AN EVALUATION OF THE DEVELOPMENT, IMPLEMENTATION AND OUTCOME OF A PILOT PRESCRIPTION MONITORING PROGRAM IN NEWFOUNDLAND AND LABRADOR

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by

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A thesis submitted to the

School of Graduate Studies

in partial fulfillment of the

requirements for the degree of

Doctor of Philosophy

Discipline of Community Health/Faculty of Medicine
Memorial University of Newfoundland

May 2004

St. John's Newfoundland and Labrador

ABSTRACT

Since the late 1980s, local medical professional associations, drug dependency groups, and the police had noted an apparent increase in the inappropriate clinical and illicit use of prescription medications in Newfoundland and Labrador.

The Newfoundland Medical Board implemented a provincial government funded, province-wide, pilot Prescription Monitoring Program ("PMP") for narcotics and benzodiazepines in June 2000. Pharmacists electronically submitted batch prescription information to the Program.

The purpose of this research was to analyze the policy process used to develop and implement the pilot PMP in comparison to a published guideline and to undertake a thorough clinical evaluation of this Program using a before/after study design.

The Program did not impact the prescribing of program monitored drugs, identified substitutes, and the incidence of multiple doctoring as expected. However, increased break and enters at retail pharmacies after the Program was implemented suggested that these medications had become more difficult to access. Surveys of prescribing appropriateness indicated that the PMP might have positively impacted the prescribing of these drugs. However, various biases and a small sample size limited the ability to accurately determine the magnitude of the impact. Assessments of long-

standing prescriptions that were abruptly discontinued suggested that the PMP did not adversely impact legitimate patient access to these medications. Most suspected drug-seeking patients reduced the number of physicians they visited. A small number increased their visits. A small number of physicians had prescribing volumes that exceeded ten times the mean.

Numerous legal, budgetary, confidentiality and stakeholder participation problems hindered the Program's orderly implementation and its impact. Contrary to legislation, at least eleven pharmacies failed to report data. Some high prescribing physicians identified by the Province's drug subsidy program were located near these pharmacies. Professional regulatory groups appeared unable to accommodate the financial and legal risks necessary to address suspected inappropriate behavior among physicians, pharmacists and patients.

Specifically targeted peer prescribing reports, academic detailing and regulatory sanctions were recommended to replace the PMP. A recommendation was made to forward the names of patients suspected of double doctoring to the police. The Province's drug subsidy and physician payment programs may suffice as a necessary future data source for specifically targeted interventions. Researchers concluded that the Program had a marginal positive impact.

ACKNOWLEDGEMENTS

Many individuals across a variety of organizations assisted with this research. Firstly, I offer my sincerest appreciation to the many pharmacists, physicians and patients who provided the necessary clinical information for evaluation.

I am specifically grateful to my research supervisor, Dr. Brendan Barrett, who was always available for guidance and direction throughout the tenure of my academic program. In addition, I thank Dr. Patrick Parfrey who repeatedly encouraged me to pursue this program. As well, I acknowledge the remaining members of my research committee, Drs. Doreen Neville and James Feehan for reviewing previous drafts of this research and for their insightful comments and direction.

The data analyzed in this study originated from a variety of sources. I am particularly indebted to Ms. Dorothy Rhodes of IMS Health, Canada and Ms. Pauline Kavanagh, Mr. John Downton and Ms. Kelly Kavanagh of the Pharmaceutical Services Division of the Department of Health and Community Services ("DOHCS"). As well, additional Department officials including Ms. Heather Roberts, Mr. Reg Coates, Ms. Coleen Owens and Dr. Blair Fleming provided information and insight throughout the course of this research.

I would also like to thank those who participated on the research team including Ms. Hilary Vavasour RN, Dr. Barry Pitter and Ms. Debbie Marshall RN. In addition, several physicians voluntarily contributed in evaluating the clinical information.

I also acknowledge senior officials of the Newfoundland Pharmaceutical Association, the Newfoundland Medical Board and the Newfoundland and Labrador Medical Association for encouraging their respective members to participate in this research. As well, I recognize the professional efforts of Ms. Carol Ann Mason, RN who administered the pilot Prescription Monitoring Program. The financial contribution of the DOHCS towards this research is also acknowledged.

Finally, my sincerest appreciation and gratitude is extended to my wife, Angela, whose assistance and support throughout my academic program were immeasurable. I dedicate this research to our son, Brian, and to the memory of our fathers, Gerald J. Doyle and William J. Cadigan.

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LIST OF ABBREVIATIONS

ACF	Advocacy Coalition Framework
ADS	Atlantic Data Systems
BDD	Bureau of Dangerous Drugs
CBN	Conception Bay North
CCBs	Calcium-channel blockers
CEG	Clinical Epidemiology Group
CIHI	Canadian Institute for Health Information
CHF	Congestive heart failure
CMAJ	Canadian Medical Association Journal
CRI	Canadian Research Index
DOHCS	Department of Health and Community Services of the Government of Newfoundland and Labrador
DPIS	Drug Programs Information System
ER	Emergency room
FFS	Fee-for-service
GP(s)	General Practitioner(s)
HCCSJ	Health Care Corporation of St. John's
JAMA	Journal of the American Medical Association
MCP	Newfoundland Medical Care Commission
MMC	Maritime Medical Care
MPPP	Manitoba Prescribing Practices Program
NLCHI	Newfoundland and Labrador Centre for Health Information
NLMA	Newfoundland and Labrador Medical Association
NLPDP	Newfoundland and Labrador Prescription Drug Program
NMB	Newfoundland Medical Board
NPA	Newfoundland Pharmaceutical Association

NSAIDs	Non-steroidal anti-inflammatory drugs
PMANS	Prescription Monitoring Association of Nova Scotia
PMP	Prescription Monitoring Program
PRC	Patient Research Centre
RNC	Royal Newfoundland Constabulary
TPP	Triplicate prescription program

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CHAPTER 1

INTRODUCTION

1.1 GENERAL OVERVIEW

Since the late 1980s, Newfoundland and Labrador medical and pharmaceutical professional associations, drug dependency groups, the Royal Newfoundland Constabulary ("RNC"), and provincial health agencies had noted an apparent increase in the inappropriate personal use of some prescription medications. Some prescription medications were also being diverted to illicit uses and there were suspected instances of indiscriminate prescribing. There were also reports that inappropriate prescription medication use was increasing at local junior and senior high schools. Narcotics and benzodiazepines appeared to be the most commonly abused substances.

The Newfoundland Medical Board ("NMB" or the "Board") in co-operation with the Provincial Government and professional stakeholder groups implemented a pilot Prescription Monitoring Program ("PMP" or the "Program") in June 2000 to test its effectiveness in combating the abuse of narcotics and benzodiazepines. A PMP normally involves regulatory authorities issuing special prescription pads to physicians, dentists, and veterinarians who wish to prescribe from a defined list of narcotics, barbiturates, stimulants and other controlled drugs. This defined list of drugs varies slightly between jurisdictions. When a prescription for one of the listed drugs is dispensed, the pharmacist submits an electronic copy of the prescription to the regulating body. The PMP's

computerized database is programmed to alert authorities to unusual prescribing practices. PMPs are common in other jurisdictions; however, there had been no thorough clinical evaluations of their effectiveness.

Unfortunately, despite the formal support of stakeholder groups through their respective professional associations, the process for developing and implementing the pilot PMP in Newfoundland and Labrador that began in 1996 lasted approximately four years. Consequently, this process was considered neither efficient nor timely in dealing with the policy problem as described at the onset of this chapter. Many administrative, legal, budgetary and stakeholder participation problems contributed to the delay. In addition, pharmacist compliance problems limited the effectiveness of the Program since its implementation in 2000.

The purpose of this thesis is to analyze the policy process used to develop and implement the pilot PMP in accordance with a published guideline and to provide a thorough clinical evaluation of the initiative. The nine chapters of the thesis describe the policy development, implementation and evaluation process, each with its own sub-evaluation. This introductory chapter defines what a policy is, describes the approaches and problems associated with policy-making, and explains the role of research in policy-making as described by leading policy development academics.

This researcher became involved with developing the PMP during the summer of 1996. At the request of the former provincial Deputy Minister of Health, my initial task was to prepare a discussion document for stakeholder consideration outlining the merits of PMPs in other jurisdictions. I subsequently participated for several years on a multi-stakeholder working group to develop the proposed pilot project. During this time, I designed and undertook a survey of physicians to determine which Program features they desired. In 1997, I designed under the supervision of the Clinical Epidemiology Group ("CEG") at Memorial University a thorough clinical and policy evaluation protocol for the proposed PMP. I initiated the pre-PMP evaluation during the fall of 1999 under the supervision of the CEG.

1.2 BACKGROUND TO POLICY-MAKING

There are some variations in the definition of a policy amongst authors. For example, a policy may be defined as a statement by government of what it intends to do or not to do and may include laws, regulations, rulings, decisions, orders or some combination of these.[1] Others have defined a policy as a series of specific decisions that should occur in a systematic order.[2] The sequence usually commences with a description of a particular problem, followed by a decision to do something about it, and an outline of the best way to proceed. A policy typically involves interactions amongst many related decisions. The study of policy involves examining the multiple interactions amongst many individuals, groups and organizations.[2]

At the clinical level, policies are viewed as rules to establish, control or change the behavior of institutions and/or individuals in order to confront a particular issue or problem.[3] They simplify the decisions that would otherwise have to be made by practitioners on an individual basis such as determining the effect of practice on outcomes, whether benefits are greater than harms, and if health outcomes are worth their costs.[4]

Other authors sometimes refer to clinical policies described above as practice policies, which are intended to influence the use of resources by practitioners. In contrast, service policies address issues related to resource allocation and the pattern of services provided. Governance policies are intended to influence organizational and financial structures.[5]

A health policy is defined as a course of action by governments, possibly through legislation, regulation or even inaction, that impacts on the health of the population.[6] From examining the definitions of these various policy categories, it would appear that a health policy is much broader than clinical policy. However, health policy would be expected to influence clinical policy since it can influence resource allocation and legislation governing specific clinical activities.

The development and implementation of a PMP has components of both clinical and health policies. The PMP influenced the manner in which physicians and

pharmacists practiced at the clinical level; however, it also involved public funding and legislation and regulations to be enacted by government and was aimed at a health problem not entirely within the control of the clinicians.

The PMP could also be partly categorized as a "public policy." Adhering to this definition requires only that the policy be partly developed within the framework of government. The financial and legislative requirements by government to enable the PMP to function satisfy this definition.[3] Many authors caution that the process of public policy-making is not straightforward. Decision-making is not a rational, logical linear process where information and research determine policy decisions. It is a highly political process where power and vested interests are among the primary driving forces.[7]

This thesis may be categorized as a "health policy analysis" which is a relatively new field of study. It covers a wide range of activities including, in part, an exercise by university researchers to determine how policy is formulated and its impact on health problems.[7]

1.3 LIMITATIONS OF INCORPORATING RESEARCH INTO POLICY-MAKING

It is consistently argued in the literature that research should play a critical role in policy-making by defining the extent of the policy problem and then providing information on policy options.[5] It appears that the use of evidence-based medicine and

decision-making increased during the 1990s in Canada and the United Kingdom because of demands for increased accountability by politicians, bureaucrats, clinicians and industry. Supporting this claim has been the expansion of health technology assessment organizations and technology assessment journals. However, the uptake of research into policy has been slow due to unrealistic expectations on the part of both decision makers and researchers and not related to a lack of research or a lack of need for it.[8]

A Professor of Health Services at the London School of Hygiene and Tropical Medicine, Nick Black, argues that research has limited effectiveness in the effort to develop service policies in health care. Some of the reasons include: policymakers having goals other than clinical effectiveness; research evidence being treated as irrelevant because of its source; lack of consensus about the evidence; sources of competing evidence; an environment which is not conducive to policy change; and inadequate knowledge by purveyors of the research. With respect to governance policies, Black further adds that the role of research has been limited because the policies are driven by ideology, value judgments, financial pressures and political realities.[5]

Black further suggests that the role of research in policy-making is several fold and varies by the local circumstances and those involved. It is less effective in local policy because this involves more negotiations and uncertainty. In addition, if there is consensus amongst stakeholders as to the policy goal, research is more likely to play a greater role. Another important constraint is that policymakers have to accept the other

legitimate/strong influences on decisions, such as social, electoral, ethical, cultural and economic factors. This implies that research may have a greater influence through a process of continuous communication between researchers and policymakers throughout the entire policy-making process.[5]

A former McMaster University Health Policy Professor, Jonathan Lomas, surmises that there are four areas of misunderstanding between researchers and policymakers. The first is two-fold in the sense that policymakers communicate with researchers late in the policy development process and this does not provide the researcher sufficient time to incorporate additional components into the research. Likewise, researchers arrive with findings too late in the decision-making process.[8]

Another problem is that researchers are rational thinkers and do not accommodate the reality that decisions are made in a political and institutional manner. Consequently, researchers underestimate the role of values in decision-making and over estimate the influence of facts. Failure to understand and accommodate the political and institutional realities leads to unfulfilled expectations of research in decision-making. An additional constraint surrounds the manner in which university researchers are organized. Being organized around disciplines rather than issues makes it more cumbersome for decision makers to include researchers without having to involve multiple disciplines.[8]

The final problem is the inability of researchers to report their findings in a manner that is applicable to the specific audience using it. For example, legislative decision makers who include politicians and bureaucrats are most likely to use summarized research rather than large reports. Administrative decision makers such as program managers and hospital executives are more apt to use the applied health services research and clinical research to influence their decisions regarding facility location, program design and human resource mix. Clinical decision makers such as physicians are most concerned with specific questions of patient selection criteria and information related to clinical guidelines and would, therefore, be most interested in clinical research. Finally, private sector representatives such as pharmaceutical companies are most interested in research findings that can be translated into profitable ventures. Private sector interests, according to Lomas, raise ethical questions over the objectives for research.[8]

Similar to Lomas, United Kingdom health policy researcher, Dr. Chris Ham, proposes that to maximize the impact of academic research, researchers must go beyond publishing to ensure good communication with policymakers and to present their ideas in a user-friendly manner.[7] Black goes further to specify three means by which research can be more influential: (1) changing researcher attitudes to understand in greater detail the policy process and that decisions are influenced by other factors; (2) changing funders' understanding of how research influences policy by expanding efforts to enhance the link between researchers and policymakers; and (3) changing the manner in which research is

conducted such that policymakers become more involved in the conceptualization and undertaking of research.[5]

Eddy describes a range of approaches for progressively involving research in clinical policy.[4] Under the author's "global-subjective approach," a policy results from the opinions of those who consider all the information at once. This approach has limited effectiveness because there are no explicit identification of outcomes, no analysis of the evidence that the practice would have on outcomes, and no assessment of patient preferences. Eddy's "evidence-based approach" is more advanced than the "global-subjective approach" because it explicitly describes the available evidence on a subject. However, it does not explicitly evaluate or estimate the magnitude of benefits/harms. Eddy's "outcomes-based approach" appears to be an extension of the "evidence-based approach." This approach involves anchoring the evidence to policy and explicitly estimating the outcomes of alternative practices. The final approach referred to by Eddy is the "preferenced-based approach." It is the most complete because all the components are explicitly performed and, most notably, includes an assessment of patients' preferences for outcomes.[4]

1.4 ROLE OF RESEARCH IN EVALUATING POLICIES

Once a policy has been implemented, research has a dual role to play in the monitoring of the policy and the measurement of outcome. With respect to monitoring

the policy, research can be used to assess if the intervention is being delivered to those who would benefit from it with the optimal use of resources. This involves an assessment of the relationship between costs and effects.[3]

Research plays an additional role in determining whether objectives of the policy have been achieved.[3] If the policy problem persists, policymakers can then use the results of research to determine if the existing intervention requires amendment to better address the policy problem or perhaps policymakers may have to consider an alternative approach. Without adequate data, policymakers would have limited, perhaps biased, anecdotal information regarding the usefulness of the intervention.

In order to analyze the policy process used to develop and implement the pilot PMP, it is necessary to apply a suitable framework. The following chapter reviews the policy evaluation literature and proposes a framework for the analysis.

CHAPTER 2

SELECTING THE FRAMEWORK FOR ANALYSIS

Health care interventions are often designed on an ad hoc basis without an explicit process for implementation and evaluation. Examples might include expanding the provincial formulary to include a new drug or the introduction/expansion of a health care program at an acute care institution. Such interventions may result from policymakers responding to anecdotal evidence provided by stakeholder group(s) with a vested interest in the expansion. Unfortunately, such programs may be clinically ineffective or at the very least not cost-effective. However, once such programs are introduced, they are likely to become entrenched in the health care delivery budgets for decades to come. Consequently, to ensure that beneficial health outcomes are maximized from limited resources, a more prudent approach would be to follow an explicit process for policy development, implementation and evaluation.

The introduction of a pilot PMP throughout Newfoundland and Labrador was a policy initiative that involved multiple stakeholders and the allocation of significant resources. In addition, there was some suggestion that it might lead to negative clinical effects for some groups of patients. Consequently, a pilot PMP should have been implemented in an orderly manner and subjected to a thorough evaluation.

The specific purpose of this chapter is to select a framework to evaluate the policy process. To achieve this, a review of the generic components of two broad-based public

policy approaches is described. This is followed by a review of the academic health policy literature and the results of a discussion with a national health policy expert. The rationale for the chosen policy template is also discussed.

2.1 DESCRIPTION OF TWO BROAD-BASED PUBLIC POLICY EVALUATION APPROACHES

Two broad-based public policy textbooks, one by Dunn[9] and the other by Brewer and deLeon[10], were chosen for review based on their inclusiveness in describing the entire policy-making process. For comparison purposes, the policy process for each model is described under the generic headings of: (1) identifying policy problems; (2) identifying policy options; (3) policy recommendation, implementation and monitoring; and (4) policy evaluation. While these public policy textbooks provide valuable insight into the policy-making process, it should be noted that they involve large United States-based programs or policies that require substantial policy analyses (and associated cost) exceeding that required to evaluate the Newfoundland and Labrador Pilot PMP.

