publications. The use of PEC information by the Pharmacy and Therapeutics Committee, the perceived influence of the PEC on specific parts of the formulary system, and adoption of the TriService Formulary are covered in the formulary system section.

The PEC lipid therapy review and recommendations are used as a specific example of information distributed to local facilities. "The Management of Hyperlipidemia" was published in the October 1995 issue of "PEC Update" (96-01).⁽⁵⁾ The lipid therapy section of the survey has questions regarding the PEC lipid therapy review. The perceived value of the review and recommendations, its distribution beyond the pharmacy to sections in the facility, acceptance of the recommendations, and its influence on local lipid formulary decisions are described by survey question responses.

Prescription Data

The prescription dispensing data is very straightforward. The variable of interest is the change in marketshare for pravastatin relative to all other FDA approved HMGCoA drugs. The PEC recommended pravastatin as the TriService Formulary (TSF) drug of choice to represent the HMGCoA class.

The PEC lipid therapy review was chosen as an example of a specific recommendation for several reasons. The patient population most likely to be treated with HMGCoAs, the retirees and their dependents, is relatively stable. The majority of patients are not likely to be on active military duty. A dispensing pattern change is less likely to be related to an in or out flow of a large patient base due to a mobile Active Duty population. The drug recommendation also made this an attractive example. The PEC HMGCoA recommendation, pravastatin, was not expected to have a majority marketshare in Air Force facilities prior to the PEC publication. There has been no

definitive literature establishing any of the four products as the superior selection. All products are well established on the market. The distribution of the PEC lipid review, October 1995, is well timed for reasonable access to before and after data collection.

Prescription dispensing data for each of the FDA approved HMGCoA drugs used for lipid reduction therapy is collected. The time period is one year before and one year after the distribution to facilities of the PEC lipid therapy review (Figure 3.1). The changes in marketshare among this class during the selected time period are expected to show a shift to pravastatin. The change in overall volume of HMGCoA prescriptions dispensed is not of interest.

A consistent growth after October 1995 of a minimum of five percent in pravastatin marketshare for at least two consecutive periods compared to predistribution marketshare is considered adopting pravastatin. An assumption is made that this criteria will represent a change in therapeutic policy at the facility. The five percent level is an arbitrary level selected to account for random change, such as patient movement, and be sensitive enough to reflect a change in policy when applied over time. Facilities where pravastatin has a consistent, at least two periods, decrease in marketshare of five percent or more, even with an overall majority marketshare for pravastatin, after distribution will be considered as not adopting the PEC recommendation. Facilities where marketshare did not demonstrate a change will be considered as adopting if pravastatin had a majority marketshare before and after distribution or not adopting with a less than majority share.

Survey Testing

The survey package was pretested in a sample of nine pharmacy administration graduate students and two Air Force pharmacists. The Air Force pharmacists were selected for their experience in research and because they were not currently pharmacy directors. Seven surveys and comments were returned in the requested time period. Comments included some wording changes, a change in the order of one question and separating one question into multiple parts. The Air Force pharmacists expressed concern over the availability of prescription dispensing data due to the computer system conversion that had taken place over the past four years. Facilities replacing their computer system during the period of interest may not have access to complete data.

After revision, a survey packet was sent to two Air Force facilities as a second level test. The sites were requested to complete the surveys and make note of any areas of confusion or uncertainty. Both surveys were returned in the requested time. Both were complete with no questions noted. A reliability check to evaluate the consistency of responses within two sets of questions was as follows:

Questions 13, 14, and 18 - If the response to 13 is "not read",
response to 14 and 18 should equal 0

Questions 22 and 24 - both responses should be 0 or
a value greater than 0

The test sites had a perfect match on these questions. Complete prescription data was

available at both sites. Each site was called to discuss the returned survey. The phone call did not identify any concerns or problems that may not have been written down with the package. These two sites are included in the analysis since no substantial modification of the instruments were based on their responses.

Sampling

The survey package was sent to the director of pharmacy at the 61 Air Force facilities via first class mail or by fax. The complete survey packet included the two instruments (Appendix A and B), a cover letter from Colonel Young, Air Force Associate Chief for Pharmacy, (Appendix C), an overview of the project (Appendix D), directions for completion (Appendix E), and an addressed, posted return envelope. The requested response time was two weeks from the mailing date. The fact that this was a research project and not an evaluation of compliance with the PEC was stressed in the cover letter. This was also stressed in the cover letter by Colonel Young. Participants were told that no facility specific information would be released without their permission.

The approach described by Dillman⁽³⁾ was adapted to this project to maximize response. The expected return rate is 80%. This is attainable with a relatively small, closed population and the ability to use senior leadership to encourage participation. With these characteristics, not all of the Total Design Methods will be used.⁽³⁾

Sampling Method:

- 1) Send Survey Packet by Mail / FAX

- 2) Mailing plus 16 days - A Follow up/Reminder FAX to non-respondents
- 3) Mailing plus 26 days - Telephone Follow up and Fax Survey Packet as needed to non-responders

Analysis Plan

Within a quasi-experimental design, the focus of analysis is to describe relationships found to exist in the data compared with the hypothesized relationships.⁽⁶⁾ Frequencies and correlations are used to describe the responses to Part A. Testing for statistical significance is conducted on the HMGCoA dispensing data.

Demographic information is collected from survey responses and used to compare and group facilities. Prescription volume and the number of pharmacists on staff was described by Browning as having a significant influence on adoption.⁽²⁾ These two variables, considered to represent pharmacy workload, are used in cluster analysis to group similar facilities. The optimal solution from hierarchical cluster analysis, using single linkage, complete linkage, average, and Ward's methods will identify the number of clusters and the seeds for FASTCLUS, a nonhierarchical procedure, to refine the solution. A desirable solution has a high R-Squared, low Semipartial R-Squared, and relatively small Root-mean-square standard deviation (RMSSTD).⁽⁸⁾ SAS is the computer package used for all statistical analysis.⁽⁹⁾

The overall opinion of the PEC, significance of PEC influence on the local

formulary system, and influence of the lipid therapy review are compared across facilities. Additionally, characteristics of PEC-facility communications are described. We are not testing a model of adoption or pursuing any causal links based on the results. However, correlation of questions that are conceptually related are tested. These questions are as follows:

- a) Rating of the “PEC Update” (Q14) and the overall rating of the PEC (Q16)
- b) Rating of the “PEC Update” (Q14) and relative rating of the PEC as an information resource (Q18)
- c) Rating of the overall PEC influence on local formulary selections (Q19a) and the influence of the lipid therapy review on lipid formulary selections (Q25a).

All of these questions are on a five point scale.

The reliability check conducted in the pretest is used on the survey responses. The questions are compared as follows:

Questions 13, 14, and 18 - If the response to 13 is “not read”, response to 14 and 18 should equal 0

Questions 22 and 24 - both responses should be 0 or some value greater than 0

Formal testing of internal consistency of the survey will not be performed on the series of scales. Each scale is an independent measure of an opinion or attitude and is not constructed for representation of a causal model.

Hypothesis Testing

H1: Pravastatin will have a greater marketshare of HMGCoA drugs in the period after distribution of the PEC lipid therapy review when compared to the period before distribution of the review.

Pravastatin marketshare is the dependent variable and time is the independent variable with observations before and after the distribution of the PEC lipid review. The marketshare of pravastatin in the population before the PEC recommendation is compared to the marketshare after distribution. Having multiple measures before and after supports analysis of changes over time. We can detect changes in level and rate of change in marketshare.

The analysis uses the General Linear Model procedure in SAS.⁽⁹⁾ The data are repeated measures on the same subjects over time. An analysis using a block statistical design with each facility representing a block is a possibility. However, the assumption of homogeneous covariance for each of the treatment levels, or sphericity, is not likely to be tenable for repeated measures over time. Sphericity is needed for a block univariate analysis, or should use an adjusted degrees of freedom when not met.⁽¹⁰⁾ With repeated measures, the best predictor for the value of the next observation is the previous one. The correlations between pairs are likely to change as time advances from the initial point. Multivariate Analysis of Variance (MANOVA) is often recommended when sphericity is violated. Pillai's Trace, a multivariate test that has been shown to be more powerful than an adjusted univariate test in this type data, will be used for the F-test of the

hypotheses.⁽¹⁰⁾

Two contrasts are of interest for this project. The first is similar to a pre-post test in that it compares the before and after periods. It tests for a change in level. The summed mean pravastatin marketshare for each period before distribution is subtracted from the summed mean marketshare for each period after distribution. The contrast equals 0 and is not significant for means that are equal.

$$\frac{(\sum X \text{ before})}{4} - \frac{(\sum X \text{ after})}{4}$$

The second contrast looks at the rate of change in marketshare before distribution and following distribution. It compares the slope of the two periods. Even with a change in level, if the slopes are equal, the contrast is not significant and any events observed in the after period could be just an extension of events already in motion.

$$(\Delta X \text{ before}) - (\Delta X \text{ after})$$

H2: Facilities rating the PEC lipid therapy review and recommendations as useful will have a larger increase in pravastatin marketshare than facilities giving a neutral or not useful rating.

Pravastatin marketshare is the dependent variable and a composite “usefulness” rating and time are the independent variables. A composite rating of the usefulness (Q22) and

significance (Q25a) of the lipid therapy review is calculated for each facility. The composite is an average of their response to the two questions. Both questions are on a 5 point scale. A composite greater than three is used as a cutoff to group facilities. The overall test looks for a difference in mean pravastatin marketshare at any level. The levels of particular interest are the first period (October 1994), the period just before PEC recommendation distribution (October 1995), and the final period (October 1996). A significant effect indicates the level of pravastatin marketshare is different.

REFERENCES

1. Romano, CA. "Diffusion of technology innovation," Advances In Nursing Science 13(2) (1990):11-21.
2. Browning, WC et al. "Diffusion of innovation: Computer technology in hospital pharmacy," American Journal of Hospital Pharmacy, 41(11)(1984):2343-2347.
3. Dillman, DA. Mail and Telephone Surveys: The Total Design Method. New York: Wiley, 1978.
4. Churchill, G. Marketing Research. New York: CBS College Publishing, 1987.
5. "Management of Hyperlipidemia," PEC Update, 96(1) (October, 1995):1-19.
6. Cook TD and Campbell DT. Quasi-Experimentation. Boston: Houghton Mifflin Company, 1979.
7. Kirk RE. Experimental Design: Procedures for the Behavioral Sciences . Pacific Grove: Brooks Cole Publishing Company, 1995.
8. Sharma, S. Applied Multivariate Techniques . New York: John Wiley & Sons, Inc., 1996.
9. SAS/STAT. PC/Windows Version 6.11, SAS Institute, Cary, NC.
10. Kirk RE. Experimental Design: Procedures for the Behavioral Sciences . Pacific Grove: Brooks Cole Publishing Company, 1995: 270-273.

