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PHARMACEUTICAL CARE IN A COMMUNITY-BASED SETTING: A PILOT STUDY OF THE ECONOMIC, CLINICAL AND HEALTH-RELATED QUALITY OF LIFE OUTCOMES

by

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A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of

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To Mom-
who rarely allows circumstance to be an excuse for missed opportunity

To my husband Ron and children Rochelle & Joel-
for bringing meaning and joy to my life; no matter what the circumstance

ABSTRACT

This pilot study used a randomized control design to evaluate the impact of pharmaceutical care on 30 patients in a community pharmacy. Specific study objectives included: (1) providing pharmaceutical care to community dwelling residents who were at risk of experiencing drug-related problems; (2) evaluating the impact of pharmaceutical care using economic, clinical and humanistic outcomes; and (3) describing a documentation process that fostered consistent reporting of patient information during the study.

This study established effect and sample sizes for outcome variables in an age-independent risk population residing in the community. Notable trends in the treatment group included decreased physician visits, fewer medications utilized and improved Medication Appropriateness Index (MAI) scores. As well, changes observed in the treatment group's health-related quality of life scores had improved economic and clinical implications.

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This project began early in 1994 as a personal vision to demonstrate a practice philosophy I believed in with passion. Prior to teaming with Dr. Farris, and while still working as a community pharmacist, I wrote a research proposal that I believed might demonstrate the positive impact a caring practice philosophy could have on improving patient outcomes and at the same time help reduce the unnecessary drug-related costs to our health care system. Without the help of Ginette Bernier and Fares Attalla, this project may not have materialized. They were pivotal in arranging an opportunity for me to present my proposal to those who could make the decision to fund such a project. Subsequently, I am very appreciative of the

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Finally, a special thank-you to Pamela Lavold, who not only endured the exhaustive role as study pharmacist for this project, but shared my enthusiasm, vision and passion for pharmacy. Her professional standards explicate pharmaceutical care.

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HRQOL	Health-related quality of life
IDID	Identification, definition, intervention and documentation
MAI	Medication appropriateness index
MCS	Mental component score
PCS	Physical component score
PIR	Pharmacist intervention report
PWDT	Pharmacist work-up of drug therapy
SF-36	Short-form 36 health-related quality of life survey

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CHAPTER ONE

INTRODUCTION

" an invasion of armies can be resisted, but not an idea whose time has come "
- Victor Hugo

Four major sectors within the Canadian health care system have been identified as requiring better efficiencies in the delivery of their services. These sectors include: institutions, professionals, continuing care and pharmaceuticals (1,2). Of these four health care sectors, pharmaceuticals rank third in the overall consumption of resources (3). Factors which attribute to the rise in pharmaceutical expenditures have been identified as: (1) above-average increases in the cost of pharmaceuticals, (2) increases in the number of purchases per patient, and (3) increases in the quantity per purchase (1). In addition, irrational drug use, adverse drug reactions and drug-related hospital admissions are preventable add-on costs that contribute to the inefficiencies of pharmaceuticals and compromise patient health outcomes (4). The need for a more efficient drug-use system is evident by the consistent reporting of escalating drug costs, drug-related hospitalizations, and inappropriate prescribing (5,6,7). A community-based advocate for ensuring safe, effective and appropriate drug-use is paramount as the trend towards shorter hospital stays results in acutely ill patients with complex drug therapies depending on their families for care (1,2). In addition, the drug-use process should be compatible with the patient's level of education, income, work, living conditions and personal choices when considering the patient's health needs (8). The community pharmacist could be the best positioned health care professional to assume this responsibility because of their accessibility to the patient,

knowledge in pharmacotherapy and ability to tailor the patient's drug therapy according to the influences that impact an individual's health (8,9).

Traditionally, pharmacists have not participated in the drug-use process as a provider directly accountable for patient outcomes. As newcomers to patient-focused care, pharmacists should expect they will need to demonstrate how their role contributes to optimizing therapeutic outcomes and the cost-effective utilization of resources within the health-care system (10). The opportunity for pharmacists to demonstrate their full potential as caregivers within the health care team has arrived.

Total drug costs to a health care system can be described by the equation: (drug product cost + pharmacist's dispensing fee - patient's out-of pocket cost) x utilization + cost of adverse drug reactions, therapeutic failures and inappropriate therapy (11). Regardless of payer, the components of the cost equation which increase the cost of pharmaceuticals and reduce the quality of patient care include adverse drug reactions, therapeutic failures and inappropriate drug therapy. Inappropriate drug utilization in hospital and ambulatory settings has been quantified to exist in up to 51% of medications prescribed (5,8,12,13). In Canada, a study of drug-related hospitalizations found 23% of study admissions were drug-related, and 13% of the drug-related admissions were the result of an adverse drug reaction (5). Treatment failures resulting from adherence problems to medication regimens is another preventable ineffeciency that adds to the drug-related costs on the health care system (14). Ambulatory findings suggest that the current drug-use system may not provide sufficient benefits to the patients that would outweigh the costs to the system (1,15). Herein lies the axiom for pharmaceutical care.

Pharmaceutical care has been defined as the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (16). It is a philosophy of pharmacy practice that shifts the pharmacist's focus from drug-distribution to being accountable for patient drug-therapy outcomes. The pharmacist ensures that the patient's drug-therapy is appropriate and optimal by identifying, preventing and resolving drug-related problems using drug therapy care plans to monitor and follow-up on the patient's progress (16). The underlying principle is for the patient and pharmacist to have a cooperative working relationship, where the patient grants the pharmacist authority to work towards specific therapeutic outcomes for the patient (16,17). The provision of pharmaceutical care is a model of pharmacy practice that may contribute to improving health-related quality of life and minimize the add-on costs of drug mismanagement to the health care system.

Pharmacists are typically the last professional link between the patient and drug consumption. Traditionally, the drug-use process involves the pharmacist dispensing the medication as prescribed by the physician to the patient (9). The notion of utilizing the pharmacist's knowledge in therapeutics and pharmacology began in the mid 1960's, an idea which was the advent of the clinical movement in hospital pharmacy (16,18). Although the clinical movement preceeded the idea of pharmaceutical care, the primary difference is pharmaceutical care emphasizes patient experiences rather than drug or disease management throughout the drug-use process. As well, pharmaceutical care turns the episodic drug-use process into a system of continual care by nature of a feedback loop created by monitoring and follow-up on the patient (16,18). Within this drug-use system, the pharmacist gathers relevant patient information, designs a care plan to implement and monitors the patient's progress according to specific goals of therapy in cooperation with physicians, other

care-givers, and the patient (16,18). The responsive nature of this drug-use system should inherently adapt to societal trends such as cultural diversity, advancing technology and an aging population. Community-based pharmaceutical care represents a model of health care delivery that may be consistent with several of the health goals for Alberta, namely appropriate, accessible and affordable healthcare that enables people to make optimal health choices (19). Examples of how the pharmaceutical care could be consistent with these goals might include documentation and follow-up on screenings for blood pressure, blood glucose or peak flow measurements as part of an individual's drug-therapy monitoring or community-based health programs such campaigns for smoking cessation and ultra-violet ray protection (19,20,21).

Several alternatives to pharmaceutical care have attempted to address the issue of saving pharmaceutical costs. Typically, these alternative are isolated to the drug distribution system and include mail order and discount pharmacies, formularies and increasing copayments (22,23). These alternatives generally provide the drug at a reduced cost by charging a minimal dispensing fee, dispensing the lowest cost alternative drug or passing a larger portion of the drug cost to the patient. Unfortunately, these alternatives have not addressed inappropriate drug use or accounted for the costs associated with drug mismanagement (22). Another detrimental consequence of these alternatives is the deterioration of the physician-patient-pharmacist relationship. Pharmaceutical care hinges on the cooperation and communication between this triage (24), a relationship that has been the focus of a joint collaboration between the Canadian Pharmaceutical Association (CPhA) and the Canadian Medical Association (CMA) to recognize the partnership between the patient, physician and pharmacist in achieving optimal outcomes from drug therapy

(23). Pharmacists have traditionally been outsiders to patient information, however as part of the Joint Statement between CPhA and CMA, the "sharing of relevant patient information for the enhancement of patient care" has been recognized (24). Clearly, the drug-use system must facilitate the opportunity for joint communication to occur, therefore efforts to improve efficiencies must focus on the providers and receivers of care, rather than the drug itself. As newcomers to a role in direct patient care, pharmacists must now provide clear evidence that their contribution improves the clinical, economic and quality of life outcomes of patient care.

Objectives

The goal of this pilot study was to evaluate pharmaceutical care in a community-based setting using economic, clinical and health-related quality of life outcomes. The specific study objectives included:

(1) Provide pharmaceutical care to community dwelling residents who are at risk of experiencing drug-related problems;

(2) Evaluate the impact of pharmaceutical care versus traditional pharmacy services using economic, clinical and humanistic outcomes; and

(3) Describe a documentation process that fosters consistent reporting of patient information during the provision of pharmaceutical care.

Nature of the Study

In this study, pharmaceutical care was implemented in a sole-practitioner community pharmacy. The study pharmacist provided care to the treatment patients using a patient-directed, needs-based philosophy (17). This approach required the pharmacist to incorporate the patient's clinical, economic and humanistic perspectives when making decisions concerning the patient's drug therapy. In addition, all the

pharmacist's interventions and patient outcomes were documented to facilitate continuity of care and monitor the patient's progress. All interventions were tailored in an attempt to accomodate the values, preferences and perceptions of the patients' well-being (25,26). This approach did not render the patient an autonomous decision-maker or passive recipient, but the locus in their care.

The study site was a community pharmacy in south central Edmonton which represented a population with above city averages for income, education, and proportion of community dwelling seniors. This site was selected because it represented many of the unique challenges that have been identified in a community practice setting including: communication barriers with physicians, limited and untimely access to confirmed medical information about the patient and a disruptive working environment (27). These are among the barriers that have been said to affect the quality and ability of the community pharmacist to take responsibility for the patient's drug therapy (27). This study used criteria to identify individuals in the ambulatory setting who might benefit most from pharmaceutical care. As well, these criteria were used in newspaper advertisements and flyers to recruit suitable subjects into the study (Appendix 1). Following an information session and informed consent, the volunteers were randomized into either the treatment or control group. Treatment volunteers were contacted by the study pharmacist for an initial interview which initialized the 6 month study period. Control volunteers continued to receive services from their usual pharmacies. The study pharmacist used documentation forms to collect clinical and humanistic data during the patient interview, develop care plans and monitor patient outcomes (Appendix 2).

In this study, the impact of pharmaceutical care was evaluated using the following: (1) drug and medical service utilization cost data collected for 6 months prior and 6 months during the study period, (2) medication appropriateness scores at the end of the six month study period (Appendix 3), (3) health-related quality of life scores at the beginning and end of the study period using the SF-36 Health Survey (Appendix 4), and (4) consistency and effectiveness of documentation to identify, prevent and resolve drug-related problems.

Significance

The economic and clinical benefits of clinical pharmacist interventions in a hospital, outpatient clinic, or managed care organization are well documented in the literature. However a gap remains in the literature regarding the impact of pharmaceutical care on these and health-related quality of life in the community setting (28). At the time of this study, there were no studies which used the combination of economic, clinical and humanistic outcomes to evaluate the provision of pharmaceutical care in an uncontrolled retail pharmacy.

The value of this study is that it operationalizes the need to involve patients in the decision-making process of their care. The change from a traditional medical model to patient-focused care is reflected in the theoretical work by Kozma and colleagues, who suggest that care be evaluated using non-clinical parameters as well. According to Kozma's Economic, Clinical and Humanistic Outcomes (ECHO) model, these outcomes need research and development to better understand the differences in perspectives among the players and identify the relationships among outcome variables that best explicate the model (29).

Findings from this study may show trends in how pharmaceutical care saves drug and/or medical service resources, improves health-related quality of life and/or improves the medication regimens of individuals at greatest risk of a drug-related event. In addition, it may provide useful directives to other researchers interested in the evaluation of pharmaceutical care or other patient-focused interventions such as utility of instruments to measure outcomes and sample sizes necessary achieve adequate power. Positive findings from the outcomes used in this study would serve as further evidence for the societal need and professional obligation to adopt pharmaceutical care as the standard for pharmacy practice. Negative or insignificant outcomes might indicate that different patient outcomes may be necessary to assess the impact of pharmaceutical care or identify that a longer study period is required to capture the full expression of patient outcomes. Whether positive or negative, the experience of using the outcomes described in this study may contribute to the overall experience of evaluating patient care. Finally, positive findings would futher legitimize the need for widespread implementation of pharmaceutical care and recognize that pharmacists should be equitably remunerated for their cognitive contributions to patient care.

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CHAPTER TWO

LITERATURE REVIEW

The scientific literature is a bibliography of events that describe truth. William James said, "Truth happens to an idea, it becomes true, and is made true by events." Reviewing the literature increases the researcher's awareness about the work of colleagues and prepares the researcher to develop and test new hypotheses as an extension of what is already believed to be true. Critical evaluation of the literature should guide the researcher in making methodological decisions and clearer interpretations of results when making inferences about her own study initiatives.

This chapter is a compilation of literature that influenced the focus and formulation of the hypotheses and design of this study. A literature search was performed on Medline, Embase and Ecolit using the following keywords: pharmaceutical care, patient-focused care, pharmacist interventions and pharmacist cognitive services. These terms were combined with medication appropriateness, health-related quality of life, evaluation, impact or cost-effectiveness and retrieved approximately 1200 records across the three databases. Approximately 40% these records were editorials and theoretical papers related specifically to pharmaceutical care. Thirty-two percent of these records were studies that evaluated economic outcomes as a result of drug utilization services provided by pharmacists in a tertiary care setting. Drug utilization studies in an institution were not included in this literature review because the setting and provision of services lacked generalizability to pharmaceutical care provided in a community pharmacy. Although the positive impact of pharmacist interventions using various methodologies and outcomes appear in the literature, this search

revealed that few community-practice studies employ a randomized-controlled design to evaluate the economic, clinical or humanistic outcomes in response to pharmaceutical care. Further, there were no studies in the published literature evaluating all three of these outcomes using a radomized-controlled design at the time of this study.

Section I of this chapter will establish the need for pharmaceutical care as a standard model of community pharmacy practice in the following subsections: (1) Influences on the costs of pharmaceuticals; (2) Pharmaceutical care defined; (3) Pharmaceutical care: Responding to current trends in health and (4) Pharmaceutical care: Evaluating a standard for pharmacy practice. Section II describes the implementation and evaluation of pharmaceutical care using economic, clinical and humanistic outcomes.

Section I - Pharmaceutical Care: Establishing the Need

1) Influences on the costs of pharmaceuticals

Drugs are the most extensively studied treatment modality, yet the literature shows that modern medicine fails to control the preventable risks of sub-optimal drug therapy i.e., inappropriate or ineffective pharmacotherapy (1,2). In Canada, over 90% of the population visit a physician annually; the per capita average being 6-7 visits a year (3). Two-thirds of these physician visits result in a medication being prescribed (4). Considering an estimated 220 million prescriptions are dispensed by community pharmacists annually in Canada (5), a relative proportion of Johnson and Bootman's estimated 76 billion in drug-morbidity costs to the United States health care system (5) could translate into 1.1 billion in preventable costs to the Canadian health care system. This estimate is feasible given the findings from a recent Canadian study that

reported community pharmacist interventions saved the health care system approximately 388.5 million (5). This saving is considered conservative because unlike the Johnson and Bootman model, the savings due to avoidance of costs associated with hospitalizations, emergency room visits, and direct/indirect costs to patients and employers were not included (6). According to Johnson and Bootman, the largest components of drug-related morbidity and mortality were costs associated with hospitalizations and admissions into long-term care facilities (6).

Adverse drug events such as treatment failures and adverse reactions can be attributed to patient idiosyncrasies; however, the literature suggests that a large proportion of drug-related morbidity is preventable (7). A review of Canadian studies evaluating medication appropriateness show the average rate of inappropriate utilization to be 18.2% for drug indication, 16.8% for choice of drug , 30.2% for drug administration and 42.7% overall (8). These studies were hospital residency projects in academic teaching centers, therefore the findings might reflect an over-estimate for drug administration inappropriateness and under-estimate of inappropriate utilization for indication and choice of drug (8). A cross-sectional survey by Willcox, et al., showed that 23.5% of older American adults are at risk of an adverse drug event as a result of receiving at least one contraindicated drug (9). In Canada, work by Grymonpre showed that adverse drug events contributed to 19% of hospital admissions in the elderly population (10).

In addition to the costs of medication inappropriateness are the morbidity costs of noncompliance. These events happen regardless of drug therapy appropriateness and include: (1) not having a prescription filled or refilled, (2) taking too much or too little medications, (3) changing dosing intervals or omitting doses, (4) stopping

medications too soon, (5) taking medications without a prescription, (6) combining medications with other over-the-counter medications, and (7) combining medications with alcohol (11). The consequences of noncompliance can be delayed recovery, increased severity of illness, need for more intensive therapy and hospital admission. A review of literature on the prevalence, consequences and costs of noncompliance shows that about 50% of patients are noncompliant with their prescribed regimens. Specifically, 33% of these patients either do not fill their prescriptions or take the medications at all. Of patients who fill their prescriptions, 17% do not take their medications as prescribed. Grymonpre, et al., found that of 863 hospital admissions, 60 admissions were directly related to non-compliance (10). A conservative estimate of the economic costs of noncompliance in Canada is $7-9 billion per year (11).

The drug-use process has not changed in almost 25 years and the need for a more responsive system has been evident for many years. Inadequate patient follow-up resulting in delayed response to patient symptomology continues to contribute to the incidence of drug-related problems (2,10,11,12).

The drug-use process assumes available medications are safe and effective as determined by Canada's Health Protection Branch and traditionally follows six steps: (1) prescriber determines patient's need for medication; (2) prescriber chooses medication; (3) prescriber selects regimen; (4) patient obtains medication; (5) administration/consumption of medication by patient and (6) effects of therapy and feedback (13). Typically, steps 1, 2 and 3 of the drug-use process are performed by a medical or dental practitioner, and in step 4 the medication is obtained from a community pharmacist by the patient.

A causal analyses of adverse drug effects found that problems within the drug-use process can be the result of the drug itself or during the prescribing, dispensing or consumption step of the process. Some adverse drug events are the result of iatrogenic reasons; described by one author as bad luck (2). Although it is difficult to identify how to improve preventable drug injury, studies have shown improved patient outcomes and a potential reduction of drug injury by using a systematic means of monitoring patient progress (2). Formularies and physician education programs demonstrate changes in prescribing, but show little evidence of improved patient outcomes (14). Studies which do show improved patient outcomes, often at lower costs, usually have revised the drug use process to enhance the collaboration and cooperation between patients, pharmacists, physicians and other caregivers within the drug-use process (15,16). The major elements that can reduce problems encountered in the traditional process are effective monitoring and improved flow of information between the patient, physician and pharmacist (2,17,18). What the traditional process lacks is a timely way to determine the patient's health status in response to the drug therapy. To accomplish this, a formal feedback loop is required to change the drug-use process from an episodic event into a continual care system (2). Pharmaceutical care may provide a continual care system.

2) Pharmaceutical care defined

Pharmaceutical care is defined as " the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include: cure of disease, elimination or reduction of a patient's symptomatology, arrest or slowing of a disease process and prevention of a disease or symptomatology" (19). Pharmaceutical care involves designing, implementing and monitoring a therapeutic plan that will optimally produce desired patient outcomes.

Implementing and monitoring require the pharmacist to identify, resolve and prevent drug-related problems arising from under-treatment, over-treatment and inappropriate treatment. Pharmaceutical care requires cooperative communication between physicians, patients, and pharmacists, whereby pharmacists accept direct responsibility for any aspect of care they could have affected (7).

The need for pharmacy to change its practice paradigm and accept the responsibility of patient care is influenced not only by inefficiencies in the drug-use process, but by the North American economy as well. It has been suggested that the changes in pharmacy practice were preceded by distinct changes in the United States economy (20). For example, the apothecary model focused on compounding during the agricultural era and dispensing or drug distribution during the industrial area. At present, the economy is said to be in an informational era, which corresponds to the cognitive practice model, namely pharmaceutical care (20). Changes specific to the evolution of practice of pharmacy include: new drug technology, the expansion and influence of the pharmaceutical industry, advances in computer technology, and changes in the demographic structure of modern society i.e., the increasing proportion of elderly and ethnic patients and acuity of illnesses (14).

During the latter part of the industrial era, clinical pharmacy emerged within hospital settings and the pharmacist's role was an information resource or therapeutic advisor to physicians (20). One commentary suggested that many clinical practitioners believe pharmaceutical care is not distinct from clinical pharmacy, however the writer supports that although the two roles are similar in function, they differ in responsibilities and relationships (20). For example, in contrast to clinical pharmacy, pharmaceutical care pharmacists are responsible to the patient and not to the

physician, hospital or insurer. When possible, pharmaceutical care requires the pharmacist to integrate the preferences of a patient into their clinical care, and clinical activities are tailored to improve clinical status as well as promote a better health-related quality of life (20,21,22). Similar to medical and nursing care, pharmaceutical care denotes a covenantal relationship between patient and practitioner and evokes the philosophical ideals of a patient-focused profession (21,23).

The pharmaceutical care process can be summarized in the following nine steps (24):

Step 1 Establish the pharmacist-patient relationship - receive authority from the patient to intervene on their behalf and make a professional commitment to the patient.

Step 2 Collect, synthesize and interpret the relevant information with the patient.