2.1.1 Identifying Policy Problems

Dunn explains that a well-defined description of the policy problem is an important component of the problem-centered approach for policy analysis. The author defines a policy problem, in part, as an unrealized value, need or opportunity for improvement that can be achieved through public action. At this stage of the problem-

centered approach, the analyst should thoroughly describe the policy problem, its causes and underlying values that could then lead towards attempts to propose policy solutions.[9]

The author also describes the process of problem structuring as a policy analytic procedure related to the policy problem. This procedure involves the analyst challenging the assumptions underlying the definitions of the problem, including looking for hidden assumptions, diagnosing causes, determining objectives, synthesizing conflicting views, and sketching new policy options. Dunn surmises that problem structuring is a crucial but often misunderstood component of policy analysis. Consequently, he cautions that many times policy analysts will solve the wrong problems or provide the wrong solution to the right problem. Dunn further adds that the policy problem in many instances may actually be a complex system of problems that is associated with high levels of conflict between stakeholders.[9]

The "initiation" step as described by Brewer and deLeon is comparable to the policy problem stage for Dunn and is the first phase of the policy process. This stage involves two components of relevance in this context. The first is recognition of the problem, which may merely involve the perception of a problem, threat or opportunity. The second includes identification of the problem context. This involves analytically describing the problem, threat or opportunity and assigning it a priority within the organizations involved.[10]

Brewer and deLeon describe the problem recognition stage as involving a conflict or tension regarding patterns of behaviour such that it must be given attention. The identification of the problem allows the analyst to assess the extent of the problem, its importance, the implications of leaving it unattended and the relative priority in addressing it. The authors caution analysts about defining a problem without adequate information or without consideration of plausible future conditions. As well, they warn about examining symptoms as opposed to underlying or root causes of policy problems.[10]

These authors advocate identifying those individuals and organizations affected by the policy problem, those likely to be involved in the solution and how they relate to each other. In addition, it is also important to determine which groups are best suited to act to correct the problem. The final task in identifying the problem is to assign boundaries in order to isolate the problem from the surrounding environment in an effort to make the policy problems manageable.[10]

As a last consideration in the initiation step, Brewer and deLeon advise policymakers to clearly define policy objectives or goals. This is important because setting objectives will influence which policies are chosen, guide the implementation phase, and assist in determining the criteria for evaluating the program or policy. They caution that many times this stage of the policy process is vague or even not considered and this can contribute to program failure since it is difficult to evaluate programs without clear objectives.[10]

2.1.2 Identifying Policy Options

Dunn refers to the generic process of identifying policy options as "policy futures" and defines this as the outcomes of specific courses of action that may achieve values and the ultimate resolution of a policy problem. The author links "policy futures" with "forecasting" to provide policy relevant information about future potential outcomes that may result from undertaking policy alternatives, including doing nothing. More specifically, it considers the consequences of existing and proposed policies, outlines the constraints on achieving objectives, and provides input on the political feasibility of different options. Dunn describes the ability to forecast as a critical component of policy analysis as it allows one to obtain a prospective vision or foresight. However, while he describes several approaches to forecasting, they are limited by assumptions that may not hold true, institutional incentive systems, and policy issues in other sectors of the economy.[9]

The examples used by Dunn are very broad-based U.S. government programs and policies to address problems such as national poverty, pollution and crime. Despite this, he describes the objective of forecasting policy futures as being fourfold. Firstly, forecasting policy futures may be used to estimate the consequences of existing policies such as doing nothing. They can be used to provide projections regarding the consequences of a variety of new policies. Thirdly, forecasts can be used to estimate the necessary changes in the components of new proposed policies to enhance their

probability for success. Finally, the forecast may be used to estimate the probable support and opposition to proposed policies by policy stakeholders.[9]

Dunn also describes the numerous potential sources of policy alternatives. In summary, they may originate from: experts in the problem area; those believed to be insightful about a problem; innovative analysis; scientific theories; the beliefs, values and needs of stakeholders; experiences of other jurisdictions with similar problems; interventions used to address problems of a similar nature; and those who generally advocate theories of social justice.[9]

Brewer and deLeon describe the activities of the policy options phase as overlapping between the "initiation" and "estimation" steps. As discussed earlier, during the initiation phase, the policy analyst should collect the necessary information to identify a range of potential policy choices. However, the estimation category of the policy development stage is where the risks, costs and benefits associated with each option are accurately determined. Similar to the process described by Dunn, this stage can involve empirical projections of the probabilities and consequences of the proposed options and an assessment of the political desirability of the various options.[10]

These authors propose that the policy analyst explore a variety of policy alternatives that are appropriate, possible and feasible in relation to the policy problems to be addressed. Furthermore, Brewer and deLeon suggest that inaction and radical

action should be included as plausible alternatives. The analyst's role at this stage is generally described as providing the necessary information to allow a decision maker to weigh the necessary trade-offs in selecting a policy option.[10]

Brewer and deLeon also strongly promote the idea of creativity and innovation in the development of policy alternatives. They contend that creativity is frequently absent in this stage because policymakers, particularly those in government, may generally opt for safe and quick solutions rather than taking the necessary time and resources to pursue creative alternatives.[10]

2.1.3 Policy Recommendation, Implementation and Monitoring

Dunn describes policy recommendation, implementation and monitoring as occurring across a number of stages of the problem-centered policy analysis approach. For example, the recommendations stage requires the analyst to describe the benefits and costs of alternatives that have been projected from the forecasting stage. It addresses additional issues related to risk, externalities, criteria for making choices between policy alternatives, and consideration of who will assume administrative responsibility for the implementation of policies.[9]

The recommendation stage is also where the policy analyst produces information regarding the probability that plausible courses of action will provide the outcomes of

value to individuals, groups or even society. It involves transforming information regarding policy futures into information about policy actions that will lead to valued outcomes. Therefore, this stage requires information regarding the consequences of different policy alternatives and, equally important, requires an assessment of which alternatives are the most valuable and why. Consequently, Dunn also describes the recommending policy action stage as involving ethical and moral issues.[9]

Dunn suggests that the recommendation stage requires more of a normative rather than empirical analysis because the analyst is attempting to answer the query of what "should" be done. This involves going beyond facts to consider the values associated with particular outcomes.[9]

Cost-benefit analysis and cost-effectiveness analysis are described by Dunn as two major approaches involved in making a policy recommendation. Both approaches are intended to measure all projected costs and benefits to society of various policy options. Cost-benefit analysis measures both costs and benefits in monetary terms. However, under cost-effectiveness analysis, costs are measured in monetary units while effectiveness is measured in units of goods, services or another valued effect.[9]

Dunn describes that monitoring is used to provide policy-relevant knowledge regarding the outcomes of previously adopted policies that can assist policymakers in the policy implementation stage. More specifically, monitoring can assist in determining the

extent of compliance with policy, assess the extent of unintended outcomes of past policies, identify implementation constraints and determine responsibility for non-adherence to past policies.[9]

Monitoring is noted as fulfilling additional major functions in policy analysis. Firstly, it may be used to measure the level of compliance by program administrators, staff and stakeholders with required standards and procedures. It may also fulfill an accounting role by assessing whether resources and services are received by the groups or individuals for which they were targeted. Also, from an accounting perspective, monitoring may be used to produce information to assess social and economic changes that result from the implementation of broad public policies and programs over time. Finally, monitoring is used to provide information to assist in explaining why the outcomes of public policies and programs vary.[9]

Brewer and deLeon define "implementation" as the execution of the selected policy option. They describe it as a critical stage of the policy-making process that is frequently overlooked, resulting in many program failures. The implementation stage may have been overlooked because it is difficult to describe and classify analytically.[10]

These authors advise that policymakers should not underestimate the power of small, perhaps even politically disadvantaged, groups to redefine the policy intentions of those with formal authority. They argue that the difficulty experienced in isolating the

implementation process affects the analyst's ability to understand, analyze and manage this stage. Based on large program successes and failures, they propose a list of implementation factors that are worthy of consideration in the policy-making process that are further described below. They include the roles, powers and functions of those who are the source of the policy; the clarity of the policy; the support for the policy among those affected by it; the complexity of the administration particularly where multiple administrative agencies are involved; the incentives for implementers; and resource allocation.[10]

Brewer and deLeon note the significance of the policy source is relevant because different policy initiators (in the context of government) have varying roles, powers and functions. In their illustration, central government agencies that have influence over the bureaucracy will have the most influence over implementation. In terms of the clarity of the policy, the authors note that while the intent of the policy may be clear, the means of implementing it may be left exclusively with the agency administering the program. This can lead to confusion about the purpose of the policy as it filters down towards those on the front line who are most influenced by the policy.[10]

Brewer and deLeon also note that how a policy is implemented or whether it is ever implemented is strongly determined by those most affected by the policy. In their examples, the authors cite the need to consider those likely to support or oppose the policy both within and outside government. They also advise that consideration be given

to the resources that such parties have and their willingness to expend resources on a particular issue. In terms of the complexity of administration, the authors advise that the greater the number of institutional entities involved in the policy, the more difficult it is to implement. This is because each group will have its own expectations, interests and perceptions. As well, the further the decision maker is from the implementing group and those affected, the more difficult the implementation.[10]

These authors advise that the successful implementation of a policy may depend on providing incentives to the implementing agency. They suggest that positive implementation incentives are more likely to be successful than negative incentives. The concluding factor affecting the successful implementation of a policy according to Brewer and deLeon is sufficient resource allocation. This includes both the quantity and distribution of funds and time. Necessary funds are required to allow the implementing agency to address both anticipated and potentially unanticipated implementation concerns while sufficient consideration is required in terms of setting realistic timelines for implementation.[10]

2.1.4 Policy Evaluation

The evaluation stage of the problem-centered policy analysis approach described by Dunn is used to provide policy-relevant knowledge regarding differences between expected and actual policy performance. At this stage, the policymaker should be able to

determine the extent to which policy problems have been addressed, allow clarification of the values underlying a policy and assist, if necessary, in restructuring policies and problems. Dunn lists three necessary criteria for a policy or program to be evaluated: clearly defined policy or program; well specified policy goals and/or objectives; and necessary explicit assumptions that relate the policy actions to the goals/consequences of the program.[9]

Dunn further describes the role of the evaluation stage as producing information that can be used to determine the value or worth of policy outcomes. He notes that policy outcomes have value because they contribute to program goals and objectives. To conclude that a policy or program has achieved a particular level of performance would imply that the original policy problems have been addressed.[9]

The nature of the evaluation stage differs from the other components of the policy process. It is not just an exercise of collecting data and information about policy actions; rather, it assists in assessing the worth or social utility of these outcomes.[9]

Dunn suggests that information from the evaluation stage that indicates potentially inadequate policy performance may be used to restructure policy problems. In this instance, policy goals and objectives may be redefined. The evaluation stage may also lead to instances where a previously dismissed policy alternative may now become the preferred action.[9]

The final consideration of the problem-centered policy analysis approach described by Dunn is referred to as "policy performance." At this juncture, the analyst must assess the extent to which a given policy outcome contributes to the achievement of values. Dunn notes that policy problems are rarely solved and in many instances may be resolved, reformulated or remain unsolved. To understand if the policy problem fits into one of these categories requires information about the policy outcomes and whether or not these outcomes have contributed to achieving the values associated with the initial policy problem.[9]

Unlike the other components of their six-phase policy-making model, Brewer and deLeon describe the evaluation phase as being retrospective in practice. They stress the importance of the evaluation phase in the public policy process in addressing whether the program has been successful or unsuccessful, measuring performance, and determining who conducts the assessment and their intentions. They also stress the additional need to consider the intentions of those who request the evaluation in terms of how they intend to use the results. [10]

Brewer and deLeon note that a number of conditions are necessary to improve the role of evaluation research in decision-making and program operations. For example, program objectives need to be well-defined, plausible and realistic. In addition, the potential uses of evaluation information need to be well-defined. The authors caution

analysts to ensure that the evaluation results can be attributed to the program rather than to confounding factors.[10]

These authors also describe the evaluation step as linking with the other phases of the policy-making model. For example, similar to Dunn's views, they advise that the evaluation may sometimes reveal information about problems that were unforeseen in the problem initiation phase. This in turn may warrant explicit action using the six-phase policy-making model proposed by these authors. As well, the evaluation phase may lead to a better or more accurate description of the policy problem or it may generate new data, which could be used to improve the estimation of outcomes of the various alternative policy options. Brewer and deLeon also describe the evaluation phase as being able to permit mid-course corrections in policy to improve its implementation. Finally, the results of evaluations may be used in terminating a policy or program. However, they recognize that the evaluation itself will rarely result in a smooth policy or program termination. This is because those negatively affected will often question the accuracy and fairness of the evaluation.[10]

In conclusion, both the Dunn and Brewer and deLeon approaches provide thorough, explicit methodologies for developing, implementing and evaluating large public policies and programs. Both approaches stress the need to thoroughly describe the policy problem and its causes, and assess underlying values. However, at the early stages of policy-making, the Brewer and deLeon approach appears to place greater emphasis on

how stakeholders are affected by potential policies. Consideration is also provided by both approaches in identifying potential policy options and explicitly estimating their consequences in terms of risks, benefits, costs and political feasibility. Dunn's approach is particularly helpful in identifying various sources of potential alternative policy options. While the generic policy recommendation, implementation and monitoring criteria are not fully synchronized between the two approaches, there is considerable overlap. It would appear at this stage that the Dunn approach individually, explicitly identifies each component while the Brewer and deLeon approach focuses attention on the roles, powers and functions of those who are affected by the policy and their potential to oppose it. Finally, both approaches stress the need for comprehensive public policy and/or program evaluations. This allows the analyst to measure the extent to which policy problems have been addressed, assess the value of outcomes and, if necessary, to restructure the policy problem and potentially repeat the policy-making process.

These broad-based approaches provide a comprehensive overview of the policy-making process particularly as they relate to substantial public policy initiatives with national and international implications. However, in comparison, the pilot PMP was a small initiative with a budget of approximately $300,000 annually. While the above approaches provide some valuable insight, a more specific, readily applicable health policy analysis template was desired. The following section describes a review of the health policy literature.

2.2 REVIEW OF THE HEALTH POLICY LITERATURE

Literature on health policy development and evaluation was reviewed with the objective of identifying a policy analysis framework more specific than the broader frameworks described above. This involved an electronic search of the Medline database using the MeSH terms: "outcome-and-process-assessment-health-care-methods," "decision-making" or "health-services-research." Articles for review were limited to those published in English since 1985. The search was further limited using any one of the following truncated key words: "method," "approach," "technique," "process," or "evaluation." A total of 109 abstracts were reviewed. Nine articles were selected for additional consideration, as they appeared most relevant to the current exercise of evaluating the policy and clinical aspects of the pilot PMP. References for these nine articles were also reviewed. A second independent literature search was conducted by library staff at the Canadian Coordinating Office for Health Technology Assessment and did not yield any additional references.

The literature searches provided only a few references that focused specifically on a comprehensive approach for policy development. Many of the articles identified in the search related to only one component of the evaluation process. Others were not considered applicable in this instance, as they were associated with psychology and basic science applications. Most of the papers reviewed proposed the same general approach to policy development; however, three authors' publications were further considered in the

context of the development, implementation and evaluation of a pilot PMP. Peter Tugwell and co-authors'[11] and Jonathan Lomas'[3] approaches were the most thorough. A third author, Hepler,[12] offered some practical guidance in carrying out the exercise.

The Tugwell approach is outlined in a paper entitled "The Measurement Iterative Loop: A Framework for the Critical Appraisal of Need, Benefits and Costs of Health Interventions."[11] Tugwell and co-authors propose that health information be segregated into groups to form a sequential progression beginning with quantifying the burden of illness; identifying the likely cause; determining interventions to address it including their efficiency; monitoring the introduction of the intervention; and, finally, determining the extent to which the burden of illness has been reduced.[11]

The literature describes the measurement iterative loop as a decision-making framework for policymakers who are involved with planning and paying for health services. The iterative loop allows policymakers and researchers to follow an approach to provide the best evidence about the capabilities of technology and programs to effectively and efficiently reduce the burden of illness in the population. It involves measuring the effectiveness of technology and programs towards reducing morbidity and mortality and improving quality of life compared to their respective alternatives and to cost.[13] Tugwell describes the process as iterative because the reduction in illness resulting from health care interventions is rarely totally effective indicating that several repeats of the loop may be necessary.[11]

Those who have tried to develop and implement policy using the Tugwell approach have formed some criticisms. A 1992 study used the measurement iterative loop as a framework for examining the economics of common therapies for acute non-specific low back pain.[14] The study determined that the burden of illness associated with low back pain was inaccurately measured; there was little knowledge of provider and patient compliance with therapy; and the cost of therapy could have been used as a guide since no treatment appeared definitely superior. The study eventually suggested bed rest was the most economical alternative. The authors criticized the iterative loop process in this application. They found that the loop was in one direction and did not allow for second order interactions among the components of the model. In addition, the authors have suggested, and Tugwell has acknowledged in his original article, that the conditional probabilities associated with the components of therapeutic effectiveness were assumed to be probabilistically independent and could have been combined in a simple multiplicative model. Those components included diagnostic accuracy, efficacy, and provider and patient compliance. The authors conceded that the use of the iterative loop was of benefit for clinical decision-making and rational use of resources and served as a means for research and policy formation.[14]

A 1998 study by Hepler[12] reported in the American Journal of Hospital Pharmacy entitled "Economic Aspects of Clinical Decision-making: Evaluating Clinical Programs" stressed the importance of program evaluation and issues to consider when conducting them. Like other authors, he described the evaluation process in six steps: defining the

objective, defining the program to be evaluated, choosing indicator variables, evaluation design, presenting results, and providing follow-through.[12]

A 1993 publication by Lomas in the International Journal of Technology Assessment in Health Care entitled "Making Clinical Policy Explicit: Legislative Policy-making and Lessons for Developing Practice Guidelines" described the generic process for making policy decisions. The publication provided a theoretical approach to policy-making and included a practical example using the proposed approach in attempting to implement a clinical practice guideline for the use of caesarean section. It was initiated because of concerns about potentially inappropriate medical care and unexplained variations in clinical practice. This example bridged the gap between evidence-based and actual practice and allowed the reader to experience the every day problems associated with implementation, most notably addressing professional stakeholder interests.[3]

The Lomas article argued that the policy-making process could have been improved by closely adhering to the legislative policy-making process used by governments. Lomas surmised that public policy legislation is usually formally developed and written, publicly debated and has official means of being enforced or implemented. This process provides greater accountability and responsiveness to evidence, people's interpretation of evidence (vested interests) and values. The values category involves assessing the relative priorities of the available facts. Lomas proposed that the process of policy-making should involve formal analysis and research, formal

hearings, open debate and lobbying to identify and address the facts, vested interests and values.[3]

Those involved in Canadian health policy analysis support the use of the Lomas approach in the policy evaluation of the pilot PMP because it is based, in part, on the Advocacy Coalition Framework ("ACF") model developed by Sabatier.[15] The ACF model allows the analyst to describe the policy events and to predict policy outcomes. It is predicated on the ability to examine factors such as the external policy environment, the policy sub-system, and the formal and informal structures for decision-making. Lomas adopts this broad policy framework to a clinical setting while the current application uses the framework in a broader context. (Personal communication – Dr. M. Rachlis, September 8, 2003.)

The ACF model is based on a number of factors that permit the understanding of policy change over a period of at least a decade. This timeframe allows for at least one policy cycle that may include policy formulation, implementation and reformulation. Sabatier argues that policy analysts focus their analysis on the policy sub-system and the interaction of different institutions. He describes the policy sub-system as including a variety of "actors" of private and public organizations, including government, who are actively concerned with the policy problem and who strive to influence government policy. The author suggests that policies and programs are influenced by value priorities

of stakeholders, their perceptions of the magnitude of the policy problem and the efficacy of the policy instruments.[15]

In an additional paper, Lomas further describes a framework (similar to the ACF model) for understanding how policies are made. He divides the decision-making environment into three interrelating domains. The first is referred to as the institutional structure for decision-making, which includes those who officially and unofficially have a voice in decision-making. It may include governments, policy brokers, coalitions, stakeholders and citizens.[16]

The institutional domain is influenced by the remaining two domains: values and information. The values domain is derived from a complex interaction of interests, beliefs and ideologies. Interests involve views about how the "world" should be; for example, prescribers may oppose a pilot PMP because drug monitoring affects clinical efficiency. Beliefs relate to how the "world" actually is; for example, some may oppose a pilot PMP because research suggests it is ineffective. Finally, ideologies relate to how the "world" ought to exist; for example, some may suggest that a third party ought not to be monitoring private health information. The information domain includes producers and purveyors of information and functions primarily to influence the beliefs component of the values domain. In summary, the values and information domains are inputs into the institutional structure for decision-making, which ultimately determines policy.[16]

The use of the generic process for making policy decisions described by Lomas was the primary template for this thesis because it thoroughly described specific criteria that could most readily be applied in this application. For example, there were incomplete information and interpretations of information by stakeholders; there were conflicts over stakeholder values; and policy implementation required extensive stakeholder involvement. The approach outlined three generic stages for making decisions: (1) definition of the problem; (2) policy-making; and (3) implementation of the policy.[3]

The process of defining the problem also included identifying stakeholders. This step involved attempting to quantify the extent of the policy problem by comparing changes in the standardized rates of events or procedures between areas over time. The identification of stakeholders included various medical professional associations, patient groups and more generally those with any concern over changes in procedures, including the public.[3]

The policy-making stage involved collecting and synthesizing information to generate alternative policies. In their specific clinical application of this generic model, the project team completed a comprehensive review of research evidence for each alternative approach. A panel was then selected from stakeholder groups to represent their interests. The panel reviewed the evidence collected and was actively involved in choosing the policy to be implemented. The intent was to allow the stakeholders to use

their values in selecting the appropriate policy; however, the chosen policy would be anchored to research evidence.[3]

The policy implementation stage generally involved three steps. The first was to disseminate and publicize the chosen policy. In Lomas' example, this included personal letters to individual stakeholders such as physicians and administrators and the presentation of the policy at various conferences and publication in bulletins. Secondly, the implementation step involved additional consultation with opinion leaders within the discipline of obstetrics, in Lomas' example. The third step was to monitor and revise the policy as necessary. This involved the committee of stakeholders appointed by the Minister of Health proposing revisions based on newly available research. The proposed revisions were based on a similar process used to identify the original policy and consequently could be viewed as a second iteration of the policy process. In conclusion, decision makers found a greater willingness by stakeholders to cooperate in the process.[3]

Since the Lomas publication was considered a key article in this research, its indexing terms were used in a specific search for additional applicable templates for consideration. This involved an electronic search in the Medline database between 1966 and 2003 using the MeSH terms ("health-policy"/all subheadings in MIME, MJME) and ("Public-Policy"/without subheadings in MIME, MJME) and ("policy-making"/without subheadings in MIME, MJME).