CHAPTER FOUR

Results

This chapter presents the research results. The overall response rate is presented first. This is followed by a summary of survey responses divided into the four general headings from the survey: (1) demographics; (2) communication; (3) formulary system operations; and (4) PEC lipid therapy recommendations. The HMGCoA prescription dispensing data results are presented in the next section. The final section presents the results of testing hypotheses.

Response

The minimum target of an 80% response rate was surpassed with 49 out of 61 survey packets returned for a rate of 80.3%. Table 4.1 presents a breakdown of response by method of distribution and follow-up period. The surveys were distributed by first class mail and by FAX. The selection of distribution method was arbitrary for a given facility. The FAX method of distribution generated the best rate of response, 67%, during the initial period compared to first class mail, 49%. This was an unexpected effect. The first follow-up, a FAX reminder, yielded an additional 12 responses (20%).

The second follow-up, a telephone call and additional survey if requested, generated three (5%) more bringing the total to 49 (80.3%).

As expected from this population, the majority of responses were received in the first period. An examination of the twelve non-responders did not reveal any particular pattern. There was no geographic pattern or known facility characteristic that made non-responders different from responders. During the third follow-up, all eventual non-responders indicated that they had received the survey packet and would try to return it. There is nothing apparent to support that the non-responders would have reversed the findings or would be any different on average than the responders.

Seven of the 49 returned surveys had one or more incomplete answers for Part A of the survey. Table 4.2 presents usability of the returned surveys. Six of the seven had one question and one had two questions that were not usable. The data to answer the questions was either not available or the respondent did not answer an opinion question. The latter was the case for only two surveys and was a different question on each survey. These sites are not included for analysis of these questions. The sample size used for calculations is 49 unless otherwise noted.

Table 4.1
Response Results

DISTRIBUTION	SURVEY PACKETS	PERCENT
First Class Mail	37	61%
FAX	24	39%
TOTAL	61	100%
RESPONSE		
Initial Period		
Mail (n=37)	18 (49%)	30%
FAX (n=24)	16 (67%)	26%
Total	34	56%
First Follow-up	12	20%
Second Follow-up	3	5%
TOTAL	49	80.3%
Non-Respondents	12	19.7%

Table 4.2
Survey Data

RESPONSE	TOTAL	Complete
Part A (questionnaire)	49	42 6 - 1 missing question 1 - 2 missing question
Part B (dispensing data)	49	23-49 range by period
Part B - By Period (a period is a month of data)	Complete Surveys	
Periods 1-9		23
Periods 2-9		35
Periods 3-9		38
Periods 4-9		40
Periods 5-9		41
"After" Only		46
No Data Available		2
No HMGCoA Stocked		1

Two other surveys were not useable as received. Telephone follow-up was used to complete the response on these two surveys. One required a partially missing page to be refaxed and the second needed clarification of a response that was not clearly marked. The planned reliability check found consistent responses. Questions 13, 14, and 18, and questions 22 and 24 were found to be perfectly matched as either zero or some value greater than zero. This held each of the question groups on all returned surveys.

Response to Part B for the 49 returned surveys was not as complete. The computer conversions taking place at Air Force facilities, raised as a concern during pre-testing, was a factor. Table 4.2 provides a breakdown of responses with complete prescription dispensing data by time period. Analysis was done on selected periods using only facilities with complete data. For example, dropping the October 1994 period left 35 out of 49 surveys with complete data for the eight remaining observations. These responses are discussed in detail in the prescription dispensing and hypotheses testing sections.

The results of grouping similar facilities are presented in Table 4.3. Average monthly volume for Fiscal Year 1996 and the reported total number of pharmacists on staff were the variables used for cluster analysis. These two variables are typically used to represent pharmacy workload. As previously discussed (Chapter 3, page 23), workload may have an influence on adoption. Three groups of facilities resulted. The groups can logically be titled Low, Moderate, and High workload facilities. These groupings are used throughout the rest of the chapter.

Ward's method of hierarchical cluster analysis on standardized data was selected to provide seeds for FASTCLUS, a nonhierarchical procedure, to refine the solution. The three group solution seeds from Wards method had R-Squared (0.852), Semipartial R-Squared (0.091), and Root-mean-square standard deviation(RMSSTD) of 7341 compared with 14,557 overall. The values obtained indicate a desirable solution with a high R-Squared, low Semipartial R-Squared, and relatively small RMSSTD.⁽²⁾ The FASTCLUS

procedure improved the overall R-Squared to 0.877 for a three group solution.

Convergence occurred after three iterations. As expected, the groups were relatively more different with respect to prescription volume than number of pharmacists (R^2 - volume 0.876; R^2 - pharmacists 0.5). The results provide three groups of facilities that are relatively more homogeneous with regard to workload than the overall sample.

Table 4.3
Cluster Analysis

DESCRIPTOR	WORKLOAD		
	Low	Moderate	High
Number of Facilities	24	22	3
Means (std dev)			
Prescription Volume	9,600 (5,827)	36,100 (9,061)	81,200 (1,297)
Pharmacists	1.5 (0.78)	4.6 (2.8)	8.3 (2.5)

Demographics

A summary of the responses to the demographic section of the survey is presented in Table 4.4. The overall results indicate the majority, 53%, of Pharmacy Directors have a Bachelors degree only, while 41% have a Bachelors and an advanced degree. The average Pharmacy Director has over 13 years experience as a pharmacist and has been in their current position for an average of just under two years.

Table 4.4
Pharmacy Director Demographics

ACADEMIC DEGREE(S) ¹	TOTAL	GROUPING		
		Low (n=24)	Moderate (n=22)	High (n=3)
BS	26 (53%)	16 (66%)	10 (46%)	0 (0%)
PharmD	3 (6%)	3 (13%)	0 (0%)	0 (0%)
BS and PharmD	7 (14%)	1 (4%)	4 (18%)	2 (67%)
BS and Masters	12 (25%)	3 (13%)	8 (36%)	1 (33%)
Other Combinations	1 (2%)	1 (4%)	0 (0%)	0 (0%)
YEARS IN PRACTICE (Average)	13.8	10.5	16.6	19.3
Range	1 to 30	1 to 30 (54%<10)	6 to 26	16 to 24
IN CURRENT POSITION (AvgYears)	2.11 ²	2.2 ²	1.8	3.7

¹ a summary of responses to questions 1 a-c; Number of facilities (percentage of column total).

² an outlier (23 years) was not included in the calculation.

The distribution of academic degree among the three groups of facilities is also shown in Table 4.4. The returned surveys included data on 164 Active Duty and civilian pharmacists working at Air Force healthcare facilities located in the Continental US. Of these, 80% had entry level degrees as their only degrees. Those with advanced degrees included 8.5% having BS and PharmD degrees and 11% having BS and a Masters.

Average monthly prescription volume, new and refill, for Fiscal Years 1995 and 1996 was available from 48 respondents. Table 4.5 gives a breakdown by group of the responses. Average monthly prescription volume declined over the two year period. A decline was reported by 63% of respondents. This is at least in part due to policy changes throughout the Air Force during this timeframe. Most notable is moving from 30 to 60 and then to 90 days supply as the recommendation for dispensing maintenance medications. This comment was noted on the margin of several surveys.

When Fiscal Year 1996 was compared to 1995, respondents indicated that pharmacy inventory (44%) and expenditures (57%) had increased. On average 60% of prescriptions filled at responding facilities are written by their staff, either Active Duty or civilian contract providers.

Table 4.5
Pharmacy Operation Results

WORKLOAD ¹	TOTAL	GROUPING		
		Low (n=24)	Moderate (n=22)	High (n=3)
Prescriptions-Monthly Average ²	(n=49)			
Fiscal 1995	26,400	10,400	37,000	80,000
Fiscal 1996	25,900	9,600	36,100	81,200
Change	(500)	(800)	(900)	1,200
FACILITY OPERATION				
Prescription Volume ³	(n=48)		(n=21)	
Increased	17 (35%)	7 (29%)	8 (38%)	2 (67%)
Decreased	30 (63%)	17 (71%)	12 (57%)	1 (33%)
No Change	1 (2%)	0 (0%)	1 (5%)	0 (0%)
Source of Prescriptions	(n=49)			
Internal Providers	60%	65%	56%	56%
External Providers	40%	35%	44%	44%
Pharmacy Inventory Compare FY 96 to FY 95 ³	(n=48)	(n=23)		
Increased	21 (44%)	10 (42%)	9 (43%)	2 (67%)
Decreased	18 (37%)	10 (42%)	7 (33%)	1 (33%)
No Change	9 (19%)	4 (16%)	5 (24%)	0 (0%)
Pharmacy Expenditure Compare FY 96 to FY 95 ³	(n=49)			
Increased	28 (57%)	14 (58%)	12 (55%)	2 (67%)
Decreased	12 (25%)	7 (29%)	4 (18%)	1 (33%)
No Change	9 (18%)	3 (13%)	6 (27%)	0 (0%)

1 a summary of responses to questions 3-7.

2 average of new and refill prescriptions filled per month over the year.

3 number of facilities (percentage of column total).

The availability of provider specialties and student training is reported in Table 4.6. Most facilities had Primary Care departments (88%). Of the respondents, 59% had Primary Care, Family Practice, and Internal Medicine departments in the facility. These three departments are likely to see the majority of patients, especially those receiving lipid lowering therapy, seeking care at the facility. Cardiology and gastroenterology departments were reported by 16 % and 22% respectively. At least one additional specialty at the facility was reported by 94% of responders. The specialties listed on the survey are of interest in the context of this project. A training program for students, interns, and/or residents was reported by 39% of facilities.

Table 4.6
Reported Provider Specialties

PROVIDER SPECIALTIES ¹	FACILITIES
Primary Care	43 (88%)
Internal Medicine	36 (73%)
Family Practice	43 (88%)
All Three (PC, IM, FP)	29 (59%)
Cardiology	8 (16%)
Gastroenterology	11 (22%)
Other	46 (94%)
TRAINING PROGRAMS	19 (39%)

¹ a summary of responses to questions 8-9; Number of facilities (percentage of total).

Communication With PEC

A summary of this section is presented in Table 4.7. All pharmacy directors indicated that they read the "PEC Update". The "Update" is the main source of communication between facilities and the PEC. A clear majority (92%) reported reading the publication within a month of receiving it. As an information resource, it was rated "useful" to "very useful" by 88% of respondents.