Step 3 List and rank the patient's drug-related problems in order to define and priorize all actual and potential drug-related problems.

Step 4 Establish a desired pharmacotherapeutic outcome for each drug-related problem needing resolution or prevention using a desired outcome that is quantitative and measurable.

Step 5 Determine feasible pharmacotherapeutic alternatives that could achieve the desired outcome.

Step 6 Choose the pharmacotherapeutic regimen that best suites the preferences of the patient.

Step 7 Design a therapeutic-monitoring plan to determine whether desired outcomes have been achieved.

Step 8 Implement the regimen and monitoring plan with the help of the patient and other health-care professionals responsible for the patient. Document outcomes and decisions made.

Step 9 Follow-up to measure success on both an individual and long-term basis and document and respond to the findings accordingly.

Pharmaceutical care might be accepted as a practice standard for pharmacists by society if patients expect to receive information that benefits their health. A 1988 survey by Connell and Crawford suggested pharmacists were not recognized by the public as a primary source of health information. Possible conclusions to these findings were that pharmacists themselves don't feel it is their role to provide health information beyond prescription counseling or that the information provided by the pharmacist was not what the public wanted (25). Yet, several studies support the need for pharmacists to assume a patient advocate role. Faden, et al., reported that physicians often do not include the patient in their decision process about drug-use and routinely disclose less information than what patients wish to receive (26). This report is consistent with findings by Lilja and Larsson, concerning discrepancies between what the physicians say they discuss with their patients to the information the patients say they actually receive (27). Further, as drug technology increases the available medical armamentarium, the complexities of medications and patient care requires professional advocacy in the community setting (28).

A survey by Hirsch and Gagnon on the perceived value of pharmacy services by consumers, physicians and insurers found that consumers wanted personalized services related to their medications and more drug information than what pharmacists are typically providing (29). Physicians believed that pharmacists were competent and knowledgeable and should be providing more drug information to patients (29). This perception is supported by pharmaceutical opinions in Quebec; a reimbursed community pharmacy service that addresses drug-related problems in pharmacotherapy. From a retrospective survey, the investigators found that the implementation rate of pharmaceutical opinions was 77.7% in patients and 58.1% in physicians (30). A study of 31 northern Florida families caring for a family member

found that they would have benefited from a pharmacist's assistance even though their medication-related tasks accounted for only 7.7% of the family caregiver's time. Thirty-two percent of family caregivers reported problems related to medications and 71% reported problems in managing medications (31). Although these findings suggest that society may be ready for pharmacists to play a direct role in patient care, a recent survey of community pharmacists in Canada suggests that pharmacists perceive only 45% of their patients and 37% of physicians are receptive to their patient care activities. The response rate to this national study was very low, but of the respondents, only 15% of pharmacists in community practices were participating in patient care activities. As well, documentation of interventions and patient outcomes was lacking in the daily routine of the community pharmacist (32).

Pharmaceutical care defines the pharmacist's role in patient care. The traditional drug-use process can transform into a continuous care system by a formalized feedback loop when follow-up and documentation of pharmacists interventions and patient outcomes occur.

3) Pharmaceutical Care: Responding to current trends in health

Health was once defined as an absence of illness. Being healthy was something one had as a result of good fate (33). Traditionally, the perceived connection between health and health care was the number of physicians and hospital beds available to a community (33). Today, a broader perspective of health is being realized. The global trend in health care is a shift from the medical model toward the health model, a concept which emphasizes wellness through disease prevention and health promotion (34,35).

Community pharmacists who provide pharmaceutical care contribute to disease prevention, health promotion and the cure or reduction of disease by providing care that is tailored to the health needs within the communities they serve. For example, a study in London (UK), identified that the average urban community pharmacy serves 50 people with diabetes, 150 people with asthma, 15 patients discharged from a hospital within the past 7 days, 8 people with colostomies, 750 elderly, 3 people with coeliac disease, 20 people with cancer (4 of whom receive terminal care), 1 patient with cystic fibrosis, 500 people on antihypertensive therapy, 200 people with a disability, 2 people who are HIV positive, 300 children under 5 years, and 30 women who are pregnant (36). Having an overview of the health needs within each community pharmacy provides a population database of acute illness in the community, and would allow pharmacists to direct the appropriate resources towards various groups according to identified health needs. Understanding and responding to the drug-related health needs of the community is the challenging objective pharmacists have been called to enlist as part of the World Health Organization's "Health for All by the Year 2000" campaign (37).

A recent survey of 570 community pharmacists across Canada showed that of the 15% of pharmacists who provide pharmaceutical care to specific patient groups, the most common groups of patients are those with diabetes, hypertension, asthma, seniors, cardiovascular disease and HIV/AIDS (32). Other disease prevention or health promotion activities include smoking cessation programs, screenings for high blood pressure, serum cholesterol and blood glucose, ultra-violet ray protection and immunization awareness programs (32). At present, assessing the effectiveness of these activities in improving the health status of a community is difficult because follow-up, monitoring and documentation of outcomes are rare (32). The advantage

of providing these programs within a pharmaceutical care system would be the documentation of the patient outcomes in response to these activities which would assist in the evaluation and remuneration of the community pharmacist's contribution to community health.

In addition to the focus on health promotion and disease prevention comes the urgent need to reduce the costs of health care delivery (33). Institutions, professionals and pharmaceuticals are among the major health care sectors identified as needing improvement in the delivery of services (33). Cost-containment strategies such as downsizing in institutions and health care organizations have left much of the care previously done in hospitals to the home (33,38). Medical professionals have also experienced changes to the remuneration of their services which has reduced or limited their earning potentials (33). Efforts to reduce the costs of pharmaceuticals have focused on increasing the co-payment requirements or implementing restrictive formularies, rather than promoting the appropriate utilization of drugs (6). These changes have created a business-oriented health care environment and presents challenges to Canada's universal, publicly-funded health care system. When costs are shifted to the patient through increased co-payment requirements for medication or user fees and de-insured services for medical care, the quality and equity of care may become a function of the patient's ability to pay (33).

In response to this challenge, there is an emphasis to determine and subsequently deliver only what is safe, effective and appropriate at public expense (23,33). Similarly, the document "Health Goals for Alberta", identified that in order to improve efficiency, "a collaborative approach of responding to health needs was necessary and required a vehicle that demonstrates the accountability and

effectiveness of services and programs to the health system" (39). When operationalized, the vehicle to demonstrate the pharmacist's accountability and effectiveness of services to the health system may be pharmaceutical care.

Pharmaceutical care can encompass the promotion of health and disease prevention, as well as ensure that all aspects of a patient's drug therapy are safe, effective and appropriate. In addition to improved health status, the economic impact of widespread practice of pharmaceutical care could also be significant. Pharmaceutical care requires an understanding of all aspects of a patient's health disposition. Studies in the community setting have shown that monitoring and follow-up of the patient's response to drug therapy transforms the current drug-use process into a formal system of patient care (15,40) which is responsive to the needs of the individual, the community and the health care system.

4) Pharmaceutical Care: Evaluating a standard for pharmacy practice

The previous sections established that the current drug-use process limits the maximal benefits of pharmaceuticals to society. In an effort to improve drug-use efficiency, the pharmaceutical care paradigm has been recommended as the new standard for pharmacy practice. Standards of practice are an identifiable set of criteria using structure, process or outcome variables as a measure of success or quality (41,42). Structure variables in a community pharmacy can reflect the capacity to provide quality and include size, financial position, physical facilities, personnel, qualifications of providers, administrative structure, operations and equipment (18,41,42). Process variables are the actual events of patients receiving care and incorporate technical functions such as dispensing the correct medication and interpersonal processes such as willingness to listen and empathy (18,41). A process

standard of pharmaceutical care would include a safe and efficient drug management system, so that the pharmacist's knowledge and skill are focused on detecting, preventing and resolving drug-related problems for the patient and documenting their activities and the patient's outcomes. A randomized controlled study among health maintenance organizations (HMO's) showed that when given the opportunity, treatment pharmacists spent more time with the patients and would contact the HMO more often to offer suggestions to optimize the patient's drug therapy. A follow-up questionnaire to the control pharmacists revealed that process issues such as a lack of time and inaccessible patient data precluded them from providing patient-oriented activities (43).

The quality of pharmaceutical care, as with any assessment of patient care, is best determined by the values of individuals and society (18,42). Outcomes used as indicators for quality pharmaceutical care should be measurable assessments of the patient's experience and documented (44). Typically, outcomes have been the number medication errors, number of unnecessary drugs, number of adverse effects or reductions in drug costs (18). With pharmaceutical care, the pharmacist is paying attention to the five D's of outcomes: disability, discomfort, dissatisfaction, death and disease; a combination of clinical and humanistic outcomes (42,44). Typically, health care professionals have been less willing/able to establish valid normative standards for outcomes as compared to processes of care (45).

To link the pharmacist's interventions with meaningful outcomes for the patient the Economic, Clinical and Humanistic Outcomes (ECHO) model provides a theoretical framework that integrates traditional clinical-based outcomes with contemporary measures of economic efficiency and quality (46). The ECHO model identifies and

defines three general dimensions of outcomes: economic, clinical and humanistic as follows (46):

1. Clinical Outcomes: medical events that occur as a result of disease or treatment.

2. Economic Outcomes: direct, indirect and intangible costs compared with the consequences of treatment alternatives.

3. Humanistic Outcomes: consequence of disease or treatment on patient functional status or quality of life measured along several dimensions, ie., physical function, social function, general health and well-being and life satisfaction.

Application of the ECHO model has occurred in the ambulatory setting using one or a combination of two of these outcome variables. Table 2.1 summarizes the more recent studies which used economic, clinical or quality of life outcomes variables to examine the effect of pharmaceutical care or pharmacist interventions. Studies using economic or clinical outcome variables are most prominent. Economic variables include estimates of savings per prescription or intervention (15,47,48) or reductions in health services utilization (6,49,50). Clinical outcomes used to evaluate quality of care include increasing patient knowledge or decreasing risk of an adverse drug event (43,49,51). Other clinical outcomes used in recent studies include measures of blood pressure and compliance (40), medication appropriateness (9,12,17), drug-related problems and drugs discontinued in response to pharmacists' recommendations (10,48,52). Health-related quality of life assessments in the reviewed studies include those using the SF-36 Health survey which measures both psychological and physical well-being (40,53).

Table 2.1: Characteristics of pharmacist intervention studies reviewed

REFERENCE	OBJECTIVE	SAMPLE SIZE	STUDY TYPE	IMPACT	OUTCOME MEASURE
Knowlton C., Knapp D. (43)	Determine the effect of a pharmaceutical care educational intervention (PC) on the costs of drug benefits in an HMO	27 comparable pharmacies that were preferred providers for an HMO.	randomized controlled. Pharmacies block randomized by state.	Intervention pharmacists reduced prescription costs by 8.3% per patient per month. Also, intervention pharmacists suggested medication changes 1.9 times more than control pharmacists.	Economic
Iverson, P (47)	Savings as a result of a pharmacist's intervention	3,798 prescriptions from one pharmacy over 4 months	descriptive	A savings of $16.74 per prescription was realized.	Economic
Lipton H, Bird J (49)	Improve patient compliance, prescribing and medical care utilization after pharmacists' consultations	706 geriatric patients being discharged from hospital	randomized controlled	Intervention patients were more knowledgeable about medications and on fewer medications and less complex regimens. No effect on service use or charges.	Economic, Clinical
Lobas et al. (15)	Examine the effect of pharmaceutical care on medication costs and quality of care	184 patients targeted in a university hospital family practice clinic for 14 month study period	post-intervention evaluation single group	Pharmacist's made 360 recommendations and 82.5% were accepted. The annual extrapolated cost avoidance was $19,076 US.	Economic, Clinical
Kimberlin et al. (52)	Examine effects of a PC educational intervention for pharmacists on detecting drug-related problems	Pharmacists N=102 Patients N=762	controlled	Intervention pharmacists were 1.6 times more likely to discuss medications with the patients.	Clinical
Rupp M. (51)	Estimate the economic value of routine screening and resolving of prescribing-related problems	89 community pharmacists practising in 5 states	observational	627 of the 33,011 prescriptions screened identified problems, 127 of which could have resulted in harm to the patient had the pharmacist not intervened. Costs of medical care avoided was $122.98 per problematic prescription.	Economic, Clinical

Table 2.1: Characteristics of pharmacist intervention studies reviewed (cont'd)

Willcox et al. (9)	Examine inappropriate prescribing in elderly Americans	6171 patients 65 years or older	cross-sectional survey	23.5% of community residing elderly received at least one contraindicated drug that most commonly increased risk for cognitive impairment and sedation.	Clinical
Stuck et al. (12)	Quantify the prevalence of inappropriate drug use in community - residing older persons	414 subjects aged 75 and older selected from a previous sample	cross-sectional survey	6.9% of prescribed medications were considered inappropriate, the most common being long-acting benzodiazepines.	Clinical
Grymonpre et al. (10)	Determine role of drug therapy (drug-related adverse patient event DRAPE) in medical admissions	863 eligible admissions to the Health Sciences Center, Winnipeg	prospective survey	Of the 863 admissions, 162 exhibited at least one DRAPE. 48% were adverse drug reactions, 27% nonadherence, 19% treatment failure, 10% medication error and 14% alcohol and drugs.	Clinical
Hanlon et al. (17)	Evaluate the effect of clinical pharmacist interventions on improve inappropriate prescribing	208 ambulatory patients aged 65 or older with 5 or more chronic medications in a Veterans Affairs Medical Center	randomized controlled trial	Inappropriate prescribing declined 24% in the intervention group vs. 6% in control group and fewer intervention patients experienced adverse drug events. There were no significant differences in health-related quality of life.	Clinical, Humanistic
Mason JD. . Colley CA. (48)	Examine the cost reduction associated with identifying drug-related problems	Two general medicine ambulatory care clinics associated with a large, tertiary-care teaching hospital.	controlled trial	Extrapolated savings were annualized to yield $185 per intervention. Potential cost savings of $176,724.	Economic
Borgsdorf et. al. (50)	Examine pharmacist medication-review service at a managed care facility	2720 ambulatory medications were reviewed over 12 months. 836 patients were seen during a 23 month period	before after time series	64.9% of medications reviewed each month were problematic. A savings of $644 US per patient was realized in reduced utilization of health care resources particularly in unscheduled Dr visits and fewer hospital days.	Clinical, Economic

Table 2.1: Characteristics of pharmacist intervention studies reviewed (cont'd)

Park JJ. et. al. (40)	Determine the impact of comprehensive pharmacy services on hypertensive patients in a chain setting	27 intervention and 26 control subjects.	randomized controlled	Inappropriate application of statistics limits the interpretation of findings. Discussion suggests trends of improved blood pressure control and improved quality of life.	Clinical, Humanistic
Sisson E. et. al. (66)	Examine and quantify pharmaceutical care in community practice	972 of 1672 community pharmacists in Virginia	mail survey	Low volume pharmacies (<150 prescriptions/day) were able to provide a higher level of pharmaceutical care based on the Community Pharmaceutical Care Index .	Clinical
Munroe WF. et. al. (54)	Evaluate the economic impact of disease management model of care	188 intervention and 401 control subjects	controlled study (matched)	Pharmacist interventions realized a monthly savings of $143.95 to 293.39 per patient in health care costs.	Economic
Grymonpre et al (64)	Evaluation of a pharmacy consultation service for the elderly	20 ambulatory clients 55 years or older taking 2 or more medications	descriptive	17 of the 20 clients were experiencing some adverse drug reaction. 16 of the 20 clients were on drug without an indication. 10 of 21 prescription drugs were discontinued in accordance with pharmacist's recommendations.	Clinical
Loh EA. et.al. (6)	Examine savings associated with community pharmacist interventions in Canada	7,190 interventions from 526 pharmacies across Canada over 2 week period	survey	An extrapolated estimate of 268.2 - $388.5 million dollar savings to the health care system in 1993.	Economic
Erickson S. et.al. (53)	Determine the impact of pharmaceutical care on ambulatory patients with hypertension	40 intervention and 40 control subjects	controlled study	Improved blood pressure control was observed in the intervention group. No observed differences in the SF-36 scores.	Clinical, Humanistic

As outlined in Table 2.1, medication appropriateness, drug and health service utilization costs and health-related quality of life surveys have been used as outcome

measures to evaluate pharmaceutical care. Typically, the intervention studies were performed in academic-affiliated outpatient clinics or managed care settings, therefore the generalizability to a retail setting is limited. In addition, these studies targeted interventions towards specific diseases or age cohorts.

Of the 19 studies reviewed, only 6 studies employed a rigorous randomized controlled design to control for confounders and participant bias (17,40,43,49,53,54). Hanlon et. al., reported a significant improvement in medication appropriateness scores as a result of pharmacist interventions, but no changes in health-related quality of life (HRQOL) scores. The item suitability and content validity of the Medication Appropriateness Index had been determined in a previous study (17). The authors suggested that the veteran population appears to have greater disease burdens than their non-veteran counterparts and in such patients, overall chronic disease activity and co-morbidity may be only partially influenced by medication use. As well, the effects of interventions in a population with chronic disease may require more than one year to manifest HRQOL improvements (17).

Several limitations in the generalizability of the studies reviewed exist. First, in all but two of the intervention studies, (Rupp (51) and Iverson (47)) the study pharmacists held post-baccalaureate degrees or specialized training in pharmaceutical care. As well, many of the practice settings were not retail, therefore the intervention pharmacist provided no distributive role.

Knowlton and Knapp describe a comparable setting where the participating study pharmacists practiced in a retail pharmacy that belonged to a health maintenance organization (43). Significant findings in lower monthly prescription costs were

largely due to increased generic substitution, as mean monthly utilization showed no significant difference between groups. As well, hospital admissions rates were no different between the study groups. Although this study did not address the clinical implications of pharmacist interventions, it revealed that changes in practice behavior can occur in response to an educational intervention and that economic benefits exist when communications between the patient and pharmacist are fostered during prescription processing.

Munroe, et.al., used prescription and total medical utilization costs to determine economic outcomes from a disease management model of pharmacist intervention activities (54). Although there were no significant differences between groups in mean number of prescriptions and prescription costs, the trend towards lower monthly costs could be seen in the intervention group. Conversely, Lipton, et. al., failed to show the impact of pharmacist interventions on medical care utilization costs. One important point made by the authors concerning the lack of significant findings in medical care utilization was that drug-related problems are rarely severe enough to warrant increased medical care utilization and a sample size of several thousand might be necessary to yield a few hundred cases (49).

Finally, Park, et. al., executed a study that highlights the importance of proper analytical methodology to evaluate the impact pharmaceutical care (40). Despite the significant findings reported in improving blood pressure control and HRQOL, the inappropriate application of t-tests to compare post-study measures (rather than mean differences from baseline) between the intervention and control group hindered the interpretation of the findings.

While these studies provide background for the design, methodology and outcome variables used to evaluate pharmaceutical care in this study, the logistics of measuring all three areas of outcomes, namely clinical, economic and humanistic measures remained unknown in a retail setting. Gaps in the literature are particularly noted in the area of evaluating humanistic outcomes. As well, community pharmacists with no specific training in pharmaceutical care or advanced degrees reflect the largest portion of community pharmacists, yet they are not the largest group participating in experimental research. Community pharmacists need to demonstrate that their contributions go beyond saving drug costs. However, without evidence, the hidden value of community pharmacists in patient care cannot be revealed.

In summary, improving health status is the primary goal of health care, typically defined by the results of processes of care, namely survival and satisfaction (55). These outcomes, however are influenced by numerous variables such as genetic make-up, income and education, which are unrelated to the quality of medical care received (55). Outcome assessment should surpass the traditional physical assessments common to medical practice and include functional status along with psychological, economic and social factors (55). At the time of this study, there were no published reports which explored all three areas of outcomes in a diverse community-based population receiving pharmaceutical care from a pharmacist in a retail setting.

Section II - Pharmaceutical Care: Documentation and Implementation

1) Strategies for Documenting Pharmaceutical Care

Documenting patient information in a meaningful and practical manner is probably

one of the most challenging tasks facing the community pharmacist. At present, pharmacists lack a universally accepted standard to systematically document outcomes of patient pharmacotherapy (56,57,58). Consistency and thoroughness are important when documenting interventions and outcomes for meaningful interpretation and inferences (18,41). Among barriers identified to document pharmaceutical care were lack of time, incomplete or inaccessible patient information and the lack of an efficient way to process and integrate patient information relative to the elements of care (57,59,60).

Community pharmacists are typically involved in both the clinical and distributive elements of care, therefore documentation should ideally encompass both processes in the approach. A review of the literature revealed only a few articles that addressed documentation of pharmaceutical care or pharmacist interventions specifically. Canaday and Yarborough developed a pharmacotherapy plan called CORE-PRIME-FARM that follows the flow of a typical medical treatment process; subjective-objective-assessment-plan, also known by the mnemonic SOAP (56). The steps to CORE are: (1) recognize the Condition, (2) identify desired Outcomes, (3) plan the medication Regimen and (4) Evaluate progress. The next section PRIME classifies pharmacotherapy problems into Pharmaceutical, Risk, Interactions, Mismatch of drug and indication, and Efficacy. The Mnemonic FARM is a suggested alternative to the SOAP system denoting Findings, Assessment, Resolution and Monitoring. The authors contend that the SOAP system does not adequately address the need for patient monitoring and follow-up, which in the case of pharmaceutical care are integral in deriving at the desired outcomes (56).