Nineteen articles were identified from the above search. Most were U.S. based studies addressing specific policies for AIDS, gambling, alcohol, nursing, dentistry, tobacco control, and community and private sector involvement in health care policy. One study, which examined health sector reform in Thailand, identified the complexity of the policy process and the influences of those stakeholders with power over decision-making.[17] However, it did not follow or propose a template for policy analysis.

Table 2.1 provides a summary of the generic approach for policy-making described by Lomas that was selected as the primary template for the analysis. This thesis expands upon the Lomas approach by including a more thorough program evaluation. It also contains a chapter describing the discontinuation of the pilot PMP. The Lomas approach is consistent with the approaches by Dunn, Brewer and deLeon and Sabatier and originates from the political science literature.

The conclusion of each of the following chapters will provide a sub-evaluation to determine where the actual policy process differed from the preferred approach. Retrospective suggestions will be provided on how the process could have been improved as well as recommendations for assisting in developing future programs. The next chapter initiates the policy analysis by describing the policy problem.

Table 2.1

Summary of the Lomas Approach to Policy-making[3]

1. Definition of the Problem
   - (a) Identify Problem/Issue
   - (b) Identify Stakeholders

2. Policy-making
   - (c) Collect information and produce alternative policies
   - (d) Involve stakeholders in choosing among alternatives

3. Implementation of the Policy
   - (e) Disseminate and publicize chosen policy
   - (f) Implement policy
   - (g) Monitor and revise

CHAPTER 3

POLICY PROBLEM

The primary policy problems that the pilot PMP was intended to address were the illicit, inappropriate personal use and suspected instances of indiscriminate prescribing of narcotics (opioid analgesics) and benzodiazepines in Newfoundland and Labrador. Narcotics are drugs that are mainly used to relieve pain. Benzodiazepines are central nervous system depressants and are used medically as sedatives and to treat anxiety, sleep disorders and epilepsy.[18]

The sub-evaluation of this chapter will describe how the policy problem was formulated in comparison to the suggested approach proposed by Lomas. However, in order to fully appreciate the context of these specific policy problems, it is necessary to review the extent to which pharmaceuticals are used in today's health care system and the evidence for the extent of inappropriate prescribing across all medications as well as the potential causes. This discussion will be followed by a more detailed description of the extent of inappropriate prescribing/use of narcotics and benzodiazepines from published and grey literature. It also reviews the potential illicit use of narcotics and benzodiazepines in the St. John's area as described by local health care stakeholders.

3.1 BACKGROUND

Over the last several decades, prescription medications have played an increasing role in medical therapies. They have been substituted for some surgical procedures, resulted in reduced length of hospital stays, and enabled some patients to be effectively managed in a community setting. They are often considered a cost-effective means of medical treatment if prescribed and consumed appropriately. Unfortunately, if inappropriately prescribed or taken, they can do more harm than good and consume scarce health care resources. Currently, there is concern that a significant proportion of drug consumption is clinically inappropriate.

The consequences of inappropriate drug use are considerable. They increase pharmaceutical expenditures and other types of health care costs. Angus and Karpitz note that up to 20% of hospital admissions in Canada have been attributed to medication misuse and avoidable adverse drug reactions. They suggest that poor prescribing led to over 50,000 hospital admissions annually in Canada and that 4,000 elderly Canadians died in 1989 as a result of inappropriate drug utilization.[19]

The consumption of and expenditures on pharmaceuticals by Canadians is significant. IMS Health, Canada (a private sector research company) estimated that Canadians received 291 million retail prescriptions in 1999/2000 at a retail value of $11 billion.[20] In 2001, Canadian per-capita expenditures on pharmaceuticals were approximately $362 per person per year, comparable to per-capita expenditure for

physician services. This translated to approximately 28 prescriptions per family per year at an average cost of $35.48 per prescription.[20,21]

The growth rate of pharmaceutical expenditures is concerning. From 1960 to 1993, annual expenditures on pharmaceuticals in Canada rosé at an average annual compound rate of 12%[19] compared to the average annual inflation rate of 5.5% during that period.[22] From 1994 to 2002, the average annual growth rate was 10.8%. However, in 2001 and 2002, the annual growth rates were 15.0% and 13.9% respectively.[23] These increases were attributed to the increased per capita use of drugs, the use of more expensive new drugs as opposed to existing ones, and the rising prices of existing drugs.[19] It is acknowledged that drug costs can be compared across a number of categories; for example, prescription and non-prescription, outpatient and/or hospital, long-term care and home care and factory gate costs or to the consumer.

Health Canada data suggested that expenditures on drugs has been increasing relative to overall health care expenditures since the early 1980s. For example, drugs accounted for only 9.8% of total health spending in 1983; by 1990 the proportion had increased to 12.6% and to 14.4% by 1996.[21] Canadian Institute for Health Information ("CIHI") estimated the comparable proportion to be 15.4% in 2000.[24]

3.2 EVIDENCE OF INAPPROPRIATE PRESCRIBING AND THE POTENTIAL CAUSES

3.2.1 Definition of Inappropriate Prescribing

The extent of inappropriate prescribing is dependent on the specific definition of what constitutes inappropriateness. A review of papers discussing what the authors considered as a suitable definition of appropriateness/inappropriateness of prescribing was conducted. As anticipated, many of the definitions overlapped.

Initial consideration of what constitutes appropriate prescribing often includes the phrases appropriate, safe, effective and economic. A majority of authors have built upon the initial consideration to suggest that the most appropriate definition should include characteristics such as "to maximize effectiveness, to minimize risks, to minimize costs, and to respect patient choices." Minimizing costs involves selecting the pharmaceutical that results in the lowest overall total costs as opposed to selecting the lowest (per unit) price medication while respecting patient choices.[25]

Others have categorized inappropriate prescribing as "overuse, underuse and misuse" in the context of prescriptions for seniors. Overuse occurs when the medications are prescribed without appropriate indication for the drug. They can be underused when not prescribed in the presence of accepted indications. Misuse occurs when these

medications are prescribed in the wrong dosages, incorrect durations, or in a manner that allows for unnecessary risk or desired outcomes not being achieved.[26]

A 1997 national consensus panel divided inappropriate prescribing practices for elderly people into three categories. The first included prescribing drugs generally contraindicated for the elderly because of unacceptable risk benefit ratios. Secondly, inappropriateness could occur when prescribing leads to negative drug/drug interactions. Finally, inappropriateness could occur when prescribing leads to drug/disease interactions.[27] More generally, Health Canada's description of inappropriate prescribing includes incorrect dosages, unnecessary duplication of therapies, prescribing drugs that negatively interact, or unnecessary prescribing due to misdiagnosis and, therefore, treatment of a condition that does not exist.[21]

Hepler and Strand[28] describe a drug-related problem as an event or circumstance involving a drug treatment that prevents a patient from having an optimal health outcome. In summary, they describe eight categories of drug-related problems including:

1. Untreated indications occur when the patient has a medical condition but is not provided a drug for that indication.
2. Improper drug selection occurs when the patient is taking the wrong drug.
3. Sub-therapeutic dosage occurs when the patient is provided too little of the appropriate medication.
4. Failure to receive drugs occurs when the patient has a medical condition resulting from not receiving a drug.

5. Overdosing occurs when the patient receives too much of the correct medication.

6. Adverse drug reactions occur when the patient has a medical problem resulting from an adverse effect of a medication.

7. Drug interactions occur when patients have medical problems associated with drug-drug, drug-food or drug-laboratory interaction.

8. Drug use without indication occurs when a patient consumes medication without a valid medical reason for doing so.[28]

Hepler and Strand also discuss inappropriate prescribing as one of five causes of sub-optimal patient outcomes related to prescribing. It includes both prescribing inappropriate and unnecessary regimens. Inappropriate regimens may include inappropriate drugs, dosage form, dose, route, dosage interval or duration.[28]

In most of the above general examples of drug-related problems, the emphasis was placed on the prescribers' role in providing potentially inappropriate prescriptions. They were not specific to medications that may have a "street value." Forgione and co-authors describe various ways that prescription drugs are diverted to illicit uses. They may include: (1) schemes of illicit drug seekers, such as seeking the same or similar prescriptions from multiple physicians, obtaining prescriptions on the pretense of an actual medical need, or impersonating a physician; (2) those who forge prescriptions; (3) losses of monitored medications that may occur during transportation; (4) theft from physicians and pharmacies; and (5) physicians who may be dated, disabled, dishonest or duped. Dated physicians are those who make prescribing decisions based on obsolete, incomplete or incorrect information. A dishonest physician is one who prescribes

indiscriminately for financial gain while a duped physician prescribes unintentionally based on false information provided by the individual.[29]

A popular means to measure prescribing inappropriateness is to compare individual prescriptions to predefined criteria or to evaluate prescribing across populations. Researchers must be cautious when reviewing/comparing multiple studies of inappropriateness because of the varying definitions of what constitutes inappropriateness.

3.2.2 Evidence of Inappropriate Prescribing in Canada

Information regarding inappropriate prescribing in Canada was obtained through an electronic literature search of the Medline and IPA databases. On the advice of a professional librarian, the literature searches were intentionally broad in order to identify all relevant articles. The Medline database was searched using the terms: (canad* or explode Canada) and ((inappropriate* near2 prescri*) or (appropriate* near2 prescri*)). An additional Medline search involved the terms: ((appropriateness near5 prescri*) or (unnecessary near3 prescri*) or (improv near3 prescri*)) and ((canad* or explode Canada) or (name of each individual province or territory)) and drug*. The IPA database was searched using the terms: ((inappropriate* near2 prescri* or appropriate* near2 prescri*) or (appropriateness near5 prescri* or unnecessary near3 prescri* or improve* near3 prescri*)) and ((canad* or name of each individual province or territory)). All

articles for review were limited to those published in English between 1984 and 2003. Specific evidence regarding the inappropriate prescribing of narcotics and benzodiazepines in Canada is discussed in Section 3.2.3.

The literature searches identified numerous original research articles that described the extent of inappropriate pharmaceutical prescribing in Canada since 1984. They examined the subject across a number of drug categories, prescribing settings and patient categories such as children and the elderly. Antibiotics were the most common drug category studied. The most common reason for excluding articles in this section was because they were not original empirical studies. Other reasons for excluding studies were because they were United States based (but may have used Canadian guidelines); were discussion papers; involved developing assessment tools or guidelines; involved strategies to improve patient compliance; or were cost analyses. Some empirical studies that measured baseline appropriateness of prescribing are reviewed in Chapter 4 as they also described potential options for improving prescribing. Consequently, they are omitted from this chapter.

The purpose of this review is to illustrate that there are serious issues related to inappropriate prescription drug use in Canada. While a number of studies are reviewed, a comprehensive assessment of drug use evaluation studies in general is beyond the scope of this thesis.

Inappropriate antibiotic prescribing is of concern since it can lead to increased risks for side effects and bacterial resistance. Numerous community-based and hospital-based antibiotic studies were identified from the literature search. One community-based study involving 260 physician-patient encounters reported that 13.1% of cases had no clinical indication for an antibiotic; however, in 60% of these cases they were prescribed one.[30] Another community-based pediatric study found that 10.5% of antibiotic prescriptions for children in the greater Toronto area were inappropriate.[31] A 2002 study designed to measure the impact of empirical management of acute cystitis on unnecessary antibiotic use determined that unnecessary use was 41.4% and 40.6% for two guidelines recommending empirical antibiotic treatment without testing for pyuria.[32] Another study found that unnecessary antibiotic prescription rates were 16.1% and 20.4% for two groups involved in a study of antibiotic use for sore throats.[33] A further study by the same author determined that inappropriate antibiotic prescribing for sore throats ranged from 5.1% to 78.3% when the chance of the infection was overestimated from less than 10% to more than 50% respectively.[34]

Many articles described inappropriate medication prescribing in hospital settings. One antibiotic study suggested that 42% of cefuroxime prescriptions for pediatric patients were inappropriate.[35] Another hospital-based study reported that 40% of cefamandole prescriptions at a 900-bed teaching hospital were inappropriate[36] while a third hospital-based study found that 6%, 63% and 38% of prescriptions were inappropriate for children at three hospitals in Ontario. These included a university affiliated, a small rural

community and a general hospital, respectively.[37] Another study, which focused on cost, found that 68% of cefoxitin prescribed cases could have substituted a less expensive antibiotic cefazolin in women who underwent hysterectomies and emergency cesarean sections.[38] A further study found inappropriate peri-operative antimicrobial use occurred in 15% of cases while in 28% of the cases the dosages were deemed inappropriate or not recorded.[39] Another article found that 58.2% of cases where vancomycin was prescribed were considered inappropriate at an Ottawa area hospital.[40] A hospital-based vancomycin study that measured the impact of a therapeutic and pharmacokinetic drug monitoring service assessed inappropriate prescribing at 27% and 10% before and following the intervention, respectively.[41] A final hospital-based study designed to measure the optimal role of the pharmacist in promoting evidence-based antibiotic use for indication and dosage determined that 75% of orders in the intervention group were appropriate compared to 69% in the control group.[42]

A 2003 published study examined patient charts of those operated on for specific procedures at an Edmonton hospital between April and December 1999. It determined that 36 (36.7%) of 98 patients had inappropriate heparin prophylaxis; only 5 (5.2%) of 96 patients were appropriately treated with antibiotics pre-operatively without post-operative doses and 95% of patients were inappropriately provided antibiotics post-operatively.[43] A second study which involved the development and validation of a tool for screening inappropriate prescribing in the elderly rated the appropriateness of a series of inpatient charts at an Ontario acute care hospital. It found that 42 (12.5%) of

361 individuals had a total of 45 potentially inappropriate prescriptions involving 14 different potential drug/disease interactions.[44]

A 1990 study conducted at a Toronto hospital measured cefoxitin prescribing patterns, assessed its appropriateness of use and estimated the cost and future potential savings associated with inappropriate use. Overall, it determined that 47% of course regimes were appropriate, 42% were inappropriate, while an additional 11% were questionable. Approximately 22% of resources spent on this medication were associated with inappropriate use.[45] Another hospital-based study that intended to measure the impact of a medical education program for improving the prescribing of cimetidine found that after the program 63% of prescriptions were appropriate compared to 40% before the program.[46] A final hospital-based study that measured the effect of educational consults on allopurinol prescribing determined that 11 (22%) of 50 patients required an intervention due to a lack of indication or excessive dosage of this medication. The authors concluded that allopurinol prescribing at this specific hospital differed substantially from guidelines.[47]

The literature search also identified a number of studies that specifically examined inappropriate prescribing for the elderly. One found that 18.3% of long-term care patients at a Toronto institution were inappropriately prescribed a medication. The inappropriate cases were divided almost equally between anticholinergic drugs to manage antipsychotic side effects, tricyclic antidepressants with active metabolites and long-

acting benzodiazepines.[48] The second study examined 150 consecutive geriatric admissions to the medical ward of the Toronto Hospital. It found that 41% of patients on admission had a drug-related problem involving commonly prescribed drugs of which 96.8% were potentially avoidable. The drug-related problem was the reason for the hospital admission in 31% of these cases.[49]

A study by Anderson and co-authors examined computerized prescription claims from a universal, comprehensive drug benefit plan for the elderly with explicit criteria for appropriate prescribing in an attempt to, in part, measure the rate of potentially inappropriate prescriptions. Their results indicated that approximately 38% of those elderly patients receiving anti-depressants were given a potentially inappropriate drug. The comparable rate for those receiving oral hypoglycemics, sedative hypnotics and non-steriodal anti-inflammatory drugs were 19%, 18% and 13%, respectively.[50]

The remaining original research studies identified from the literature search examined inappropriate prescribing across a number of drug categories and settings. One that examined the appropriate use of asthma medication in British Columbia specified that inappropriate prescribing occurred when patients were prescribed high doses of a short-acting beta-agonist and low doses of inhaled corticosteroid. The study determined that 12.8% of cases involved excessive amounts of beta-agonists while 24.9% of this group used no more than 100 micrograms/day of inhaled beclomethasone. Those individuals also visited more physicians and were more likely to be admitted to hospital.

In addition, the prescribing physicians for this group were, on average, high prescribers.[51] A further study assessed the extent of adherence to renal dosing guidelines in long-term care facilities. It determined that 34.1% of prescriptions were considered inappropriate for creatinine clearance while 42.3% of residents who received prescriptions were prescribed at least one inappropriately.[52] Another study with a limited sample size, which assessed renal impairment and medication use involving psychogeriatric inpatients determined that only two (5%) of 44 medications for which dosing guidelines were available were prescribed inappropriately.[53]

A 1998 Ontario study that examined the management of common muscoskeletal problems by way of a survey to community-based general practitioners found that physicians would prescribe a nonsteroidal anti-inflammatory (as well as other therapies) in 44.7% of cases where it was not clinically warranted.[54]

A 1997 published article defined the prescribing of omeprazole as inappropriate if a first-line antiulcer drug was not prescribed within six months of the first prescription of omeprazole. It determined that 80.5% of the cases were prescribed inappropriately.[55] A second study published in 1998 involved a comparison of retrospective and concurrent drug utilization review of omeprazole. It determined that appropriateness of prescribing, according to indication criteria, was 38% during the retrospective drug utilization review and 75% during the concurrent review.[56] A final study examining the appropriateness of omeprazole prescribing for Quebec seniors following a change in formulary policy

determined that 54.7% of first time users had received this drug appropriately. The authors concluded that despite a change in the formulary criteria this drug was prescribed appropriately for seniors in the majority of cases.[57]

Two studies assessed the appropriateness of prescribing of non-steroidal anti-inflammatory drugs ("NSAIDs"). A Quebec community-based study published in 1997 determined that 41.7% of office visits resulted in unnecessary prescriptions for NSAIDs or other drugs. It was found that gastropathy due to NSAID use was correctly diagnosed in 93.4% of visits and, subsequently, appropriately managed in 77.4% of visits.[58] The second study using Saskatchewan drug plan data also examined the appropriateness of prescribing of NSAIDs in addition to H_2-antagonists and anti-depressants. It found that less than 4% of patients receiving NSAIDs or anti-depressants were prescribed dosages that exceeded the maximum recommended daily amount. However, 38.5% of patients dispensed H_2-antagonists had estimated daily doses greater than the recommended maximum. The study also found that duplicate therapy in the prescribing of NSAIDs was measured at 7.3% while the comparable rate for H_2-antagonists was 11.4% and 20.8% for antidepressants.[59]

The remaining empirical study identified from the literature search focused on the appropriateness of prescribing of antibiotics by military physicians and physician assistants. This retrospective study found that 86.2% of anti-infective prescriptions by military physicians and 85.3% of those by physician assistants were comparable to the

two sets of appropriateness guidelines. Conditions where antibiotic prescribing was of concern included bronchitis, community-acquired pneumonia, cellulitis, otitis media, pharyngitis, sinusitis and urinary tract infections.[60]

A 1998 review article by Lexchin also described the magnitude of prescribing in Canada and the circumstances where inappropriate prescribing can occur.[25] Lexchin reported one study which reviewed the prescribing of antibiotics, cimetidine, psychotropics and potassium supplements. It determined that the proportion of inappropriate prescribing was approximately 18% for drug indication, 17% for choice of drug, 30% for route of drug administration and almost 43% for overall prescribing. Additional research on prescribing to the elderly found that 45% of patients reviewed had "potentially undesirable prescribing." Another geriatric study found 14% of the cases had inaccurate doses; 31% had potential drug-drug interactions; 23% had drug contra-indications; while 39% of the cases had at least one unnecessary drug prescribed. A second geriatric study on patients with heart failure determined that 22% of patients had received digoxin inappropriately while another 36% who were not prescribed this drug could have benefited from it.[25,61-64]

The above general review suggests that there is a considerable amount of inappropriate prescribing in Canada. The magnitude of the problem varies by drug category, by setting and the criteria used to assess appropriateness. It is also acknowledged that the above review is not completely applicable to the specific policy

problem that the pilot PMP was intended to address. The following section will review the extent of inappropriate prescribing of medications of specific interest in this thesis.