Table 4.7
"PEC Update" Use Results

"PEC UPDATE" ¹	TOTAL	GROUPING		
	(n=49)	Low(n=24)	Moderate(n=22)	High(n=3)
Time To Read				
<1 Week	30 (61%)	15 (63%)	13 (59%)	2 (67%)
1 - 4 Weeks	15 (31%)	9 (37%)	6 (27%)	0 (0%)
> 4 Weeks	4 (8%)	0 (0%)	3 (14%)	1 (33%)
Informational Value				
(1=Not Useful 5=Very Useful)	3.8	4	3.6	3
Routine Circulation²				
P&T Committee	33 (67%)	14 (58%)	17 (77%)	2 (67%)
Department Chairs	10 (20%)	6 (25%)	4 (18%)	0 (0%)
All Providers	8 (16%)	4 (17%)	4 (18%)	0 (0%)

1 a summary of responses to questions 13-15; Number of facilities (percentage of column total).

2 circulated to at least one site outside the pharmacy department.

The “PEC Update” is sent to all pharmacy directors each month. The majority (82%) of pharmacy directors routinely circulate the “PEC Update” outside of the pharmacy department to at least one other site in the facility. The “Update” is routinely distributed to the P&T Committee in 67% of the facilities responding. Only eight (16%) indicated that the “Update” was routinely sent to all providers in the facility.

Questions 10-12 explored communication beyond the “Update”. Thirty-nine (80%) pharmacy directors indicated they had access to the World Wide Web and 27 of those had visited the PEC site. Six facilities (17% n=36) had been visited by a PEC

Table 4.8
Additional PEC-Facility Interaction

ADDITIONAL COMMUNICATION ¹	FACILITIES
PEC Staff Visit (n=49-13=36)	6 (17%)
Unknown (n=49)	13 (27%)
Attended Presentation By A PEC Staff Member	
One	20 (41%)
Two or more	18 (37%)
None	11 (22%)
World Wide Web Access	39 (80%)
Visited PEC Site (n=39)	27 (69%)
Average Usefulness Rating (1=Not Useful 5=Very Useful) (n=27)	3.0

¹ a summary of responses to questions 10-12; Number of facilities (percentage of column total).

staff member during the last two years. Thirteen facilities responded they did not know whether a visit had taken place or not during the time period. The PEC has received good exposure through presentations at meetings with 78% of respondents having attended at least one presentation in the last two years. Eleven directors (22%) reported they had not attended a presentation by a PEC staff member.

Communication of information is the basic function of the PEC. Therefore, the “overall opinion” question was included in this section. Table 4.9 reports the results from this question. The PEC was rated as “favorable” (score=4) or “very favorable” (score=5) by 69% of respondents(n=48). An “unfavorable” (score=1or2) rating was reported by 13% while 18% were “neutral” (score=3). As expected, there was a high correlation (Cronbach alpha 0.8, $p < 0.0001$) between the reported value of the “Update” as an information resource (question14) and overall opinion of the PEC (question 16).

Table 4.9
Overall Rating of PEC

OVERALL OPINION ¹	TOTAL (n=48)	GROUPING		
		Low(n=24)	Moderate(n=22)	High(n=3)
Average Rating (1=Very Unfavorable 5=Very Favorable)	3.7	3.8	3.6	3.3

¹ a summary of response to question 16.

Formulary System Operations

A summary of responses to questions from this section is presented in Table 4.10. Thirty (61%) of the directors responding indicated the facility had adopted 95% or more of the PEC TriService Formulary products. Relative to other resources used by the local P&T, 57% of pharmacy directors responding rated PEC therapeutic class reviews as “significant” or “very significant”. As expected, response to this question was highly correlated with the value rating given to the “PEC Update” (Questions 18 and 14; Cronbach alpha 0.70, $p < 0.0001$).

Question 19 asked directors to rate the PEC influence on five aspects of their local formulary system: (1) Formulary selections; (2) Newsletter; (3) Pharmacy budget; (4) Prescribing patterns; and (5) Pharmacy inventory (Table 4.10). Respondents (67%) reported that PEC reviews and publications had a significant or higher influence on formulary selections. The influence on prescribing patterns were rated by 82% as neutral or not significant. This could reflect a perception by pharmacy directors that the PEC influence occurs at the P&T committee level rather than with individual providers independent of the committee system.

PEC influence on the local newsletter had an average rating of neutral (3.1). Air Force regulations require distribution of a P&T newsletter to providers in the facility. Only 45% of directors reported using information from the “PEC Update” in more than three issues of their local P&T newsletter during the past year. Table 4.10 gives a

summary of responses. The majority (84%) of directors serve as the editor of their P&T publications.

Table 4.10
Formulary System Interaction

FORMULARY ¹ ISSUES	OVERALL (n=49)	GROUPING		
		Low (n=24)	Moderate(n=22)	High (n=3)
Percent Adoption: TriService Formulary Range	90% (50-100%)	92% (70-100%)	88% (50-100%)	96% (90-100%)
Relative Role of PEC Reviews (1=Not Significant 5=Very Significant) (Average)	3.5	3.6	3.5	3.3
Influence of PEC Reviews (1=Not Significant 5=Very Significant) (Average)				
Formulary Selections	3.8	3.8	3.8	3.7
Local Newsletter	3.1	3.0	3.1	3.3
Pharmacy Budget	3.3	3.1	3.4	2.7
Prescribing Patterns	2.6	2.7	2.6	2.0
Pharmacy Inventory	3.1	3.2	3.1	2.7
Local Newsletter Use ²	3.5	4.4	3.1	4.3

1 a summary of responses to questions 17-20.

2 average number of issues out of last 12 that contained material from a "PEC Update".

PEC Lipid Therapy Recommendations

The “Management of Hyperlipidemia” disease and therapy review was rated as “useful” or “very useful” by 61% of respondents. Responses to this section are summarized in Table 4.11. The majority (63%) of directors rated the quality of this review as “high” or “very high” when compared to other PEC reviews. Thirty-four (69%) directors rated the influence of the lipid therapy review on lipid formulary selections as “significant” or higher. This was highly correlated with the overall PEC influence rating on formulary selections (Questions 25 and 19; Cronbach alpha 0.708, $p < 0.0001$). The PEC lipid review influence on prescribing patterns and therapy costs were rated as less significant (see table). At least parts of the hyperlipidemia review were distributed outside the pharmacy to at least one other department by 78% of respondents. Pravastatin, the PEC recommended HMGCoA of choice, was reported as “adopted” by 69% of those responding.

Prescription Dispensing

As presented in Table 4.2, there were surveys returned with only part of the requested HMGCoA dispensing data. Data were not available at these sites due to an Air Force wide computer system conversion. Specifically, data from the time periods before the PEC lipid review distribution were missing. In many cases, respondents included comments about utilization or reported estimates when data were not available. These estimates, however, were not included in the analysis.

Table 4.11
 PEC Hyperlipidemia Therapy Review

LIPID THERAPY ¹	OVERALL	GROUPING		
	(n=49)	Low (n=24)	Moderate(N=22)	High(N=3)
Usefulness Rating (1=Not Useful 5=Very Useful)	3.5	3.5	3.9	3.0
“Adopt” Pravastatin (Facilities with “yes”)	34 (69%)	14 (58%)	18 (82%)	2 (67%)
Relative Quality of Review (1=Very Low 5=Very High)	3.7	3.6	3.8	4.3
Influence of Review				
Formulary Selection	3.7	3.5	3.9	3.0
Prescribing Patterns	3.1	3.2	3.0	2.7
Therapy Cost	3.2	3.1	3.3	2.7
Review Circulation ²				
P&T Committee	33 (67%)	14 (58%)	16 (73%)	3 (100%)
Department Chairs	15 (31%)	7 (29%)	7 (32%)	1 (33%)
All Providers	12 (24%)	7 (29%)	5 (23%)	0 (0%)

1 a summary of responses to questions 22-26.

2 circulation of all or part of the review to at least one site outside the pharmacy department.

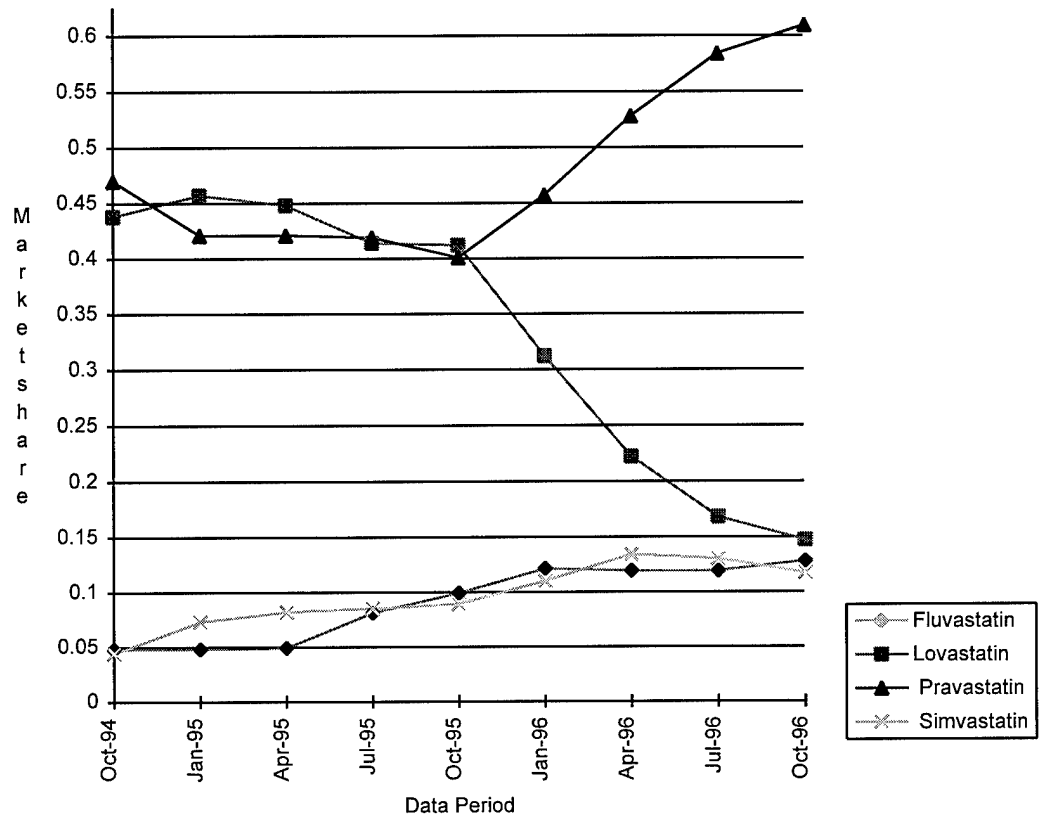
The mean marketshare of each of the four FDA approved HMGCoA drugs by period is presented in Table 4.12. Changes occurred during the study for all products. The changes before PEC distribution, periods one through five, show a distinctly different pattern than the pattern after October 1995 (Period 5). Figure 4.1 plots the data from Table 4.12 and highlights the relative increase in the market share for pravastatin.