Rupp suggests a four stage problem-solving approach he describes as IDID, or Identification, Definition, Intervention and Documentation. Rupp developed the Pharmacist Intervention Report (PIR) that cues the pharmacist to document important information along the problem-solving process (57). This report does not incorporate patient perspective, past medical and medication history or follow-up as part of the documentation process. The major strength of the PIR is the concise nature of the report which has specific coding fields for the pharmacist's interventions that could be incorporated into a larger electronic database.

Strand, et al., presents a systematic method to examine a patient's drug therapy in a way that facilitates the identification and intervention of drug-related problems called the pharmacist's work-up of drug therapy (PWDT) (58,61). The strength of this format is that it standardizes the documentation of patient-care activities, medical and medication database and therapeutic strategy. It consists of the following steps: (1) establish a comprehensive patient database, (2) identify drug-related problems, (3) described desired therapeutic outcomes, (4) list all therapeutic alternatives, (5) describe therapeutic outcomes, (6) establish a drug-therapy monitoring plan (61).

The Health Plus Version of documenting a patient medical and medication history was an unpublished format used in a study at the University of Michigan (62). A strength in the design of the form was it extracted information about the patient's lifestyle, perceptions and expectations in addition to their medical and drug histories. This format incorporated the same six stepped process as the PDWT.

For the Pharmaceutical Care Project in Minnesota, the pharmacists used a patient care documentation software program that included patient demographics, relevant

medical history, complete medication record, pharmacists' assessments of patient, care plans and problem statements, goals for resolving or preventing identified problems and patient outcomes (63). One significant weakness identified in this process (by a convenience sample of three pharmacists who have worked with documentation software) was the duplication and lack of integration of information between the dispensary and patient documentation software packages. In addition, the patient care database was often situated away from the dispensing area making it difficult to integrate documentation of patient care along with dispensary functions .

In summary, documentation as a process should have an accessible structure, meaningful interpretation, and consistency in data collection (59). Finding an efficient documentation process remains an unresolved issue in the pharmaceutical care system. An efficient and accessible method of documentation should report patient care and outcomes in a consistent and meaningful way without duplication of information or lack of regard to the distributive components of the drug-use process. The documentation processes discussed in this review appear to have agreement in the type of information necessary to develop monitoring and care-plans, namely a complete drug and medical history review and a problem solving process that can address potential or actual drug-related events. What remains unknown are the issues of timeliness, practicality, consistency and accuracy of using these documentation strategies in the community pharmacy setting.

2) Implementing Pharmaceutical Care

A review of the literature shows that pharmaceutical care has been implemented in the ambulatory setting using 3 distinct strategies, including (1) consultative services (64),

(2) the integrative patient-specific model (15,17) and (3) the disease management model (40,54). The successful implementation of any of these models might include: (1) ability and motive to sustain the provision of pharmaceutical care services, (2) public demand and (3) remuneration. The primary focus for all the models was patient directed to achieve specific outcomes using a problem solving, monitoring and documentation process. The generalizability of the models was limited because the practice settings did not reflect the retail environment and services were oriented to specific age or disease groups. As well, the provision of pharmaceutical care was by pharmacists with either advanced degrees or pharmaceutical care training.

Perhaps the most difficult model of pharmaceutical care to implement in a community pharmacy setting would be the consultative service because it lacks the structures of the traditional drug-use and distribution process. This model of consultative service was implemented to service patients aged 55 and older (65). The objective was to characterize and document drug-related problems using the University of Michigan focused drug therapy review program and the pharmacist's work-up of drug therapy (PDWT). Eligible clients were referred to the program and a medication history was conducted by a trained volunteer in the client's home using a standardized instrument called,"The Home Medication History", designed to gather specific detailed information on drug therapy and medication-taking behaviors. The pharmacy consultant reviews the history using a drug therapy review instrument which provides a standardized and comprehensive method to process the information gathered and identify and document drug-related problems. Consultation was made first with the primary care physician and then the client to address any actual or potential drug-related problems and a letter summarizing the information was provided to the physician. The limitations of implementing this model in the retail setting were the

exclusion of the dispensary component of the drug-use process and lack of opportunity for relationship development between the patient and the pharmacist providing the care. This was evidenced by the fact that the processes of obtaining patient information for care plan development were not the result of direct communication between the patient and pharmacist (65).

The integrated patient-specific model of pharmacy practice consists of three basic components: a philosophy to guide those providing the services, a definition of the work to be completed and a managerial framework that helps the philosophy and definition function in actual practice (66). The philosophy of practice must accommodate the achievement of desired patient outcomes by ensuring rational drug therapy. Safe and efficient drug procurement and distribution must also be available as support to the patient-specific clinical services. The integration of clinical and distributive components were originally defined for an institutional practice, but can be modified to the community pharmacy setting. Defining the work was done explicitly and the pharmacist providing the clinical services was directly responsible to the patient for drug-related outcomes. The process of drug-problem identification, resolution and prevention used a consistent method for documenting interventions and outcomes. The degree of integration was dependent on the extent to which a managerial framework supports these activities. An internal organizational structure must allow the pharmacist to focus on the patient and related activities and financial resources should be directed toward the clinical functions of the practice as much as distributive. As the final requirement, documentation must be consistent and allow the pharmacist's contribution to be quantified (66). The integrated patient-specific model provides an overall understanding of the need to integrate distribution with patient focused activities. Several projects studying pharmaceutical care outcomes in

ambulatory patients have adopted this integrated patient-specific model including: the Pharmaceutical Care Center at the University of Illinois' Chicago Medical Center (57) and the Minnesota Pharmaceutical Care Project (53). Similar to the holistic concept of an integrated patient-specific model, is the client-centered model of medication decision-making and management. In this model, the client collaborates with the care providers to identify treatment goals, choose from regimen options, self monitor symptoms and evaluate and revise drug regimens accordingly (67).

The final model considered in the implementation of pharmaceutical care was the Disease Management Model. This system provides care according to disease-specific modules that contain a recommended course of action, explanation for that action and is designed to teach pharmacists to manage therapeutics (54,68). This method employed clinical practice guidelines to influence physicians' practice. In addition the modules contain a continuous quality improvement component for continuous evaluation of the patients, pharmacists and pharmacy performance. The application of the disease management model is less favorable for community pharmacists, because the concept depends on guidelines directed to physicians and access to appropriate data (69). Typically, disease management programs focus on compliance and education for patients and physician. This model is limited by its specificity and fails to address the vast drug-related morbidity and mortality that exists in the community setting (6).

Widespread implementation of pharmaceutical care has not yet occurred. Presently, pharmacists seem reluctant to accept and invest in the necessary practice and structural changes that facilitate patient-oriented care (70). Other factors hindering implementation in community pharmacy include how pharmacists are remunerated

and how closely the distributive components of the drug-use process will remain tied to the community pharmacist's role. Whether the standard model of pharmaceutical care follows the consultative service, integrates the distributive and clinical functions of care or concentrates on populations having specific disease states; optimizing patient outcomes in response to pharmacotherapeutic interventions has become a patient care role community pharmacists cannot afford to ignore.

Conclusion

Community pharmacists are faced with a client base having complex drug therapy needs. Two Canadian studies examining the resolution of prescription problems in the community setting found that 1.75 - 2.0 % of all prescriptions required some level of intervention (5,71). This intervention rate translates in 4.4 million problematic prescriptions annually in Canada. Adverse drug reactions, therapeutic failures and drug-related hospitalizations represent a serious deviation from the expected therapeutic and cost benefits of drug therapy. In Canada, an estimated cost of preventable drug-related morbidity to the health care system was 1.1 billion dollars annually.

The opportunity for community pharmacists to expand their distributive role in the drug-use process and adopt a patient-focused practice that facilitates identifying, preventing and resolving drug-related problems is present. Consistent documentation of the pharmacists' interventions and pertinent patient outcomes is paramount for legitimizing pharmacists as patient care professionals (22). As well, pharmacists should be able to demonstrate the impact of their interventions on individual and community health.

It has been suggested that evaluating pharmaceutical care requires a multidimensional approach to capture the important attributes of the patient care process. The multidimensional approach incorporates economic, clinical and humanistic outcomes which have been described as guiding principles when assessing the value or contribution of services to care (46). Several models of pharmaceutical care have been implemented to maximize the pharmacotherapeutic benefits within a depleting source of health care resources. Common to all models, is the desire to improve the patient's health outcome in response to drug therapy and reduce risk of any drug-related problems . The strengths of adopting the integrated patient-specific model of pharmaceutical care was the comprehensive approach which focused on building professional relationships between the patient, pharmacist and other caregivers, and promoting enabling behaviors and practice changes that have suggested improved patient outcomes and efficiencies within the traditional drug-use process.

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CHAPTER THREE

METHODOLOGY

Methodology is the navigator of research. It describes the process by which the researcher arrived at their results and conclusions. Therefore, methodology is important in determining whether the findings of a study can infer truth in the phenomena of interest within the universe. Selecting a randomized controlled-trial methodology is discussed first, followed by choice of study site, subjects and intervention. A description of the instruments used to evaluate outcomes, collect data and an analysis plan completes this chapter. Human subject approval was granted by the University of Alberta Research and Ethics Committee, Department of Medicine and is shown in Appendix 5.

Methodological Approach

1) Randomized Control Design

The purpose of this study was to evaluate the impact of pharmaceutical care on patient outcomes in a community-based setting. Specifically, the objectives were to :

(1) Provide pharmaceutical care to community dwelling residents who were at risk of experiencing drug-related problems;

(2) Evaluate the impact of pharmaceutical care versus traditional pharmacy services using economic, clinical and health-related quality of life outcomes; and

(3) Describe a documentation process that would foster consistent reporting of patient information during the provision of pharmaceutical care.

A randomized controlled design was selected to accomplish these objectives because it represents the gold standard for research by providing the strongest causal inference between the predictor variable, i.e., receiving pharmaceutical care, and the outcome variables being measured. Randomizing subjects implies there was an equal chance of being assigned to either the control or treatment group and theoretically equally distributing confounding factors that may be present, i.e., sex, age, pathophysiology, socioeconomic status. In addition, randomizing the subjects reduced the sample size necessary to achieve a statistical level of significance in the outcome measures (1).

Recruited subjects were randomized into groups following a brief presentation about the nature of the study and signing informed consent (Appendix 6). The randomizing procedure followed a block technique where the number of subjects were equally distributed among the study groups (2). This was accomplished by having the subjects select a SF-36 survey at random from a pile of surveys which had previously been marked as treatment or control. The names and phone numbers of subjects randomized into the treatment group were forwarded to the study pharmacist, who then scheduled an in-person interview and initiated the six month study period. Control subjects continued to receive their pharmacy services from pharmacies other than the study site as they normally had. A six month study period was used as this was a feasible time period for the study pharmacist to perform the responsibilities consistent with pharmaceutical care and minimize bias due to loss of patient follow-up.

2) Site Selection

Medicine Shoppe at Whitemud Crossing in south Edmonton was the site selected where the study subjects received pharmaceutical care. It is a sole owner-operated pharmacy providing only professional products. Based on the 1990 municipality of Edmonton Neighborhood Profiles, this location serves a population with above average income, education and proportion of community-dwelling senior residents (3). This site was selected based on the outcomes of an interview between the pharmacist and principle investigator that indicated a strong likelihood that the pharmacist was committed to providing pharmaceutical care according to study protocol for the time period of the study. The interview followed a modified version of the template for evaluating clinical pharmacists (4), and is shown in Appendix 7. In addition, the investigator considered the following structural components: suitable pharmacy design, convenient and accessible location, operational hours, services and technical support. Process components considered interpersonal skills, dispensing procedures and continuing education. From the interview, the investigator selected this site because the pharmacist supported the pharmaceutical care philosophy of practice and had implemented a disease management program for asthma. The pharmacist was highly motivated, displayed strong interpersonal skills and held screening programs for high blood pressure, high cholesterol and high blood glucose monthly in her pharmacy. In addition, the pharmacy was designed to facilitate private counseling and pharmacist - patient interaction with all over-the-counter and prescription purchases.

3) Choosing Subjects

Most studies describing the benefits of pharmaceutical care or related types of pharmacist interventions have occurred in well controlled environments such as

academic outpatient clinics or for specific populations of a particular disease state or age group. Since pharmaceutical care has been mandated as the professions' standard for delivery of its services, it should be provided equitably (5,6). Comparing the effectiveness between pharmaceutical care and traditional pharmacy services requires the measurements to be made in real world conditions. To expand on the current knowledge about the effects of pharmaceutical care in the community, this study population included all community-dwelling residents who received pharmaceuticals from a community pharmacy. The target population were community residents who would likely benefit most from pharmaceutical interventions provided in the community setting. The accessible population were residents who would likely benefit from pharmaceutical interventions, lived in south Edmonton during the period of November 1, 1995 to October 31, 1996 and saw the recruitment advertisements (2).

Subjects were recruited into the study by responding to advertisements and articles in local newspapers and community flyers, inserts in purchases at a large food chain store in the area (permission was obtained), postings at churches and community centers in the area, request for referral letters to local physicians and a public broadcasting announcement made on a local radio station. The advertisement strategies invited residents who met specific criteria to participate in a study that would help them know more about their medications. These criteria were prognostic indicators that had been established to identify ambulatory individuals who were at greatest risk of an adverse drug reaction and included: (1) takes 5 or more medications in present drug regimen, (2) takes 12 or more medication doses per day, (3) medication regimen changed four or more times during the past 12 months, (4) has history of non-compliance, and (5) takes medication(s) that require therapeutic

monitoring, i.e., blood levels of drug are within appropriate therapeutic range for individual (7).

For the purposes of this study, two criteria were modified to read as follows: (4) has difficulty to remember to take medications and (5) currently taking medications for long term conditions like arthritis, high blood pressure, sleep disorders, asthma, depressive illness or stomach problems. The investigator felt the average layperson would better understand a simplified definition of non-compliance and relate to specific conditions that likely required drug monitoring to avoid adverse drug events rather than use the term therapeutic monitoring. These prognostic indicators were used as inclusion criteria to enhance the likelihood of the pharmacist intervening to identify, prevent or resolve drug-related problems. In addition to these criteria, the investigator required that participants be 18 years or older, reside independently in the community and belong to a third party insurance plan. These additional criteria were necessary to ensure that all participants could complete the health survey independently, were of legal age to consent to participate in the study and provide an accurate account of prescribed drug costs data. Specific exclusion criterion besides refusal to participate were not developed, i.e., language barriers, complex disease states, psychological disorders, to preserve the greatest degree of generalizability.

The strengths of the self selection sampling method include: (1) inclusion criteria identified the target population relevant to the research question, (2) the accessible population contacted the investigator which minimized time spent with individuals not suitable for the study and (3) participants meeting the criterion and who were motivated to respond to the ads had an interest in study and increased likelihood of commitment to the study protocol (7). The disadvantage of self-selection is that

volunteers are not typical of the general population (8). Respondents may be more involved and aware of their health status and medications and communicate differently with their primary caregivers. This involvement may result in medication-taking behavior that differs from the non-volunteering population. On the contrary, the volunteers may have been individuals who were experiencing problems and responded to the advertisement in hopes that they could bring resolution to their medication problems, and the findings in this population could be exaggerated.

4) Intervention

The study pharmacist provided pharmaceutical care to 16 study patients and documented all her intervention activities and clinical outcomes according to the patient's perspective and needs-based approach. A patient's experience with the intervention, namely Pharmaceutical Care, began with an introductory phone call and a face-to-face meeting with the study pharmacist to take the patient's medical and medication history along with lifestyle information, i.e., typical diet, exercise, interests and routine activities. During this meeting the patient also had an opportunity to discuss their health goals, expectations and any immediate concerns. Using this information, the study pharmacist addressed any immediate concerns or related needs and arranged to follow-up with the patient within the week to discuss any issues relevant to the individual's drugs, disease(s) or symptomatology. The pharmacist then developed a careplan for the patient and contacted the patient to discuss the expected outcomes. In the event that a drug-related problem was identified, the information was communicated to the patient's physician. At the onset of the study, the study pharmacist treated the patient's current medication like new medications. Typically, the patient would receive an educational session with the pharmacist to enhance the understanding of their diseases, medications and lifestyle

factors and identify ways with the patient to optimize their response to the pharmacotherapy or prevent a drug-related problem. The pharmacist would counsel the patient on all new prescriptions, and in some cases it was necessary for her to reinforce the counseling on standard refills. The pharmacist would call the patient within a suitable time frame to ensure no adverse effects were occurring. If side-effects were occurring, i.e., dizziness or drowsiness, the pharmacist would determine from the patient's perspective whether the medication warranted reassessment. Subsequent monitoring continued until an acceptable outcome was established and the pharmacist would make less frequent calls to follow-up on the patient's progress. When the drug therapy outcomes were less than optimal, the pharmacist would provide the patient's physician with a recommendation to change a specific medication to an alternative. As well, the pharmacist provided recommendations and incorporated the same level of intervention for non-prescription products as deemed necessary. The pharmacist tried to maintain scheduled follow-up communications and monitoring by telephone or formal appointments to ensure minimal distractions and document all activities and outcomes in a timely manner. It became evident that many treatment patients preferred to call or visit the study pharmacist outside appointed times she made with the patients.

The pharmacist found that the careplan did not adequately facilitate documenting the frequent changes in patient outcomes and progress. To rectify this, a section called patient progress notes (Appendix 2) was added to the documentation process. In these notes, all communications related to the pharmacist's interventions and patient outcomes were written in a free-text format, similar to physician charting. The documentation process was an unstructured free-text format, however it resembled the IDID approach suggested by Rupp (57). A careplan was completed for patients only

at the onset of the study and served as a starting point, from which the study pharmacist could design an overall strategy in an effort optimize each patient's drug therapy.

The patient progress notes provided documentation on each intervention and typically included the date, nature of the intervention, communications with physician or office personnel, clinical indicators such as blood pressure or peak flow measures when applicable, patient experience with their medications and conditions, progress of condition and general wellbeing. In addition the pharmacist provided her rationale for the next appropriate intervention based on the new patient information. Other services available to the treatment subjects included screenings and educational clinics held in her pharmacy for patients with diabetes, asthma, hypercholesteremia, migraines and hypertension. Dispensary functions were shared between the study pharmacist and technician in accordance to normal practice standards for pharmacists in Alberta.

5) Instruments and Data Collection Procedure

Economic, clinical and health-related quality of life outcomes between the treatment and control groups were compared using: (1) medication and medical services costs, (2) medication appropriateness index (MAI) scores and (3) health-related quality of life scores. In addition, data from the pharmacist's documentation was analyzed to describe the clinical progress of the intervention group and define the types of interventions performed by the pharmacist during the six month study period. The instruments will be described first followed by the data collection procedures. Administrative data for medication and medical services costs and MAI and SF-36

health survey scores were selected as outcome measures based on previous studies which showed evidence of their practicality, reliability, validity and accuracy.

i. Assessing Economic Outcomes

To demonstrate explicitly that pharmaceutical care offers a cost savings to the health-care system and society, an analysis that measured the drug and health service utilization costs between populations receiving traditional pharmacy services versus pharmaceutical care was required. To accomplish this, an analysis of the costs of medications and health services from an administrative database for a time period of six months before the study and six months during the study was used. Pre-intervention economic baselines were determined for health service utilization using cost data from Alberta Health. The application for data request and approval for release conditions is shown in Appendix 8. Payments to practitioners were extracted from claims paid for basic services to physicians, chiropractors, oral surgery, optometry and podiatry. Basic services includes: office visits, radiological examinations not performed in hospitals and fee for service services such as surgery and anesthesia provided in hospitals. Medical laboratory services were not included in basic service cost estimates.

Hospital morbidity data provided the number of inpatient separations, sum of patient days, and number of day procedures. It was not possible for Alberta Health to capture all possible admissions, as the data extract was performed before all Alberta hospitals had submitted their data. Due to time constraints, the data extract was performed after all Edmonton hospitals had submitted their data, and as part of the post-interview follow-up, verbal confirmation was received that no hospitalizations outside Edmonton occurred in either the treatment or control groups. This latter process

increased the liklihood that Alberta Health data did capture all possible hospitalizations relevant to the study population during the intervention period. Using provincial rates, hospital costs were estimated using an average rate for hospital days and day procedures in an Edmonton area hospital. A day procedure estimate of $292.00 and average hospital day estimate of $847.50 was determined from correspondence with Alberta Health (9). Exact cost estimates would have required information such as case mix descriptions and this analysis was beyond the scope of this project.

Drug utilization claims were obtained by formal request from the participants' various drug benefit plans. Drug claims data typically included the generic name and/or drug identification number (DIN), date of claim, quantity of drug dispensed and amount paid by the benefit plan. The acquisition cost for each drug from the 1994 Alberta Health Drug Benefit List was used in the analysis to estimate the drug costs.

ii. Assessing clinical outcomes

Assessment of clinical outcomes can be defined as endpoints of the disease (typically ascertained by the physician) or the patient's experience in response to pharmacotherapy or disease (10). Clinical outcomes from the patient's experience may be subjective and complex, particularly when there are multiple disease states and medications involved (8,11). In this study, clinical characteristics about the patient's experience with medications and disease were extracted from care plans and patient progress notes. Symptomatologies and drug-related events identified and resolved by the pharmacist represent the patient's perspective. Because appropriate diagnoses, treatment and pharmaceutical care do not always result in positive clinical

outcomes, a clinical outcome variable which could not be biased by the subject, clinician or study pharmacist was necessary.