3.2.3 Evidence of Inappropriate Prescribing of PMP Monitored Drugs

The purpose of this section is to generally review the published and grey literature with respect to the extent of inappropriate prescribing of narcotics and benzodiazepines in Canada. However, a detailed study of this literature relating to problems outside of the illicit and inappropriate personal use or indiscriminate prescribing of these medications is considered beyond the scope of this thesis.

Specific information regarding inappropriate prescribing of narcotics and benzodiazepines was obtained through electronic literature searches of the Medline and IPA databases. The Medline and IPA databases were searched using the terms: ((canad* or name of each individual province or territory) and (appropriateness near5 prescri*) or (unnecessary near3 prescri*) or (improv* near3 prescri*) or (appropriate* near2 prescri*) or (inappropriate* near2 prescri*)) and (narcotic* or benzodiazepine*). All articles for review were limited to those published in English between 1984 and 2003.

The grey literature was reviewed in an attempt to obtain more information regarding the illicit and inappropriate personal use and indiscriminate prescribing of prescription narcotics and benzodiazepines. To achieve this, the Canadian Research

Index ("CRI") was searched for publications by provincial, federal and non-government organizations. The search used the terms narcotic and benzodiazepine followed by a code to ensure the single or plural version of the search term would be identified. Abstracts of papers between 1982 and 2002 were reviewed. As well, personal contact was made with officials from some common sources of the identified information such as the Office of the Solicitor General of Canada, Health Canada – Office of Controlled Substances, Statistics Canada and the Addictions Foundation of Manitoba.

Some of the published studies that measured the appropriateness of PMP monitored drug prescribing also evaluated potential educational interventions to improve prescribing appropriateness. Consequently, they are omitted from this section and are discussed in more detail in Chapter 4 as potential options for improving prescribing. Other studies were excluded because they only discussed uses for benzodiazepines, were related to government policies associated with the drug approval process and pharmaceutical advertising and they did not measure appropriateness of prescribing.

A number of published studies that examined the prescribing of benzodiazepines in Canadian settings were identified. One 1990 community-based British Columbia study found that 24% of all elderly people were given at least one benzodiazepine prescription during the year and that 17.1% of these were deemed inappropriate because the prescription exceeded the maximum two-month limit of 20 diazepam equivalents daily.[65] Another study found that night sedation with benzodiazepines was common for

geriatric patient populations at two Ontario hospitals. While the sample size was small, the study concluded that approximately 75% of cases were inappropriate, primarily because the majority were on a benzodiazepine for more than 30 days.[66] A 1994 Quebec study found that 14% of the elderly in that province had been prescribed a long-acting benzodiazepine in 1990, a practice that should be avoided.[67] A more recent study examining benzodiazepine, cardiovascular and nonsteroidal anti-inflammatory prescribing in Quebec found that 46% of the study population experienced at least one or more questionable prescriptions and that 33% of the total elderly population of Quebec had received benzodiazepines for more than 30 consecutive days.[68] A recent survey found that the prevalence of benzodiazepine prescribing in older people in Ontario steadily declined between 1993 and 1998. This survey also determined that physicians were prescribing more short-acting than long-acting benzodiazepines and they were substituting benzodiazepines with antidepressants more often for elderly people.[69]

A 2002 pre/post retrospective cohort study examining the prevalence of inappropriate prescribing at licensed nursing homes in Ontario found that the rate of patients receiving at least one inappropriate prescription decreased from 25.4% before admission to 20.8% afterwards. The most common inappropriate prescriptions after admission were for anticholinergic antidepressants (6.4%) and long half-life benzodiazepines (5.9%). Significant predictors of inappropriate prescribing included: patients who were younger than 85; those with more than one prescriber; a prescriber

greater than 50 years of age; a male physician; a non-specialist physician; and a non-urban physician.[70]

A 2001 study conducted in British Columbia attempted, using data from the province's triplicate prescription program, to identify unusual or unexpected patterns of prescribing of methylphenidate (Ritalin) to children and adolescents. The study determined that the rate of prescribing in children increased from 1.9 per thousand to 11.0 per thousand over a six-year period. It also calculated the rate for those who had never received this drug before as some children had prescriptions in multiple years. This rate increased from 1 per thousand children to 4.7 per thousand over a five-year period and then declined to 3.5 per thousand in the final year of study. As well, there was almost a threefold difference in the rate of prescribing to children between health regions in the province. The study concluded that while trends of prescribing were consistent with other settings and accepted standards, the prescribing of this medication to children required further consideration, including regional and socioeconomic differences of patients, the involvement of general practitioners in prescribing, continuity of care, and appropriate time intervals between prescriptions.[71]

In another publication by the author of the above study, he undertook, in part, surveys of physician practice patterns to determine trends and agreement between the recommended prescribing of psychostimulants to children and actual practice. It was determined that it was uncommon to find physicians practicing according to expert

recommendations more than 70% of the time. The study concluded that the therapeutic management might have been suboptimal for a minimum of 30% of children who were receiving prescriptions for attention-deficit hyperactivity disorder.[72]

A 2002 patient survey of prescription medication use in an Alberta aboriginal population who were accessing addiction treatment concluded that there were significant issues in relation to how patients accessed medications that were misused. While researchers expected this group to have a high rate of inappropriate use, 48% of respondents reported that they used prescribed medications inappropriately. Sedatives or relaxants were the most inappropriately used prescription medications. Of the medications inappropriately used, 52% of the respondents reported receiving the drugs from a friend or stranger, 45% were purchased on the street and 41% reported they were obtained by prescription from a physician.[73]

The above-noted study addressed issues similar to the policy problem under consideration in this thesis. However, it had some limitations that limited the validity of the findings and the ability to generalize them to Newfoundland and Labrador. For example, the survey was conducted entirely on an aboriginal group of individuals who accessed addiction treatment. As well, while the questionnaire was anonymous, the seriousness of the topic may have resulted in under-reported responses. The survey also listed the most commonly used medications rather than requesting respondents to identify the medications they used; consequently, they may have overreported their use. In

addition, some information on the treatment received was incomplete limiting the interpretability of these results. Finally, the sample size was small.

Most of the information reviewed from the grey literature did not refer to issues associated with the illicit and inappropriate personal use of prescription medications. The focuses were primarily on issues related to the illegal use and distribution of common street drugs such as cocaine, heroin, tranquilizers, hallucinogens and stimulants. Many reports were non-empirical and United States based. Despite this, a number of publications and data were reviewed that addressed the inappropriate diversion of prescription medications in Canada. The following discussion is limited to this material.

The most comprehensive document from the grey literature addressing the primary policy problem described in this thesis was a 2002 federal report of the Special Committee on Non-medical Use of Drugs entitled "Policy for the New Millennium: Working Together to Redefine Canada's Drug Strategy."[74] A section of the federal report was devoted to the misuse of prescription drugs. The Special Committee on the Non-medical Use of Drugs received a number of submissions from professional pharmacy associations and Provincial Colleges of Physicians and Surgeons. Their identification of the problem to be addressed was limited to individuals who misused prescribed drugs to the detriment of their own health and those who resold them for profit. They also noted the theft of prescription medications from pharmacies as a

potential source for illicit trade. However, the contribution of prescribers who were suspected of indiscriminately prescribing was not discussed.[74]

The Committee attributed the lack of education and awareness among physicians, pharmacists and the general public regarding the risk of misusing prescription drugs as a potential source of the problem. They proposed that education and awareness programs for patients, physicians and other health professionals be developed to address this problem. Those making submissions noted that codeine, hydromorphone HCL (Dilaudid), oxycodone HCL (Oxycontin), pentazocine HCL (Talwin), methylphenidate (Ritalin) and oxycodone (Percocet) were the common prescription medications of abuse. In some instances, their "street value" was cited as being eight times their retail value.[74]

Those making submissions to the Committee made some anecdotal observations that may have implications for Newfoundland and Labrador. They suggested that the illicit trade of prescription medications might be proportionately more common in smaller cities and rural areas where common street drugs such as heroine and cocaine were less available.[74]

The Committee strongly endorsed the use of PMPs in limiting the growth of prescription drug misuse by curbing the activities of those who were double doctoring. Furthermore, they promoted the implementation of real-time PMPs (similar to British Columbia's PharmaNet Program) to permit health professionals to have immediate access

to individual patient drug profiles at the time medications were being prescribed or dispensed. Interestingly, they argued that this might improve the privacy of patients who might be currently subject to ad hoc conversations between pharmacists and physicians regarding their suspected inappropriate access to prescription medications.[74]

The Committee also identified the use of Internet prescribing as a source of concern for medications that may be sold on the street. This mode of prescribing has been cited as a means to potentially avoid the intended monitoring effect of PMPs. It was noted that addressing this matter would require consideration of complex legal and ethical issues. It was also suggested that over-the-counter drugs containing dextromethorphan, antihistamine and codeine were potentially problematic and should be considered as part of a comprehensive drug policy.[74]

The Bureau of Drug Surveillance of the Therapeutics Products Program at Health Canada provided statistics regarding the incidences of diversions, thefts, losses and forgeries of controlled substances in Canada between 1984 and 1998.[75] In most instances, these data illustrated a slightly downward trend for each type of diversion. However, senior officials of the Office of Controlled Substances cautioned that these statistics are misleading. They noted the reporting of these statistics is mandatory; however, reporting has not been monitored since the early 1990s. Consequently, statistics may have been lower due to incomplete reporting, rather than a decrease in incidence as the report suggested. (Personal communication – B. Erickson, Project

Manager, Office of Controlled Substances, September 24, 2003.) In addition, others have cautioned that trends in drug offences are directly influenced by police enforcement levels.[76] Statistics regarding theft in the St. John's area of monitored drugs and forgeries are discussed in greater detail in Chapter 6 of this thesis.

3.2.4 Potential Causes of Inappropriate Prescribing

The literature searches described above identified a number of papers that discussed the reasons or rationale for inappropriate prescribing. Two papers were thorough review articles[19,77] while another was published by an author with considerable experience in evaluating pharmaceutical use.[25] Also included was a paper that was prepared for the National Forum on Health.[78] A number of reasons were proposed as to why there was considerable inappropriate prescribing in Canada. However, there was a lack of empirical evidence regarding the relative contribution of each of the proposed factors towards inappropriate prescribing.

Approximately eight collective reasons appear to account for the prevalence of general inappropriate prescribing by providers of health care in Canada and all may not be applicable to the policy problem under consideration in this thesis. They included inadequate training at medical schools, aggressive marketing efforts by pharmaceutical manufacturers, inadequate quality assurance, consumer expectation, lack of knowledge by prescribers, the mere convenience of writing a prescription, and the excessive quantity

of "me-too" drugs. It was also proposed that physician reimbursement policies played a role in inappropriate prescribing.[19,25,77,78]

It has been suggested that an excessive proportion of prescribing was inappropriate due to a rapidly changing selection of available products and that the training provided at medical schools was often outdated by the time physicians were busily engaged in independent practice. Also, the sources of information on drugs used by prescribers appeared less than adequate and perhaps, in some instances, biased. Such sources included continuing medical education, scientific meetings, journals, pharmaceutical sales representatives and advertisements in journals.[77] Additional sources included newspaper articles, consumer advertising, the internet, health professional colleagues and professional society bulletins.

One review article[19] and research conducted for the National Forum on Health suggested that a major reason for the high rate of inappropriate prescribing was the large expenditure by pharmaceutical manufacturers on marketing efforts. In 1995, this was estimated at $900 million, or 15% to 20% of sales, which was more than twice the amount invested in research by the pharmaceutical manufacturers.[19] It was noted that the pharmaceutical sector was fiercely competitive with each manufacturer seeking brand-name recognition of their products by physicians, to build consumer allegiance, and to earn profits. The results of such marketing expenditures was particularly concerning when one considered that it was directed primarily towards physicians. There

was also concern that the marketing efforts directed towards physicians were biased. The authors suggested that physicians would not compare and contrast information they receive from manufacturers. As well, pharmaceutical representatives were not expected to provide objective information on alternative drug and healing therapies, nor promote competitors' products. The article cited other research, which suggested that print advertisements exaggerated the clinical benefits of drugs. Finally, the authors noted weaknesses associated with codes of conduct for promotional activities, particularly the lack of penalties for violations.[19,78]

Lexchin identified additional articles, which were subsequently reviewed, that addressed potential causes of inappropriate prescribing. As summarized by Lexchin, they suggested that the more frequently physicians saw pharmaceutical representatives, the more likely they were to use pharmacotherapy versus more appropriate non-pharmaceutical options. In addition, these physicians were more likely to prescribe a particular antibiotic inappropriately, less likely to prescribe generically, and more likely to use more expensive medications. High-volume prescribers had significantly more interactions with pharmaceutical representatives than the average prescribing physician.[25,79-84]

Consumer expectation was cited as a contributing reason for inappropriate prescribing and one would expect its relative influence to vary depending on the medication under review. For example, consumer expectation would be expected to

influence the prescribing of antibiotics, narcotics and benzodiazepines. Anecdotally, in carrying out this research, some physicians responded with the rationale that these medications were provided at the patient's request because if the prescription were to be declined, it would be obtained elsewhere.

Another reason for inappropriate prescribing was the lack of knowledge by prescribers about the indications for specific medications. Proponents of clinical practice guidelines advocate that physicians should acquire knowledge of new medications from scientific sources. However, surveys of Canadian physicians indicated that they received more pharmaceutical information from pharmaceutical company sales representatives than from peer-reviewed journals. This contrasted with results of other surveys that asked physicians to rank what they believed to be credible sources of information and ironically they failed to include pharmaceutical company sales representatives.[25,85,86] Authors of clinical practice guidelines have also been subject to criticism. A 2001 published study found that developers of Canadian drug therapy guidelines need to be more rigorous and thorough in their methods or at least the description of their methods for developing such guidelines.[87] Others argued that there should be one Canadian guideline for each subject and that it be produced at the national level. As well, it was proposed that the guidelines be federally funded and consistent with established criteria for assessing guidelines.[88]

The mere convenience of writing a prescription complemented by the mode of physician reimbursement was also proposed as a reason for inappropriate prescribing. For example, general practitioners in Canada provided their patients with a prescription during approximately 50% of office visits. This accounted for an estimated 230 million prescriptions annually. When combined with a fee-for-service practice, the prescription became a mechanism to close the patient visit since the practitioner understood the medical problem and a therapy was chosen. Studies have proposed that physician incomes were directly linked to office throughput and heavy prescribing was a means of increasing throughput.[25,78] There was some evidence that the type of physician reimbursement might influence the choice of drugs. A Montreal study which compared salaried physician's benzodiazepine prescribing in government-funded community health centers with fee-for-service group practices found that only 25% of fee-for-service physicians prescribed the benzodiazepines for less than 30 days compared to 50% of the salaried physicians. As well, salaried physicians were approximately three times as likely to provide explicit warnings about the use of benzodiazepines.[25,89]

A final rationale for the rate of inappropriate prescribing was associated with the production of "me too" drugs.[19] With approximately 5,000 medications on the Canadian market, solo practitioners only prescribed between 121 and 218 different drugs and 50% of all prescriptions written by general practitioners were within 27 different medications.[25] Health Canada's Drug Product database notes that there are some 24,000 products marketed under the human pharmaceutical and biological drugs, veterinary

drugs and disinfectant product categories.[90] It was suggested that of the 400 newly patented drugs in Canada between 1991 and 1995, only 8% were considered breakthroughs; 49% showed moderate improvement while 43% were line extensions. In addition, many of the breakthrough medications were associated with cancer treatments and not administered by general practitioners. Consequently, general practitioners were not required to learn about a large number of new medications. It appeared pharmaceutical companies concentrated their "me too" medications on areas with a high number of end users.[19,25]

Soumerai and co-authors[91] discussed the use of a conceptual framework for organizing both the clinical and non-clinical factors that influenced physician prescribing. The framework addressed three sequential stages of behavioural changes referred to as predisposing, enabling and reinforcing factors. Predisposing variables were described as the prescriber being aware that consensus guidelines for the appropriate prescribing of a particular medication existed; having knowledge of information supporting the use of the guideline; believing that it was efficacious; and having attitudes or values related to the recommended approach.[91]

Soumerai further argued that physician behaviour change might be limited due to inadequate enabling skills. For example, the prescriber must have the necessary skills for administering the therapy and to effectively address patient and/or family demand for less efficacious therapy. The final stage of the conceptual framework involved the need for reinforcing factors. Proponents of the framework argued that once a new approach had

been tried, continued adherence to the new approach may be enhanced by using multiple and positive reinforcements. In the case of appropriate prescribing, examples of positive reinforcements may be through peers, reminders and feedback. Soumerai concluded that prescribing interventions that address all three stages of the framework were most likely to be effective.[91]

3.3 INAPPROPRIATE PRESCRIBING/USE OF NARCOTICS AND BENZODIAZEPINES IN THE ST. JOHN'S AREA

An estimate of abuse of prescriptions for analgesics and sedatives in the St. John's area was obtained during the summer of 1996 as background information for the PMP discussion document. This information was obtained from the RNC's Drug Investigation Division, the Newfoundland Pharmaceutical Association ("NPA"), the NMB and the Newfoundland Medical Care Commission ("MCP"). MCP information was based on their access to computerized files of physician claims for insured services.

The 1996 interview between this researcher and key RNC investigators provided some indication of the extent of prescription medication abuse in the St. John's area. The information they provided originated from their drug investigations and from drug informants. Much of the information was anecdotal, and due to the illegal nature of the activities discussed, its accuracy could not be assessed.

The RNC estimated that 90% of prescription drugs used on the street in the St. John's area were provided to patients who had been "double doctoring." Double doctoring is defined as seeking or obtaining a prescription for a substance contained in the schedules of the Controlled Drugs and Substances Act without disclosing to the prescriber any previous similar prescription(s) within the previous 30 days. The RNC estimated the remaining 10% was associated with break and enters at pharmacies. Local drug informants also identified up to six St. John's general practitioners who repeatedly prescribed the abused drugs without verifying indication. As well, over half of the St. John's area general practitioners were believed to have been duped into prescribing the abused substances by patients who were double doctoring. It was crudely estimated that the questionable practices of five or six local general practitioners supplied one third of the illicit trade and double doctoring accounted for two-thirds of the illegal activity. The most commonly abused substances at that time included Ritalin (methylphenidate), benzodiazepines and other sedative agents.

The police estimated that in 1996 prescription drug abuse was increasing in St. John's area high schools and to a lesser extent in junior high schools. They believed that up to 200 individuals were being prescribed abused substances for inappropriate use. The RNC also believed that it was realistic to assume that each individual who double doctored utilized the services of at least two distributors who sell illicit drugs at the street level, suggesting that at least 600 individuals in the St. John's area were involved in trafficking drugs obtained from inappropriate prescriptions. Many of the distributors

were high school students and young adults in the local neighbourhood. Police were familiar with the existence of four to five well established "pill pushers" in each local junior and senior high school within their jurisdiction. As mentioned, this anecdotal information provided by the RNC originates from their drug investigations and drug informants.