Table 4.12
HMGCoA Marketshare by Period

PERIOD	DRUGS			
	Fluvastatin	Lovastatin	Pravastatin	Simvastatin
Oct 94 (Period 1) _{n=23}	0.048	0.438	0.47	0.044
Jan 95 (Period 2) _{n=35}	0.048	0.457	0.421	0.073
Apr 95 (Period 3) _{n=38}	0.049	0.448	0.421	0.082
Jul 95 (Period 4) _{n=41}	0.081	0.414	0.419	0.085
Oct 95 (Period 5) _{n=41}	0.099	0.412	0.401	0.089
Jan 96 (Period 6) _{n=44}	0.121	0.312	0.457	0.110
Apr 96 (Period 7) _{n=46}	0.119	0.222	0.528	0.134
Jul 96 (Period 8) _{n=46}	0.119	0.168	0.584	0.130
Oct 96 (Period 9) _{n=46}	0.128	0.147	0.609	0.117

Figure 4.1

HMGCoA Marketshare by Period



Criteria were established before the survey distribution to classify facilities as adopting the pravastatin recommendation (Chapter 3, pg. 21). Adoption is defined as a five percent increase in pravastatin marketshare for two consecutive periods following the PEC lipid review distribution. Facilities are compared by this criteria and by their response to the pravastatin adoption question on the survey (Q23). There were 46 facilities with data available. There were 31 facilities (67%) that responded yes to adopting pravastatin and met the marketshare change criteria. Two facilities (4%) responded yes to the survey question, but failed to meet the marketshare criteria. Five facilities (11%) responded no to the survey question but demonstrated adoption by meeting the marketshare criteria. The remaining eight facilities (17%) responded no to the pravastatin adoption question and did not meet the criteria. The adoption status described by the dispensing data appears to coincide with the survey responses for the majority (78%) of respondents.

The overall means of pravastatin marketshare are presented in Table 4.13. Calculation of the overall mean uses all available data for each period. The decision to not use estimates for missing data observations reduced the sample of useable surveys. Facilities with data in period one, October 1994, were the least available (n=23). We believed that deleting this period from the analysis would have little effect. By dropping period one, 35 complete surveys were available. Using observations from periods two through nine gives four data points on each side of the October 1995 distribution of the PEC lipid review and recommendations. This group of 35 facilities, with complete data

for periods two through nine, is considered as the reference group. Most of the analysis is presented on this sample.

Table 4.13
Pravastatin Marketshare Means

OBSERVATION ¹	ALL SURVEYS ² (all available data/period)
October 1994 (Period 1)	0.470 (n=23)
January 1995 (Period 2)	0.421 (n=35)
April 1995 (Period 3)	0.421 (n=38)
July 1995 (Period 4)	0.419 (n=41)
October 1995 (Period 5)	0.401 (n=41)
January 1996 (Period 6)	0.457 (n=44)
April 1996 (Period 7)	0.528 (n=46)
July 1996 (Period 8)	0.584 (n=46)
October 1996 (Period 9)	0.609 (n=46)

¹ a period is one month of HMGCoA prescriptions;
periods 1-5 are "before"; periods 6-9 are after

² the mean of pravastatin marketshare; n = surveys with complete data for the respective period

The group of 35 facilities shows changes over time that are similar to all other possible groups of facilities with complete data. Table 4.14 presents the mean pravastatin marketshare over time for each of these groups. Facilities are grouped based on having complete data for the observation periods reported. Sample size increases as each before distribution observation period is dropped. Figure 4.2 presents a plot of the mean pravastatin marketshare by period for each of the possible groups of complete surveys.

The graph demonstrates that Group 2 (n=35, periods 2-9) is similar to the other possible groups. Periods one through five are before PEC lipid review distribution and periods six through nine are after distribution. The trends, before and after, are very similar for each group. This supports the selection of Group 2 to represent the sample. Figure 4.3 presents the mean pravastatin marketshare for Group 2 only.

Table 4.14
Pravastatin Marketshare Means

OBSERVATION ¹	GROUP 1 ² (n=23)	GROUP 2 ² (n=35)	GROUP 3 ² (n=38)	GROUP 4 ² (n=40)	GROUP 5 ² (n=41)	GROUP 6 ² (n=46)
Oct 1994 (Per 1)	0.478	na ³	na	na	na	na
Jan 1995 (Per 2)	0.439	0.421	na	na	na	na
April 1995 (Per 3)	0.425	0.413	0.421	na	na	na
July 1995 (Per 4)	0.414	0.409	0.416	0.419	na	na
Oct 1995 (Per 5)	0.404	0.399	0.407	0.411	0.401	na
Jan 1996 (Per 6)	0.464	0.462	0.448	0.45	0.439	0.456
April 1996 (Per 7)	0.576	0.557	0.532	0.530	0.518	0.527
July 1996 (Per 8)	0.658	0.618	0.596	0.591	0.582	0.583
Oct 1996 (Per 9)	0.679	0.629	0.609	0.613	0.615	0.607

1 a period is one month of HMGCoA prescriptions; periods 1-5 are "before"; periods 6-9 are after