The medication appropriateness index (MAI) was selected as the unbiased indicator for clinical outcomes since the presence or absence of an appropriate medication is explicit and reflects the clinician's ability to make an accurate diagnosis and prescribe treatment in addition to the pharmacist's ability to identify, prevent and resolve drug-related problems. Appropriate drug therapy , monitoring and follow-up were expected to increase the likelihood of a positive patient experience with medications. The MAI sought to capture these aspects of drug therapy and assess the optimality of the pharmacotherapy the study subjects received. The (MAI) has been shown to provide a reliable method to assess drug therapy and has been used as a quality of care outcome measure in health services research (12,13). The MAI instrument has been validated for its clinimetric properties in evaluating the effectiveness of pharmacist interventions among veterans on many medications (12). The MAI produces a single summated score from 10 explicit and weighted criteria applied to each patient's medication as shown in table 3.1. The scores range from 0-18 per drug. High scores represented a deviation from optimal prescribing (14,15). A total score of 0 indicates no prescribing problems and a score of 18 indicates the most prescribing inappropriateness. The weighted MAI score per patient is the sum of MAI scores for each drug in a patient's regimen (14,15). The average MAI score per patient was defined as the sum of all weighted MAI scores for each drug ÷ by number of drugs per patient (15). Each of the 10 MAI criterion had an operational definition, explicit instructions and an example of how the MAI instrument is applied to a specific drug. A sample of the MAI score sheet and forms used to tabulate the summated scores is provided in Appendix 3. Previous studies have shown that MAI

assessments made by physicians and pharmacists achieve excellent inter-rater and intra-rater reliability (11,14,15).

Table 3.1 : Medication Appropriateness Index Criteria and Relative Weightings

Criterion	Relative Weight
1. Is there an indication for the drug?	3
2. Is the medication effective for the condition?	3
3. Is the dosage correct?	2
4. Are the directions correct?	2
5. Are there clinically significant drug-drug interactions?	2
6. Are there clinically significant drug-disease interactions?	2
7. Are the directions practical?	1
8. Is this drug the least expensive alternative compared with others of equal utility?	1
9. Is there unnecessary duplication with other drugs?	1
10. Is the duration of therapy acceptable?	1

iii. Assessing health-related quality of life

Health-related quality of life (HRQOL) measurement has become increasingly important in predicting health resource utilization and the evaluation of drug-related outcomes (1,11,16). HRQOL is a subjective construct with no inherent meaning outside a specific context (16). The importance of assessing HRQOL in the evaluation of pharmaceutical care is that it represents the humanistic dimension in treatment decisions, particularly when exploring the costs and outcomes of an intervention (11,17).

HRQOL is influenced by several factors including opportunity, perceptions, social well-being, psychological well-being, physical well-being and role limitations. The contribution of community pharmacists to improve the HRQOL of patients begins when each pharmacist takes responsibility for an individual's response to drug therapy and aims to reduce as much drug-related risk to the patient as possible (11,16).

HRQOL may be a suitable outcome measure for pharmacists to evaluate their contributory benefits of care. The Short-Form Survey (SF-36) is a HRQOL instrument that has been used to discriminate between patients with varying degrees of health status, i.e., depressive disorders (1). As well, the SF-36 can be used to evaluate the impact of an intervention by monitoring changes in mental and physical scores from baseline (1).

The SF-36 Survey was chosen to assess HRQOL because it provided a generic, non-disease specific measure of a person's perspective on their own health status (1,18). The SF-36 is a brief, easy to self-administer questionnaire that measures health on eight multi-item dimensions including physical functioning, role limitation due to health problems, bodily pain, social functioning, general mental health and well-being, role limitation due to psychological distress, vitality and general health perceptions. These eight dimensions represent two concepts interpreted as physical (PCS) and mental (MCS) components of health status (1). The strength of these components is their value in distinguishing between physical and mental health outcomes (1). A possible limitation of using HRQOL as an outcome is that it is under-studied in the ambulatory setting. Reports of use have been cited as sparse and

mixed, therefore interpretation should be done with caution (11). The SF-36 is recommended in a patient population likely to benefit from monitoring as it is practical, easy to self-administer and it has demonstrated an ability to detect small changes in health status (11).

SF-36 scores can potentially range from 0-100 for each component score. Content and criterion based interpretations of scores rely on established norms. Normal scores for the general U.S. population are 50 ± 10 for both MCS and PCS scores. Interpretation of low or high scores is based on norms according to established age groups and in absence or combination of common disease states. For the age strata of this study high scores range between 65-74 and reflect no physical or psychological morbidity and an excellent general health rate, versus a low score ranging between 9-29, indicating substantial physical or psychological morbidity.

iv. Patient Care Variables

Patient care was quantified and defined in this study using the pharmacist's documentation of interventions and patient outcomes in the care-plans and progress notes. Evidence of the efficiency and effectiveness of the documentation process came from the consistency in which documentation among the 16 treatment subjects occurred and the ability to translate the documented activity into the ten identified processes of care (patient care variables) that exemplify pharmaceutical care (Table 3.2). Overall effectiveness of the documentation was assessed by whether the process facilitated identifying, preventing and resolving drug-related problems in the treatment patients.

Table 3.2: Definition of coding used to identify pharmacist intervention variables in patient documentation

Pharmacist's Intervention Variable	Code of Variable	Definition of Variable
1. Patient Screening (N) normal result (Ab) abnormal result	PT(S)	Pharmacist performed screening for cholesterol, blood pressure, blood glucose, or occult bleeding.
2. Patient Interview	PT (I)	Pharmacist obtains medical and medication history.
3. Patient Monitoring (I) improves, (NC) no change, (W) worsened	PT (M)	Pharmacist contacts patient for a specific outcome related to their pharmacotherapy.
4. Patient Follow-up	PT(F)	Pharmacist contacts patient regarding general well-being and ensures patient isn't experiencing any new problems.
5. Patient Education/Counseling	PT (C)	Pharmacist provides specific drug/disease related information and suggestions to optimize patient outcomes to drug therapy.
6. Patient receives refill	PT(R)	Pharmacist provides patient with refill - classified as a dispensing activity
7. Patient receives new drug	PT(D)	Pharmacist provides patient with new drug - classified as a dispensing activity
8. Physician information	DR (I)	Pharmacist provides physician with specific information regarding patient outcomes and/or drug therapy of patient.
9. Identification of a drug-related problem	DRP	Pharmacist identifies and begins process to resolve the problem.
10. Recommendation to Physician (A) accepts, (R) rejects	DR (R)	Pharmacist provides written and/or verbal recommendation to physician concerning patient's drug therapy.

Documentation formats modified for use in this project included the Pharmacist's Drug Therapy Work-up (PDWT) and Health Plus Version 1.0 (19,20). The original format of the PDWT was modified into a careplan to be used for work-up of all drug-related problems. The pharmacist, however, found the format unmanageable as a consistent way to provide formative documentation. For study objective 3, the

documentation process maintained the interview format from the Health Plus Version 1.0 and the careplan process from the PDWT to provide an overview of each patient's current medications and establish a starting point in optimizing their pharmacotherapy. In addition, a section called Progress Notes was added to facilitate the pharmacist's documentation of all pertinent interventions and patient activity in free-text form.

Each entry described the contact between the treatment subject and study pharmacist, whether it was to describe the intervention, patient outcome or drug-related problem or patient perspective of their current drug or medical experience. Patient outcomes were clinical measures taken during screening interventions and self-reports of well-being and responses to medications during monitoring and follow-up interventions. Patient outcomes of screenings were defined as normal or abnormal and self-reports during monitoring and follow-up were translated to reflect their perception of health state as improved, no change or worsened. In addition, interventions which were recommendations to physicians on the patient's behalf were further categorized by whether the physician accepted or rejected the pharmacist's recommendation.
For intervention variable 9 from Table 3.2, "identification of a drug-related problem" follows closely with previous definitions of drug-related problems (21). Table 3.3 shows the types of drug-related problems defined for this study. Note that drug-related problems 9-11 were not original to the drug-related problems cited by Strand,

et. al., (21,22) and were added to increase the specificity of events experienced by the study patients.

Table 3.3: Definition of Drug-Related Problems

DRP	Assessment	Causes
1	Needs pharmacotherapy	Untreated condition, needs synergistic or prophylactic therapy.
2	Duplication of therapy	More than one prescribing physician, lack of understanding of pharmacologic principles.
3	Too little of correct drug	Wrong dose, inappropriate frequency, duration or administration.
4	Too much of correct drug	same as above
5	Experiencing adverse effect	Allergy, intolerance, dosage increased or decreased too fast, incorrect administration.
6	Experiencing drug/drug, drug/disease or drug/food interaction	Known contraindications of given combinations.
7	Receiving less than optimal or wrong medication for indication	Drug not indicated for condition or more effective medication is available.
8	Receiving medication for which there is no indication	No medical indication, addiction or recreational drug use, non-drug therapy more appropriate, treating avoidable adverse reaction.
9	Drug, dose and frequency correct for indication, but patient not responding to therapy	Iatrogenic reason for lack of drug's effectiveness
10	Medication requires clarification	Medication, dose or frequency changes with no apparent reason, illegible prescription
11	Non-adherence to drug regimen	Drug product not available, cannot afford drug, cannot administer drug, forgets or chooses not to take medication, does not understand instructions.

Data collection occurred as follows:

i. Medication and medical services cost data: Control and treatment participants provided the investigator with their drug benefit and Alberta health identification numbers. These identifiers were submitted to the respective agencies requesting cost data for the six month period prior to and during the study period. Data provided by Alberta Health and Alberta Blue Cross comprised the majority of the costing database. Seven of the 30 patients data came from independent drug benefit plans. Costing data typically included the drug name, drug identification number (DIN), quantity and amount of the claim paid. Details on the reimbursement structure of each benefit plan were also secured in order to calculate the acquisition costs of the drugs that were claimed but not found in the 1994 Alberta Health Drug Benefit List.

ii. Medication Appropriateness: A summated medication appropriateness index score was calculated at the end of the six month study period for each study subject. As a minimum requirement, a current medical and medication list was prepared for each study subject (12,13). For the treatment group, this information was extracted from the patient's documentation. For the control group, the investigator obtained the pertinent information from the patient during a telephone interview. MAI scores for each drug of a patient's drug regimen was assessed by a family practitioner, clinical research pharmacist, and a geriatric consultant pharmacist. The average summated MAI score from the three evaluators was used for each drug. A total average summated score for each group was calculated by summing all averaged MAI scores and dividing this sum by the total number of drugs evaluated for each group. An overall score for medication inappropriateness was compared between groups.

iii. Health-related quality of life: Control and treatment volunteers self-administered the SF-36 survey at the initial meeting after signing informed consent and again by mail at the end of the six month study period. The investigator choose the mail-out/mail back method for collecting data at the end of the study instead of a telephone interview because evidence suggested an inflation of the mental component score with telephone interviews (18). All participants were mailed a package with a letter that thanked them for their participation and provided instructions to complete and return the enclosed health survey. A pre-paid envelope was provided to return the document. On return of the second survey, the investigator advised participants that they would receive a complimentary copy of "The Pill Book". Control participants were also offered an opportunity to receive the same pharmaceutical care services at the study site under the same conditions as the original study participants for a six month period.

iv. Patient Care Variables: Patient care variables consisted of quantifying and categorizing the activities the study pharmacist reported in the patient progress notes. Clinical data for the treatment subjects was collected from the interview and careplans and counted by coding the patients outcomes documented in response to the type of intervention the study pharmacist reported to have performed. Characteristics extracted from the patient's documentation were coded and counted to provide descriptive statistics on the characteristics of the treatment subjects and pharmacist's interventions. Data collection included: (1) prescription medications, (2) over-the-counter preparations, (3) past and current medical conditions, (4) current symptoms, (5) pharmacist's intervention (6) drug-related problems identified, and (7) drug-related problems resolved.

5) Analysis

A descriptive analysis was used to define the study population's demographics, pharmacist's interventions and determine frequencies and distributions of the variables. A Chi-square test was used to ascertain the homogeneity between the control and treatment groups for data that were nominal. When cells fell below five, a Fisher's Exact was used. In cases where the data was interval and comparisons of mean differences between groups were permitted a t-test or non-parametric equivalent, Wilcoxon rank sum, was performed (23,24).

Outcome variables used to test the study hypothesis were medical and drug utilization cost estimates, MAI summated scores and SF-36 survey scores. Mean difference scores (pre-post) were compared between treatment and control groups. A t-test and Wilcoxon rank sum was performed using a two-tailed test with statistical significance achieved at p-value < 0.05 for H1 and a one tailed test with p-value < 0.05 for the remaining null hypotheses in response to pharmaceutical care versus traditional pharmacy services:

H1. Medication costs are not different between control and treatment subjects.

H2. Health service utilization are not different between control and treatment subjects.

H3. Medication appropriateness scores are not different between control and treatment subjects

H4. Health-related quality of life measures are not different between control and treatment subjects.

Results from this study follows.

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CHAPTER FOUR

RESULTS

The overall aim of this study was to evaluate the provision of pharmaceutical care in a community-based setting and describe a method of documenting activities and outcomes during the provision of pharmaceutical care. The outcomes used to explore the relationship between pharmaceutical care and patient/health system benefits included economic, clinical and health-related quality of life measures. Data for economic outcomes were collected from drug and health services claims to determine whether pharmaceutical care could contribute to reducing overall drug and health service utilization costs. The effect of pharmaceutical care on clinical outcomes was evaluated using the Medication Appropriateness Index. Health-related quality of life outcomes were assessed pre and post intervention using the Short Form-36 Health Survey.

The results from this project are presented in three sections. The first section describes the demographic, economic and clinical baselines of the study population to ascertain homogeneity between the two study groups. Section two provides results for the study hypotheses by comparing the change in differences from baseline in economic, clinical and health-related quality of life outcomes. Section three is a descriptive analysis of the study pharmacist's activities taken from the documentation of pharmaceutical care during the six month study period. All analyses performed in this study were done with SPSS 7.0.1.

Section I - Patient Recruitment and Pre-Intervention Characteristics of Treatment and Control Groups

Between November 14, 1995 and March 15, 1996, 69 individuals responded to five separate recruiting initiatives which invited individuals living in south Edmonton to participate in a study if they met the specified inclusion criteria. Inquiries ranged from individuals interested in knowing more about the study to physicians voicing concern about the legitimacy and ethics of the study. Of the 69 inquiries, 39 self-selected subjects met the inclusion criteria and attended one of the six information sessions. Thirty-three subjects gave informed consent and were enrolled into the study. Follow-up with three subjects withdrawing from the study revealed that one individual in the control group was participating in another clinical trial; one individual in the treatment group felt her participation would increase her awareness about her illnesses and this caused her too much anxiety; the third individual, also randomized into the control group, could not be reached despite several attempts. Recruitment strategies concentrated on a south Edmonton neighborhood of approximately 7000 households. Several individuals inquired whether their medications would be paid by the study. The low number of attendees in contrast to the initial inquiries may be a factor that free medications were not a benefit of participating in this study. Table 4.1 provides a summary of patient recruitment outcomes.

Table 4.1: Patient recruitment results

Type of recruitment strategy	Number of inquiries	Number of inquirers attending information sessions	Number of attendees who signed informed consent	Number of participants with-drawing from study
a) Newspaper advertisements n = 3	30	19	16	1
b) Flyers n=7000	9	7	6	0
c) Display at a large food-chain pharmacy for n=3 x 8 hr sessions	30	13	11	2
d) Letters to physicians requesting patient referrals n = 48	0	0	0	0
TOTALS	69	39	33	3

From the 69 inquiries, 33 subjects signed consent forms, however two control subjects and one treatment subject withdrew at the onset of the study, leaving 16 subjects in the treatment group and 14 subjects in the control group. All 30 subjects remained in the study for the entire study period. These subjects completed the SF-36 health survey and a demographic and medical history questionnaire following informed consent. Table 4.2 provides a summary of pre-intervention patient demographics. Note that for all tables only the p-value from the non-parametric statistical test is reported unless stated otherwise.

Table 4.2: Pre-study Patient Demographics

Characteristic	Treatment n = 16	Control n = 14	p-value[1] (two-tailed)
Gender			
male	5	4	1.0
female	11	10	
Age in years[2]			
x ± s.d.	57.43 ± 11.51	52.14 ± 19.10	.90
Household income[3]			
≤ 20,000	5	5	
> 20,000	11	9	.73
Education Level			
≤ grade 12	5	5	
> grade 12	11	9	1.0
Type of Pharmacy			
small independent or chain	3	7	.12
grocery chain or where cheapest	13	7	

1. Fisher Exact Test used unless otherwise stated
2. t-test
3. income split at median

Chi-square and Fisher Exact tests showed no statistically significant differences for patient demographics, therefore homogeneity at baseline was observed between groups for gender, average household income, education level and type of pharmacy study subjects patronized prior to the study intervention. Although no statistically significant differences were found, half of control patients received pharmacy services from a small independent versus less than one-third of treatment patients prior to the intervention. This observation is noted because pharmaceutical care is more likely to be practiced in small, independently owned pharmacies that typically have lower prescription volumes than large grocery chain or discount pharmacies which have higher than average prescription volumes (1).

Table 4.3 shows no significant differences between the pre-intervention study groups for health utilization and drug cost estimates. An analysis of the distributions of the economic variables identified two outliers in the health utilization data. Inquiry revealed that one treatment patient had been on the waiting list for triple bypass surgery prior to participating in this study and was called for surgery during the intervention phase. Follow-up on the outlier from the control group was not possible; as part of the data release conditions stated the researcher was not permitted to contact the study participants about the data. Both outliers were removed from the analysis two avoid introducing bias by removing only the outlier from the treatment group.

Table 4.3: Comparison of economic data between groups at baseline

Cost Estimates (Canadian dollars)	Pre-treatment[2] n = 16	Pre-control[2] n = 14	p value[1]
Practitioner visits	605 ± 415	495 ± 632	.34
Inpatient hospital	0	0	1.0
Day Surgery	110 ± 180	84 ± 179	.59
Prescription drugs[3]	734 ± 441	628 ± 358	.70

1. t-test and Wilcoxon rank sum
2. one outlier from each study group was omitted from analysis
3. two treatment and one control case had incomplete data

Table 4.4 shows there were no significant differences between the types of co-morbid conditions experienced in the treatment and control population prior to intervention. In addition to the most common conditions listed, the treatment group also had diagnoses of cancer, menopause, hypothyroidism, migraines, mutiple sclerosis, Sjorgen's disease, Cohen's disease and chronic fatigue syndrome.

Table 4.4: Comparison of conditions between groups at baseline

Conditions (top 7)	Treatment[2] n = 16	Control[2] n = 14	p value[1] (two-tailed)
Arthritis	10	6	.46
Insomnia/Depression	9	10	.71
Cardiovascular/ Highblood pressure	8	12	.67
Gastrointestinal	8	7	1.0
Pain/Fatigue	6	4	.44
Diabetes	3	2	1.0
Asthma	2	6	.20

[1]Fisher's Exact Test
[2]Does not sum to n because most subjects had more than one condition

As well, Fisher's Exact tests showed no significant differences in the number of co-morbid conditions among the two groups as shown in table 4.5.

Table 4.5: Multiple conditions present in groups at baseline

Number of Conditions Present	Treatment Group n = 16	Control Group n = 14	p value[1]
1	1	2	1.0
2-3	4	2	.44
4 or more	11	10	1.0

[1] Fisher's Exact Test

Table 4.6 provides additional clinical characteristics on the treatment group. An analysis using pre and post drug utilization data could not be performed because the control subjects did not provide any information regarding the medications they were taking at the beginning of the study period. If the investigator had access to a medical history for the control patients, it may have been possible to detect drug-related problems and be unethical to ignore.

Table 4.6: Pre-intervention clinical characteristics of treatment group

Clinical Characteristic	mean number ± s.d. n = 16
medications	6.9 ± 2.6
symptoms	8.3 ± 3.6
conditions	4.0 ± 1.2

Table 4.7 shows there were no significant differences between the treatment and control groups mental and physical component scores from the SF-36 health-related quality of life survey at baseline. These scores, however represent a deviation from 50 ± 10, normal scores for the general population in the United States (2). These scores are consistent with findings in other studies measuring mental (MCS) and physical (PCS) component scores in populations with co-morbidities (2).

Table 4.7: Comparison of health-related quality of life scores at baseline

SF-36 HRQOL mean ± s.d.	Pre-treatment n = 16[2]	Pre-Control n = 14[2]	p value[1]
Mental Component Score	40.4± 6.6	38.21 ± 5.5	.61
Physical Component Score	38.9 ± 7.4	39.4 ± 7.2	.64

1 t-test and Wilcoxon rank sum
2 one incomplete survey omitted from analysis

The randomization of the treatment and control group appears to be successful given that no statistically significant differences were observed for any of the variables measured at baseline. This observation suggests that subject bias and potential confounding factors are likely equally distributed between the two groups.

Section Two: Testing the Study Hypotheses

Results for the study hypothesis H1, in response to pharmaceutical care, assumed that Ho was mean differences = 0 and Ha was mean differences $\neq 0$.

H1. Overall medication costs were not different between control and treatment subjects.

Table 4.8 shows that there were no significant differences between control and treatment medication cost estimates from baseline, therefore the null hypothesis is not rejected.

Table 4.8: Between group post-intervention economic data

Prescription Drug Cost Estimates	treatment n=16[2]	control n=14[3]	p value[1]
Pre-intervention	734 ± 441	623 ± 358	
Post-intervention	1010 ± 990	911.13 ± 695	
Mean difference ± s.d.	358 ± 898	283 ± 513	.96

1 t-test and Wilcoxon rank sum
2 two pre-intervention cases had incomplete data
3 one pre-intervention case had incomplete data

An effect size of 0.14 was calculated, indicating only a low effect could be detected in an adequate sample for differences in prescription drug costs. The sample size necessary to detect this effect is approximately 698 subjects per group assuming a two-tailed $\alpha = 0.05$, $\beta = 0.20$. However, despite no significant changes in drug costs, Table 4.9 shows a significant decrease in the mean prescribed drugs utilized by the treatment group.