A 2001 published survey of junior high and high school students in the Atlantic Provinces also suggested there were problems associated with youth access to prescription medications. This study specifically addressed the medical and non-medical use of stimulants among adolescents. Of the respondents, 5.3% reported using prescription stimulants in the prior twelve months. Of these students, 14.7% reported having given some away; 7.3% sold some; 4.3% had some stolen; while 3.0% were forced to give up some of their medication. The study concluded that of those students taking prescription stimulants, the vast majority were doing so appropriately. However, there was a relationship between medical and non-medical stimulant use and a diversion of these medications to unsanctioned use.[92]

Discussions with the NPA in 1996 confirmed the RNC's anecdotal evidence of prescription drug abuse in the St. John's area. There were approximately 63 pharmacies in the vicinity of St. John's. The NPA believed that pharmacists at each location could describe three to four cases of anecdotal evidence of drug abuse. Local pharmacists who

conducted checks determined that several suspected abusers were regular customers of multiple drug stores throughout the capital city.

The NMB also reported in 1996 that they received periodic complaints concerning the suspected abuse of prescription medications. In most instances, the caller would not identify the parties involved or provide a written complaint. The Board followed up a complaint when a physician was identified. They referred callers to the police for complaints concerning patients suspected of double doctoring.

During the 1996 review, MCP's Audit Department cited a 1988 internal study on physician over-servicing and patient double doctoring. This study was initiated to demonstrate the need for increased scrutiny of the use of MCP insured services by internal auditors and has not been repeated since 1988. It involved a computerized review of the utilization patterns of beneficiaries, referred to as the "Multiple Services Listing" and identified over-utilization using set criteria. Threshold levels were defined for patients who received five or more services in a week or ten or more within a month. Once critically and chronically ill patients were screened from the group, three categories of over-users remained.[93]

Users in "category one" received an excessive number of services from a general practitioner. This activity was common in rural communities where physicians were relied upon for support and comfort, in addition to medical attention. Physicians

involved in this activity also serviced a large number of nursing home patients and this was believed to also encourage over-utilization. "Category two" users included patients who sought excessive services from specialists. Internal medicine and psychiatry were the specialities most over-utilized. MCP suggested that excessive levels of service provided in this category were undoubtedly the responsibility of the provider since specialists' visits were not patient initiated. However, in actual practice many patients demand to be seen again and seek multiple referrals from general practitioners.[93]

"Category three" patients were those of interest for this thesis. It included those who seek excessive physician services for the purposes of over-utilizing prescribed narcotics, other often abused substances, and for no apparent reason - other than no one physician appeared to be monitoring the patient's overall care. MCP retrospectively audited patient medical records to determine the breakdown of overuse.[93]

The 1988 MCP audit demonstrated that there were 563 cases (patients) of abuse listed in the three categories (Table 3.1). Category one accounted for 85 cases, with an approximate average annual fee-for-service physician billing per individual patient of $2,000. There were 50 abusers listed in category two at an average annual cost in terms of fee-for-service physician billings to MCP of about $3,200, while category three accounted for the remaining 428 cases at an average annual estimated fee-for-service physician billing cost of $2,200 per case. The patterns of abuse were most prominent in urban centres. Total annual costs to MCP in terms of fee-for-service physician billings

for the three categories of over-utilization were estimated at $1.3 million. Category three was estimated to account for over $900,000 of this amount.[93]

Table 3.1
Summary of MCP's 1988 Multiple Services Review[93]

Categories	*Number of Patients*	*Average Annual Fee-for-service Physician Billing Cost per Patient*
Category One - Number of patients receiving excessive services from a general practitioner	85	$2,000
Category Two - Number of patients receiving excessive services from specialists	50	$3,200
Category Three - Number of patients receiving excessive physician services for the purposes of obtaining narcotics or for no apparent reason	428	$2,200
Estimated total annual costs to MCP for three categories		**$1.3 million**

MCP initiated a number of audits of beneficiaries described under category three. A review of physician records demonstrated that patients in this category did not indicate to the prescribing physician that a previous prescription for narcotics had been received in the prior 30 days. The audit also showed that a common group of general practitioners in the St. John's area had seen each of the over-utilizers at least once. Police informants identified the same physicians as "known" sources of inappropriate prescriptions.[93]

MCP was reluctant to initiate police investigations of suspected abuse because of their legal interpretation of the Act respecting their activities. Patient confidentiality was the primary concern. Initially, it was felt that the Bureau of Dangerous Drugs ("BDD") could act as an intermediary between the MCP and the police since the BDD was empowered under the Act. The BDD was a former federal agency responsible for administering federal regulations regarding the medical and scientific use of psychoactive drugs.[94] However, MCP's legal interpretation of their Act suggested that they should not disclose information to anyone that would commence a police investigation. MCP corresponded with physicians informing them of patients who were suspected of double doctoring. As well, they notified physicians suspected of over-servicing. However, no formal process existed because of the confidentiality limitations resulting from MCP's interpretation of their Act.

3.4 SUB-EVALUATION

The purpose of the sub-evaluation section of this chapter is to compare how the "policy problem" was identified and articulated in contrast to the approach proposed in the policy development framework by Lomas. In addition, it provides retrospective suggestions of how the policy development stage could have been improved.

The Lomas approach proposed that the "definition of the policy problem stage" contain two important criteria: identifying the problem/issue and identifying stakeholders.

3.4.1 Identification of the Policy Problem/Issue

To identify the problem/issue, Lomas proposes that policymakers examine variations in practice utilization rates over time and between jurisdictions such as community and urban centres. The use of surveys may be used to determine utilization rates. Building on this approach, a more general notion of a data defined problem analysis could have been used. Both quantitative and qualitative data may help to better describe the problem. As well, several sources and viewpoints may be needed to be sure that all aspects of the policy problem have been examined.

The identification of the policy problem in this instance was limited to an ad hoc review by a number of stakeholders. There was no explicit process or framework for formulating policy used to guide the process. Consequently, researchers and stakeholders used an informal, unsystematic approach for collecting information related to the policy problem. Stakeholders had not prepared any information prior to their interviews and spoke candidly about their perceptions of the extent of narcotic and benzodiazepine misuse based on their own experiences. Alternatively, stakeholders could have been provided with academic reviews of the extent of inappropriate prescribing generally across a number of medications and specifically any that related to narcotic and benzodiazepine use. This would have alerted them to the potential inappropriate prescribing of these drugs in addition to their illicit use. Consequently, stakeholders in

this instance may have concluded that the policy problem was too narrowly conceived or limited to the illicit use and indiscriminate prescribing of these medications.

Most of the policy problem information provided by stakeholders during the preparation of the discussion document was circumstantial. In the case of the RNC, the interview was limited to only one officer and there was no substantiation of the information provided during a general conversation with the researcher. The information provided by the NPA was supplied by the Secretary-Registrar and was again anecdotal based on past verbal communication with pharmacists over several years. This information did indicate that there were numerous anecdotal cases of inappropriate narcotic and benzodiazepine use; however, it is now believed that the problem involved many of the same individuals repeatedly. Similarly, information provided by the Registrar of the NMB was also anecdotal and there was no indication of the quantity or frequency of complaints that had been received or the extent to which follow-up with the identified parties achieved success.

MCP referenced and provided a copy of their internal 1988 Multiple Services Listing that documented the extent of inappropriate physician service use and was suspected to heavily involve those who were inappropriately obtaining drugs for inappropriate use. While this information was the most detailed, it was prepared eight years prior to the consideration of the PMP and twelve years prior to its introduction.[93]

A retrospective analysis of the policy problem stage indicated that there were additional options available to policymakers and researchers to enhance the quantity and quality of the information obtained to be more consistent with the explicit approach proposed by Lomas. Baseline components of the protocol for the subsequently completed clinical evaluation of the PMP could have been initiated to provide quantitative data to describe the policy problem. For example, two readily available data sources, IMS Health, Canada and the Newfoundland and Labrador Prescription Drug Program ("NLPDP") could have been used to provide a baseline indication of the extent of narcotic and benzodiazepine prescribing in the province over time. Specifically, IMS Health, Canada data would have enabled policymakers to determine if the extent of narcotic and benzodiazepine prescribing in this Province, measured by per-capita consumption, was greater than in other provinces, particularly those with PMPs. Similarly, the same process could have been followed to determine the per-capita consumption of narcotic and benzodiazepine substitutes over time and in comparison with other jurisdictions with and without PMPs. Ironically, the advisory committee designing the Program requested IMS Health, Canada information to determine the necessary number of PMP prescription pads that would have to be printed prior to the introduction of the Program, but not for determining the extent of narcotic and benzodiazepine use. The NLPDP data has some major limitations since it only captures data on prescriptions that are dispensed to patients who are receiving old age supplement benefits or social assistance. IMS Health, Canada data is obtained by sampling retail pharmacies that voluntarily participate.

MCP information was available to allow policymakers to determine the number of individuals who had visited multiple fee-for-service general practitioners during thirty-day periods throughout the province over time. A longitudinal analysis of this information would have provided an indication of the number of individuals directly involved in obtaining inappropriate prescriptions by way of double doctoring. More importantly, if a longitudinal analysis of these data had been conducted, it would have allowed policymakers to determine if the problem was compounding.

It was hypothesized that those responsible for break and enters and armed robberies at pharmacies were in desperate search of drugs to fuel personal addictions or for illicit sale. A review of police records for pharmacy break and enters and armed robbery statistics in the St. John's area over time would have better enabled policymakers to understand the dynamic characteristics of this category of drug seeker. In addition, including of an RNC official on the advisory committee would have facilitated obtaining statistics collected by the police.

If appropriateness surveys of narcotic and benzodiazepine prescribing had been completed during the preparation of the initial discussion document, it would have provided policymakers with baseline information on the extent to which these drugs were being inappropriately prescribed in the community. This could have potentially enabled consideration of other interventions, in addition to the PMP, or at the very least led to changes in the design of the PMP. The appropriateness surveys could have involved

obtaining clinical information on a sample of narcotic and benzodiazepine prescriptions in the community and having that information assessed by a panel of physician and pharmacy specialists. Because of the voluntary nature of this research, it would be unlikely to provide information on those seeking these medications for illicit use, but rather provide information on prescriptions to individuals that were inappropriate from a clinical standpoint.

Discussions between stakeholders prior to the implementation of the PMP focused on the illicit use of narcotics and benzodiazepines and did not include inappropriate clinical use generally. Some examples of serious inappropriate clinical prescribing include using benzodiazepines for extended periods of time, using long half-life benzodiazepines where short acting drugs would be preferred, and the use of two or more benzodiazepines and/or narcotics concurrently. It may be argued that this was potentially a more significant problem than the illicit use or indiscriminate prescribing of these medications. However, if measurements of inappropriate clinical use of these medications had been completed prior to introducing the PMP, the potential magnitude of this problem may have been discussed between stakeholders, and a broader definition of inappropriate prescribing (other than illicit use) may have emerged. Consequently, interventions other than or in addition to a PMP may have been pursued at this juncture.

In summary, a more thorough undertaking of the policy problem stage would have involved an assessment of readily available quantitative data from a variety of

sources such as IMS Health, Canada, NLPDP and MCP. If these data had been assessed (as described in Chapter 6) at this juncture, policymakers may have concluded that the illicit use aspect of the policy problem was limited to a relatively small number of individuals suspected of multiple doctoring and a limited number of physicians suspected of indiscriminate prescribing. This in turn may have led policymakers to consider more specific policy alternatives for this issue (as discussed in Chapter 4) as opposed to the broad-based PMP.

3.4.2 Stakeholder Identification

According to Lomas, identifying stakeholders involves examining the role of those groups and individuals that have an interest in changing or introducing a particular policy. If stakeholders are involved in the formation of policy from the outset, they will be more likely to modify their practice pattern in compliance with the policy. Examples of relevant stakeholders in this instance include regulatory bodies, professional provider associations, voluntary organizations, public and private payers for health care services, researchers and legal specialists.

In 1996, the NMB agreed to chair a stakeholder advisory committee responsible for the overall design of the PMP following the distribution of the discussion document. While they were not legally obliged to undertake this role or to eventually administer the Program, this was common practice in other provinces and jurisdictions with PMPs. In

addition, it was widely speculated that much of the inappropriate and illicit use of narcotics and benzodiazepines was due to indiscriminate prescribing by a small number of general practitioners. The Board has a responsibility for disciplining physicians that inappropriately prescribe and, therefore, they had at least an indirect role to play in the formation of the Program but not necessarily in its administration.

The NPA had significant interest in the manner in which the PMP was to be implemented and administered. From the outset, the NPA proposed that an electronic PMP be introduced and that the data be collected at the pharmacy level and transmitted to the Program. Consequently, the NPA wished to ensure that their members were in agreement with the additional computer requirements, costs, training, and ongoing submission of confidential data. As well, the NPA was concerned that the PMP might lead to an increase in the incidence of break and enters into pharmacies if prescriptions were denied.

The Newfoundland and Labrador Medical Association ("NLMA") played a similar role on behalf of physicians throughout the province. They desired that the Program not infringe on the clinical autonomy of physicians nor provide a ready access for the NMB or others to scrutinize physician prescribing patterns. As well, they wanted a monitoring program that was not too inconvenient for physicians that could result in inefficiencies at the clinical level.

The Department of Health and Community Services of the Government of Newfoundland and Labrador ("DOHCS") had a direct interest in the administrative cost of the PMP and the cost of reimbursing medications for residents insured under the NLPDP. Insured residents under the NLPDP included those receiving social assistance or the senior citizen income supplementation benefits. The proposed increases to the budget for the Program did contribute to some delays in implementation. However, a more significant concern was that once the PMP was in place, physicians could alter their prescribing patterns in favour of more expensive, non-monitored drugs leading to increases in the NLPDP budget.

The Clinical Epidemiology Group at Memorial University was made responsible for undertaking a thorough clinical evaluation of the PMP and had assigned one of their researchers to this exercise as part of his academic requirements for a PhD in Community Medicine. Consequently, there was an interest on their part to ensure that all barriers were overcome and the project proceeded.

It appeared that two stakeholder groups had interests in the activities of the PMP but were not included on the advisory committee. They included the RNC and local drug dependency groups. The RNC provided the information that initially led to the PMP and would be influenced by the potential success of the Program. The extent of success of the Program would have a direct impact on their requirement to deploy police resources in the community to address the "street use" of prescription medications. As well, they

were familiar with the "street use" of prescription medications and the plausible means of circumventing the Program once introduced. In addition, RNC members would be called upon to investigate potential break and enters into pharmacies that might occur as a result of the Program. They could have provided first hand knowledge of how illicit users of narcotics and benzodiazepines responded to the PMP.

In retrospect, the advisory committee could have invited representatives of drug dependency groups to participate in the formation of the PMP, since they were responsible for providing information and counselling to those afflicted with prescription medication dependency. In addition, representatives of the John Howard Society could have been consulted to hear how the PMP might affect those incarcerated for illicit drug-related activity.

The use of focus groups, administered by trained facilitators, would have been a plausible means to involve stakeholder groups in the policy problem/identification stage. A series of focus groups that included a cross section of stakeholders represented on a geographic basis could have been implemented. As well, those who expressed opposition to the proposed PMP should have been formally invited to voice their opposition and to present alternatives to address the policy problem. This may have assisted in addressing subsequent problems identified in the policy implementation stage. In retrospect, representatives of the professional associations that participated on the PMP advisory committee were expected to forward the views of their members regarding the policy

problem without having an adequate means to collect and assimilate those views. The focus group approach may have provided a better understanding of the inappropriate use and prescribing of narcotics and benzodiazepines by certain patients and prescribers in specific geographic areas.

Alternatively, the use of a stakeholder survey with specific questions regarding the extent of medication misuse, administered on a geographically representative basis, might have obtained similar information.

Table 3.2

Summary of the Policy Problem Stage

- There was a need for a data defined policy problem analysis.
- Identification of the policy problem was limited to an ad hoc review by a number of stakeholders.
- Baseline components of the subsequently completed clinical evaluation could have been used to more appropriately describe the policy problem.
- Consideration should have been provided to assessing the appropriateness of the clinical use of narcotics and benzodiazepines in addition to their illicit use.
- The RNC and local drug dependency groups should have been included on the PMP's advisory committee.

CHAPTER 4

POLICY OPTIONS AND EVIDENCE OF THEIR EFFECTIVENESS

Numerous options are described in the literature and are sometimes used by various governments, provider organizations and third party payers to alter the manner in which pharmaceuticals are prescribed. The purpose of this chapter is to describe the potential interventions to address inappropriate prescribing in Canada generally with specific emphasis on those applicable to narcotics and benzodiazepines in community-based settings. This chapter also focuses on the evidence regarding the effectiveness of the interventions specifically intended to improve the prescribing of these medications in the community. The approaches currently used by the DOHCS and the NMB to curb suspected, blatant over-prescribing and illicit distribution of often misused medications are also reviewed. A detailed description of how PMPs function in other Canadian provinces is provided. The sub-evaluation section of this chapter examines how the actual process for gathering and reviewing the evidence for various policy options differed from the suggested approach by Lomas.

Information regarding potential interventions to address inappropriate community-based prescribing in Canada was obtained from the literature search described in the previous chapter and from additional, more specific searches in the Medline and IPA databases. The search in the Medline database involved the terms: ((canada* or explode 'Canada-'/all subheadings in MIME, MJME) and (inappropriate prescribing or appropriate prescribing and improve or improving or intervention* or

policies or policy)) or (prescribing and (canada* or explode 'Canada'/all subheadings in MIME, MJME) and audit or feedback) or ((canada* or explode 'Canada'/all subheadings in MIME, MJME) and (prescribing and improve or improving or intervention* or policies or policy)). The IPA database was searched using the terms: prescribing and (improve or improving or improvement or audit or feedback or options or intervention* or policy or policies) and ((canad* in ti) or (canad* in ab)). Results were limited to articles printed in English and published between 1985 and 2003.

Articles were sorted according to their practical applicability to address potential inappropriate prescribing in community-based settings across all medications and those that were more relevant to the prescribing of narcotics and benzodiazepines in these settings. Additional interventions to improve prescribing were also found in a pharmacoepidemiology publication by Soumerai and co-authors.[91]

4.1 GENERAL INTERVENTIONS FOR IMPROVING THE PRESCRIBING OF PRESCRIPTION MEDICATIONS

A variety of general interventions are available for use in Canada for improving prescribing of prescription medications in the community. Educational interventions such as academic detailing (face-to-face outreach), group education, and providing prescribers with written information (audit and feedback) can be specifically used to improve the prescribing of narcotics and benzodiazepines. Consequently, they are discussed in detail in Section 4.2. Additional measures such as pharmacist interventions;

interventions to influence the role of pharmaceutical sale representatives; formulary restrictions (reference-based pricing, special formulary authorization, listing/not listing products and tiered co-payments); reminder and decision support systems for prescribers; advice from physician opinion leaders; and financial incentives and penalties are not specifically applicable for the inappropriate prescribing of narcotics and benzodiazepines. These are only briefly addressed as a detailed discussion of these interventions is considered beyond the scope of this thesis.

Table 4.1 briefly outlines the general interventions identified from the literature search and by Soumerai and co-authors[91] for improving the prescribing of prescription medications.