2 the mean of pravastatin marketshare for groups of surveys with complete data

3 this period not available for all surveys

Figure 4.2

Pravastatin Marketshare Mean by Period

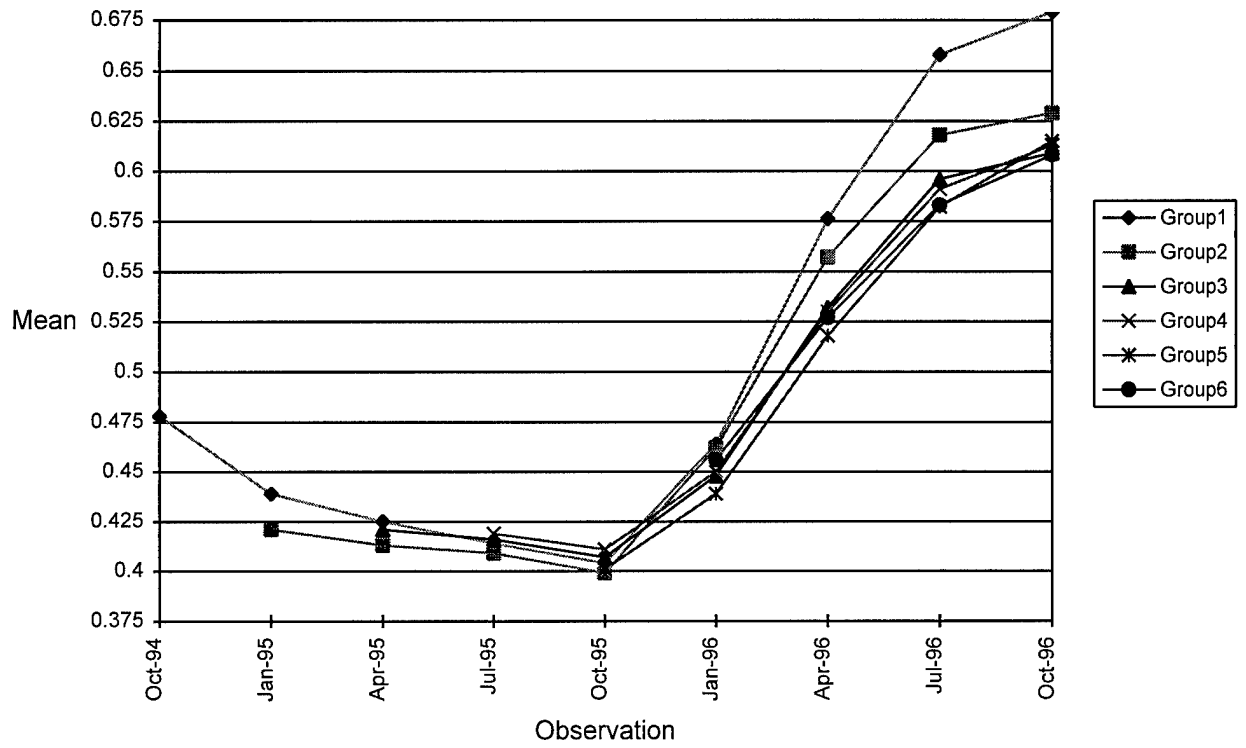


Figure 4.3

Pravastatin Marketshare - Group 2

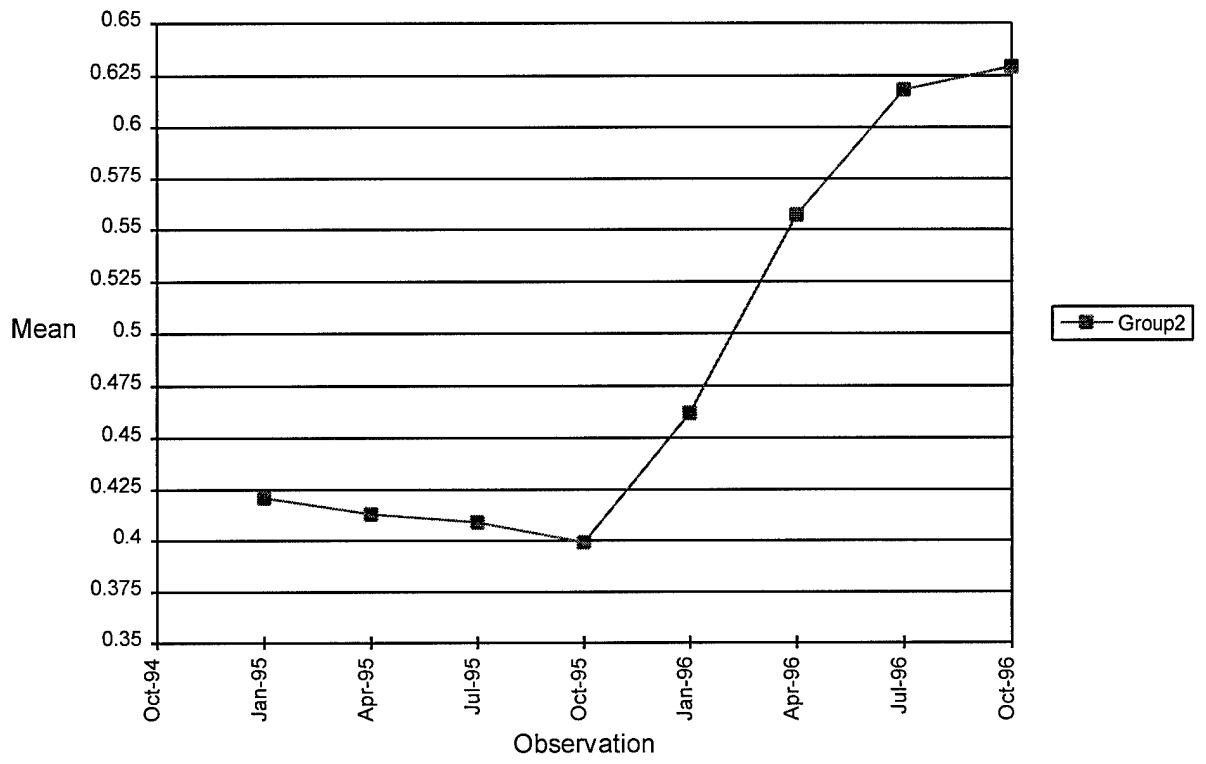
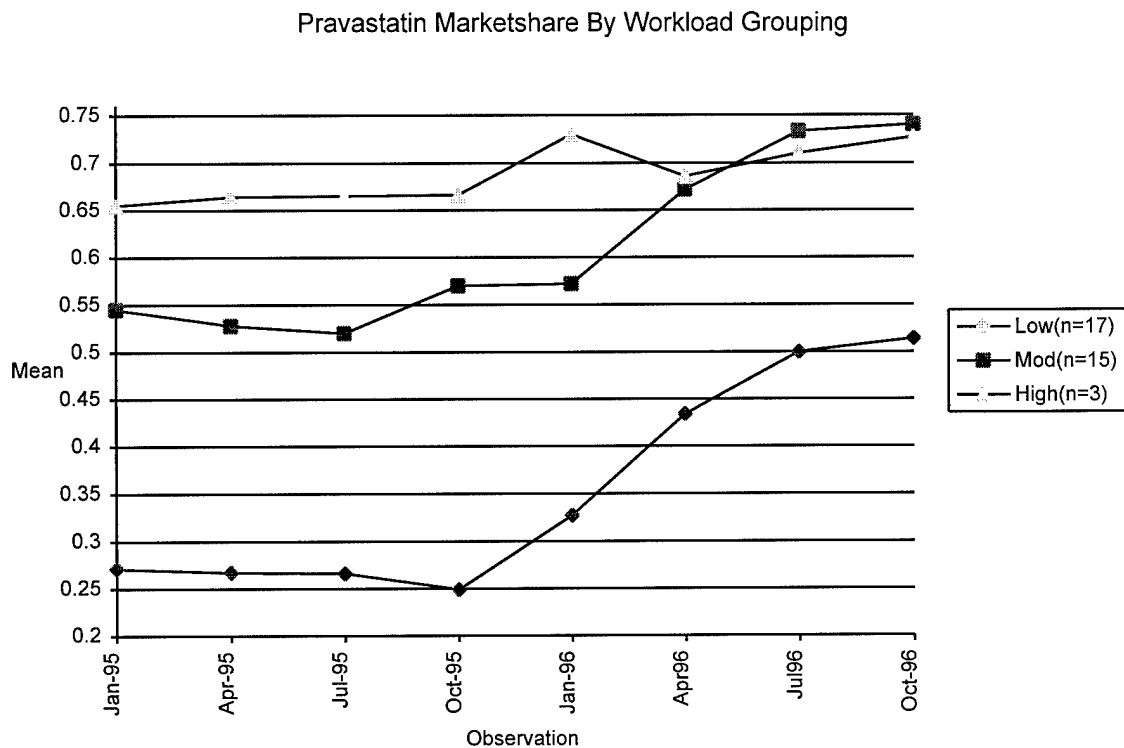


Figure 4.4 presents Group 2 (n=35) pravastatin marketshare means by workload grouping. The High workload group starts the observation period with a high marketshare and increases slightly. The other two groups are very similar in the change of marketshare over the study. However, the Moderate workload group starts higher than the Low workload group and stays about the same distance above that group throughout. The Low workload group finishes at about the marketshare where the Moderate group starts. The Moderate group has the highest mean pravastatin marketshare at the last observation (Oct 96) while the Low workload group has the highest incremental increase.

Figure 4.4



The standard deviation was relatively constant through the study period. It ranged from 0.47 at the first observation to 0.38 for the last (Periods 2-9 n=35). The change was a fairly smooth decline over the nine observations. However, the change is not enough to make any inferences about possible effects. Additionally, the quasi-experimental design would make it difficult for meaningful interpretation. This indicates there is a large amount of variation in the data. This would support that while a clear trend is taking place overall, each facility is retaining a degree of autonomy. The standard deviations were similar for the three workload groups.

Hypothesis Testing

Table 4.15 presents the results of statistical tests of hypotheses. F-tests using Pillai's Trace are reported.

H1: Pravastatin will have a greater marketshare of HMGCoA drugs in the period after distribution of the PEC lipid therapy review when compared to the period before distribution of the review.

The results support the hypothesis of a shift in marketshare toward pravastatin.

Table 4.15
Hypothesis Tests - Reference Sample

CONTRASTS OF MEANS ¹	F VALUES (Pr > F)
Change in Level	10.81 (0.002)
Change in Rate	14.14 (0.0006)

¹ means for periods 2-9; n=35

The level of pravastatin marketshare was significantly higher ($p < 0.002$) in the periods following distribution of the PEC lipid therapy review (periods 6-9) compared to before distribution (periods 2-5). This is tested with the first contrast which is comparable to a t-test comparing an overall mean marketshare before and overall mean marketshare after the PEC review distribution. The second contrast looks at the rate of change in pravastatin marketshare in the before versus the after periods. The comparison indicates a significantly ($p < 0.0006$) different rate of change in pravastatin marketshare in the two periods. As illustrated by Figure 4.3, there was a negligible rate of change in marketshare during the before the PEC review distribution periods that became a strong rate of increasing marketshare following distribution.

H2: Facilities rating the PEC lipid therapy review and recommendations as “useful” will have a larger increase in pravastatin marketshare than facilities with “neutral” or “not useful” ratings.

The group rating the PEC review as “useful” had a significantly higher pravastatin marketshare ($p < 0.008$) level following distribution than the group rating the review as “non-useful”. This supports the hypothesis.

Table 4.16 presents the pravastatin marketshare means for the two groups. Facilities were classified by taking the average of the PEC lipid therapy review rating (Question 22) and the rating of the PEC lipid review influence on formulary selection (Question 25a). A two question average of greater than 3.4 classified the facility as giving the lipid review a “useful” rating. Twenty-two facilities met the criteria while thirteen did not ($n=35$). The marketshare means for the “useful” rating group changed from a stable level before PEC review distribution to a strongly increasing level in the after distribution periods (Figure 4.5). The “non-useful” rating group changed from a decreasing marketshare, to an increasing marketshare before returning to a decreasing marketshare over time.

Table 4.16
Pravastatin Marketshare By Lipid Rating

OBSERVATION	LIPID REVIEW "Useful" (n=22)	RATING Non-Useful (n=13)
Jan 95 (Per 2)	0.364	0.518
April 95 (Per 3)	0.368	0.490
July 95 (Per 4)	0.373	0.470
Oct 95 (Per 5)	0.370	0.448
Jan 96 (Per 6)	0.431	0.515
April 96 (Per 7)	0.557	0.558
July 96 (Per 8)	0.657	0.551
Oct 96 (Per 9)	0.706	0.499

Figure 4.5

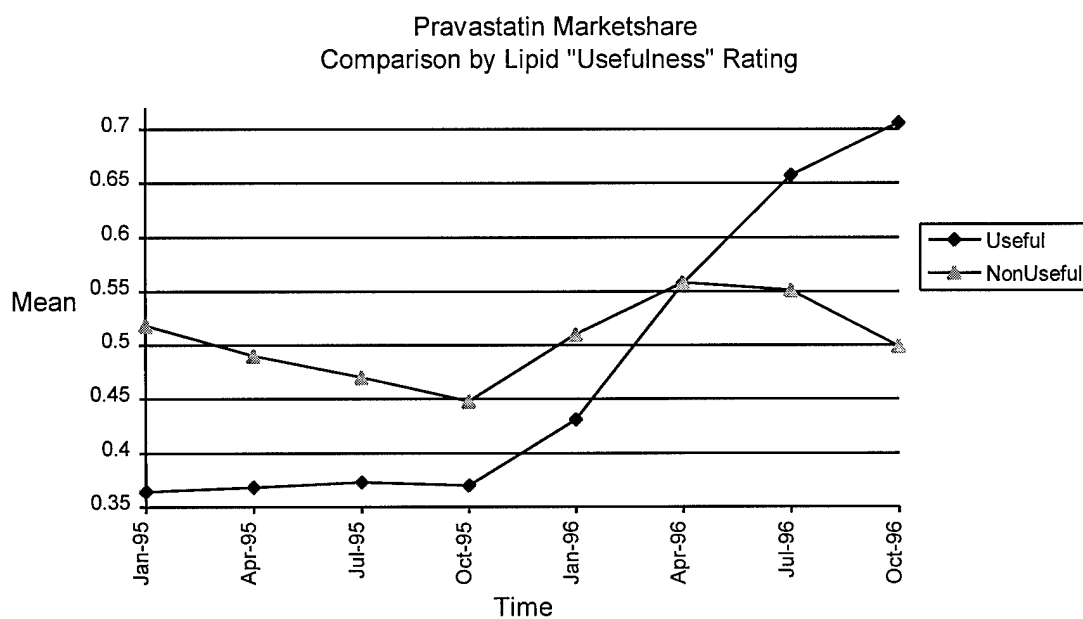


Table 4.17
Hypothesis Tests - Lipid Review "Useful" Rating

COMPARISON OF MEANS	F VALUES
Overall Change in Level	7.95 (p<0.008)
Change in Rate	3.52 (p=0.069)
Jan 1995-Apr 1995 (Per 2-3)	3.42 (p=0.074)
Jul 1995-Oct 1995 (Per 4-5)	0.016 (p=0.90)
Oct 1995-Jan1996 (Per5-6)	2.55 (p=0.11)
Jul 1996-Oct 1996 (Per 8-9)	7.02 (p<0.012)

1 pravastatin marketshare means for period 2-9;n=35

2 "useful" composite rating for lipid review (>3.4)n=22

3 "non-useful" composite rating for lipid review n=13

There was a significant difference ($p<0.008$) in pravastatin marketshare between groups of facilities classified by their rating of the PEC lipid therapy review. The comparison of means (Table 4.17) presents the overall effect of "useful" versus "non-useful" rating of the review and the effect for selected periods. The selected period comparisons indicate the fluctuation that occurred in the "non-useful" rating group when compared with the "useful" rating group.