Table 4.9: Treatment group pre and post - intervention number of medications

Mean ± s.d Medications	PRE n = 16	POST n = 16	p value[1]
prescribed	6.9 ± 2.6	5.3 ± 2.0	.02

1 Wilcoxon Rank Sum

H2. Overall health service utilization costs were not different between control and treatment subjects.

Table 4.10 shows no significant changes between the study group's health services utilization cost estimates overall. A downward trend in practitioner visit costs in the treatment group was observed and this variable was tested seperately. An effect size of 0.4 and sample size of 77 subjects per group was calculated for this variable. For health care utilization overall, an effect size of 0.3 was calculated using the mean difference between each cost estimate variable and dividing by the standard deviation of the control variable's mean difference. The sample size necessary to detect this effect using a one-tailed alpha of 0.05 and beta of 0.20 is 137 subjects per group.

Table 4.10: Effect of pharmaceutical care on health services utilization data

Economic Variable mean cost ± s.d.	treatment n=16	control n=14	p value[1]
pre-intervention			
Practitioner visits	605 ± 415	495 ± 632	
Inpatient hospital	0	0	
Day Surgery	110 ± 180	83.± 179	
post-intervention			
Practitioner visits	455 ± 269	493 ± 567	
Inpatient hospital	37 ± 148	0	
Day Surgery	73 ± 200	42 ± 106	
Mean Difference ± s.d.			
Practitioner visits	-150 ± 394	-2 ± 361	.29
Inpatient hospital	37 ± 148	0	-
Day Surgery	-37 ± 210	-42 ± 225	-
Sum of health services	-97 ± 681	319 ± 1472	.48

[1] t-test and Wilcoxon rank sum

H3. Medication appropriateness between control and treatment subjects at post-intervention showed no significant difference.

Table 4.11 shows there were no significant differences in MAI scores, however a trend of less medication inappropriateness in the intervention group was observed. An effect size of 0.6 was calculated, indicating a moderate to high effect. The sample

size necessary to detect a significant effect would have been 34 subjects per group assuming a one-tailed $\alpha = 0.05$, $\beta = 0.20$.

Table 4.11: Effect of pharmaceutical care on medication appropriateness scores

	treatment n = 16 N = 90 drugs	control n = 14 N = 91 drugs	p value[1]
summated MAI score	1.22 ± 0.79	1.87 ± 1.12	0.07

[1] t-test and Wilcoxon rank sum

H4. Health-related quality of life did not differ between control and treatment groups.

Table 4.12 shows no differences between the pre and post intervention findings from the health-related quality of life SF-36 surveys at the $p = 0.05$ level. The effect size calculated for both the mental and physical component scores (MCS and PCS respectively) was 0.3, indicating that pharmaceutical care has a low to moderate effect on HRQOL scores. The sample size needed to detect a significant difference between the groups would be 137 subjects per group assuming $\alpha = 0.05$, $\beta = 0.20$.

Table 4.12: Effect of pharmaceutical care on SF-36 Scores (HRQOL)

MCS & PCS Scores mean ± s.d.	treatment n=16	control n=14	p value[1]
pre-intervention			
MCS	46.4 ± 12.6	43.24 ± 13.3	
PCS	34.4 ± 10.6	36.8 ± 11.6	
post-intervention[2]			
MCS	49.7± 12.8	43.8 ± 10.9	
PCS	35.4 ± 12.2	38.2 ± 11.4	
mean difference ± s.d			
MCS	3.5 ± 7.9	0.4 ± 11.2	.78
PCS	1.5 ± 7.8	3.0 ± 5.6	.55

1. t-test and Wilcoxon rank sum
2. one post intervention survey missing from each group)

Section Three: Description of the Pharmacist's Interventions

A descriptive analysis of the study pharmacist's activities is described in the following section. Intervention participants received pharmaceutical care from the

study pharmacist at her pharmacy. Control participants obtained pharmacy services from their regular pharmacies in the usual manner. Activity data was not obtained from control patient's pharmacists during the intervention period to avoid the potential for the Hawthorn Effect, whereby the awareness of the study could heighten the level of typical intervention that occurred between the control patient and the pharmacists providing pharmacy services (3).

Table 4.13 summarizes the pre-intervention treatment patient's clinical characteristics and the patient care activities they received over the 6 month study period. This data provides background for interpreting and quantifying the interventions documented by the study pharmacist.

Table 4.13: Pre-intervention patient characteristics and summary of pharmacist interventions

Characteristics for 16 treatment patients	mean ± s.d occurrences per patient
Prescribed medications	6.9 ± 2.6
Over-the-counter medications	3.6 ± 2.6
Symptoms	8.3 ± 3.6
Conditions	4.8 ± 2.6
Drug-related problems identified	4.6 ± 2.4
Drug-related problems resolved	2.4 ± 1.6
Pharmacist interventions - non-dispensary	30.9 ± 14.8
- dispensary	11.9 ± 5.7

From these observations the population takes approximately one prescribed or over-the-counter medication per symptom or condition present. On average, this population experienced one adverse drug event for every 1.5 drugs prescribed and the pharmacist was able to resolve about half of these drug-related problems. This data

supports the evidence in the literature of the risks of polypharmacy and experiencing an adverse drug event (4).

Table 4.14 shows that non-dispensing activities represented 72% of activity overall, suggesting that patients with multiple conditions and medications require intense monitoring and follow-up. Patient monitoring, counseling and follow-up activities comprised the largest component of non-dispensary activity.

Table 4.14: Distribution of pharmacist's activities

Pharmacist's Intervention	Percentage of overall activity n=709
1. Patient Screening	4.2%
2. Patient Interview	2.3%
3. Patient Monitoring	14.4%
4. Patient Follow-up	19.5%
5. Patient Education/Counseling	17.1%
6. Patient Receives Refill	19.2%
7. Patient Receives New Drug	4.4%
8. Physician Information	2.5%
9. Identification of a Drug-Related Problem	10.3%
10. Recommendation to Physician	6.2%

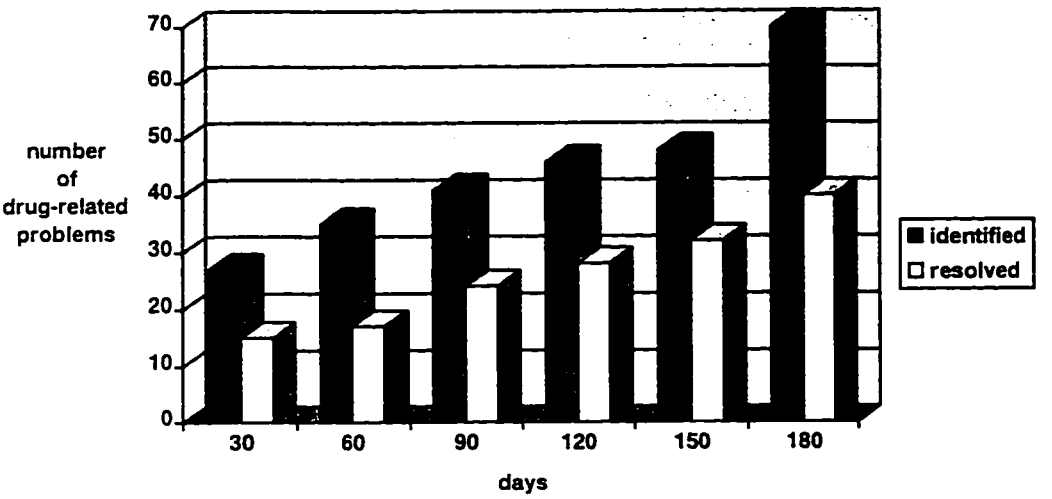
Table 4.15 quantifies and categorizes the drug-related problems experienced and resolved among the patients in the treatment group. The most common drug-related problems identified were adverse effects, not responding and non-adherence. Problem resolution was most successful for drug-related problems, needs pharmacotherapy, not responding and clarification, although only one case of clarification was observed.

Table 4.15: Number of patients experiencing each type of drug-related problem identified & resolved in treatment group

Drug-related Problem Type	Frequency of Identified Drug-related Problem	Percentage of time problem resolved
1. Needs Pharmacotherapy	7	85%
2. Duplication of Drug	4	25%
3. Too Little Drug	5	60%
4. Too Much Drug	2	50%
5. Adverse Effect	19	47%
6. Drug Interaction	2	50%
7. Wrong Drug	4	25%
8. No indication	2	50%
9. Not Responding	13	69%
10. Clarification	1	100%
11. Adherence	7	40%

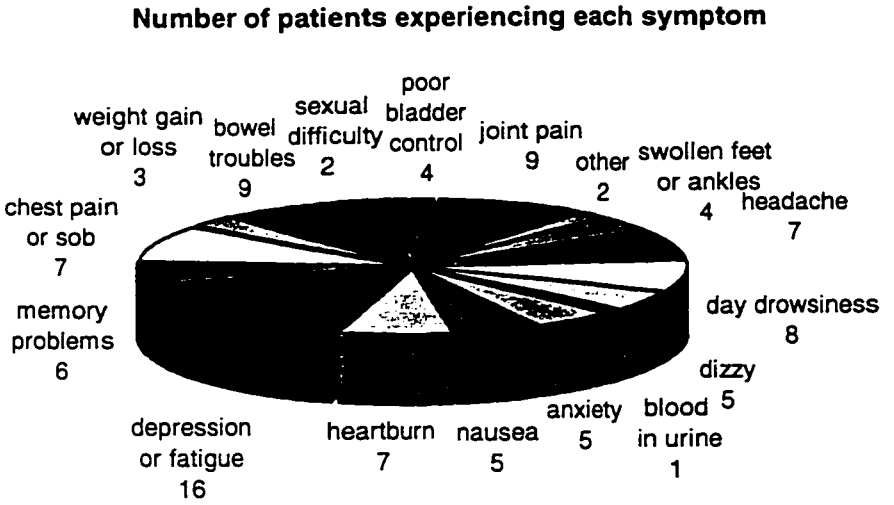
Graph 4.1 shows that over the six month study period the majority of drug-related problems were identified in the first month and last month of the study. Over the six month period 46% of the total drug-related problems were identified in the first two month period, 14% identified in the second two month period and 40% identified in the last two month period. Fifty-seven percent of all identified drug-related problems were resolved evenly over the six month study period.

Graph 4.1: Number of drug-related problems identified and resolved over six month study period



Graph 4.2 shows that the treatment group experienced several symptoms concurrently, and depression and fatigue were the most predominant presenting symptoms. Bowel problems, joint pain, day drowsiness and gastrointestinal symptoms were also prevalent symptoms experienced by the treatment group. The level of symptomatology occurring in this population is consistent with some of the findings in the National Population Health Survey where arthritis, migraines and asthma are among the common conditions (5). The high incidence of headaches, shortness of breath and joint pain are also indicative symptomatology of the most common chronic conditions experienced by Canadians. Depression or chronic fatigue were experienced by all treatment patients, which explained why the treatment group scored lower than norms for the general US population, but consistent with MCS and PCS score norms for the US population having hypertension, myocardial infarction, congestive heart failure, diabetes type II and clinical depression combined (2).

Graph 4.2: Distribution of 103 Symptoms Experienced by 16 Treatment Patients on Initial Interview



In summary, the evaluation of economic, clinical and humanistic outcomes in response to the provision of pharmaceutical care showed no statistically significant finding. The effect size varied from 0.14 - 0.6 indicating that the effect of pharmaceutical care on the various response variables ranges from low to moderate. The most outstanding effect pharmaceutical care demonstrated in this pilot study was the overall decrease in number of medications utilized by the treatment group, however this was limited to a within group comparison as baseline data for number of prescribed drugs taken by control participants was not requested .

A discussion of these results and their significance to future practice research follows in Chapter five.

Notes to Chapter Four

1. Sisson EM, Israel MK. Extent of community-based delivery of pharmaceutical care in Virginia. Pharmacotherapy 1996;16:94-102.

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CHAPTER FIVE

DISCUSSION

"Knowing without application is merely useless information"

Pharmaceutical care has been mandated as the model of pharmacy practice that might best respond to the unnecessary costs of drug-related morbidity and improve a patient's health-related quality of life (1,2). The economical and clinical benefits of pharmaceutical care have been demonstrated in an ambulatory population, yet there remains a gap in the literature on studies which combine these outcomes together with health-related quality of life to evaluate pharmaceutical care provided in a community pharmacy setting (3,4,5). Therefore, an examination of the economic, clinical and humanistic outcomes in response to the provision of pharmaceutical care in a community pharmacy was conducted.

Overall, this pilot study sought to evaluate the impact of pharmaceutical care on patient outcomes and describe one pharmacist's experience using a free-text format to document her interventions and patient outcomes. Specific study objectives included: (1) Provide pharmaceutical care to community dwelling residents who were at risk of experiencing drug-related problems; (2) Evaluate the impact of pharmaceutical care versus traditional pharmacy services using economic, clinical and health-related

quality of life outcomes; (3) Describe documentation process that fostered consistent reporting of patient information during the provision of pharmaceutical care.

This chapter provides an interpretation of major findings presented in chapter four. Section one discusses recruitment, homogeneity among control and treatment subjects, limitations of the study's self-selected population and the generalizability of findings using a national population health survey as a comparison. Section two discusses major findings relative to the four study hypotheses. Section three describes how the effectiveness and efficiency of the documentation was assessed. Section four provides a critical assessment of the pilot study, identifying limitations that should be considered when interpreting the findings and when designing future studies. Finally, this chapter provides conclusions from this pilot study.

Section One: Patient Recruitment, Homogeneity , Limitations and Generalizability

The major goals of the recruitment process were to have an adequate and unbiased sample of patients within a limited time-frame and budget. Recruitment initiatives were concentrated in areas having the highest independent living elderly population since past studies have shown elderly populations consume the highest number of medications per capita (6,7). In addition, recruiting patients outside the area where the study site was easily accessible might result in a higher drop-out rate if long distances for traveling between home and the study pharmacy were necessary (8).

The majority of inquiries came from ads placed in the community newspaper and an information booth about the study in a large food-chain pharmacy. The newspaper ads had the highest response rate (63%) and the subsequent signing of informed consent (53%). This finding might reflect that participants who responded to the invitation to participate had a higher level of interest in their medications and were therefore motivated to initiate the inquiry. Conversely, only 43% of individuals making inquiries at the information booth attended the informed consent session, of which 36% agreed to participate. The high visibility and convenience for individuals to approach the information booth while waiting for their prescriptions may explain this observation. As well, persons making the inquiry could have been picking up medications for someone else, therefore the interest of the individual inquiring did not necessarily reflect the interest of the individual meeting the study criteria.

The primary selection bias to consider in terms of generalizability is that responders are often more healthy than their non-responding counterparts, therefore the self-selected sample may underestimate the extent of individuals residing in the community who have an increased likelihood of drug-related risk (8). Conversely, the study participants may represent a less healthy population than their non-responding counterparts if they were individuals who felt they were not well managed or informed about their complex drug therapies and medical conditions. Regardless, the use of randomization and selection criteria in both printed and verbal forms decreased the opportunity for selection bias since the recruitment strategies were not

limited to whether persons could read or patronize a particular pharmacy. As well, recruitment occurred over a six month period and in theory the randomization process controlled for potential confounding variables.

The poor response rate to the various recruitment strategies in a higher than average elderly neighborhood also poses some limitations when generalizing the findings of this study. A poor response not only resulted in a sample size with inadequate power, but overall, may reflect the perceptions of older community-residing adults, with higher than average income and education, towards their need for a pharmacist to enhance their medication taking experience. "Income security and knowledge for problem solving improves people's ability to have a sense of control and mastery over life's circumstances" (9,10). Because the target population was educated and affluent, they may have not perceived a need for knowing more about their health and medications and therefore did not inquire or participate in the study. It would be useful to determine if individuals of a lower socioeconomic status meeting the study criteria would have a greater perceived need and therefore be more motivated to participate in this type of study. Lassila found that the oldest and least educated of the elderly population used the most drugs (6). The mean age of this study population was 54.9 $\pm$ 15.5 years which indicates that the sample was of an older adult but not an elderly population.

The intent of this study was to address the vast drug-related morbidity in an at-risk population according to medication and medical characteristics rather than focusing on a specific age or disease cohort. Future recruitment strategies should be targeted toward a more diverse socioeconomic population. As mentioned previously, this study's sample may not be representative of all subjects who meet drug-related risk criteria for an adverse drug reaction, as they were an above average income and educated population. However, they are likely representative of similar socioeconomic older adults living in Canadian cities.

By nature of the randomized-controlled study design, confounding by baseline variables was eliminated in the treatment and control groups. Baseline measures were established to compare mean differences in variables measured in response to pharmaceutical care. Homogeneity between the two study groups at the beginning of the study was established for the following costs: physician visits, hospital stays, day surgeries and prescriptions. As well, there were no significant differences at baseline for number and type of conditions, number of medications and health-related quality of life scores between the treatment and control groups.

Both the treatment and control groups had similar cost estimates to national per capita estimates for total health expenditures which included hospitalization, physician visits, prescriptions, research and pensions and benefits for people with illness (10,11). In Canada, the per capita total health expenditure was approximately

$2,000.00 for the age group 45-64 in 1995. The average health expenditure estimate per study subject over a one year period was $2180.00, which is consistent with the national findings for this age group (10,11).

The most prevalent conditions among the treatment and control population were cardiovascular disease (67%), mental disorders (63%), musculoskeletal (53%), gastrointestinal (50%) and respiratory disorders (27%). These findings are consistent with the most prevalent conditions associated with direct costs of illness estimates for Canada in 1993 which include cardiovascular disease, injuries, respiratory disease, musculoskeletal, digestive, cancer and mental disorders (11). The complexity of the study populations medical status was also equally distributed between the treatment and control group, where 70% of the study population presented with four or more co-morbidities.

Health-related quality of life was determined using the SF-36 Physical and Mental Summary Scales. This health measure distinguishes between a physical and mental health outcome, therefore an individual's sense of well-being can be assessed despite the presence of a chronic condition. Content and criterion based interpretations of scores rely on established norms and are further defined by physical and psychological morbidity and etiology (12). Scores were stratified into nine levels where high scores typical in the general U.S. population are level one and reflect scores between 65 - 74, indicating no physical or psychological morbidity and an

excellent general health rate. Low scores rated as a level 9 and ranged between 9-29, indicating substantial physical or psychological morbidity and a poor general health rate (12). The mean of each group's score was compared to general U.S. population norms for the 45-54 age group having various co-morbidities similar to the study population. Baseline scores for the mental (MCS) and physical (PCS) component scores was established at the beginning of the study period for both groups. Control subjects had a mean MCS score of 38.2 ± 5.5 and PCS score of 39.4 ± 7.2. Treatment patients had a mean MCS score of 40.4 ± 6.6 and PCS score of 38.9 ± 7.4. Statistical tests showed no significant difference between the study groups at the beginning of the study period, however the overall study group average for the PCS (35.5 ± 10.96) and MCS (44.9 ± 12.82) were well below the norms found in the general U.S. population for the 45-54 year age strata (PCS 49.64 ± 9.67 and MCS 50.53 ± 10.02). The mean scores for the treatment and control groups combined were typically at or below the 25th percentile scores of general U.S. populations presenting with angina, arthritis, pain and hypertension. The mean group score was in the 50th percentile of the MCS norms for depression, defined as self-report of 2 weeks or more feeling sad, blue or depressed in past year; or two years or more of feeling sad or blue most days; or feeling sad much of the time in past year (12). These measures confirm the medical complexity found in the treatment and control groups, as they were among the most severe found in populations with similar conditions. The high prevalence of depressive symptoms among the sample population is of particular interest, as a past

study found this characteristic the most important factor related to inappropriate medication use (13).

The impact of having inclusion criteria based primarily on medical conditions and drug use resulted in a study population with vast, complex medical and medication profiles. One advantage of the inclusion criteria was the increased likelihood that study patients would experience a drug-related event. However, resolution of problems presented by this population were not as immediate or obvious, therefore the impact of the pharmacist's intervention in terms of economic, clinical or health-related quality of life outcomes may not be realized during the study period of six months. Another advantage of the inclusion criteria was it was not disease, gender or age specific, therefore this population could have greater generalizability. However, by the nature of population demographics surrounding the study site, the generalizability of the findings in this study is limited to older adult populations of above average socioeconomic status. A possible disadvantage of the inclusion criteria was that limiting subject eligibility made recruitment of an adequate sample size difficult. As was the case with this study, a clear interpretation for some of the findings was limited by the lack of power. Despite these disadvantages, the results from this pilot study are useful to determine the utility of the evaluation instruments and to calculate effect and sample sizes of various outcome variables for use in future community-based studies examining pharmaceutical care.

Section Two: Testing the study hypotheses

The study hypotheses tested for significant differences between means of the treatment and control groups in response to the provision of pharmaceutical care. The three areas of measure were economic, clinical and health-related quality of life; consistent with the current focus within the health care system as a whole (14). As established in the background, pharmaceutical care has a mandate to enhance the efficiencies and effectiveness of the drug use process, ensuring that rational drug use occurs in response to patients' health needs and goals (15).