Table 4.1

Summary of General Interventions for Potentially Improving the Prescribing of Prescription Medications in Community-based Settings

General Intervention	Common Method(s)	Considerations
1. Educational Interventions*	Academic detailing (face-to-face outreach) Group education Written information (audit and feedback)	Some value for controlling illicit prescription use.
2. Pharmacist-related	Pharmacist advises physician when a prescription differs from a guideline.	Most commonly used in institutional settings for antibiotics. Also used for medication over-use and errors, to control costs and unnecessary hospitalization. Unlikely of value to control illicit prescription use.
3. Pharmaceutical Sales Representative	Education program to permit residents to better understand the role of pharmaceutical representatives.	Unlikely of value to control illicit prescription use.
4. Formulary Restrictions	Reference based pricing Special formulary authorization Listing/not listing products Tiered co-payments	Mostly implemented to control cost. Only applicable to patients covered by the formulary. Limited value for controlling illicit prescription drug use.
5. Reminder and Decision Support Systems	Computerized system alerts physician to change prescribing. Physical labels on charts.	Mostly used in the United States.
6. Advice from physician opinion leaders	Experienced physician promotes new pharmaceutical product.	Mostly applicable in hospital settings.
7. Financial incentives and penalties	Provides financial incentive for physician to improve prescribing.	Applicable in capitation based funding approaches.

* Described in detail in Section 4.2.

Most pharmacist-related interventions to curb inappropriate use of pharmaceuticals occurred in acute care institutions and were applicable to antibiotics. They were primarily intended to reduce costs. Their application typically involved pharmacists notifying and discussing with the prescribing physicians when a prescription differed from the clinical guideline for specific drug use or an equally effective medication was available at a lower cost. Some also monitored the over-use of medications, unnecessary prolonged hospitalization, medication errors and the benefit of prescribing reassessment.[35,42,95-98] One study, which was conducted in a long-term care setting, suggested that pharmacists could effectively notify physicians when long-acting benzodiazepines were inappropriately prescribed for the elderly.[48] The pharmacist-related interventions described above are not normally considered for medications which may be used illicitly since the dose/duration of the prescription (which are readily subject to scrutiny by the pharmacist) may be acceptable but there are multiple independent prescribers. For example, it is unlikely that antibiotics would have a "street value" or that patients would visit multiple practitioners to obtain them compared with narcotics or benzodiazepines.

The professional relationship between pharmaceutical sales representatives and physicians was believed to be associated with the expanded use of pharmaceuticals. Two studies from the literature search focused on this relationship. One was a review article that attempted to identify the attitudes towards the relationship between physicians and the pharmaceutical industry and the impact this had on the knowledge, attitudes and

behaviour of physicians.[99] The second study involved testing a structured approach for interaction between family medicine residents and pharmaceutical sales representatives. The suggested intervention included a structured educational program that would permit residents to better understand the role of pharmaceutical sales representatives and enable the residents to gain more from their interaction with them.[100]

Formulary restrictions were primarily described in the literature as a means to control cost. Most articles in this category focused on the use of referenced-based pricing which is defined as a reimbursement ceiling established by third-party payers as a means to control expenditures. It can be used across a variety of drug categories where the substitution of drug therapies are practical.[101-105] Another study involved the mere introduction of a formulary in a long-term care setting.[106] Of the remaining studies, one was a survey to determine the restricted use of second and third generation antibiotics in hospital settings in Canada.[107] The final study involved restricting payment for proton-pump inhibitors to those cases which followed an established algorithm. In these cases, special formulary authorization was provided on a case-by-case basis.[108]

Similar to the previous general interventions to restrict inappropriate prescribing, formulary restrictions are predicted to have a limited value in addressing the illicit use of drugs that have a "street value." This is because patients may purchase the medications (many of which are relatively inexpensive) privately for subsequent resale or inappropriate use in the community. As well, a proportion of individuals suspected to be

involved in such activity would not be covered by provincial drug subsidy programs and, therefore, not directly affected by formulary restrictions.

Soumerai and co-authors described the use of computerized reminder and decision support systems that enabled physicians to reduce errors by alerting them to undertake specific actions as a result of patient information provided to them in the form of laboratory findings and diagnosis. However, they only cited the use of such systems in United States settings. The authors also described the use of physician opinion leaders in the United States as a means to influence the prescribing of new pharmaceutical agents. This approach found that as the opinion leaders adopted new drugs, others followed. However, there remained some uncertainty whether this type of intervention could improve prescribing outside a hospital setting for other conditions, or if it was cost effective.[91]

The use of most financial incentives and penalties described by Soumerai and co-authors were illustrated in the context of capitation-based prescribing budgets where savings on pharmaceuticals were reinvested in other health services or provided to physicians as rewards or penalties.[91] The authors described such approaches as being applicable in the United Kingdom, United States and Germany. They were described in response to escalating drug costs. Similar to previously described general interventions to improve prescribing, the use of reminder and decision support systems, physician

opinion leaders and financial incentives and penalties described by Soumerai were likely to have limited value in addressing the illicit use of drugs that have a "street value."

4.2 SPECIFIC INTERVENTIONS FOR IMPROVING THE PRESCRIBING OF NARCOTICS AND BENZODIAZEPINES IN COMMUNITY-BASED SETTINGS

Table 4.2 briefly outlines the specific interventions for potentially improving the prescribing of narcotics and benzodiazepines in community-based settings.

Table 4.2

Summary of Specific Interventions for Potentially Improving the Prescribing of Narcotics and Benzodiazepines in Community-based Settings

Intervention	Common Method(s)	Considerations
1. Education		
a) Academic Detailing	Trained physician or pharmacist provides one-on-one educational visit to prescriber.	High cost per prescriber. Can specifically target certain prescribers. Requires information on existing prescribing patterns. Conflicting evidence of effectiveness.
b) Group Education	Teach prescribers through rounds, conferences, lectures, seminars and tutorials.	Cost per prescriber depends on group size. Need to specifically target those prescribers who require improvement. Most practical with small group sessions. Some evidence of effectiveness.

Table 4.2

Summary of Specific Interventions for Potentially Improving the Prescribing of Narcotics and Benzodiazepines in Community-based Settings

Intervention	Common Method(s)	Considerations
c) Written Information	Provide feedback to prescribers concerning individual prescribing patterns and recommendations for change.	Requires information on existing prescribing patterns. Can target specific providers. Some evidence of effectiveness.
2. DOHCS Formulary and NMB Regulatory Interventions	Limit formulary beneficiaries that receive monitored drug prescriptions from multiple pharmacies to one pharmacy. Report prescribers with suspected inappropriate prescribing patterns to NMB. NMB investigation of prescribers based on complaints from the community.	Limited to formulary beneficiaries. Some formulary beneficiaries may pay privately. Lack of formal complaints. Lack of information. No formal evaluations; however, some evidence of effectiveness.
3. Prescription Monitoring Programs	All prescribing information for monitored drugs sent to a central database for analysis. Program issues warnings to prescribers about potential inappropriate prescribing patterns and patients that may be inappropriately obtaining prescriptions.	Requires full participation of pharmacists/physicians. Requires ability to act on information obtained. Some evidence of effectiveness.

Interventions to address the inappropriate prescribing of narcotics and benzodiazepines in the community may be categorized as: (1) education initiatives; (2) interventions by regulatory authorities and third-party payers; and (3) prescription monitoring programs. The educational approaches used to control the prescriptions of

analgesics and other regulated drugs could be further described as academic detailing, group education, and written information approaches. The methods section of individual papers identified from the literature search within each category were reviewed to determine how these interventions were administered. Unfortunately, most did not provide a thorough description. However, the majority of the papers discussed the need to undertake a baseline analysis or auditing of the inappropriateness of prescribing prior to undertaking the intervention.

A number of approaches were used to obtain information on the effectiveness of the various educational interventions for improving prescribing. Firstly, the previous literature searches were reviewed for relevant articles. Secondly, specific literature searches for evidence of the effectiveness of each individual educational approach were undertaken in the Medline and IPA databases. The first Medline search involved the terms: (prescrib* or prescription* and ((canad*)) or (explode 'Canada-'/all subheadings in MIME, MJME) and prescriber*. The second Medline search involved the terms: (prescrib* or prescription* and (academic detailing or group education) and (prescrib* or prescription* and (canad*) or explode 'Canada-'/all subheadings in MIME, MJME)) or ((written and prescriber* or dissiminat* and prescriber*) and (prescrib* or prescription* and (canad*) or explode 'Canada-'/all subheadings in MIME, MJME)). The IPA database was searched using the terms: (canad* and (prescrib* or prescription*) and (academic detail* or group education*)) or (canad* and prescriber*). These literature searches were restricted to community settings in Canada and published in English

between 1985 and 2003 to enhance the generalizability of these applications to the current policy problem being addressed. As discussed in Chapter 3, the policy problem in this instance was limited to the illicit and inappropriate personal use of narcotics and benzodiazepines as well as suspected indiscriminate prescribing by a limited number of physicians.

One study by Anderson and co-authors[109] published in 1996 (discussed in detail in Section 4.3.2) identified from the literature searches evaluated the impact of educational interventions in addressing the potentially high prescribing of medications specifically under consideration in this thesis. Consequently, a search of the Web of Science database was undertaken for potential citations since 1996 that may have referenced this article. As well, the indexing terms from the Anderson study were used to search the Medline database from 1984 to 2003. The keyword field of the IPA database was also searched since it cannot be searched using the thesaurus feature. No additional relevant articles were identified.

The Cochrane Database of Systematic Reviews and Database of Abstracts of Reviews of Effectiveness were also searched for reviews of the effectiveness of the educational initiatives for improving prescribing using the term prescri* in the title. The Cochrane Controlled Trials Register was searched for the term prescri* in the title and canad*. Relevant citations are discussed in Section 4.3.4 entitled Summary of Cochrane Reviews.

The papers chosen for discussion included those that contained original research results and were conducted in community-based settings in Canada. Many of the original research articles evaluated the use of multiple prescribing interventions. The following section describes each education intervention and the evidence of its effectiveness.

4.3 DESCRIPTION OF EDUCATION INITIATIVES TO IMPROVE PRESCRIBING BEHAVIOUR AND EVIDENCE OF THEIR EFFECTIVENESS

Educational interventions can be sub-divided into three specific categories: academic detailing, group education and written information.

4.3.1 Academic Detailing

Academic detailing involves the use of specifically trained clinical pharmacists or physician counsellors whose role is to deliver an educational message to a prescriber through face-to-face, one-on-one educational visits. It involves very low teacher-to-learner ratios and, consequently, is expensive and difficult to administer outside of academic institutions. It is modelled similar to the manner in which pharmaceutical sales representatives target physicians in order to elevate the sales of their products.[25,109] Many times physicians and pharmacists are surveyed to determine the most appropriate material to include in the detail.[110] As well, the detail may be conducted by a pharmacist to enhance results.[111]

Academic detailing experts advise that to maximize the effectiveness of this intervention, policymakers should follow a multi-step process: conducting interviews to determine the baseline rationale that underlies current prescribing patterns; concentrating detailing programs on specific categories of physicians and their opinion leaders; approaching the exercise with clear goals and objectives; using a variety of referencing and sources of information to instil a perception that the message being delivered is unbiased; stimulating physician involvement in the process; using concise information and repeating it; and following up with repeat visits.[112] In order to ensure the cooperation of the physician, other investigators advise limiting the actual detail or physician visit to thirty minutes and the number of messages provided.[113]

Another academic detailing process that is most applicable in an institutional setting involves placing a display and educational information in an area of the hospital where physicians enter and exit. Specially trained pharmacists and physicians staff the display and counsel passing physicians on the use of specific medications. For example, one application described in the literature involved using this process for increasing the appropriate use of meperidine for alleviating postoperative pain. This approach was intended to reach the maximum number of physicians in a relatively short time frame.[114]

The academic detail approach may also be used to improve prescribing in both institutional and ambulatory settings for conditions such as asthma, diabetes, otitis media, hypertension, anxiety, acute bronchitis, and congestive heart failure.[111,115]

Two studies identified from the literature search specifically measured the impact of academic detailing in a community setting. One study involved community pharmacists in Newfoundland and Labrador providing an academic detailing intervention to randomly selected physicians treating patients with congestive heart failure ("CHF"). The purpose of the detail was to address under-utilization of ACE inhibitors in treating CHF. Physicians who were randomized to the intervention group were provided with academic detailing regarding the use and dosage of ACE inhibitors and angiotensin II receptor antagonists for the prevention and management of CHF. Control group physicians were provided this information at a later date. The authors concluded that the pharmacist academic detail did not affect prescribing or dosages of ACE inhibitors but was of value as a quality assurance tool.[111] However, some of the limitations identified in this study may explain why the academic detail was of limited effectiveness in this instance. For example, the use of ACE inhibitors was high prior to the intervention; there was a lack of evidence to recommend prescribing high or maximally tolerated dosages (especially to the elderly); and there were concerns about adverse effects and outcomes in elderly patients. However, unlike some of the evaluations to be discussed, this study focused only on the efficacy of a single intervention.[111]

A second study attempted to evaluate the use of evidence-based detailing conducted by a pharmaceutical manufacturer for improving the appropriateness of prescribing of antibiotics for otitis media. The study involved over 1,200 physicians and was conducted in Ontario in 1999. The randomly selected intervention group received

special manufacturer detailing with an educational pamphlet at least twice over a six-month interval compared with regular detailing. It was hypothesized that the market share for the preferred first line therapy for otitis media would increase. The authors concluded that physician prescribing for this particular indication was not altered by the special manufacturer detailing.[116] However, the objectives, to increase the utilization of amoxicillin and to reduce the use of third line antibiotics, may not have been achieved due to a number of limitations with the study. For example, the prescription database used to measure the outcome data only captured approximately 30% of the total prescriptions. Consequently, the database may not have been sensitive enough to measure the effect of the intervention. As well, the investigators were unable to separate out prescriptions dispensed for the indication of interest (otitis media) from those dispensed for other indications. In addition, they were also unable to separate out prescriptions dispensed for pediatric patients only. The authors also noted that the detailers had limited training. Finally, there were significant differences between the intervention and control groups for factors other than the intervention.[116]

The limitations identified in the above-noted studies may have mitigated the measured impact of academic detailing in these applications. However, the use of academic detailing in the above applications were for prescribing problems unrelated to those of interest in this thesis, most notably intended inappropriate personal use, illicit sale, and indiscriminate prescribing of narcotics and benzodiazepines. Consequently, academic detailing was maintained as a potential policy option in this research.

4.3.2 Group Education

Group education involves teaching prescribers through rounds, conferences, lectures, seminars and tutorials on appropriate prescribing and therapy use. It enables education initiatives to reach more prescribers at a lower cost per recipient than one-to-one interventions.[109,117]

Group education seminars may involve only a few physicians at a time and most are limited to one or two hours in duration. More sophisticated methods of group education involves undertaking preliminary research to determine the extent of the prescribing problem prior to introducing the intervention. This could be achieved by requesting that physicians complete a questionnaire designed to gauge their knowledge of the appropriate use of a particular medication or group of medications. Administering a pre/post type questionnaire would allow investigators to determine how the intervention had affected various groups of physicians. It is recommended that there be limits on the issues to be addressed to ensure the retention of information presented. For example, one group education intervention involved a dialogue with instructors regarding hypertension, its therapy, compliance problems of patients with therapy and the need to deal with patient ignorance, poor compliance and unsuccessful outcomes of patients. In this example, the use of an initial baseline survey of physicians helped to determine the activities that the intervention should address.[118] The intended outcomes were changes in prescribing rates, net savings and prescriber attitudes.[119]

One study evaluated multiple educational strategies (including group education) in modifying the prescribing of regulated analgesics. The 1996 study by Anderson and co-authors involved randomizing 54 of 100 top prescribing physicians to: (1) receive a letter from the College informing them of their prescribing status; or (2) attend a one-day workshop on pain management; or (3) be assigned to a control group. After a six-month interval, there was no change in the prescribing habits of the control group. The workshop group showed a 33% reduction in their prescribing pattern and the simple notification group showed a 25% reduction in their prescribing pattern. Limitations of the study included: (1) prescribing patterns were followed for only six months after the intervention; (2) the study only examined changes in the prescribing patterns of high-volume prescribers while the effect on moderate prescribing patterns was uncertain; (3) the intervention's effect on the prescribing patterns for substitute, less desirable drugs and more desirable drugs was uncertain; and (4) changes in patient outcomes were not measured. The authors believed a larger and longer follow-up assessment study would have been worthwhile.[109]

Another paper, using a before/after design, involved the use of an educational strategy to curb the inappropriate prescribing of benzodiazepines by family medicine residents at an Ottawa medicine centre. Residents were notified of their prescribing patterns through presentations and provided with a computer-generated profile of their prescribing patterns. Audit rounds were also implemented to discuss individual reasons for variances in prescribing patterns. The study found that initially prescribers were not

adhering to the four guidelines for appropriate benzodiazepine prescribing. It also concluded that the educational program caused a significant positive change in the proportion of new prescriptions for short-acting benzodiazepines among all prescriptions for benzodiazepines from 12% to 67%. As well, there was an insignificant reduction in the mean daily dose of benzodiazepines prescribed, expressed as diazepam equivalent across all age groups and the mean duration of treatment reduced to 20 days from 25 days.[120] The authors noted that much of the impact of this intervention may have been related to the "shock" of doctors recognizing that their prescribing pattern was not what they had perceived. As well, there were some limitations of this study that could have influenced its applicability to community-based settings. For example, it was undertaken in a teaching practice where there was frequent time for discussion, supervision and reinforcement. As well, the study did not evaluate the potential extent of over prescribing or under prescribing of benzodiazepines. It focused on new prescriptions without further detailed recording.[120]

Another study evaluated the use of a multi-educational strategy for influencing the use of antibiotics in an Ontario community. This before/after study involved four small group continuing medical education sessions that were provided by a physician and research pharmacists to local physicians, pharmacists, home care nurses and industry representatives. Simultaneously, community educational strategies were provided at the local town hall and educational material distributed at physician offices, clinics and pharmacies. Presentations were also made to school and community groups. The study

concluded that the dual educational strategies were successful in reducing the number of antibiotic prescriptions by nearly 10%. As well, physicians in the study group were 29% less likely to prescribe second-line antibiotics than physicians in the rest of the province. The authors recommended a multi-educational strategy in dealing with the inappropriate prescribing and use of antibiotics.[121]

There were three important limitations of this study. Unfortunately, it did not quantify the effects of specific components of the program since the intervention was designed to be implemented in its entirety. As well, there was no access to patient-specific data linking diagnosis, laboratory tests and drug use. Finally, the data access limitations did not allow for the tracking of individual patients to determine if those patients who were not treated required more follow-up visits than treated patients.[121]

4.3.3 Written Information

The written information approach involves providing feedback concerning individual prescribing patterns to prescribers. It is less costly than the other forms of educational interventions previously described.[109] There are multiple versions of this approach.