The two groups, based on pravastatin marketshare means, were somewhat different, although not statistically different ($p=0.074$), during the before observation periods. The

“non-useful” rating group marketshare level was declining toward the “useful” rating group marketshare level (Figure 4.5). At the time of distribution, the marketshare levels were very similar ($p=0.90$). In the initial period following distribution of the PEC review, the observed change in pravastatin marketshare was not significantly different between the two groups (periods 5-6; $p=0.11$). They both began to increase. This can be described as a period of evaluation and trial of the PEC review consistent with the innovation decision process. The change in pravastatin marketshare for the two groups clearly changed during observation periods seven through nine with a statistically different marketshare level in the last period ($p<0.012$). The change over time depicted in Figure 4.5 and the statistical significance describe a very different change over time of dispensing patterns for the two groups.

CHAPTER FIVE

Discussion

This chapter presents a discussion of the results and limitations as they relate to the research questions. It also addresses issues related to the design and other findings observed during data analysis.

Not having a control group or randomization weakens the design. The multitude of potentially influential factors outside of the observed variables also weakens any conclusions. Diversity of personnel, changes in personnel, pharmaceutical sales representatives, effectiveness of local P&T process, and budget constraints name only a few external factors. However, a rigorous quasi-experimental design enables some control over these factors where possible. Personnel, for example, tend to change during the summer in military facilities. The survey was conducted in January and most likely represents a relatively stable period. Using multiple data points and evaluating trends in the data over time help account for unique, uncontrolled factors and strengthen the design.

A potential source of bias is from respondents providing the expected “correct”

answer. This would bias the results toward finding adoption. Efforts were made to reduce this possibility. The cover letter stressed that this was not part of any official evaluation. We stated that facility specific information would not be used unless first obtaining permission from the respondent. This was also stressed by Colonel Young in his letter that accompanied the survey. While there were two survey responses indicating adoption that were not supported with the dispensing data, the variance in the responses and the candid comments included on some surveys support that this type of bias was not a problem.

There is good distribution throughout the United States. This reduces the possibility of regional practice patterns or geographic differences in patient populations disproportionately affecting the results. A comparison of results by geographic region indicated similar patterns throughout the sample. Additionally, no particular pattern of geographic location or facility size is apparent in non-respondents.

External validity and generalizability were not primary concerns in selecting the population. The Air Force only population was selected to allow the assumption of a consistent administrative structure and similar formulary system characteristics between facilities. Adding Army, Navy, or civilian facilities, while improving external validity, would negate this assumption and increase nuisance variables. Anecdotally, relative to health care policy, the Air Force has the least centralized structure of the three services. Therefore, response from Air Force facilities is likely to have the most facility variation

and any observed change be more representative of adoption decisions than action on a policy directive. Our finding of adoption in the Air Force population is likely be similar for the Army and Navy. However, results are not intended to be generalized beyond Air Force facilities.

Anecdotal evidence indicates that historically, there may be some seasonal change in expenditure patterns due to the budget cycle in many military facilities. This is a potential source of variation in the HMGCoA data. The fiscal year and budget cycle begins in October for all facilities. Some facilities tend to buy when money is available and sometimes reduce purchases and curtail dispensing as the fiscal year closes if money is running short. Changes such as Prime Vendor and automation have reduced these variations in recent years. Using dispensed prescriptions rather than purchases minimizes the potential of budget cycle variation to have an influence on results. Additionally, data collection covers two budget cycles and is therefore less susceptible to events in a particular year. The increase in the pravastatin marketshare was sustained throughout the year after the PEC recommendation distribution. There did not appear to be a budget cycle effect.

The high turnover of pharmacy directors raise the issue of the relationship of the survey and the dispensing data. The survey was completed by the current director while formulary policy reflected by the dispensing data may have been under a different director. The reported average time in the current position was 2.11 years. Of the

respondents, 21 (43%) were in their current position on December 1994. This is based on the survey mailing date and the directors response to the time on station question (Q1c). When the January 1995 through October 1996 sample (n=35) is divided based on pharmacy directors that were and were not in that position as of December 1994, pravastatin marketshare results are not different between the two groups ($p < 0.18$). While the role of chance in finding a difference or not in the two groups cannot be ruled out, the data appears to support a conclusion of no difference.

Use of the TriService Formulary (TSF) is a directive from the Department of Defense. It is not possible to separate the effect of this policy and the effect of PEC adoption. The data, however, describe that the PEC has an informational role beyond being an instrument of policy. There is high correlation of responses to questions rating usefulness and value of the PEC published work. Additionally, on average, the PEC was rated as significant or very significant as a resource when compared to other resources used by 57% of pharmacy directors. The variation found in dispensing patterns and opinion support that decisions are being made on information versus implementation of only a directive. We believe this supports a strong influence of adoption when compared to the influence of policy.

The relationship of dispensing trends and adoption of PEC publications is only descriptive. Full adoption of the PEC as an information resource may occur with no change in dispensing pattern or vice versa. Several of the many plausible alternative

explanations why a change in dispensing pattern occurred have been discussed.

However, the selected time frame, using multiple measures before and after to compare dispensing trends, and the opinion of decision makers and data showing use of PEC materials are a description of adoption and strengthen the relationship.

The results of testing the difference between groups rating the PEC lipid recommendation as “useful” or “non-useful” further strengthen the adoption-marketshare relationship (Figure 4.5). This comparison demonstrates the innovation decision process. The steps of evaluation and trial before an adoption decision is made are illustrated by the response over time of the two groups. The rate and direction of change in marketshare was almost identical for both groups in the first time period after PEC review distribution (Figure 4.5; period 5-6). This marks evaluation and trial of this specific recommendation. The adopting, or “useful” rating group, continued marketshare growth while the “non-useful” rating group reversed to a declining marketshare. The “non-useful” rating group make a non-adoption decision following trial of the PEC recommendation. As previously discussed, there are other factors that are contributing to these changes. However, the repeated measures over time show a pattern consistent with a trial period followed by a decision.

The passage of time and other events in formulary decision making, specifically lipid therapy, are recognized threats to any conclusions. It is plausible that time and external factors (e.g. other literature or information sources, etc.) may explain as much

behavior change than possible adoption of the PEC. However, the literature does not contain any influential papers during this period that would motivate similar behavior as that observed in this study. The Expert Panel of Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults issued in 1993 was the most significant published event regarding this class of drugs around this time.⁽¹⁾ This report did not, however, make specific product recommendations. It dealt with therapy approaches given certain patient characteristics and overall therapy objectives for lowering blood cholesterol. The report may have influenced use of HMGCoA as a class or dosing, but it is unlikely to have affected drug product selection to the extent observed in the data. Additionally, in the time between the report and the start of this study, any influence is likely to have stabilized.

All drug products have been on the market for at least two years before the October 1994 start date. There were price fluctuations for all four drug products during the study period. These changes are assumed to be in response to the PEC review. However, the net result of price changes during the period kept approximately the same relationship between the products.

The selection of pravastatin has been previously discussed. Using only one therapeutic category limits any generalization to other classes. We felt it was more important to control internal validity than attempting to generalize to all therapeutic categories. Pravastatin was selected as an example of a specific recommendation to

either support or raise questions regarding the description of PEC adoption from the survey responses. The overall question of interest is evaluating the use and perceived value of PEC materials, not whether each recommended drug is in use. The PEC recommendation was the only significant occurrence regarding HMGCoA product selection during this period.

While some variation was considered likely, the dramatic difference in the beginning level of pravastatin marketshare by pharmacy workload groups was not expected. One explanation is that High and, to a lesser extent, Moderate workload facilities had already recognized pravastatin as an optimal choice. This would demonstrate Rucker's description of the information needs of formulary systems.⁽²⁾ The High workload facilities have the largest number, most experienced, and academically senior staff according to responses. They are also likely to have resources available to devote to a more rigorous review of a therapeutic class before they make a decision on product selection. Relatively similar staff distinctions can be made between Moderate and Low workload groups.

All workload groups, on average, had an increase in pravastatin marketshare following the PEC recommendation publication ($p < 0.002$). This indicates the PEC also likely influenced facilities that already had pravastatin as a drug of choice. The largest change occurred in the Low and Moderate workload groups. This perhaps indicates a large influence of the PEC resources relative to other resources available to the P&T

committee at these facilities. This is also reflected in the “usefulness” rating of the lipid review. The average scores were 3.5, 3.9, and 3.0 by the Low, Moderate, and High workload groups respectively (1=not useful; 5=very useful). The overall average of pravastatin marketshare for all facilities was over 61% at the end of the study period compared with 15% for lovastatin, 13% for fluvastatin, and 12% for simvastatin. Pravastatin began the study with a 47% marketshare.

The marketshare change criteria was developed as a way to classify facilities. It was based on the assumption that a change of five percent in consecutive time periods would represent a policy change rather than external influences. The results indicate this was an accurate method to describe facilities. It matched well with survey question responses and the prescription data in describing a facilities action on pravastatin. However, this is not tested or proposed as a predictive measure beyond its use in this study.

The ratio of facilities reporting an increase in pharmacy inventory to those reporting a decrease in pharmacy inventory was similar between groups classified as adopters or non-adopters by the pravastatin marketshare criteria . Of the 46 facilities with pravastatin data, 36 were classified as adopters and ten as non-adopters based on the marketshare change criteria. Of the adopters, 28 (78% n=36) reported an inventory increase and 8 (22% n=36) reported an inventory decrease. Eight (80% n=10) of the ten non-adopters reported an inventory increase and 2 (20% n=10) a decrease. When inventory change

was grouped by the “usefulness” score calculated for hypothesis testing (H2), the results between groups were similar. This appears to indicate that an increase in inventory may not be related to adoption of PEC recommendations. However, without randomization, chance and multiple other factors cannot be eliminated. The data do not support a conclusion, but identify an area that needs more study.