Evaluating pharmaceutical care solely on the outcomes of the findings from this study were limited by the small population sample. For example, an effect size of 0.3 was determined for the impact of pharmaceutical care on the overall health service utilization costs, indicating that for a moderate difference to be detected between the groups in this study with an alpha of 0.05 and beta of 0.20, a sample size of 137 patients in each group was required. The power for this variable in the current study was 0.16, which means there was only a 16% chance of detecting a 30% difference between the mean differences in costs between the treatment and control group. The effect size was provided for each variable in the results section and should be considered during the discussion of the findings.

H1. No significant difference in medication costs was found between groups at the end of the six month study period. In fact, both groups showed an upward trend from pre-study medication costs data. The increase in medication costs at the end of the intervention amounted to approximately $3.56 per prescription. This increase might be explained by a combination of factors including the annual increases in drug acquisition costs, new drugs being added to the drug insurance benefits list and drug therapies incorporating more expensive drugs. Lowering drug costs in a population with complex drug therapies and disease states can occur only if it were suitable to reduce the overall number of medications or substitute therapies for the lower cost alternatives. Knowlton and Knapp reported a reduction in drug costs of 8.3% per patient per month, mostly as a result of generic substitution (3). Paradoxically, a significant reduction in overall number of drugs was observed in the treatment group, a finding similar to Lipton and Bird, who found intervention patients were on fewer medications, had less complex drug regimens, and knew more about their medications (16). It is important to note that decreasing drug costs and drug utilization is not always indicative of an appropriate outcome of pharmaceutical care. For example, proper disease management of asthmatic patients in one study has shown that an appropriate economic outcome was an increase in drug utilization and drug costs at the end of the intervention period (17).

H2. Although there were no significant findings in mean differences between treatment and control groups for doctor visit, hospitalization and day surgery costs, a

downward trend for physician visit costs was apparent in the treatment group as compared to the control group, which showed no change. The downward trend observed in the treatment group for physician visit costs may be attributable to the strong follow-up and monitoring role by the study pharmacist. The pharmacist's interventions may have resolved drug/health-related issues for which the treatment patients normally visited their physician. The lack of change observed for hospitalization and day surgery costs may be explained in part by two findings in the per capita total health expenditures for Canadians. First, hospital spending has declined and pharmaceutical costs have increased (11). This may reflect the trend to provide care in the ambulatory setting using medications versus interventions requiring hospitalization. Second, since 1975 spending increased dramatically with age, in particular, per capita costs increased four-fold after the age of 65 (11). As noted previously, the overall per capita cost for health service utilization in the treatment and control group was consistent with the national findings within the same age strata (11). Because the average age of the study population was 55, the dramatic increase in hospitalizations would not be expected for another ten years based on national findings. However, given the study population had medication and medical histories characteristic of a 65 and older population (7,11), it would be reasonable to expect health service utilization to be similar, however this was not the case. A possible explanation may be that adults 55 - 60 years of age are less likely to require hospitalization for less than optimal drug therapy and disease management than the 65 and older age population.

H3. The mean difference between medication appropriateness index scores for treatment (1.2 ± 0.79) and control (1.9 ± 1.12) groups was insignificant ($p=0.07$) at the end of the study period, however an effect size of 0.6 was calculated, indicating a high effect could be detected in a sample with adequate power. As it stands, the sample provided a power of 69%. The possible range for the index score was between zero (no inappropriate criteria met) and 18 (all inappropriate criteria met). The expert panel found that treatment subjects had drug therapies meeting at least one of the four criterion with a relative weight of one. Comparatively, the control group had drug therapies where either one of the four criterion had a relative weight of two or two of the criterion weighted one. These weightings provide an indication of the severity and frequency of inappropriateness (18). A trend of less severe and less frequent inappropriateness was observed in the treatment group. This finding is similar to Stuck, et al., (13) who reported that 6.9% of prescribed medications in community-residing older persons were considered inappropriate and Hanlon et. al., who found a 24% decline in medication inappropriateness within a veteran's ambulatory medical center as a result of pharmacist interventions (4). Twenty of the possible ninety medications evaluated in the treatment group received scores of zero by all three raters, versus the control group, where only 7 of the possible 91 medications received a score of zero by all three raters. Of the identified drugs having inappropriate scores, the most prevalent cause of drug inappropriateness in the treatment group was unnecessary drug duplication (10%) followed by no drug

indication (5%). Opiod analgesics and anxiolytics were the two most problematic areas for medication inappropriateness. Similarly, Stuck, et al., found the most common inappropriate medications prescribed were long acting benzodiazepines (13). The medications having a high incidence of duplicate therapy among the treatment patients' drug-related problems were the opiods. Drug therapy duplication was relatively easy to identify by the pharmacist, but the resolution of this problem required the cooperation of patients and physicians. Further, drug dependency was noted by the pharmacist as an identified drug-related problem in several patients. Dependency on these classes of medications is a well known and complex event that may require a longer or more intensive rehabilitation period than the 6 months offered in this study. The most prevalent causes of medication inappropriateness among prescribed medications in the control group included no drug indication (10%), directions incorrect (8.7%) and drug-disease interactions (8.7%). The most problematic drug classes in the control group include gastrointestinal, antidepressants and anxiolytics.

Clinically significant drug-drug interactions were not found for any of the evaluated drugs. This may be the result of drug interaction software programs built into most computerized dispensing systems used in the community setting. A baseline measure of medication inappropriateness was not taken because randomization should account for any confounding effects on the scores. As well, the homogeneity of medication and medical characteristics among the treatment and control group was established at

baseline, strengthening the finding that pharmaceutical care may have contributed to improved medication appropriateness in the treatment group.

H4. There were no significant mean differences between the treatment and control group's MCS and PCS health-related quality of life scores. Mean score differences for MCS and PCS scores did, however, show an upward trend in both groups. Few comparative studies for health-related quality of life have been published. However, of the three reviewed in this paper, no significant differences in response to pharmaceutical care were found (4,19,20). The upward trend observed in this study's findings may have been a seasonal factor (21), as the first survey was completed during the winter months of November through March and the second survey was completed 6 months later during late spring to summer. The effects of seasonal influences on physical and mental component SF-36 scores are unknown, however future studies should consider the potential effect of seasonal influences when comparing follow-up measures to baseline when they occur in distinctly different seasons of the year.

Although the null hypothesis could not be rejected, interpretation of the differences from baseline in both groups is worthwhile noting. Using data from an observational study (MOS) on the functional status and well-being of adult patients sampled from various systems of care are norms for MCS and PCS changes over one year across various conditions (12). From this data, scores were considered to reflect changes in

status as worse or better if the differences were greater than ± 2 standard deviations from the mean. Patients were considered to have stayed the same if scores were within ± 2 standard deviations of the mean (12). The MOS population was a good comparator as this population had similar demographics, i.e. majority of participants were females, educated beyond high school level with an average age of 58 years, and co-morbid conditions, i.e. hypertension, clinical depression, sciatica/back pain, musculoskeletal conditions to the study population. Thus, average differences after one year follow-up in the MOS population were similar to those in the current study population after 6 months, showing that the health status for most patients having chronic conditions does not change easily.

Rates to predict health services utilization, depression, stress and life satisfaction in the general U.S. population have been stratified into 9 levels for MCS and PCS (12). Pre-study MCS scores for the treatment group were within the level 5 range (where 1 is best and 9 is worst) and the PCS score was a level 7. The control group's MCS and PCS scores both fell in the level 6 range. This finding, although not statistically significant may have clinical and economic implications. Following the study, the treatment group's MCS score moved into the level 4 range and the PCS score raised to a level 6. The control group's PCS score remained unchanged at level 6. The clinical significance could be that the treatment group shows a trend of improvement in response to pharmaceutical care. The move up by one PCS level reduces the likelihood of the treatment population having a recent visit to the physician by 7%.

This trend is also reflected in the savings observed in the treatment group's physician visit costs. As well, an improved score by one MCS level shown by the treatment patient's score increases the likelihood of life satisfaction by 15%, stress reduction by 12% and decreased utilization of mental health treatment by 3% (12).

Pharmaceutical care had a low to moderate effect on MCS and PCS scores, therefore to detect a statistically significant difference between groups a sample size of 137 subjects per group would have been required. Despite statistically insignificant mean differences for MCS and PCS scores between the two study groups, the treatment group did show a trend of improvement. In addition, small changes in scores based on levels of risks for using health service utilization, mental health treatment and life satisfaction indicate the scores are important predictors that could have significant economic, clinical and quality of life implications.

Section Three: Documentation and Pharmacist Interventions

Pharmaceutical care was documented for 16 treatment patients during the typical routine of a community pharmacist in her independently owned and operated pharmacy over a six month period. As evidence of the pharmacist's provision of care to the treatment patients, the study pharmacist provided the investigator with all the documentation completed for each treatment subject following the study period.

The study pharmacist initiated each patient's study period with a face-to-face interview to obtain a medical and medication history profile and information about

the subjects' lifestyle and personal health goals. The study pharmacist found that the interview process helped establish a professional relationship by increasing the patient's awareness about how the pharmacist would work with them to optimize their drug therapy. As well, the patient's past and present medical and medication history along with lifestyle information was paramount in identifying, preventing and resolving drug-related problems and developing careplans.

Careplans were developed using a format similar to the PDWT or Pharmacist's Work-up of Drug Therapy (22). Careplans were initially to be developed for each drug-related problem and to document monitoring and follow-up activities. This process became unworkable for the study pharmacist, and careplans became a map which established a starting point that directed interventions towards optimizing the patient's drug therapy in the continuum of care. To maintain continuity in the care, patient progress notes written in a free-text format replaced the careplan as a system to document the pharmacist interventions, communications and outcomes relevant to optimizing the patient's drug therapy. Each entry included the date, reason for contact, description of patient's outcome, plan for resolution if there was a problem and general comments on the patient's well-being and perceptions of progress toward specific goals of therapy. As well, the pharmacist integrated dispensing activities which made interventions such as compliance monitoring more convenient.

Pharmaceutical care provided by the study pharmacist was based on her assessment of the study patients' needs. There were two primary requirements of the study pharmacist. First, patient care services should be provided in accordance with the philosophy of pharmaceutical care and second, all patient-related activities, outcomes and relevant communications had to be documented in a manner which allowed meaningful follow-up and monitoring of the patient. As the treatment patients had complex co-morbidities and drug therapies, the study pharmacist found that documentation of her interventions toegether with the patient's perspective about their medications was critical when making decisions to optimize drug therapies.

Evidence of the efficiency of the documentation process was the consistency of data gathered on all 16 subjects, which included capturing drug and non-drug factors, patient perceptions and actual outcomes of drug therapy. Medication and medical histories, careplans and progress notes were completed on all subjects and read line by line to code the pharmacist interventions and patient outcomes that led to drug-related problems being identified, prevented and resolved.

Evidence of effectiveness of the documentation process comes from comparing the overall medication appropriateness between treatment and control subjects and quantifying drug-related problems reported as identified and resolved in the progress notes. The documentation process revealed that 40 of the 70 identified drug-related problems were resolved after six months. The most immediate changes were in

response to the prescription needing clarification or if the patient had an indication and required therapy. In addition, there was a trend of better medication appropriateness in the treatment versus control group at the end of the intervention period (1.22±.79 and 1.87±1.12, p=0.07 respectively) in response to pharmaceutical care.

At the time of this study, there were no published literature which evaluated a documentation process that had been implemented in a community pharmacy. Coding free-text entries, though useful from the study pharmacist's perspective, was not easy to integrate into an electronic database. From a researcher's perspective, the patient's documentation was subjective, based primarily on pharmacist and patient perceptions, self-report and ability to recall; resulting in potential observation or information bias. From a practice perspective, the strength of the free-text format was its acceptability as a routine process that successfully captured the dynamic and subjective nature of patient outcomes and facilitated the pharmacist in working with the patient to optimize their drug therapy.

Section Four: Limitations

The small sample size of this pilot study limits the interpretation of findings as trends, rather than conclusive evidence. The data suggests that providing pharmaceutical care to patients who are at greater risk of a drug-related problem is worthwhile, especially in terms of reducing physician visits while improving medication

appropriateness and a patient's view on their overall health status. However, the time frame of this study also presents a significant limitation. Seasonal differences and long term effects were not captured in the time frame of the study's six month period. As well, the pharmacist's documentation was based solely on the patient's self-report and the pharmacist's assessment. In turn, the interpretation of the pharmacist's documentation was by the investigator, which can potentially result in misclassification during the coding process; a form of observation bias.

Another limitation to consider is that pharmaceutical care was evaluated based on the provision by one pharmacist. It is important to determine whether similar findings would be apparent in another style of community pharmacy or by a different pharmacist. In this study, an external reviewer did not determine whether the intensity of the pharmacist's interventions was suitable to the needs of the patients. As well, the prevalence and type of drug-related problems among a risk population in this setting is unknown and it was not determined whether the study pharmacist identified all the actual drug-related problems and competently resolved them. Finally, this study did not establish the type of pharmacy services received by control patients who patronized pharmacies other than the study pharmacy.

Section Five: Conclusions

This pilot study implemented and documented pharmaceutical care in real world terms. The findings contribute to the current body of literature about a population

that is typically overlooked because they are not yet elderly. The level of intervention required in the study population supports the implementation of pharmaceutical care according to risk characteristics that are not age specific. As a result of the non-elderly population, it was difficult to compare the findings of this study with many of those reviewed. Therefore, the importance of this pilot study is that it established effect and sample sizes for outcome variables that represent an age-independent risk population residing in the community and receiving pharmaceutical care from a community pharmacist. The trends noted in this pilot study demonstrated that pharmaceutical care has positive influences on a patient's drug therapy which can have significant influences on economic, clinical and health-related quality of life outcomes. These findings should encourage future researcher's to use randomized controlled designs and the ECHO model of evaluation to strengthen the associated benefits between pharmaceutical care and outcomes in an uncontrolled setting.

Future studies evaluating pharmaceutical care in the community setting should consider increasing the generalizability of a risk population by recruiting a more diverse socioeconomic population. This would best be facilitated by having more than one study pharmacy participate and neighborhood profiles could assist the investigators in selecting areas with diverse socioeconomic backgrounds. Having a larger sample of pharmacists could also provide a clearer understanding of the impact personal attributes of the pharmacist, i.e., friendliness, mannerisms and interest in patient care, on patient outcomes. As well, a more collaborative effort with

physicians and home care nurses may recruit a more generalizable sample population using the same inclusion criteria, and the acceptance of team care might better facilitate the pharmacist's role in optimizing drug therapy. This may, however, result in less generalizable findings as communication barriers between health care professionals would be less in a collaborative design. Within the randomized controlled design, a stratified analysis between outcomes of pharmaceutical care and patient perspectives of the pharmacist's role would provide insight to the non-clinical components of patient care. In addition, recruitment strategies of study participants should incorporate an incentive that is representative of the time and effort for volunteers to participate. Experience from this pilot suggests that better participation may have occurred if the incentive had a greater financial value, i.e., discounts or free medication. The expectation that participants should recognize the value of the pharmaceutical care they are receiving is premature at the onset of the study period.

If the free-text format of documenting pharmacist interventions is used to measure the activities of pharmaceutical care, assistants should be trained to code the documentation and use a standard format that summates and categorizes the activities over time. In a large scale study, however, this may not be feasible. Therefore, a standardized way of reporting specific interventions and subsequent outcomes needs to be addressed. For research purposes, the Pharmacist Intervention Report described earlier could be modified to incorporate patient outcomes. The report would allow the pharmacist to check categories of interventions and outcomes that best describes

the event. Software which could facilitate the documentation and collection of such data would be optimal. In addition, documentation should also capture an understanding about the intensity of interventions, i.e., time to perform each intervention, ratio of scheduled phone or face-to-face interventions vs. unscheduled interventions, which could provide better data when considering remunerative issues. As well, external evaluators who are experts in the provision of pharmaceutical care could assess whether the intensity and nature of interventions suited the needs of the patient.

With respect to cost estimates for physician visits and hospitalizations, more specificity is needed. In particular, knowing the proportion of physician visits related to adverse drug events would give a clearer understanding of the trend for physician visits to decline in response to pharmaceutical care. A collaborative design would best facilitate this measure. In terms of hospitalization costs, specifying admissions that are drug-related would give a more precise measurement of these costs.

Total drug costs, dispensing fees and fill dates should be gathered in addition to acquisition cost and total number of each drug, as this information may identify how pharmaceutical care can impact the costs of drugs within the drug-use process. For future use of the Medication Appropriateness Index, a more extensive medical and medication history as well as current drug cost data should be provided to the raters.

Although none of the null hypotheses could be rejected, this pilot study served to establish effect and sample sizes for research that uses the ECHO model to evaluate pharmaceutical care in an uncontrolled setting. Trends found in this study include lower costs for physician visits, improvements in medication appropriateness and improvements in health-related quality of life scores. The free-text format of documenting interventions and outcomes permitted the pharmacist to capture and respond to the patient's perspectives and responses to drug-therapy. As well, the process of documentation used in this study was effective for identifying and resolving drug-related problems and quantifying the nature and extent of pharmaceutical care provided to patients who are at greatest risk of an adverse drug event.

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APPENDICES

Appendix 1

Recruitment advertisement for flyers and newspaper

Would you like to know more about the medicines you take?

We are now looking for volunteers to participate in a medication-related health outcomes study. This study is being carried out by the Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta. Participating requires attending an information session and about 1-2 hours of your time. *All volunteers completing the study will receive the latest edition of* "The Pill Book" - *a home reference guide to prescription medications, and a medication record.*

If you or someone you know are interested in learning more about this study please call Wendy at 492 - 0092. Participants must be 18 years or older, live in the community setting, belong to a drug insurance plan and meet *one* of the five criteria below :

1. **Currently taking 5 or more prescribed medications daily.**
2. **Currently taking 12 or more doses of prescribed medications daily.**
3. **Finding difficulty in remembering to take your medications.**
4. **Taking medications which have changed 4 or more times in the past year.**
5. **Currently taking medications for long term conditions like arthritis, high blood pressure, sleep disorders, asthma, depressive illness or stomach problems.**

Pharmaceutical Care Research & Education Project.... ***what pharmacists can do to help you get the most from your medications***

Please call 492 - 0092 for more information today!

- Pharmaceutical - CARE
Research & Education Project

Appendix 2

PT NO: _____

Pharmaceutical Care Research & Education Project

Patient Interview: Treatment Group

Name: _____

AHC #: _____

Drug Insurance Plan _____

No. : _____

Date of Birth: _____ Age: _____

Male _____ Female _____ Height _____ Weight _____

Address: _____

Phone: _____

Best Time of Day to Call: _____

Interviewer: _____

Date of Interview: _____

Time Started: _____ Time Ended: _____ Total Time: _____

Complete this section following interview:

Participant Interest:

1	2	3	4	5	6	7	8	9	10
Not Interested									Very Interested

Follow-up checklist - The following has been completed for this patient:

1. Patient Interview____
2. Copies of current medication obtained: _____(date)
   transferred: _____(date)
3. Care Plan Developed _____
4. First intervention session scheduled: _____ (date)
   completed: _____ (date)

PATIENT HISTORY

1a) Are you allergic to any medications? If yes, What happens?

Yes _____ No _____

Medication	What happens?
a. _____	_____
b. _____	_____
c. _____	_____

b) Do you have any intolerance's to medications, if yes describe:

_____

_____

2a) What are your current medical conditions?

_____

_____

b) Are you using any Medic Alert jewelry or a wallet card; or another method to alert doctors or emergency help about serious allergies or medical problems? If yes, describe:

_____

_____

c) Past medical history. Explain._____

_____

_____

d) Any hospitalization in the past six months? Explain. _____

_____

_____

_____

3) Do you see a regular family doctor? ☐ No ☐ Yes Dr. _____

Please indicate whether or not you have been treated by any of the following health care professionals in the past six months and the number of times.

Profession	Number of times seen	Name & Contact Number
☐ Dentist	_____	_____
☐ Pharmacist	_____	_____
☐ Physiotherapist	_____	_____
☐ Optometrist/Opthalmologist	_____	_____
☐ Chiropractor	_____	_____
☐ Podiatrist	_____	_____
☐ Home Care Nurse	_____	_____
☐ Social Worker	_____	_____
☐ Physician	_____	_____
☐ Specialist (Specify area)	_____	_____

4) Family History of disease

_____

_____

_____

_____

_____

_____

_____

5) Now I'd like to do an initial screen for your blood pressure glucose and cholesterol.

	Reading/date	3 months	6 months
bp:	_____	_____	_____
glucose:	_____	_____	_____
cholesterol:	_____	_____	_____

LIFESTYLE

1a) Can you tell me a little about your average day.(ie, work, leisure, school, hobbies, sports)

_____

_____

_____

_____

_____

b) Has your daily activities been affected by medication use? If yes, explain._____

_____

_____

c) What time do you usually get up in the morning; go to bed at night?

_____

d) When do you usually eat breakfast, lunch, and dinner? Describe typical diet.

_____

_____

2) Are there any particular things you usually do to help you remember to take your medications? (Probe: like any kind of reminder? E.g.: calendar, pill box, scheduled meals)
Yes _____ No_____

If yes please describe what you do. _____

_____

3) Please indicate use of the following:

Caffeine:_____ cups / day Coffee_____Tea_____Cola_____

Alcohol:_____ indicate per day/week _____ # _____glasses wine/beer

Cigarettes, cigar, pipe _____ per day (circle form)

recreational drug use (if applicable)

4) Do you live alone? Yes_____ No _____

Who else lives with you? (Interviewer's note: Check all that apply to the patient. Write in the relationship of the "other" type of person living with him/her.)
Spouse _____ Children _____ Other_____

5) Is there anyone who helps you get or take your medications? Yes _____No____
Who? _____

6) Are the costs of medications a concern?_____

7) Is your physician aware of your financial concern?_____

Pharmaceutical Care Research & Education Project 1995
Treatment Group Survey: Adapted in part from Health Plus Version 1.0
University of Michigan

PRESCRIBED MEDICATION INFORMATION

I'd like to talk with you about the medicines your doctor has prescribed for you. I am going to ask you a set of questions about each medicine you take. * Please include all "prescribed" medications including OTC's that have been "prescribed".