Detailed audit and feedback is a written information approach that involves monitoring a physician's prescribing practices in order to provide feedback to the

physician with specific recommendations for changes. This approach has some weaknesses: the physician has to recognize that there is a prescribing problem to begin with; the person receiving the feedback must have the capability to act on it; and physicians may never respond if they are not able to do so immediately. Unfortunately, this intervention has mostly been implemented in controlled academic settings, large practices or outpatient clinics.[25]

Written information may also take the form of identifying to physicians their patients who are using an extreme number of prescriptions. The correspondence will state the potential dangers of over medication and suggest specific measures to reduce them.[122]

Written information approaches that are designed to reduce the costs of prescriptions will inform physicians on a regular, periodic basis of their prescribing patterns with estimates of potential cost savings achievable without compromising care. This approach is based on the notion that physicians prescribe brand-name medications too often because they are unaware of the more complicated generic terms or because brand-name terms are easier to remember. The information submitted to physicians also includes suggestions to potentially reduce side effects.[123] In some circumstances, the written information may be targeted to those believed to be influential amongst the physician community.[124]

A more general written information approach would include mailing drug bulletins or general brochures to physicians. The information is prepared for either a specific or broad topic and used to influence the prescribing of community-based and hospital-based physicians. Additionally, the information may cite alternatives for treating a particular condition.[125] This intervention can also be used to address conditions other than inappropriate prescribing such as the enhanced provision of preventative care and the general management of conditions such as hypertension.[126]

One Ontario study published in 1999 evaluated the impact of a written information educational intervention for improving antibiotic prescribing. This study involved 251 randomly selected family physicians who were forwarded their prescribing profiles (from provincial formulary data) and guidelines-based educational bulletins every two months for a six-month period. The authors concluded that the two-tiered intervention limited cost increases for antibiotics in the feedback group compared to the control group (change of $0.05 compared to $3.37). It also increased the use of first-line antibiotics by 2.6% compared to a decrease in the control group of 1.7%. As well, a follow-up survey determined that the approach was well received by 82% of responding physicians.[127]

However, this study had some limitations including the inability to evaluate whether the measured changes in prescribing patterns (for the elderly patients with Ontario Drug Benefit Program coverage) were generalized to other patients in the

practice. Since there was no information regarding the numbers of patients presenting to physicians' offices with symptoms of an infection, the authors were unable to determine if the intervention influenced the rate of antibiotic prescribing. In addition, since participation by physicians was voluntary, assessment of the impact of the intervention on those prescribers who declined to participate was unknown. Moreover, their practices were significantly different from the participants' practices. For example, the participants prescribed a higher proportion of first-line agents and lower cost medications than the non-participants.[127]

A 2003 study conducted in Ontario involved similar peer prescribing feedback as the above-noted research except that the authors desired to determine its impact on benzodiazepine prescribing. They hypothesized that physician peer prescribing feedback and distribution of educational material would result in reductions in the prescribing of long acting benzodiazepines, long-term benzodiazepine prescriptions and potentially harmful combinations of benzodiazepines with additional psychoactive drugs in the elderly. Those physicians randomized to the intervention group received confidential profiles of their benzodiazepine prescribing patterns along with evidence-based educational bulletins. The control group was provided feedback and educational bulletins about first line anti-hypertension drug prescribing for elderly patients.[128]

This study found that the proportion of long-acting benzodiazepine prescriptions dropped slightly (0.7%) in the intervention group while it increased marginally (1.1%) in

the control group. This difference was not considered clinically significant. In addition, combination prescribing of benzodiazepines and prescriptions for long-term benzodiazepine therapy were similar for both the intervention and control groups.[128]

The authors cited a number of reasons why the peer prescribing intervention did not influence benzodiazepine prescribing in comparison to its application for antibiotic prescribing. They believe it may have been easier to change prescribing for antibiotics because they were normally used for acute conditions, as opposed to benzodiazepines which were many times intended for chronic conditions in the elderly. Many elderly patients were taking these medications without harm for extended periods and physicians might have been reluctant to change therapy. Secondly, there was greater public awareness of potentially excessive antibiotic prescribing compared with benzodiazepines. In addition, participating physicians might have had practices with higher levels of appropriate prescribing leaving limited room for improvement. Finally, diagnostic uncertainty may be greater with benzodiazepines for the elderly compared with antibiotics. The authors suggested that it might be difficult to distinguish between anxiety and depression in the elderly.[128]

A Quebec-based study published in 2001 involved randomising a group of elderly patients over age 75 to experimental and control groups. These patients were also living in the community, considered at risk of losing their autonomy and taking more than three medications per day. For a sub-group of the experimental group, a team of physicians, a

pharmacist and nurse reviewed the medications and diagnosis and forwarded to the respective physician (along with supporting scientific documentation) their suggestions to reduce the number of potentially inappropriate prescriptions. The recommendations provided to the prescribing physicians related to therapeutic overlapping, lack of diagnosis (therefore, no indication for a drug), drugs that should be avoided or used in small dosages for the elderly, stopping benzodiazepines, use of hypolipidemic agents, inappropriate dosages and drug interactions.[129]

This study found that the average number of potentially inappropriate prescriptions per patient dropped by 0.24 in the intervention group and by 0.15 in the control group. There was a decline in the average number of potentially inappropriate prescriptions per patient of 0.31 in the sub-group of the intervention group that were subjected to individual case conferences. The results between the intervention and the control groups were not statistically significant and the authors concluded that the program did not influence the rate of potentially inappropriate prescriptions.[129]

Some limitations were associated with this study. There was limited information on the quality of prescribing as the methodological approach focused on the patient rather than the physician. As well, it was not known how many physicians may have simultaneously prescribed for these patients or how many pharmacies may have been involved. It was believed that the number of prescribing physicians was a risk factor for patients receiving potentially inappropriate prescriptions and that a single dispensary

limited the risk. In addition, the study was conducted over a one-year period resulting in potential confounding factors affecting prescribing. As well, investigators were familiar with some of the participating physicians, which may have biased the results. Finally, it was observed that there was a lack of consensus on some prescribing practices and, therefore, physicians may not have followed recommended advice because they disagreed with the advice.[129]

A 1998 published study measured the impact of various educational interventions (including written information) such as media stories, a national warning letter, a teleconference, small group workshops, and newsletters on the appropriate first-line prescribing of antihypertensives in British Columbia. The study used a variety of methodologies to measure the impact of each intervention across all physicians who had prescribed these medications to elderly residents province wide. It determined that physicians continued to prescribe ACE inhibitors and calcium-channel blockers ("CCBs") as first line therapy, contrary to guidelines, for at least 33% of patients. As well, the proportion of patients prescribed CCBs as first line therapy declined from 22% to 15% over three years. The authors concluded that the educational interventions did influence the appropriate first-line prescribing of thiazides and CCBs. While the results were not considered to be dramatic, they suggested that changes in prescribing practices occurred gradually with the accumulation of minimal, incremental impacts from the educational interventions and media attention.[130]

The primary limitations of this study were the lack of controls for the main analysis (which involved a large number of physicians) and the small number of physicians in the controlled sub-studies. Therefore, confounding may have occurred in the main analysis while the statistical power was limited for the sub-studies.[130]

The final study was a retrospective survey conducted in Quebec in 1992. It involved remunerating pharmacists to send advice to a patient or physician regarding a patient's drug profile or the therapeutic value of a prescribed treatment. The authors found that most of the opinions (86.7%) were forwarded to patients as opposed to physicians (13.3%). The most common recommendations to prescribers were to replace one drug for another, to change the dose or dosing schedule, or to discontinue treatment. The potential for adverse effects, interactions, and the underuse of a medication were the primary reasons for recommendations to be sent to prescribers. The most common recommendations to patients were about compliance, improving the therapeutic effect of a medication or replacing a drug with a non-drug treatment. The study found that 77.7% of patients followed the recommendations while only 58.1% of physicians complied. The authors concluded that the pharmacist's opinion was a valuable intervention for both patients and prescribers and, interestingly, it allowed pharmacists to continue to be reimbursed even if they suggested a non-pharmaceutical intervention.[131]

There were two important limitations of this research. The first related to the study design. It was a descriptive study without controls. Consequently, as the authors

noted, the behaviour of those receiving the pharmacists' advice could have been influenced by confounders such as patient-physician communication, patient-pharmacist and physician-pharmacist communication (other than the intervention) and information provided by alternate sources such as mass media and continuing education. The second limitation was related to the community pharmacy chosen for the study. It was selected because it had the largest number of opinions billed for when the first definition of the opinion was in force. Consequently, opinions provided from this setting may be different from those provided elsewhere.[131]

Overall, the long-term positive impact on prescribing of the above-noted educational interventions was uncertain because most studies examined prescribing after a short follow-up period. Only MacLure's[130] study, which used a written information intervention, involved a three-year follow-up period. Another written information study by Hux[127] involved a one-year follow up. However, other studies that showed a positive impact from a group educational intervention involved only a six-month follow-up period.[109,110] Only in one instance did the authors note this as a limitation of their research.[109]

4.3.4 Summary of Cochrane Reviews

Three relevant studies were identified from the Cochrane collection regarding the effectiveness of educational interventions in changing physician prescribing behaviour.

One review published in 1999 included an assessment of a significant number of specific interventions, some of which included education materials, conferences or educational meetings, educational outreach visits, and audit and feedback. Many of the studies reviewed single or multifaceted interventions while the comparators were normally usual practice or no intervention control. Study designs were limited to randomized control trials or pre-test and post-test measures. The majority of the studies were conducted in the United States. They involved a variety of outpatient, teaching, community and hospital settings. They also included a wide range of therapeutic conditions, most of which were chronic.[132]

The authors cited that approximately 51% of the interventions demonstrated a positive significant change compared with the control group. However, they also suggested that the effect of specific interventions was indeterminable due to wide and overlapping confidence intervals. The authors drew limited conclusions; however, they noted that the distribution of educational materials alone appeared to have little effect on changing physician prescribing patterns while a combination of interventions had some effect.[132]

The second review involved an analysis of the effectiveness of educational interventions for improving prescribing in primary care settings. Studies included in the review were identified from a variety of indices including Medline, IME, ICYT and ERIC and published between 1988 and 1997. The interventions were grouped under a

number of categories including dissemination of printed and audiovisual material; group education; feedback of physician prescribing patterns; individual outreach visits; reminders at the time of prescribing; educational computer software; and formulary controls. Only one of the 51 studies that met the inclusion criteria were Canadian.[133]

The authors found difficulty in arriving at conclusions regarding the effectiveness of different intervention strategies to improve prescribing because of the diversity of primary health care practices and the methodologies used in the studies. They did, however, conclude that intervention strategies that were more personalized appeared to have higher levels of effectiveness. They also found that 57% of studies assessing active strategies reported positive results compared with 38% of those assessing passive strategies. The authors defined active strategies as those where the physician was involved in developing the intervention and/or there was personal contact. Alternatively, passive strategies were those where the physician received unsolicited information with no involvement or personal contact. They also noted that a combination of passive and active strategies should reduce the chances of failure compared to active strategies alone.[133]

The authors also acknowledged some limitations of their review including methodological problems with the studies reviewed, the low external validity and a shortfall in data regarding the efficiency of the various interventions. They strongly

recommended further study before any prescribing strategy was implemented on a large scale basis.[133]

A third review published in 2001 assessed the effects of audit and feedback on the practice patterns of health professionals and on patient outcomes. The review included randomized controlled trials of audit and feedback interventions identified mainly from a Medline database search up to June 1997.[126]

The review included 37 studies, most of which were United States based. However, the reviewers noted the reporting of study methods was inadequate for the majority of studies. For example, in most instances the randomization process could not be determined, data analysis information was absent and power calculations were not discussed. Despite this, the reviewers concluded that audit and feedback could be effective in improving prescribing and diagnostic test ordering. They describe the effect as small to moderate and advise those attempting to improve prescribing and diagnostic test ordering not to rely solely on this approach. They were unable to recommend the optimal characteristics of feedback in general or specific situations.[126]

4.3.5 Summary of Review Articles on Education Initiatives

Two review articles obtained from the literature searches focused on the potential effectiveness of educational-based interventions to improve prescribing appropriateness in the community.

The first review, published in 1996 in the CMAJ by Anderson and Lexchin, reviewed research on evaluating the techniques that have been used in Canada to improve prescribing behaviour. It found that a significant proportion of prescribing practice was inconsistent with criteria for appropriate care. As well, there was minimal research completed in Canada on methods to improve prescribing in primary care.[77] This review concluded that the mere dissemination of printed material to physicians did not improve physician prescribing. However, educational interventions that involved face-to-face contact between prescribing experts and the physician (academic detailing) did lead to improvement. They also reported that approaches which involved providing written feedback to physicians in the form of specific recommendations for change in the use of medications could also improve practice. While cost estimates were not provided, the authors described both successful interventions as expensive. However, they were cost-effective in reducing prescribing costs if targeted correctly. The authors also noted that interventions using both education and feedback appear to have been more effective than those involving just one strategy.[77]

The Anderson and Lexchin article cited several weaknesses identified in the review of studies evaluating interventions to improve prescribing. They noted that almost all of the studies reviewed were conducted in academic family practice units, large group practices or outpatient clinics limiting their generalizability to community settings throughout the country. There were also limited data on patient outcomes. In addition, the authors suggested that the studies examined only limited components of prescriptions such as costs, poly-pharmacy, the prescribing of specific medications or the treatment of specific problems.[77]

The second review, published by Lexchin in the International Journal of Health Services in 1998, also included studies evaluating both ineffective and effective prescribing interventions.[25] This study was more recent and a more thorough review article on the appropriateness of physician prescribing than the prior review. However, it did review some of the same original studies.

Lexchin found that ineffective interventions included traditional medical education including large group lectures, conferences and mailing printed materials to physicians. Group lectures and conferences were unsuccessful because there was no attempt to determine practice needs or to encourage practice change. He offered a number of reasons why such interventions were unsuccessful: the failure of guidelines to accommodate practicing physician circumstances while focusing too heavily on scientific knowledge; physician disagreement with guidelines that were written by national experts;

and the influence of nonclinical factors such as financial incentives or not considering the likelihood of malpractice suits.[25]

Lexchin also cited a variety of additional interventions that have been shown to be ineffective. They ranged from government warning campaigns, providing prescribers with a directory of products listed on formularies, mailed warnings and labelling changes. Some of these interventions reduced prescribing of the targeted medications but led to an increase in the use of substitute products.[25]

Lexchin also summarized the literature with respect to interventions that were effective in improving prescribing patterns. I reviewed the original studies referenced by Lexchin and only one of five was Canadian. As well, Lexchin's findings regarding successful prescribing interventions are similar to the Anderson review and another review by Soumerai and co-authors that mostly focused on United States based studies.[134]

Successful interventions reported by Lexchin and others included academic detailing and audit and feedback.[25,135,136] Academic detailing was credited with reducing inappropriate prescribing ranging between 12% to 49%.[25,135] As well, the positive effects of a fifteen-minute detail could last up to two years,[25,137] and up to 85% of all attempted details were completed.[25,125,138]

Neither Lexchin nor the original authors quantified the evidence supporting audit and feedback. However, they were used in a variety of applications including attempts to change lengths of hospital stays, tests and procedures, adherence to clinical practice guidelines and prescribing. Lexchin described this intervention as being successful when certain conditions were met. These conditions included physicians realizing that their prescribing needs improvement, the prescriber receiving the feedback being able to act on it, and physicians possibly not improving their prescribing if unable to do so immediately.[25,136]

4.4 DESCRIPTION OF DOHCS AND NMB INTERVENTIONS TO INFLUENCE NARCOTIC AND BENZODIAZEPINE PRESCRIBING IN COMMUNITY-BASED SETTINGS

The NLPDP is a provincial government subsidized program for pharmaceuticals administered by the DOHCS. It has approximately 100,000 beneficiaries in the province. People who are eligible are those who qualify for "income support" from the Department of Human Resources and Employment or the "senior citizen income supplementation." The latter group includes those residents who are 65 years of age and over, are in receipt of the Guaranteed Income Supplement and who are registered for Old Age Security Benefits. Those in the income support program receive 100% prescription drug coverage including the dispensing fee. The seniors program pays for the drug ingredient cost only while the dispensing fee is paid by the senior as a co-payment.

Manufacturers of new drug products may submit a request to the NLPDP to have them included for coverage. Reviews are conducted and the drug is added to the formulary, if approved. Factors for consideration in the review include clinical effectiveness, cost of the therapy and clinical efficacy relative to other drug therapies. Coverage status is provided under two categories. Most drugs listed under open benefit are available to beneficiaries without restrictions, while a limited number are available with limitations. Those requiring special authorization are only available to beneficiaries who meet specific criteria. As such, a request must be made on the patient's behalf by a physician, dentist, nurse practitioner or pharmacist. There have been no changes to the formulary in terms of process for coverage determination in recent years.[139]

The DOHCS administers two interventions through the NLPDP to reduce the volume of suspected inappropriate prescriptions of narcotics and benzodiazepines in the community. Firstly, the NLPDP continuously identifies claimants who receive narcotics and benzodiazepines from two or more pharmacies within a three-month period. When this occurs, the prescribing physicians and respective social worker are provided correspondence advising them of the patient's claim information. The NLPDP then limits reimbursement to one pharmacy. However, patients may continue to inappropriately see multiple physicians and pharmacies if they pay for these drugs privately. While NLPDP officials acknowledge that some recipients continue to pay for these medications privately, approximately 200 claimants within each three-month period are restricted to one pharmacy for public reimbursement. Most of these claimants reside

in urban centres. The number of restricted recipients varies by approximately 10% per period while the initiative has been in effect for approximately 15 years. Patients are not limited to specific prescribers; however, there are approximately ten physicians consistently writing prescriptions for these claimants. (Personal communication - J. Downton, Director of Drug Programs, DOHCS, August 18, 2000.)

Secondly, NLPDP officials correspond with the NMB to express general concerns with the prescribing patterns of a select group of physicians. The NMB is responsible for the public protection and governance of the medical profession.[140] The NLPDP has reported approximately six physicians to the NMB over the past decade. (Personal communication - J. Downton, Director of Drug Programs, DOHCS, August 18, 2000.)

The NMB confirmed that they received periodic complaints during the early 1990s from the DOHCS indicating problems with the prescribing patterns of specific physicians and some patients who visit multiple physicians. Unfortunately, under current legislation, the NMB felt they were unable to intercede to undertake a thorough investigation of the circumstances because the prescription profiles they received from the DOHCS did not include patient names. Consequently, the Board suggested that past legislation would have required them to obtain patient consent to permit them to review individual medical records. This was impractical given the potential illicit nature of the cases. (Personal communication – Dr. R. Young, Registrar, NMB, September 25, 2000.)

The NMB also received periodic unsolicited phone calls regarding patients who may be inappropriately receiving narcotics and benzodiazepines. Many of these calls were from relatives of the suspected abuser and refused to identify themselves. Consequently, the Board was reluctant in most circumstances to contact the identified physician because of the potential frivolous circumstances of the complaint. As well, physicians could potentially interpret this as harassment by the Board. In instances where the NMB contacted the physician, they changed their prescribing patterns. The Board continued to track the prescription rates over a six-month period of a limited number of specific physicians using NLPDP data records. Their quantity of prescriptions declined and remained at a reduced level over time. The NMB suggested that the introduction of an official PMP with supporting legislation would permit them to request specific information from physicians and enable the Board to intercede and curb the inappropriate actions of a limited number of prescribers. (Personal communication – Dr. R. Young, Registrar, NMB, September 25, 2000.)

There was no empirical evidence regarding the impact of the ad hoc interventions used by the DOHCS and the NMB to curb the inappropriate use and prescribing by a select number of patients and physicians, respectively.

4.5 PRESCRIPTION MONITORING PROGRAMS (PMPs)

Prescription monitoring programs are primarily intended to reduce the diversion of prescription drugs for illicit purposes. They have been credited with generally reducing inappropriate prescribing and educating the public, physicians and pharmacists about various drugs.[141] In addition, they may be helpful in identifying patients who are abusing prescribed drugs, physicians who are inappropriately prescribing, and trends in drug use which may require intervention in terms of re-education or other public policy intervention.[141,142]

PMPs may use a triplicate prescription program ("TPP"), an online computerized system, or a manual data entry method. The TPP is the most common form of prescription monitoring throughout Canada and the United States. Governments normally implement these programs in co-operation with medical and pharmacy licensing and regulatory bodies. Nova Scotia, Manitoba, Alberta and Saskatchewan and numerous states in the United States use triplicate monitoring for controlled substances.[94,142-145] (Personal communications – Officials of Prescription Monitoring Programs across Canada, Summer 1996 and Fall 2002.) British Columbia began with a TPP but evolved to a program that uses duplicate forms for prescribing controlled drugs as well as a computer system where pharmacists enter data electronically at the time of dispensing and forward it daily in a batch format to the Provincial PharmaNet Program. The PharmaNet Program forwards the information to the

College of Physicians and Surgeons. Most PMPs have been implemented since the late 1980s.[143]

The TPP normally involves the regulating authorities issuing special prescription pads to the physicians, dentists and veterinarians who wish to prescribe from a defined list of narcotics, barbiturates, stimulants and other controlled drugs. The list of drugs controlled under the programs varies slightly between jurisdictions. When a prescription for one of the listed drugs is written, a copy is retained by the prescriber, a second copy is retained by the pharmacist while the pharmacist submits the third copy to the regulating body. The information is entered into a computerized database that is programmed to alert authorities of suspected unwanted prescribing practices. An online computerized PMP allows up-to-date prescribing information to travel rapidly between the pharmacist and the central database.[141]

TPPs are also used as a patient drug information source for physicians. They can provide prescribers with information by telephone regarding a patient's previous prescriptions for controlled substances. Information could include the drugs prescribed, quantities, and the area(s) where the prescription was provided and dispensed.[141]

In many instances, patients request physicians to prescribe substances that are often abused. Sometimes these patients will intimidate the physician, office staff and other patients resulting in a situation where the prescription is issued to mitigate the disruptive

atmosphere. The mandatory TPP relieves some of the overt pressure from the physician by illustrating to the patient that a copy of the prescription will be forwarded to authorities and that both parties are subject to review.