The trends from prescription data were overall well matched with survey response. Facilities that rated the PEC high were also high in use of pravastatin at the end of the study. It should be noted, however, that there were a number of facilities with high pravastatin marketshare at the beginning of the study. This number was higher than expected. All but three of these facilities remained high at the end of the study. These three also reported not adopting pravastatin and on average, rated the PEC influence as low. This adds support to the link of the survey and prescription data in describing adoption.

REFERENCES

1. "Expert Panel of Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," Journal of the American Medical Association , 269 (1993):3015-23.
2. Rucker, TD. "Effective Formulary Development- Which Direction?," Topics Hospital Pharm Management, 1 (1981):29-45.

CHAPTER SIX

Conclusion

Air Force medical treatment facilities have, on average, adopted the Pharmacoeconomic Center as an information resource. This is supported by the pattern of acceptance and use described by respondents. Our results do not provide a definitive test of “adoption”. However, the data indicate that a majority of facilities are actively using the PEC materials. A significant shift toward the use of a PEC recommended drug, pravastatin, that coincides with distribution of that recommendation further supports a picture of adoption.

The innovation decision process is illustrated with the change in marketshare over time. There was an evaluation and trial period following the distribution of the PEC lipid therapy review that preceded an adoption decision by facilities. During this trial period, on average, all facilities had an increasing pravastatin marketshare. After this trial period, two groups emerged. Those rating the lipid review as “useful” had a continued increase in pravastatin marketshare while the “non-useful” rating group reversed to a decreasing marketshare. This describes that the PEC is considered as a resource by this

population, but that adoption decisions are made on the specific recommendations made by the PEC.

Pharmacy directors' responses indicate an overall favorable opinion of the PEC. The majority of directors are routinely reading the "PEC Update" and circulating it to their local P&T committee. PEC therapeutic reviews are having a significant to very significant influence on local formulary selections according to 67% of respondents. On average, pharmacy directors reported that 90% of the TriService Formulary listed products had been adopted. This describes the majority of facilities making full use of the PEC as an information resource, which defines adoption.

A clear change in dispensing patterns for the four HMGC_oA drugs occurred during the study period. This class of drugs was selected to test the actual response to a PEC formulary recommendation. Pravastatin, the PEC drug of choice for this class, significantly increased in marketshare ($p < 0.002$) following the PEC recommendation relative to the period before distribution of the PEC recommendation. The dispensing data collected show an essentially flat trend in pravastatin marketshare during the year prior to the publication of the PEC lipid therapy review. This changed to a significantly upward trend ($p < 0.002$) in the period after publication. The results support that, on average, facilities are putting the PEC HMGC_oA recommendation into practice.

The results indicate that local formulary systems are adapting recommendations to local needs. There is a good deal of variation in the pravastatin marketshare between facilities. The survey responses and this variance indicate that the PEC materials are an additional, but not the only, resource used by local formulary systems. The data support that the PEC has added additional information, but has not replaced local decision making. This could also demonstrate that the local formulary system, anchored by the P&T committee, remains in the best position to respond to local patient needs. The strong trend of increased pravastatin use coupled with the reported significance of the PEC influence indicate, for this therapeutic class, that the PEC provided useful input to the decision process.

Future Research

The next logical step is to move the evaluation of PEC reviews and therapy guidelines to the patient level. The PEC treatment guidelines and drug of choice recommendations should represent optimal efficiency and patient outcome when put into practice. As noted earlier, there is a good deal of variation of pravastatin use between facilities even though the upward trend is significant. An important question would be to evaluate patient outcomes and resource consumption when recommended guidelines are followed and not followed at the patient level.

The relation of formulary selection and prescribing patterns need further study. Pharmacy directors indicated that the PEC was having the least significant effect on

prescribing patterns, but having a relatively more significant effect on formulary selection. Is the PEC having an effect on provider behavior outside of formulary selection and what does this mean to optimal patient outcome? This could indicate an opportunity for development by the PEC of educational materials for use at the local level. Additionally, what effect will PEC recommendations have when market conditions change such as price reductions and the introduction of new products in a therapeutic class? The use and effects of treatment guidelines beyond drug selection should be evaluated.

The relatively low use of PEC materials in local newsletters is a similar issue. Recognizing that the PEC information may be distributed by other methods, the local newsletter is the formulary system communication link. This may be a missed opportunity that should be considered by the PEC. The PEC should explore ways to encourage distribution of their findings to all participants in the local system. The effect on prescribing, costs, and patient outcome of any new services should be measured.

The results indicated a facility had an average of 1.6 HMGC_oA drug product inventory line items in October 1994 and 2.3 in October 1996. A line item count by product strength was not collected. Additionally, 44% of respondents reported that pharmacy inventory increased in 1996 compared with 1995. There are a number of explanations for this slight increase. Without randomization, a chance occurrence cannot be ruled out. New drug approvals are also a possibility. Expanding the number of

strengths or packages sizes could also explain the change. Using the pravastatin example, this could be an elevation due to a phased change from one drug to another as the drug of choice. This change would be expected to reverse over time. The question of whether the PEC is putting facilities in a position to add more inventory line items than they would otherwise carry should be explored.

The PEC is using an aggressive evaluation system to develop treatment guidelines and drug recommendations for the major disease states. Air Force pharmacy directors opinion of the PEC as a resource and demonstrated action on one particular PEC recommendation indicate a good level of acceptance for their work. We believe these results describe adoption. Further study should explore ways for the PEC to improve communication and enhance its adoption as a resource by local formulary systems, and assess patient outcome effects.

APPENDIX



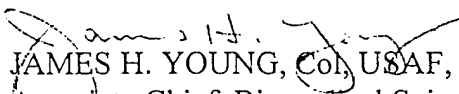
DEPARTMENT OF THE AIR FORCE
HEADQUARTERS 89TH AIRLIFT WING (AMC)

MEMORANDUM FOR AIR FORCE PHARMACY DIRECTORS

SUBJECT: Participation In A Research Project

FROM: James H. Young, Col, USAF, BSC
Associate Chief, Biomedical Sciences Corps for Pharmacy

1. The attached surveys request data on the characteristics of your MTF and on Jones lipid-lowering drug dispensing. This data is being requested by Capt George for use in meeting the degree requirements assess of the AFIT Master's program. The results may also provide useful information to and improve the Air Force benefit from the Pharmacoeconomic Center (PEC). I encourage you to participate.
2. This is not an evaluation of your compliance of PEC recommendations. This is not for any type of official review or action. Please respond completely and accurately.
3. Thank you in advance for your prompt cooperation.


JAMES H. YOUNG, Col, USAF, BSC
Associate Chief, Biomedical Sciences Corps for Pharmacy

Research Project Summary

***Adoption of the Pharmacoeconomic Center As A
Resource By Air Force Medical Treatment Facilities***

Capt George E. Jones, Jr.*

The Pharmacoeconomic Center (PEC) was developed by DoD in 1993. The PEC uses a monthly publication, "PEC Update", to communicate with DoD Medical Treatment Facilities (MTF). The PEC has established and updated a TriService Formulary (TSF) and published several therapeutic category reviews in the "PEC Update". The PEC is a new source of information and specific drug selection and use guidance for DoD facilities.

This project will look at adoption of the PEC as an information source by Air Force MTFs. The PEC lipid therapy review, "Management of Hyperlipidemia" ("PEC Update" 96-01) will be used as a sample set of recommendations. Specifically, the selection of pravastatin as the HMGCoA of choice.

There are two parts to this project -

PART ONE - A survey to be completed by the Pharmacy Department Chairperson

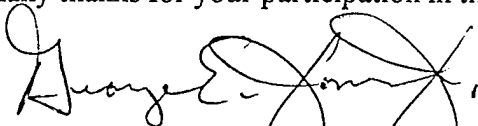
PART TWO - Dispensing information for HMGCoA drugs.

There are directions for each part of the project. The survey will take about 10-15 minutes. The dispensing information requires retrieving data from CHCS.

The results should describe Air Force opinion and use of the PEC. It will also assess adoption of the lipid therapy recommendations. Hopefully, the results will identify opportunities to improve the benefit from PEC resources for MTFs.

Please complete and return by 24 Feb 1997. Use the return envelope or FAX (803-777-2820) the (a) Survey and (b) Dispensing Data.

Many thanks for your participation in this project!



George E. Jones, Jr., CAPT, USAF, BSC

*This project is in partial fulfillment of the requirements for the Degree of Master of Science in the College of Pharmacy, University of South Carolina.

SURVEY DIRECTIONS

TIME: It should take approximately 10-15 minutes to complete this survey.

WHO SHOULD COMPLETE: This survey should be completed by the **Pharmacy Department Chairperson**. Questions are asking for your opinion or estimate based on your experience.

HOW TO COMPLETE:

1. Select only 1 answer unless otherwise stated.
2. Please give your best estimate for Rx volumes, percentages, and frequency questions.
3. Scaled question example: (circle only one response)

What best describes the influence of "Pharmacy Journal X" on your decisions?

Not Significant					Very Significant
	1	2	3	④	5

4. Questions may be discussed with other pharmacy staff. For example, if another staff member meets with the P&T or works directly with inventory.
6. Please contact Capt George Jones if clarification is needed.

E-Mail: jonesg@phar2.pharm.sc.edu Voice: 803-777-7838 Fax: 803-777-2820

NAME AND FACILITY:

I am requesting the name of the facility and the person completing the survey. This is for **follow-up** and **feedback** only. A summary of results will be provided to you at the conclusion of the project. Nothing submitted for publication or presentation will include facility or pharmacist reference without the permission of the Respondent.

Thank you for your participation in this research project!