	(a)	(b)	(c)	(d)	(e)	(f)	(g)
	Drug Strength Dosage Form (PO, TOP, Ih, Inj, Liq)	Label Directions	If different from label, how often and how much of this do you take each day?	If you're taking this medication differently from the label directions can you explain why?	How long have you been on this medication? (Month/Year)	Can you tell me (or what illness or medical problem you're taking this medicine for)?	Do you feel this medication is working for you?
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							

Key: PO = Oral Ih = Inhaler Liq = liquid
TOP= Topical Inj = Injectable

Pharmaceutical Care Research & Education Project 1995
Treatment Group Survey: Adapted in part from Health Plus Version 1.0
University of Michigan

NON-PRESCRIBED MEDICATIONS

Now I'd like to ask you about any medications you might be taking that are not prescribed by your doctor. Please include those recommended by a friend, relative, nurse or pharmacist.(Include vitamins, naturopathic supplements and prescription medications prescribed for someone else.) (Note: to assist patient you may prompt by describing some common conditions for which OTC's might be used, i.e.: headache, joint pain, cough/cold/flu, insomnia, stomach upset/gas, diarrhea, constipation, hemorrhoids, dry skin, itching, dandruff, diet aids.)

(a) Vitamin/Supplement/ Drug Name/Strength (PO, TOP, inh, etc)	(b) Label Instructions (If no label instructions, why?)	(c) How often and how much usually do you take each day/ month/year?	(d) If different from label, Why are you taking this medicine this way? (Friend, Dr. or other recommended frequency, strength, tablets)	(e) How long have you been on this medicine, vitamin or supplement? (Month/Year)	(f) Can you tell me for what illness or prevention of medical problem you're taking this medicine?	(g) Do you feel this medicine is working for you?
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						

PAST MEDICATION HISTORY

What medications have you been on, what has worked and not worked?

Medication	Indication for which medication was prescribed	Why was this medication discontinued?

SYMPTOMS

Now I'd like to ask you about some symptoms. In the past 6 months have you experienced any or been troubled by any of the following:

Symptom (Symptom hard to explain)	If yes, describe	How long? How often? Frequency?	How do you manage it?	Pharmacist Comments (See Notes)
1. Headache				
2. Daytime Drowsiness				
3. Dizziness/Light-headedness				
4. Anxiety/ Nervousness				
5. Nausea/Stomach Upset				
6. Heartburn				
7. Depression				
8. Forgetfulness/ Memory problems				
9. Diarrhea				
10. Constipation				
11. Weight gain/loss ≥ 5 lbs				
12. Shortness of breath/ Wheezing				
13. Blood in urine/stool				
14. Fatigue				
15. Sexual Difficulty				
16. Bladder problems				
Incontinence /inability to control bladder				
difficulty urinating				
17. Swollen feet/ ankles				
18. Chest pain or pressure				
19. Joint Pain				
20. Other				

Probe: Are there any other symptoms that you've experienced in the last month? Note: Consider all possible drug & non-drug causes. is the symptom caused by any therapy patient may be taking or is lacking, or is patient on medication for which an indication does/doesn't exist, is it the best therapy for the patient - why or why not?

PATIENT'S PERCEPTION

1) Do you think that any of your medicines might be causing symptoms or making them worse?

Yes_____ No_____

If yes, which ones?

Medication	Symptom	Explain Why?

2. Do you experience any of the following? If so describe.

Sensory Limitations			Describe
a. Trouble seeing words on RX label	Yes	No	_____
b. Trouble hearing	Yes	No	_____
c. Trouble swallowing medication.	Yes	No	_____
d. Trouble opening RX containers	Yes	No	_____

3) If using any of the dosage forms below, please describe your level of comfort with use.

Demanding Dosage Form	Medication	Administration Difficulty Accurate Technique
a. Inhaler/rotohaler	_____	_____
b. Transdermal patch	_____	_____
c. Injection	_____	_____
d. Sublingual/buccal	_____	_____
e. Liquid (po, top, otic)	_____	_____
f. Opthalmic product	_____	_____

4) Do you have any personal health goals? (May need to prompt patient - i.e. understand medications better, reduce symptoms and the number of medications, improve daily activity, etc.)

_____
_____
_____

CLOSING

Thank you very much for answering our questions. Is there anything else you wish to add to help us understand your experiences with your medications and your medical treatment?
Yes_____ No_____

What is it?

_____
_____
_____

Are there any specific questions that you would like to have answered about your medications?
Yes_____ No_____

Question	Pharmacist Response
_____	_____
_____	_____
_____	_____
_____	_____

Note: At this point pharmacist should be able to identify some initial approaches suited to patient's health goals.

Advise patient that a care plan will be developed for their next session and any specific questions that were not addressed today, be addressed once the next follow-up session is scheduled. Follow-up should occur within one to two weeks of initial appointment if possible. Scheduling the follow-up should incorporate refills, medication changes, patient education sessions, etc., and utilize phone or personal follow-up according to patient's mobility.

Pharmaceutical Care Research & Education Project 1995
Treatment Group Survey: Adapted in part from Health Plus Version 1.0
University of Michigan

Documentation Records

1. Medication Care Plans
2. Patient Encounter Summaries
3. Study Patient total contact tally sheets
4. Patient Progress Notes

Medication Care Plan for:_____
prepared by:_____ date:_____ prep. time___

List all current drug related problems	Outcomes: identify the desired outcome	Assessment : describe all reasonable drug & non-drug therapies that could produce desired outcomes

Therapeutic Plan: describe the drug & non-drug drug regimen including all changes from existing therapy	Therapeutic endpoints: describe the desired & undesired endpoints associated with plan

Monitoring Plan: for each endpoint describe what, how & when monitoring will occur	Follow-up: are the endpoints met? Describe. Will changes to care plan be required. Give recommendations and subsequent actions.

Resources & communication used to complete care plan

Major types of drug-related problems :adapted from Strand, Cipolle & Morley: Pharmaceutical Care An Introduction Based on the premise that a patient experiences a medically-related problem that could be psychological, physiological, anatomical or socioeconomic in nature, the patient could be experiencing one of the following drug related problems:
1. patient needs pharmacotherapy, but is not receiving it - a drug indication 2. patient not taking prescribed drug. 3. patient receiving too little of the correct drug. 4. patient receiving too much of the correct drug. 5. patient experiencing an adverse drug reaction. 6. patient experiencing a drug-drug or drug-food interaction 7. patient receiving the wrong drug. 8. patient taking a drug for which there is no valid indication

Patient Progress Notes:

Date:	

Patient Encounter Summary

Patient Name: _____

Reason for contact:

1 Education Session
2 Discontinued Medication
3 Refill Rx
4 New Rx
5 Initial Interview
6 Monitoring Outcome
7 Patient Request for Information
8 Spontaneous Education Session
9 Change in Drug Regimen
10 Nonprescription product

Assessment of contact (Check all that apply and describe below)

1. Duplication of therapy
2. Inappropriate Regimen
3. Inappropriate PRN
4. Side Effects
5. Intolerance
6. Allergies
7. Needs Pharmacotherapy, but not receiving
8. Patient not taking prescribed drugs
9. Receiving too little of correct drugs
10. Receiving too much of correct drugs
11. Experiencing drug-drug or drug food reactions
12. Selection/Usage of OTCs
13. Compliance Problems/Need for Aids
14. Counseling/Inadequate Medication
15. Financial Concerns
16. Drug-Disease Interactions
17. Receiving wrong drug
18. Taking drug for no valid indication
19. Experiencing adverse drug reaction
20. Demanding Dosage Forms
21. Monitoring Outcomes
22. Medical problem - refer to physician

Description of Problems (Describe each separately and identify medications involved)

Date & Reason for Contact (1-22)	Medication(s) Involved	Problem Number (1-22)	Pharmacist Action or Recommendation	Date & Follow-up Response (W, I, NC)	Resources Used (include Communications, References, etc.)

W = worse, I = improved, NC = No Change

Treatment Patient Contact Summary List	Counts (over study period)
needs a medication (rx/otc)	
subtherapeutic dose	
therapeutic dose exceeded	
adverse drug reaction	
drug-drug interaction	
drug-otc interaction	
drug - disease interaction	
drug - food interaction	
drug - allergy interaction	
drug - age interaction	
drug - pregnancy interaction	
drug- breast feeding interaction	
duration of txt too short	
duration of txt too long	
duplicate therapy	
no indication for drug	
over use of drug	
under use of drug	
inappropriate use of pm med	
dose regimen problem	
dosage form problem	
omission of required info on written prescription	
drug not available	
drug use unsupported by medical indication	
education/counselling session	
monitoring activity	
follow-up activity	

Supplement Sheets

A - Medication Schedule Charts

B - Unidentified Medications

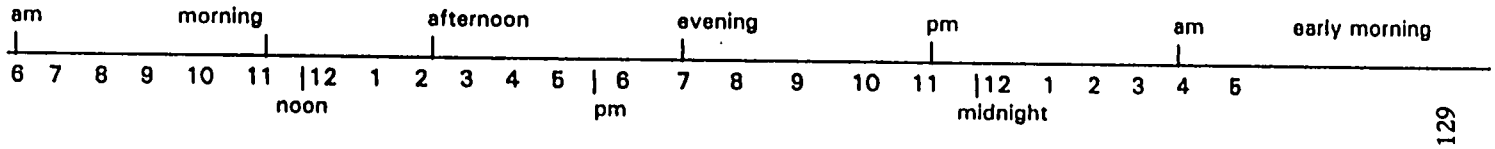
C- Home Remedy/Adjunct Product Usage

D - Social Drug Use - caffeine

E - Social Drug Use - alcohol & tobacco

Supplement Sheet A

Current Medication Schedule



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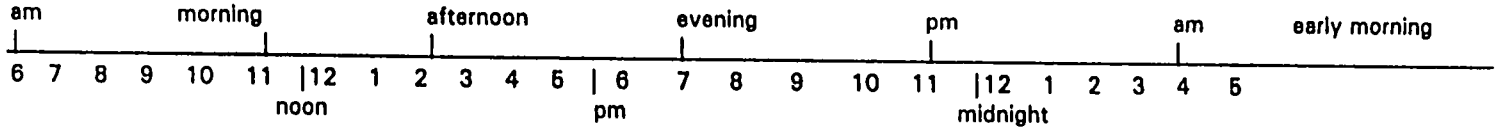
Revised Medication Schedule



Supplement Sheet B

Unidentified Medications

(Note: Drug Information Centres may be a useful reference or if you have access to a Identi-Dex).

1. a) Medication description: (form, size, color, shape, markings, numbers)

_____
_____
_____

b) Information from patient about medication: (name, use, where they obtained it, from who).

_____
_____
_____

c) Identification: (circle appropriate response)

positive probable unable to identify

name:_____strength_____
Use:_____

_____

2. a) Medication description: (form, size, color, sha pe, markings, numbers)

_____
_____
_____

b) Information from patient about medication: (name, use, where they obtained it, from who).

_____
_____
_____

c) Identification: (circle appropriate response)
positive probable unable to identify

name:_____ strength:_____
Use:_____

Supplement Sheet C

Home Remedy / Adjunct Product Usage

For each condition listed, complete the following sequence of questions.

1) The condition being treated is: _____

2) Is self-treatment of this condition appropriate and safe? (Circle the answer.)

Yes

No
|
Why is self-treatment inappropriate or unsafe?
_____
_____
_____

3) Are there any components of the home remedy/adjunct product which are potentially toxic? (Circle the answer). Refer to the Review Supplement for additional information.

Yes

No
|
Potentially toxic constituent: _____
Describe the potential toxicity: _____
_____

4) Is the manner (number of daily doses, duration of use) in which the patient is using the home remedy/adjunct safe?

Yes

No
|
Why is it unsafe? _____
_____
_____

5) If remedy/adjunct use is a problem, what possible alternatives (e.g. non-drug and/or on-prescription products) are there?
_____
_____
_____

(Note to Pharmacist: If the patient uses more than one home remedy, complete another Supplemental Form.)

Supplement Sheet D

Social Drug Usage: Caffeine

Estimate the average daily caffeine consumption.

Beverages:

a. ____C brewed coffee/day x 100mg caffeine/C coffee = _____mg caffeine/day

b. ____C instant coffee/day x 65mg caffeine/C coffee = _____mg caffeine/day

c. ____C tea/day x 40mg caffeine/C tea = _____mg caffeine/day

d. ____Glasses of pop/day x 50 mg caffeine/glass pop = _____ mg caffeine/day

e. The average daily caffeine consumption from beverages = _____mg caffeine/day

Is the total average daily caffeine consumption $\geq$ 350 mg/day? (d + e) Yes___No___

Note: If the patient embarks on a caffeine withdrawal program the symptoms for withdrawal may include: headaches, irritability, lassitude, depression.

Medications

a. Is the patient taking any medications containing caffeine? (Refer to medications overviews.)
Yes _____ No _____
|

b. How much caffeine is contained in one tablet or capsule of the product? ___mg.

c. How many tablets or capsules does the patient take on an average day?
Tablets_____ or Capsules_____

d. The caffeine consumption fro m medications is:
_____mg caffeine/tab/cap x _____tab/cap/day = _____ mg caffeine/day

Symptoms/Medical Problems

a. The following are possible SE and ADR from caffeine toxicity. Comparing this list to the medical problems and symptoms checklists place an "x" on the blank in front of the medical problem or symptoms below which this patient has:

_____Heart Disease
_____GI Upset/GE Reflux
_____Increased Urination
_____Insomnia
_____Fibrocystic Breast Disease
_____ Nervousness, jitteryness
_____Headaches

b. Does the patient experience jitteryness/nervousness from caffeine consumption?
_____Yes _____No

Supplement Sheet E

Social Drug Usage: Alcohol

If the patient consumes alcohol-containing beverages a few times per week or more frequently, complete the checklist below.

The following are possible signs and symptoms of excessive alcohol ingestion and/or alcoholism. Comparing this list to the medical problems and the symptom checklist, place an "x" on the blank in front of the signs and symptoms below which this patient has. If addition information is necessary to determine the impact of ethanol consumption on these signs and symptoms not this on the back of this sheet.

_____High Blood Pressure

_____ Cardiac Arrhythmia (increased heart rate)

_____GI Disturbances (stomach, liver, pancreas)

_____High Blood Lipids

_____Increased Uric Acid (Gout)

_____Insomnia (difficulty sleeping)

_____Depression

_____Peripheral Neuropathy (tingling or numbness in extremities)

_____Sexual Impotence

Social Drug Usage: Tobacco

If the patient uses more than 10 cigarettes a day, complete the 2 checklists below.

1. The following are possible signs and symptoms of nicotine adverse effects. Compare this list to the medical problems and the symptom checklist, place an "x" on the blank in front of the signs and symptoms below which this patient has/

_____High Blood pressure

_____Cardiac arrhythmia; increased heart rate

_____ Circulation Problems

2. Cigarette smoking alters the pharmacokinetics of many drugs, primarily by increasing the hepatic metabolism of these dru gs. The following is a list of drugs for which cigarette smoke may increase hepatic metabolism and decrease serum levels thereby altering expected effect of a usual adult dose. Compare this to the medical problems and the symptom checklist, place an "x" on the blank in front of the medication below which this patient is currently taking.

_____ Theophylline (indicate the need for a serum level.)

_____Propranolol

_____Propoxyphene

APPENDIX 3

Medication Appropriateness Index

Patient ID# _____ Evaluator _____ Date _____

Drug Code _____ Drug _____

To assess the appropriateness of the drug, please answer the following questions and circle the applicable rating:

1. Is there an indication for the drug?	A_____ Indicated	B_____	C_____ Not Indicated	Z DK
Comments:				
2. Is the medication effective for the condition?	A_____ Effective	B_____	C_____ Incorrect	Z DK
Comments:				
3. Is the dosage correct?	A_____ Correct	B_____	C_____ Incorrect	Z DK
Comments:				
4. Are the directions correct?	A_____ Correct	B_____	C_____ Incorrect	Z DK
Comments:				
5. Are the directions practical?	A_____ Practical	B_____	C_____ Impractical	Z DK
Comments:				
6. Are there clinically significant drug-drug interactions?	A_____ Insignificant	B_____	C_____ Significant	Z DK
Comments:				
7. Are there clinically significant drug-disease/condition interactions?	A_____ Insignificant	B_____	C_____ Significant	Z DK
Comments:				
8. Is there unnecessary duplication with other drug(s)?	A_____ Necessary	B_____	C_____ Unnecessary	Z DK
Comments:				
9. Is the duration of therapy acceptable?	A_____ Acceptable	B_____	C_____ Not acceptable	Z DK
Comments:				
10. Is this drug the least expensive alternative compared to others of equal utility?	A_____ Least expensive	B_____	C_____ Most expensive	Z DK
Comments:				

rev: 1/9/96

Medication Appropriate Index - Raw Score

✓ criterion that apply (weighted value)

Pt ID	Drug Class	rater P Score	rater R Score	rater Dr Score	1 (3)	2 (3)	3 (2)	4 (2)	5 (2)	6 (2)	7 (1)	8 (1)	9 (1)	10 (1)

APPENDIX 4

SF-36 Survey

COMMUNITY CARE

Pharmaceutical Care in community-based settings: a pilot study of the economic, clinical and quality of life outcomes.

SF-36 health survey and qualitative information on perception of pharmacy services

_____ control participant

____ study participant

University of Alberta–Faculty of Pharmacy & Pharmaceutical Science
3118 Dentistry/Pharmacy Centre–Edmonton, AB T6G 2N8
Phone (403) 492-0119–Fax (403) 492-3007

SF-36 HEALTH SURVEY

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle one)

Excellent 1

Very good 2

Good 3

Fair 4

Poor 5

2. Compared to one week ago, how would you rate your health in general now?

(circle one)

Much better now than one week ago 1

Somewhat better now than one week ago 2

About the same as one week ago 3

Somewhat worse now than one week ago 4

Much worse now than one week ago 5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking more than a kilometre	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past week, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	NO
a. Cut down on the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Were limited in the kind of work or other activities	1	2
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past week, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	YES	NO
a. Cut down the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Didn't do work or other activities as carefully as usual	1	2

6. During the past week, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

7. How much bodily pain have you had during the past week?

(circle one)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

8. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

9. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week -

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

4

10. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Patient Demographics

1. Please indicate which of the following conditions you currently have:

☐ asthma	☐ emotional or psychologic problem
☐ stomache disorder	☐ diabetes
☐ arthritis	☐ high blood pressure
☐ infection	☐ pain
other _____	☐ heart condition

2. Which age group in years do you belong to:

☐ under 18	☐45 - 54
☐18 - 24	☐55 - 64
☐25 - 34	☐65 - 80
☐ 35 - 44	☐over 80

3. Household net income for 1994

☐ under $20,000
☐ $20,000 - 35,000
☐ over 35,000

4. Education completed:

☐ less than grade 12 ☐ grade 12 ☐ technical school ☐ university

5. Please describe what your expectations are of a pharmacist and pharmacy services.

_____
_____
_____
_____
_____
_____
_____

6. Which of the following best describes the pharmacy you currently use:
☐ a small independant ☐ large food chain type ☐ non-food chain ☐ where-ever cheapest

APPENDIX 6

Purpose of Study /Informed Consent

Title: Pharmaceutical Care in Community based Settings: A pilot study of the economic, clinical and quality of life outcomes.

Background

This is a study to examine how pharmacists can better assist you with your medications. Typically, pharmacists will provide you with the medications your physician prescribes; checking for the accuracy of the dose and possibly any interactions that may exist with other medications you are taking. The study pharmacists will work together with you and your physician to help you identify and manage the best medications for you.

Purpose

You are being asked to participate in a research study to compare the care you currently receive from your pharmacist to a more personal model of care. This study is important because it is believed that drug use and pharmacy services may not be the best they can be.

Procedures

Participating in this study will involve:

1) being assigned to either the control or study group:

a) the control group participants keep obtaining their pharmacy services as they have in the past.

b) the study group will agree to obtain all they pharmacy services from the study pharmacist and pharmacy specified for a minimum period of 6 months at prices which are equivalent to what they pay now. The type of services they will receive include a medical and medication history interview (which lasts about 30 minutes), patient education session (a minimum of one 15 minute session), monitoring and follow-up procedures lasting usually 5 - 15 minutes. Monitoring may include blood pressure checks, peak expiratory flow rates or the withdrawal of blood via a finger stick for glucose and cholesterol monitoring.

2) completing a health survey questionnaire twice - once at the beginning of the study and again in 6 months.

3) providing you Alberta health care and drug plan identification for investigators to measure possible cost differences on the health care system as a result of the new model of pharmacy services.

Possible Benefits

Participating in this study may improve your quality of life because drug-related problems are better controlled. You may gain confidence in managing your medications and associated problems. You may learn more about your medications, their desired effects and how to monitor your reactions to your medications for your physician, pharmacist or other caregivers.

Possible Risks

If you are selected in the control group, your pharmacy services will continue as normal, so the risk is the same as you already experience. Side effects are difficult to anticipate in either group, therefore it is important that you notify your physician and any one of the investigators identified below, in the event of any unusual symptom or concern.

Confidentiality

Use of personal records relating to this study will be kept confidential. Any report published as a result of this study will not identify your name. In the case of the control group, the pharmacy in which you obtain your pharmacy services will also be kept in confidence.

We would be grateful if you would help carry out this 6 month project. If, for whatever reason, you want to stop being in the study, you are free to withdraw at any time. Your current level of pharmacy care will not be affected in any way. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study your will be promptly informed.

If you have any concerns please contact:

Wendy Gaudet, B.Sc. Pharm
Graduate Student
or
Karen Farris, B.Sc.Pharm., Ph.D, Assistant Professor
Faculty of Pharmacy and Pharmaceutical Sciences
University of Alberta
492-0092

Informed Consent

Please answer the following questions:

	YES	NO
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from this study at any time without having to give give a reason and without affecting you future medical or pharmacy care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you agree to allow the principle researchers to access and use information about your medical and medication insurance records?	☐	☐
Do you understand that your family doctor will know you are part of this study if you are in the study (treatment) group?	☐	☐

Who explained this study to you?_____

I agree to take part in this study. ☐ ☐

Signature of research subject_____
Printed Name_____
Date_____

Signature of witness_____
Signature of investigator or designee_____

Alberta Health Care Number_____
Drug Insurance Plan ID_____

APPENDIX 7

Evaluating a Pharmaceutitcal Care Pharmacist and Site for the liklihood that Pharmaceutical Care can be provided

The following template incorporates a review the performance requirements of pharmaceutical care care applicable to a community practice setting, using the Alberta Pharmaceutical Associations Standards of Practice as minimum expectations.

Basic Pharmacist functions:

1. Develop and use a patient medication profile
2. Interpret, question, clarify, verify and validate all drug-related orders
3. Provide a safe and efficient drug-dispensing system
4. Monitor drug therapy for sagety, efficacy and desired clinical outcome
5. Screen for drug allergies, drug-drug interactions, drug-food interactions and concomitant drug use
6. Detect and report drug allergies and adverse reactions
7. Recomment inital or alternative drug therapies
8. Respond to drug information requests from physicians, nurses and patients
9. Teach patients and other health-care professionals about drug use
10. Obtain medication histories by interviewing patients
11. Assist in the selection of the drugs of choice and dosage forms
12. Conduct drug-use evaluations to gauge the appropriateness of drug use and achievement of desired therapeutic outcomes
13. Apply pharmaceutical principles for selected drug therapies

Primary Pharmaceutical Care

1. Monitoring for compliance and proper drug use
2. Dispensing prescriptions
3. Counseling over-the-counter medications
4. Counseling prescription medications
5. Contacts physician and assists in choosing the right drug and dosage for the patient's needs

Secondary Pharmaceutical Care

1. Manages selected drug therapies by following approved protocols
2. Manages selected drug-delivery methods
3. Provides pharmacokinetic services
4. Participates in community outreach efforts
5. Conducts drug use evaluations

6. Answers drug-related questions from other health-care professionals and patients
7. Assists the physician in drug selection, dosage and ancillary therapy
8. Provides drug-consultation services to home-care programs or skilled nursing facilities

Study Pharmacist interview.

1. Describe your pharmacy practice experience.

2. What is your practice philosophy? Are you familiar with Pharmaceutical Care?

3. Have you ever done a patient interview to obtain prescription and OTC drug use, response and outcomes? Explain.

4. Have you ever determined from the patients interview described above, a problem list for a patient.

5. Describe how you would obtain patient information that is pertinent to determine the necessity of drug therapy?

6. If a patient is on a drug with no apparent indication, how do you handle this situation.

7. How do you assure the drug of choice for a particular patient is ordered?

8. In what ways do you determine if drug therapy is appropriate according to protocols, guidelines and standards?

9. Have you any experience evaluating drug therapy for appropriateness and monitoring the effects of a patients drug therapy?

10. In what ways do you provide educational information to patients, other health care professionals or collegues?

11. What type of continuing education activities do you participate in?

Interview
comments._____

APPENDIX 8

Request and conditions for data access

Alberta HEALTH

For Alberta Health Use:

Request #: _____
Date Received: _____
Internal: ____ External: ____

APPLICATION FOR ACCESS TO DATA

FROM ALBERTA HEALTH FOR RESEARCH PURPOSES

PART A - IDENTIFICATION OF PROJECT DIRECTOR/CO-RESEARCHERS

1. Project Director

GAUDET, Wendy R.
Name (last name/first name/initials)

Address: University of Alberta, Faculty of Pharmacy
3-118 Dentistry-Pharmacy Centre, Edmonton, AB. T6G 2N8

Telephone: (403) 492-0092 Fax: (403) 492-3007

Internet Address: wgaudet@gpu.srv.ualberta.ca

Institutional Affiliation: Faculty of Pharmacy & Pharmaceutical Sciences
(include department if relevant)

Position: Graduate Student

Academic Advisor (if student): Dr. K. Ferris

Please also provide a curriculum vitae including: education; research experience; knowledge of subject and three references.

2. Co-Researchers (if applicable)

a) Dr. K. Ferris
Name (last name/first name/initials)

492-2020
Telephone

Institutional Affiliation: Faculty of Pharmacy & Pharmaceutical Sciences
(include department if relevant)

Position: Assistant Professor

Academic Advisor (if student): _____

b) Dr. Y.K. Tam
Name (last name/first name/initials)

(403) 492-3071
Telephone

Institutional Affiliation: Professor, Faculty of Pharmacy & Pharmaceutical Sciences, University of Alberta
(include department if relevant)

Position: Professor

Academic Advisor (if student): _____

PART B - DESCRIPTION OF RESEARCH PROJECT

Please attach the following information:

1. A detailed description of the research project (include the objectives of the project and the proposed method of analysis).
2. A brief literature review and information on recent publications in the field of the proposed research study.
3. The expected period of time during which access to these records may be required.
4. A summary of benefits to health of Albertans that will be derived from the proposed research project.
5. If the requested information is person specific and/or person identifiable, an explanation of why the research project cannot reasonably be accomplished without access to personal information. Also provide a copy of the Ethics Committee's approval.

PART C - DATA REQUIREMENTS

1. Please specify type of data required.

Aggregated X Disaggregated _____

If disaggregated:

Individual Identifiable _____ Individual Anonymous _____

Please provide a detailed listing of the data source and data elements required:

Refer to page 4-5.

2. Will data from Alberta Health be linked/merged with data from other source?

Yes ____ No X

If yes, state nature of linkage:

3. Will the study involve direct access to individuals?

Yes X No ____

If yes, include copies of introductory letter to the study individuals, as well as the consent form and accompanying explanation for inclusion in the study.

4. How will the confidentiality of the data be protected by the researcher/co-researcher?

The patient information requested is aggregated and anonymous and will be analyzed and reported as such. Names of participants will not be published.

5. What methods will be implemented for data security and data disposal?

Only the principal researcher will be analyzing/coding/ entering data.

6. Will there be further phases to this study?

Yes ____ No X

If yes, when will the subsequent phases be conducted?

N/A

7. Will further data be required for subsequent phases? If so, please specify the nature of the subsequent phases and further data requirements:

A second data request will be made and is described on page 4-5.

PART D - PUBLICATION/PRESENTATION OF STUDY RESULTS

Will there be any publication or public presentation of the study results?

Yes X No ____

If yes, please identify the audience.

Association of Faculties of Pharmacy/Canadian Pharmaceutical Association
Name of the Person/Organization/Agency/Association/ Publication Professional Health Journals

PART E - AMOUNT COMMITTED TO THE STUDY

1. Amount committed to proposed study: $10,000

2. Sources of Funds:

Alberta Health ____ Others X

If Alberta Health, please specify whether the study is funded from the "Health Services Research and Innovation Fund" (HSRIF) or the "Mental Health Research Fund" (HMRF).

HSRIF ____ HMRF ____

Part B

1.0 Description

Background

There is little evidence to show how community pharmacists contribute to improving patient health-related outcomes while ensuring the most appropriate and cost-effective means of drug therapies are utilized.

Pharmaceutical Care is the accepted philosophy and system of service that has demonstrated a continuity and patient centeredness that can optimize therapeutic responses while addressing the issues of drug therapy appropriateness and cost-effectiveness.

Most studies have evaluated pharmaceutical care in an institutional, family practice or outpatient clinic setting. Often the scope has been limited to a specific age group, disease or therapeutic class of drugs. This study evaluates the provision of pharmaceutical care in a population and environment that is relative to community pharmacists.

Objectives

- To implement pharmaceutical care and a documentation process in a community pharmacy
- Evaluate the clinical, economic and quality of life outcomes in a community based population that would benefit most from a system of comprehensive pharmacy services.

Hypothesis (null)

H1. Health-related quality of life (HRQOL) in treatment patients will not differ from control group.
H2. The medication appropriateness index score pre and post study in treatment group will not differ.
H3. Medication costs will not differ between treatment and control groups.
H4. Utilization costs of health-care services will not differ between treatment and control groups.

Methods

Design: a randomized controlled study using pharmaceutical care services as the intervention
Setting: a small independently owned and operated community pharmacy located next to a medical clinic in south Edmonton.

Sample Size: 15 volunteers per group were recruited. This number allows for a 30% drop-out rate and will detect a minimum 5 point difference on the SF-36 Physical and Mental Health Summary Scales.
Recruitment: flyers, ads and articles in local and community newsletters, as well as community group bulletins reached approximately 7000 households. In addition, letters of recruitment were sent to physicians in the area and a short announcement was made on a local radio station.
Inclusion Criteria: participants in the study had to belong to a drug insurance plan, be 18 years and older and meet one of the following:
-currently take 5 or more prescribed medications daily,
-currently taking 12 or more 12 or prescribed medications daily,
-have a medication regimen that changed 4 or more times in past 12 months
-have difficulty adhering to current medication regimen
-currently on medications for chronic conditions such as arthritis, sleep disorders, depressive illness, asthma, hypertension or gastrointestinal disorders
Documentation: the study pharmacist was provided with patient documentation tools that consisted of interview, care-plan work-up, patient progress and physician communication notes as well as a daily and monthly patient planner and diary. This package
was adapted in part from Health Version 1.0 from the University of Michigan.
Measurements:
- H1. HRQOL - SF-36 Health Survey is self-administered to both treatment and control volunteers pre and post study period.
-H2. Medication Appropriateness in the treatment group will use the Medication Appropriateness Index (Hanlon et al.,1992)
-H3. Medication costs will be obtained from drug insurance plan records pre and post study period in both the treatment and control groups.
-H4. Health service utilization costs will be obtained for doctor and hospital visits from Alberta Health records pre and post study period in both the treatment and control groups.
Descriptive data is obtained from the patient interviews, care-plan work-ups, patient progress and doctor communication notes.

2.0 Literature Review

Pharmaceutical care is the model of pharmacy practice that requires the pharmacist to take responsibility for assisting the patient in optimizing their drug therapy outcomes (1,2). Achieving this goal requires the pharmacist to identify, prevent and resolve drug-related problems by monitoring and follow-up of each goal of therapy (2). In response to the need to reduce health care costs, drug therapy should improve the patient's health-related quality of life (HRQOL) and be cost-effective.

The need for community pharmacy to fully participate in the pharmaceutical care model of practice is evident by the consistent reporting of escalating drug costs, drug-related hospitalizations and decentralization of the health care team (3). Adherence problems,

inappropriate prescribing, adverse drug reactions and drug interactions are well documented in the literature, yet there is little evidence of community-based research to address these issues (4).

As the proportion of the aged in the population increases and drug therapies become more complex, there is a need for a more effective system of managing drug utilization in the community setting. The conclusion of a comprehensive literature review on the value and acceptance of ambulatory care provided by pharmacists reveals a void in community based research in the area of linking outcomes with community-based, pharmacist provided interventions (4).

Community pharmacists are well positioned to deliver pharmaceutical care because of their knowledge and training to identify, prevent and resolve drug related problems. As well, pharmacists are an accessible and trusted profession in the community. Research is necessary to evaluate the contribution pharmacists can make to the overall clinical, economic and health related quality of life issues relative to optimizing drug utilization in the community.

References

1. The Role of the Pharmacist in the Health Care System. Report of a WHO Consultative Group, New Delhi, December 13-16, 1988.

2. Hepler CD, Strand L. Opportunities and responsibilities in pharmaceutical care. Am J. Hosp. Pharm. 1990; 47:533-43.

3. Gore MJ, Why Quality of Life is such a sought-after statistic. Consultant Pharmacist Vol 9 No. 5, May 1994.

4. Bungay KM, Ware JE. Measuring and monitoring health-related quality of life. Current Concepts.

5. Hepler CD, Therapeutic outcomes monitoring: a new program to help patients manage disease. The TOM project Department of Pharmacy Health Care, College of Pharmacy, University of Florida.

6. Farris KB, Kirking DM. Assessing the quality of pharmaceutical care: one perspective of quality. The Annals of Pharmacotherapy, Vol. 27, Jan. 1993.

7. Farris KB, Kirking DM. Assessing the quality of pharmaceutical care: application of concepts of quality assessment from medical care. The Annals of Pharmacotherapy, Vol 27, Jan. 1993

3.0 Expected time of access to records

Information is requested for the study participants' health services utilization for a 6 month period prior to the study intervention. Another request will be made for data that represents the 6 month period during the study period. This request will be made in November, 1996. In summary, there will be 2 requests for cross-sectional data (see part C).

Part C.

For the first request, please provide aggregated data for the
1) costs of services and 2) number of services for the Control and Treatment Groups. The information requested includes the means, standard deviations, ranges, minimums, maximums, modes, standard errors, sums for each service and counts for each of the following categories:

Doctor Visits
Lab Visits
Hospitalizations (a) inpatient
(b) outpatient

The following tables provide the Alberta Health number and time period for which this information is required.

Controls:

Volunteer's Name	Alberta Health Care Identification	6 month period prior to study	6 month period during study
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		Aug. 1, 95 - Jan. 31, 96	Feb. 1 - July 31, 96
		Aug. 1, 95 - Jan. 31, 96	Feb. 1 - July 31, 96
		Aug. 1, 95 - Jan. 31, 96	Feb. 1 - July 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug. 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug., 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug., 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug., 31, 96
		Oct. 1, 95 - Mar. 31, 96	Apr. 1 - Sept., 31, 96
		Oct. 1, 95 - Mar. 31, 96	Apr. 1 - Sept., 31, 96

Treatment:

Volunteer's Name	Alberta Health Care Identification	6 month period prior to study	6 month period during study
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		June 1 - Nov. 30, 95	Dec. 1, 95 - May 31, 96
		Aug. 1, 95 - Jan. 31, 96	Feb. 1 - July 31, 96
		Aug. 1, 95 - Jan. 31, 96	Feb. 1 - July 31, 96
		Aug. 1, 95 - Jan. 31, 96	Feb. 1 - July 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug. 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug., 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug., 31, 96
		Sept. 1, 95 - Feb. 31, 96	Mar. 1 - Aug., 31, 96
		Nov. 1, 95 - Apr. 31, 96	May 1 - Oct., 31, 96
		Nov. 1, 95 - Apr. 31, 96	May 1 - Oct., 31, 96
		Nov. 1, 95 - Apr. 31, 96	May 1 - Oct., 31, 96
		Nov. 1, 95 - Apr. 31, 96	May 1 - Oct., 31, 96
		Nov. 1, 95 - Apr. 31, 96	May 1 - Oct., 31, 96

This initial request is specifically for the data from the volunteers records identified in the column " 6 month period prior to study" for both the treatment and control groups. Should there be any problems please contact Wendy Gaudet at 492 -0092 or Dr. Karen Farris at 492-2020.

4.0 Summary of Benefits to health of Albertans

Albertans will benefit if pharmaceutical care is the practice norm in community pharmacy because of the goals to optimize therapeutic outcomes by providing drug therapy monitoring and follow-up activities. This model of pharmacy services aims to assist individual patients in reaching better health related quality of life outcomes. As well, this type of pharmacy practice model provides a means of improving drug utilization and therefore endorses appropriate and cost-effective pharmacotherapy. These activities can have a significant impact for individual Albertans and for the community as a whole. Pharmaceutical care is a system which employs health promotion and education by the most accessible health care professional - the community pharmacist.

5.0 Access to Personal Information

The costs of health care services utilization is required to do an economic analysis and cannot be accurately achieved without the assistance of Alberta Health records and staff. Participants have agreed by way of informed consent to release their Alberta Health information to the study investigators, who recognize and agree to enforce measures to ensure patient confidentiality. The use of aggregated and individual anonymous information is one of the measures taken to secure individual participants's confidentiality.

February 5, 1997

Clarence Weppler
Alberta Blue Cross
10009-1088 Street NW
Edmonton, AB T5J 3C5

Dear Mr. Weppler:

Please find enclosed the documentation that was provided to Alberta Health in order to obtain the health service utilization data for research purposes. I have included copies of ethics approval from the Research Ethics Board, Faculty of Medicine, Alberta Health's approval for the release of data, the application for access to data, and informed consent from the subjects to release the data requested.

As you suggested I have provided the names of the subjects, their Blue Cross identification and the period for which the data is requested. The drug utilization data I am hoping to obtain for each patient includes: drug names, drug classes, quantity of each drug claimed per period, pharmacy (code is adequate), prescriber (code is adequate), total drug claim per patient for periods identified, and total costs per drug to patient for periods identified.

For Group A

Name	Blue Cross Number	Period One	Period Two	Alberta Health ID
		June 1 - Nov. 30, 199 5	Dec.1, 1995 - May 31, 1996	
		June 1 - Nov. 30, 1995	Dec.1, 1995 - May 31, 1996	
		Aug. 1, 1995 - Jan. 31, 1996	Feb. 1 - July 31, 1996	
		Aug. 1, 1995 - Jan. 31, 1996	Feb. 1 - July 31, 1996	
		Aug. 1, 1995 - Jan. 31, 1996	Feb. 1 - July 31, 1996	
		Sept. 1, 1995 - Feb.31, 1996	Mar.1 - Aug. 31, 1996	
		Sept. 1, 1995 - Feb.31, 1996	Mar.1 - Aug. 31, 1996	
		Sept. 1, 1995 - Feb.31, 1996	Mar.1 - Aug. 31, 1996	
		Nov.1.1995 - April 31, 1996	May 1 - Oct. 31, 1996	
		Nov.1.1995 - April 31, 1996	May 1 - Oct. 31, 1996	
		Nov.1.1995 - April 31, 1996	May 1 - Oct. 31, 1996	

Alberta
HEALTH

P.O. Box 2222
10025 Jasper Avenue
Edmonton, Alberta
Canada T5J 2P4

March 25, 1997

Ms. W. Gaudet
319 Island Highway
Victoria, British Columbia
V9B 1G9

Dear Ms. Gaudet:

Re: **"Pharmaceutical care in community-based settings: A pilot study of the economic, clinical and quality of life outcomes"**

Your request has been reviewed for the release of anonymous individual data to support the research project "Pharmaceutical care in community-based settings: A pilot study of the economic, clinical and quality of life outcomes". The requested anonymous individual data is available for release. The data, for the periods June 1, 1995 - April 30, 1996 and December 1, 1995 - October 31, 1996, is comprised of the following:

- Health Care Insurance Claims file - service units paid, amount paid, diagnostic service units paid
- Hospital Morbidity file (number of inpatient separations, sum of patient days, and number of day procedure (outpatient separations)

Data release is subject to your acceptance of the following conditions:

a) There will be no further contact with individuals identified in the information without prior approval by the Minister or the Minister's designate.
b) Alberta Health data:
   - shall be used solely for the purpose of the study as described in the research proposal;
   - shall not be used for any follow-up study or other study or for any other purpose without the written permission of Alberta Health;
   - will not be linked nor will there be any attempt to link the data with other databases;
   - will not be published in a manner which could identify the study participants;
   - will not be shared, copied or transferred to anyone;
   - will not be transmitted by telecommunication devices;

.../2

Alberta
HEALTH

P.O. Box 2222
10025 Jasper Avenue
Edmonton, Alberta
Canada T5J 2P4

May 15, 1997

Ms. W. Gaudet
319 Island Highway
Victoria, British Columbia
V9B 1G9

Dear Ms. Gaudet:

Re: **"Pharmaceutical care in community-based settings: A pilot study of the economic, clinical and quality of life outcomes"**

Your request has been reviewed for the release of anonymous individual drug data to support the research project "Pharmaceutical care in community-based settings: A pilot study of the economic, clinical and quality of life outcomes". The requested anonymous individual data is available for release. The data, for the periods June 1, 1995 - April 30, 1996 and December 1, 1995 - October 31, 1996, is comprised of amount paid, DIN, trade name, and quantity.

Data release is subject to your acceptance of the following conditions:

a) There will be no further contact with individuals identified in the information without prior approval by the Minister or the Minister's designate.

b) Alberta Health data:
- shall be used solely for the purpose of the study as described in the research proposal;
- shall not be used for any follow-up study or other study or for any other purpose without the written permission of Alberta Health;
- will not be linked, nor will there be any attempt to link the data, with other databases;
- will not be published in a manner which could identify the study participants;
- will not be copied or transferred to anyone;
- shall be kept in a physically secure location and access to the datafile must be restricted through the use of passwords and other security measures;
- must be returned to the Minister's representative by July 1, 1997;
- working files generated from the original data set during the course of its use must be destroyed by September 1, 1997.

.../2

IMAGE EVALUATION TEST TARGET (QA-3)

150mm

6"

APPLIED IMAGE . Inc
1653 East Main Street
Rochester, NY 14609 USA
Phone: 716/482-0300
Fax: 716/288-5989