STAFF INFORMATION

USAF SCN 96-99

1. Please indicate your pharmacy background (Department Chairperson):

a) The following Academic Degree(s) (check all that apply):

BS Pharm PharmD MS
 MBA MA PhD Other _____

b) Total (military and civilian) years as a pharmacist :

 ___ years (round to nearest year)

c) Time on station at this facility: ___ years ___ months

2. Please enter the number of persons at each degree level for your staff, military and civilian. (include yourself)

___ BS Pharm
___ PharmD
___ BS Pharm and PharmD
___ BS Pharm and Masters
___ PharmD and Masters
___ BS Pharm and PharmD and Masters
___ Other (list degrees) _____

PHARMACY OPERATIONS

3. Average number of outpatient prescriptions filled per month during FY 95 _____.

4. Average number of outpatient prescriptions filled per month during FY 96 _____.

5. Approximate breakdown of outpatient prescriptions over past 12 months:

a) ___% from **in house** (military or contract providers)

b) ___% from **external** providers (should total to 100%)

6. *What best describes the overall change in the number of pharmacy line items stocked comparing Fiscal Year 95 with Fiscal Year 96?*

- INcreased
- DEcreased
- No Change Other _____

7. *What best describes the overall change in pharmacy expenditures comparing Fiscal Year 95 with Fiscal Year 96?*

- INcreased
- DEcreased
- No Change Other _____

FACILITY INFORMATION

8. *Please check all provider specialties, military or contract, that are available at your facility:*

- Primary Care
- Internal Medicine
- Family Practice
- Cardiology
- Gastroenterology
- Other (check if more specialties - OB, Pediatrics, etc)

9. *Check all training programs with students, interns, and/or residents at this MTF:*

- None Physician
- Physician Assistant Nurse
- Pharmacist Other _____

13. On average, how much time passes between you receiving and reading an issue of the "PEC Update" :

- < 1 week
- 1-4 weeks
- 5 or more weeks
- not read

14. As an information resource, the "PEC Update" is best described as:

<u>Not Useful</u>				<u>Very Useful</u>		<u>OR</u>	<u>Do not read</u>
1	2	3	4	5			0

15. PEC therapeutic class reviews and recommendations are routinely circulated, by you or other pharmacy staff, when received to:

(select all that apply)

- Pharmacy Staff
- P&T Committee
- Department Chairs
- All Providers
- Not Circulated Other _____

16. Your overall opinion of the Pharmacoeconomic Center is best described as:

<u>Very UNfavorable</u>				<u>Very FAavorable</u>		<u>OR</u>	<u>No Opinion</u>
1	2	3	4	5			0

P&T ACTIVITIES

17. *What percentage best describes adoption of the TriService Formulary at your facility?*

NOTE: "100% adoption" of the TriService Formulary (TSF) is defined as having a TSF selection account for the majority of dispensing for each therapeutic class represented on the TSF.

____% adoption of TSF

18. *Please rate the role of PEC therapeutic class reviews and recommendations relative to other information sources used for P&T consideration of drug therapy issues:*

Not Significant					Very Significant	OR	Not Used
1	2	3	4	5			0

19. *What best describes the influence the PEC has had at this MTF on:*

Item	Not Significant					Very Significant				
a) Formulary selections	1	2	3	4	5					
b) Local P&T newsletter	1	2	3	4	5					
c) Pharmacy budget	1	2	3	4	5					
d) Prescribing patterns	1	2	3	4	5					
e) Pharmacy inventory	1	2	3	4	5					

20. *Approximately ____ out of the last 12 issues of your local P&T newsletter have had quotes and/or articles taken from an issue of "PEC Update"?*

(circle a number to fill the blank)

0 1 2 3 4 5 6 7 8 9 10 11 12

25. What best describes the influence the PEC lipid therapy review and formulary recommendations have had at this MTF on:

Item	Not Significant			Very Significant	
a) Lipid formulary selections	1	2	3	4	5
b) Lipid prescribing patterns	1	2	3	4	5
c) Lipid therapy costs	1	2	3	4	5

26. In the last 12 months, all or part of the PEC "Management of Hyperlipidemia" ("PEC Update" 96-01) was circulated to-
(check all that apply)

- Pharmacy staff
- P&T Committee
- Department Chairs
- All providers
- Not circulated
- Other _____

Facility: _____ Date: _____

Completed by: _____

Thank You For Your Time!

Please complete the HMGCoA Dispensing Data.

Use the envelope provided to return the survey **OR FAX** to 803-777-2820

RETURN BY 24 FEB 97 - 1) The survey 2) The Dispensing Data Sheet

LIPID DISPENSING DATA

Please use CHCS to complete the table. Use the following guidelines:

1. The data needed is the number of prescriptions, new and refill, dispensed during the requested time period for each HMGCoA listed.
2. Please put zeros if product was not used during the period.
3. Please place an X if you cannot retrieve the data.
4. If you carry more than one strength, combine the number of prescriptions for each strength into a single total.
5. Please do not submit any patient specific information.

Example:

↓ No DATA
↓ Not stocked

	Oct 1-31 94	Jan 1-31 95	Apr 1-30 95	Jul 1-31 95	Oct 1-31 95
Pickastatin	X	○	1,230	1,400	1,650

	Oct 1-31 94	Jan 1-31 95	Apr 1-30 95	Jul 1-31 95	Oct 1-31 95
Fluvastatin					
Lovastatin					
Pravastatin					
Simvastatin					

	Jan 1-31 96	Apr 1-30 96	Jul 1-31 96	Oct 1-31 96
Fluvastatin				
Lovastatin				
Pravastatin				
Simvastatin				

SELECTED BIBLIOGRAPHY

1. "ACP Program Update: Data Reporting," PEC Update, 96(10) (July 1996): 3.
2. Browning, WC et al. "Diffusion of innovation: Computer technology in hospital pharmacy," American Journal of Hospital Pharmacy, 41(11) (1984): 2343-2347.
3. Churchill, G. Marketing Research. New York: CBS College Publishing, 1987.
4. Cook TD and Campbell DT. Quasi-Experimentation. Boston: Houghton Mifflin Company, 1979.
5. Dillman, DA. Mail and Telephone Surveys: The Total Design Method. New York: Wiley, 1978.
6. Eng, HJ and Lairson, DR. "Prescribed Medicines: Expenditure and Usage Patterns for Selected Demographic Characteristics," Journal of Pharmaceutical Marketing & Management, 3(2) (1988):19-36.
7. Green JA et al. "Evaluating A Restrictive Formulary System By Assessing Nonformulary-drug Requests," AJHP, 42(7) (1985):1537-41.
8. Heiligenstein, JH. "Reformulating Our Formularies to Reflect Real-World Outcomes," Drug Benefit Trends, 8(8) (1996):34,42.
9. Horn, SD et al. "Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," American Journal of Managed Care, 2(3) (1996):253-64.
10. Johnson, JA and Bootman, JL. "Pharmacoeconomic Analysis in Formulary Decisions: An International Perspective," American Journal of Hospital Pharmacy 51(21) (1994):2593-98.
11. Joseph, SC. "Memorandum for Assistant Secretaries of the Army, Navy, and Air Force - Subject TriService Formulary," Washington, DC: November 10, 1993.
12. Kerlinger, FN. Foundations of Behavioral Research. Orlando, FL: Holt, Rinehart and Winston, Inc., 1986.
13. Kirk RE. Experimental Design: Procedures for the Behavioral Sciences. Pacific Grove: Brooks Cole Publishing Company, 1995.

14. Kotler, P and Armstrong G. Marketing: An Introduction. Englewood Cliffs, NJ: Prentice-Hall, Inc., 1987.
15. Kozma, CM. "Evaluation of An Expansion of Coverage in the South Carolina Medicaid Drug formulary," Dissertation. University of South Carolina, 1988.
16. Kozma, CM. "Expanding Medicaid Drug Formulary Coverage; Effects on Utilization of Related Services," Medical Care, 28(10) (1990);476-8.
17. Lingle, EW et al. "Impact of an Open Formulary System on the Utilization of Medical Services," Journal of Research in Pharmaceutical Economics, 2(3) (1990);93-123.
18. Lyon, RA. "Formulary-control Procedures In A Staff-model Health Maintenance Organization," American Journal of Hospital Pharmacy, 47(2) (1990);340-2.
19. "Management of Hyperlipidemia" PEC Update, 96(1) (October 1995):1-19.
20. Motheral, B. "Factors Influencing Utilization and Costs In a Pharmacy Benefit Program," Drug Benefit Trends , 8(10) (1996):10-12,15-18,34.
21. Operational Proponent for Department of Defense Pharmacy and Pharmacoeconomic Center (PEC) Charter. Department of Defense, Health Affairs, DOD Directive 55136.1, Washington, DC: August 29, 1995 revision.
22. Pearce MJ et al. "A Review of Limited Lists and Formularies," PharmacoEconomics 1(3) (1992):191-202.
23. "PEC Updates" Pharmacoeconomic Center Home Page.
<http://www.ha.osd.mil/hppecc2.html>. September 1996.
24. Pollard, MR and Coster, JM. "Update: Legislation - Savings For Medicaid Drug Spending," Health Affairs , Summer (1991):196-206.
25. Potyk, R. et al. "Pharmacoeconomics in the Military Health Services System," Federal Practitioner , (December, 1994): 10-21.
26. Potyk, R et al. "Initial triservice formulary ready for use," American Journal of Hospital Pharmacists , 51 (Mar 1,1994): 588,591.
27. Rifenburg, RP et al. "Benchmark analysis of strategies hospital use to control antimicrobial expenditures," American Journal of Health-System Pharmacists , 53(9) (1996): 2054-62.

28. Rogers, EM. Communication of Innovations. New York: The Free Press, 1971.
29. Romano, CA. "Diffusion of technology innovation," Advances In Nursing Science 13(2) (1990):11-21.
30. Rucker, TD et al. "Drug Formularies: Myths In Formation," Medical Care , 28(10) (1990): 928-37.
31. Rucker, TD. "Effective Formulary Development- Which Direction?," Topics Hospital Pharm Management , 1 (1981):29-45.
32. Rucker, TD. "Superior Hospital Formularies: A Critical Analysis," Hospital Pharmacy , 17(9) (1982):465-524.
33. SAS/STAT Users Guide. Version 6, Fourth Edition Volume 2. Cary, NC: SAS Institute, Inc., (1989): 891-957.
34. Schrogie JJ et al. "Relationship Between Practice Guidelines, Formulary Management, and Pharmacoeconomic Studies," Topics Hospital Pharm Management , 13(4) (1994):38-46.
35. Sloan, FA et al. "Hospital Drug Formularies and Use of Hospital Services," Medical Care, 31(10) (1993):851-67.
36. Talley, CR. "Medication Formularies in Integrated Systems," AJHSP , 53 (3) (Feb 1996): 261.
37. Thielke, TS. "Evaluating The Economic Impact of Formulary Decisions," American Journal of Hospital Pharmacy, 46(3) (1989):476-8.
38. "TriService Formulary and Preferred Drug List Development," PEC Update 94(3) (January 1994): 1-2.
39. "TriService Formulary - Revision One," PEC Update , 94(9) (July 1994):1-17.
40. Wade, WE, et al. "The Expanding Role of Pharmacy and Therapeutics Committees," PharmacoEconomics, 10(2) (Aug 1996): 123-28.
41. Walser, BL et al. "Do Open Formularies Increase Access To Clinically Useful Drugs?," Health Affairs 15(3) (Fall 1996): 95-108.
42. Zellmer, WA. "Opportunity for pharmacy leadership in integrated health care systems," American Journal of Health-System Pharmacists , 53(supplement 1) (1996): S3-4.