Other jurisdictions have found that PMPs have variable clinical impacts on prescribing patterns.[146-148] For example, prescriptions for commonly abused medications may decrease, but there can be a corresponding increase in substitute medications that are not included in the program. Preliminary data in 1997 from IMS Health, Canada indicated that Newfoundland and Nova Scotia dispensed a similar number of prescriptions for narcotics. However, Nova Scotia's population at that time was 65% greater than Newfoundland's. This suggested that these medications were over prescribed locally or perhaps under prescribed in Nova Scotia, or both.

The cost of PMPs across Canada ranges from approximately $53,000 to over several hundred thousand dollars annually.[94] The cost of these programs are primarily influenced by the population, the quantity of medications to be monitored, the use of program features such as personalized prescription pads, electronic submission of prescribing information from pharmacies, and the ability to link with other prescription monitoring initiatives. The proposed pilot project for Newfoundland and Labrador was estimated to cost $300,000 annually to administer. In addition, there were costs associated with the additional time needed by physicians and pharmacists to complete the

necessary forms and enter data electronically, respectively. As well, the Registrar and Deputy Registrar of the NMB provided considerable time to administer the Program.

4.5.1 Nova Scotia

Information regarding the Nova Scotia PMP was obtained from the Program's Description of Operations,[144] 2001 Annual Report[145] and through personal contact with program officials.

Nova Scotia implemented its mandatory triplicate-prescribing program in 1992 for all physicians and dentists wishing to prescribe any narcotic or controlled drug listed under a "Panel of Monitored Drugs." The mandate of the program is to eliminate the diversion and abuse of all narcotic and controlled drugs. The program is administered by the Prescription Monitoring Association of Nova Scotia ("PMANS"), a non-profit organization associated with the former Maritime Medical Care (currently Atlantic Blue Cross Care Incorporated). It costs approximately $304,000 annually to operate. The Nova Scotia Department of Health assumes the cost of the program.

The PMANS is governed by a board comprised of representatives from the College of Physicians and Surgeons, the Provincial Dental Board, the Medical Society of Nova Scotia, the Nova Scotia Dental Association, the Pharmacy Association of Nova Scotia and the Nova Scotia Pharmaceutical Society.

The Nova Scotia program allows the physician and the pharmacy to each retain a copy of the prescription while the pharmacy forwards a third copy to the PMANS by mail on a weekly basis for manual entry into a central provincial database. Information in the database is used to examine consumption and prescription trends of narcotic and controlled drugs throughout the Province. The PMANS uses the database information to produce reports such as the monthly double-doctoring report. It also acts as an information source for physicians, dentists and pharmacists allowing them to make better informed prescribing and dispensing decisions.

The program issues personalized triplicate prescription pads to prescribers. In order to fill a prescription, the form must contain the date, patient's name, health card number, address, and date of birth. Only one drug and dosage are permitted per form, it must be dated and is only valid for seven days. Verbal prescriptions for drugs listed under the panel of monitored drugs are not permitted.

Under the Nova Scotia program, the onus is placed on the pharmacist to ensure authenticity of the patient and/or his representative. This includes having the recipient sign for the prescription. Routine prescribing of part-fills are discouraged.

The program issues "Alert Letters" to physicians informing them about patients who have received prescriptions for monitored drugs from two or more prescribers within any thirty-day period. Letters are written for each identified patient and are forwarded to all

physicians who have issued prescriptions to the patient within a three- to four- month period. They include details of the patient's drug use and the names of the prescribers involved. Alert letters are for information purposes only since the prescriber is the only person who interprets the significance of the information provided. No reply is necessary. Pharmacists are not provided copies of alert letters.

"Explain Letters" are sent to physicians who have prescribed monitored drugs which exceed recommended dosages or prescriber instructions. These letters are sent to the primary prescriber only and indicate the specific patient's use of the monitored drug. These letters require a written response from the physician within a thirty-day period.

The Nova Scotia program provides patient profiles to physicians and pharmacists by telephone. The service is able to provide a drug history within minutes and is believed useful in reducing drug abuse. Available information includes medications received, quantities and dates, number of prescribers, number of pharmacies and verification of specific patient/prescriber information. The identities and location of the prescribers and pharmacies are not disclosed.

The Nova Scotia program also has a Program Operations Committee that determines appropriate action for physicians believed to be inappropriately prescribing. This may include the Medical Consultant for the program arranging for educational sessions.

Alternatively, the matter may be referred to the College of Physicians and Surgeons for disciplinary action.

There have been no formal evaluations of the Nova Scotia program; however, statistics regarding the reduction in the incidence of double doctoring are tracked. For example, following the issuance of alert letters to physicians regarding specific patients, those patients reduced the number of physicians they visited by 59%. Furthermore, when alert letters were issued regarding patients suspected of double doctoring to obtain Ritalin (methylphenidate), those patients reduced the number of physicians they visited by 77%.

4.5.2 Manitoba

Information regarding the Manitoba Prescribing Practices Program was obtained from their 2001 Annual Report[142] and through personal contact with a Manitoba Health official and the medical consultant with the College of Physicians and Surgeons of Manitoba.

The Manitoba Prescribing Practices Program ("MPPP") is a triplicate prescribing program initiated in 1990. It monitors prescriptions for narcotics and other controlled drugs. The program is designed to: (1) track patients whose drug use requires intervention; (2) identify prescribers who may require re-education or intervention; and (3) determine trends of drug use that necessitate the need for public/professional education on responsible

drug use. Secondary considerations include communication of drug usage information between health professionals and health authorities and cost containment. The College of Physicians and Surgeons of Manitoba administers the program.

The MPPP requires pharmacists to mail copies of prescriptions dispensed for monitored drugs on a weekly basis to the College who manually enters the prescription information into their database. The program costs approximately $86,000 annually to operate. The Manitoba Department of Health assumes the cost of the TPP. It employs a full-time co-ordinator and a data entry person on a part-time basis. The program is managed relatively inexpensively because there are a limited number of controlled substances covered. Tylenol #3 and benzodiazepines are examples of popular abused agents that are not included.

The MPPP operates in conjunction with the Drug Programs Information System ("DPIS"), which is administered by the Department of Health and was implemented in 1994. The DPIS monitors all prescription usage for Manitoba residents from data entered electronically by pharmacies at the time prescriptions are dispensed. The Prescribing Practices Program is used primarily to identify suspected double-doctoring cases while the DPIS is used in tandem to obtain a more complete patient drug use profile. The DPIS is an online, real time system. Its precise cost was unavailable but is believed to exceed several million dollars.

The Manitoba program used to have an advisory committee comprised of representatives from the physician, veterinary and pharmaceutical associations. The advisory committee was responsible for reviewing the program's objectives and making recommendations to participating agencies about responsible prescribing, optimal prescribing, prescribing guidelines and dispensing guidelines. The College currently undertakes this responsibility.

A formal evaluation of the Manitoba program has not been undertaken. However, program officials advise that the full potential effectiveness of the MPPP could not be fulfilled in recent years because of limited resources. Consequently, they have focused their efforts toward the most serious cases of suspected double doctoring and inappropriate prescribing.

In conjunction with the MPPP and the DPIS, Manitoba Health has a Prescription Utilization Review Committee and a Medical Review Committee. The Prescription Utilization Review Committee examines utilization patterns for all drugs and includes representatives from medical stakeholder groups. While prescribing information is used, the Committee is primarily concerned with utilization trends of insured medical services. Patient compliance with recommendations is voluntary. The Medical Review Committee provides physicians with information regarding their practice patterns (relative to their patient profiles) in relation to their peers.

4.5.3 Alberta

Information reported for the Alberta PMP originates from the 2002 Survey of Canadian Prescription Monitoring Programs completed by Alberta Health[143] and through personal communication with program officials and Alberta Health officials.

The Alberta triplicate prescription program was implemented in 1986 and is administered by the College of Physicians and Surgeons of Alberta. Pharmacists mail copies of prescriptions dispensed under the TPP to the College of Physicians and Surgeons on a weekly basis. The College manually enters the data into their computer system. The Alberta Department of Health and Wellness assumes the cost of approximately $400,000 annually.

Proposals about drugs to be included under the program are developed by an ad hoc committee of the Alberta Pharmacy Association in consultation with physicians and police officials. Drugs included under the program are selected opioids, barbiturates, and anabolic steroids, which have shown evidence of being diverted to illicit purposes. Methadone is included on the TPP but only physicians authorized by the federal Health Protection Branch may prescribe it. The generic names of the included drugs are printed on the back of the forms. The forms are imprinted with the physician's name and TPP number. The physician's address and phone number are manually written by the prescriber for possible

use by the pharmacist to confirm information. Physicians who perform locums and those with no permanent business address are issued unaddressed pads.

All physicians who are licensed to practice in Alberta and who wish to prescribe a triplicate controlled drug must participate in the program. As well, dentists, veterinarians and Yukon practitioners may participate. A physician is able to contact the TPP for confidential information about a patient's drug history. Physicians are notified of patients suspected of double doctoring through "alert letters."

Statistics collected under Alberta's TPP include the number of prescriptions written under the plan per month, the number of prescriptions per generic drug group (including total oral morphine equivalency), the top 30 physicians who have prescribed the highest quantity of prescriptions, the top 10 practitioners who have prescribed under each generic drug group, and the 30 practitioners who have prescribed the highest amount of oral morphine equivalency. Details of stolen triplicate prescription forms and the drugs obtained with them are circulated to prescribers and pharmacists.

Alberta Health and Wellness officials advise that there have been no formal evaluations of the TPP. As well, alternate interventions such as academic detailing and peer prescribing have not been used to influence narcotic prescribing. They have pursued such interventions with physicians on a voluntary basis with other drug categories such as antibiotics.

4.5.4 Saskatchewan

Information regarding the Saskatchewan Program was obtained from program officials and from the 2002 Survey of Canadian Prescription Monitoring Programs.[143]

The Saskatchewan Triplicate Prescription Program was introduced in 1988. The program is a joint effort between the Saskatchewan Pharmaceutical Association, the College of Physicians and Surgeons of Saskatchewan, the College of Dental Surgeons of Saskatchewan and the Provincial Government. Similar to other programs, its purpose is to eliminate the abuse and diversion of a select panel of prescription drugs. The Saskatchewan program is considered to be more inclusive than others because it includes all codeine products. They are currently considering expanding the program to include benzodiazepines.

The Saskatchewan program was introduced as a triplicate program but has evolved to a duplicate one while maintaining the triplicate name. It requests prescribers to make a copy of the prescription for their records. For most monitored prescriptions, the pharmacist will electronically forward the prescription information daily to the College of Physicians and Surgeons in a batch format. For monitored drug prescriptions dispensed to select groups (i.e., RCMP members and individuals residing on first nations reserves), the pharmacist will mail a copy of the prescription to the College on a weekly basis. The College manually enters this information into their computer system. The pharmacist is

responsible for ensuring that the form is properly completed before a prescription can be dispensed. The program is not applicable to orders issued in licensed special care homes. The physician and pharmacist are able to contact the College to obtain information on a patient's drug history.

The Saskatchewan program employs only one person and has a budget of $53,000 annually. The cost is shared between the Saskatchewan Pharmaceutical Association, the College of Physicians and Surgeons of Saskatchewan, the College of Dental Surgeons of Saskatchewan and the Provincial Government.

The Saskatchewan Pharmaceutical Association fully endorses this program. They acknowledge that it causes minor inconveniences to prescribers, pharmacists and patients but they feel the benefits outweigh the costs.

Program officials were unaware of any formal evaluations of the program; however, prescribing reports are produced if requested. The program advises physicians when three or more prescriptions for monitored drugs are written to a patient within thirty days. The program itself does not utilize other interventions such as academic detailing and peer prescribing. However, some cases have resulted in the Registrar of the College calling physicians about their prescribing trends.

4.5.5 British Columbia

Information regarding the British Columbia program was obtained from program officials, British Columbia Pharmacare officials and the 2002 Survey of Canadian Prescription Monitoring Programs.[143]

The College of Physicians and Surgeons of British Columbia introduced a TPP in British Columbia in 1990. Its formal name is the Triplicate Prescription Review Program. The focus of the program was initially directed at narcotics; however, benzodiazepines and some additional codeine products were added in 1996.

The TPP was initially a three-copy program similar to those of other provinces. Pharmacists would mail prescription information to the provincial Pharmacare office who was responsible for entering the data manually into a database. The College of Physicians and Surgeons accessed the information. The primary purpose of the program was to identify patients who were double doctoring and physicians who were inappropriately prescribing. Dentists are also included in the program.

In 1995, the B.C. Government introduced the PharmaNet Program, which is a computer database of prescription information. The pharmacist enters the program's data electronically at the time of dispensing and forwards it daily in a batch format to the PharmaNet Program. Once this program was implemented, the prescription pads for

monitored drugs were reduced to a duplicate form (although the program retained its triplicate name) and keypunch operators were no longer necessary. This system has dramatically improved the collection of information from pharmacists. The College also receives its information electronically from the PharmaNet Program on a daily basis. The PharmaNet system cost $20 million over three years to develop and has annual operating costs of $3-$4 million. The precise cost of the TPP was not readily available.

The TPP issues multi-doctoring letters each month to physicians regarding patients who have received program monitored drugs from five or more different physicians per month. The Registrar of the College corresponds with physicians who appear to be inappropriately prescribing and seek a justification. Depending on the circumstances, the Registrar may require a physician to attend re-education sessions or face disciplinary action. The College regularly sponsors educational workshops for physicians on chronic pain management, the use of methadone and addiction medicine. The program is permitted through an amendment to the Pharmacy Act of British Columbia.

4.6 EVIDENCE OF THE EFFECTIVENESS OF PRESCRIPTION MONITORING PROGRAMS TO CHANGE PRESCRIBING BEHAVIOUR

A specific literature search was conducted to obtain published evidence regarding the effectiveness of prescription monitoring programs. Since no Canadian programs have been academically evaluated, the search was expanded to include the United States

programs. In addition, discussions were held with administration officials of other provincial PMPs regarding the potential existence of internal evaluations.

The electronic search of the Medline and IPA databases was intentionally made broad to capture all relevant articles. The Medline search included the terms: ((monitor* near1 prescri* not prescription-event monitoring) or ((triplicate) and prescri*))). The IPA search included the terms: (monitor* near1 prescri* or triplicate near prescri*) not prescription-event monitoring. The searches were limited to articles published in English between 1985 and 2003. Articles that studied the effectiveness of PMPs in community-based settings were considered for review. The United States Department of Justice, Drug Enforcement Administration, Diversion Control Program's web site was also reviewed. As well, a 1992 report by the Canadian Centre on Substance Abuse that examined the impact of PMPs in three western provinces was reviewed.

A 1991 study published in the Journal of the American Medical Association ("JAMA") by Weintraub and co-authors evaluated the triplicate prescription program for benzodiazepines implemented in New York State in 1989. This study was designed to compare the psychoactive medication prescribing practices and Medicaid expenditures for two years prior to the TPP and for two years following the program. Data for the analysis were gathered from three independent sources: the National Prescription Audit (IMS America); New York State Medicaid; and Blue Cross/Blue Shield of the Rochester, New York area. The study found that the overall prescribing of benzodiazepines decreased

in the range of 30% to 60% (depending on the source of data), while prescriptions for a number of alternative sedative-hypnotics increased dramatically ranging from 15% to 136%. Prescriptions for the latter group of drugs decreased significantly in states without the PMP. The study also found that Medicaid expenditures for benzodiazepines decreased by 52% following implementation of the TPP while expenditures on alternative sedatives increased 115%. Overall, total expenditures on psychoactive medications remained fairly constant before and after the program's implementation.[146]

The Weintraub study concluded that the TPP decreased the number of prescriptions written for benzodiazepines but an undesirable increase in prescriptions for less acceptable medications resulted. The study recommended that the wider public health, patient care and financial implications of TPP regulations be studied further before they were expanded elsewhere.[146]

A second study by Weintraub examined the rates of hip fractures before and after the New York State TPP. It involved all patients over age 55 who had experienced a hip fracture between January 1, 1986 and June 30, 1991. Some patients, such as those with severe trauma, neoplasms, arthritis or who had experienced a second admission for this condition were excluded. The study found that while benzodiazepine prescribing declined following the introduction of the TPP, there was no significant change in the rate of hip fractures.[149]

A 1985 study published in the American Journal of Hospital Pharmacy by Berina and co-authors demonstrated, by way of physician surveys that used a five-point Likert scale, that physicians felt that the TPP did not hamper their ability to appropriately prescribe therapy. Physicians believed that government implemented the TPP because a few physicians and pharmacists abused their prescribing and dispensing privileges. The study determined that some were intimidated by their prescribing practices being monitored. Interestingly, those physicians who legitimately prescribed more of the commonly abused substances were most opposed to the TPP. Overall, physicians were generally supportive of TPPs.[147]

A 1992 review of the impact of TPP on benzodiazepines, published in Hospital and Community Pharmacy, discussed the subject in the context of the inappropriate prescribing of substitute drugs. Proponents of the TPP based their claim on the reduction of prescription drugs used for illicit purposes. The author did not provide quantitative evidence, but stated that opponents of such programs argued that inappropriate alternative medications were being prescribed, particularly for conditions such as cancer pain. Other negative effects included the threat to patient confidentiality, cost, additional burden of time, and the unnecessary duplication of information existing in other drug tracking programs.[148]

The review concluded that the claims of reduced benzodiazepine prescribing reflected a trend in prescribing patterns that were independent of the TPP and claims that the program influenced inappropriate prescribing of these agents were entirely unproven. The

study also concluded that TPPs had a profound negative impact on legitimate prescribing and patients had suffered unnecessarily.[148]

A 1991 study designed to measure the potential negative implications of the New York State TPP appears to support this conclusion. This study reviewed all psychiatric emergency room cases and outpatient walk-in evaluations over a three-month period following the introduction of the TPP in an urban medical centre. It identified 59 cases where benzodiazepine use was the presenting problem. Of these, 24 (41%) were determined to be related to the TPP. In all but one case, the patients presented because of the negative results associated with a prescriber changing the manner in which they previously prescribed benzodiazepines.[150]

Another study of the impact of the New York State TPP involved a retrospective analysis of sedative-hypnotic overdoses reported to the New York City Poison Control Centre for the years 1988 and 1989. It found that benzodiazepine overdoses fell slightly from 1,294 to 1,265 cases. However, there was a statistically significant increase in non-benzodiazepine sedative-hypnotic overdoses from 111 to 144 cases in 1988 and 1989, respectively. The authors concluded that the TPP did not reduce sedative-hypnotic overdoses because of the substitution towards comparable non-monitored agents.[151]

A 2001 study published in the Journal of Health Care Finance reviewed the manner in which prescription medications were diverted to the black market. It discussed the merits

of PMPs used by a variety of jurisdictions in the United States and proposed guidelines for health care professionals to protect themselves from liabilities associated from the diversion of prescription drugs. This study refuted a number of opposition claims to PMPs. It concluded that drug monitoring programs appeared to maximize the effectiveness of regulatory and law enforcement efforts while not negatively impacting patient care. They cited information provided by various program officials that support the effectiveness of these programs in curtailing drug diversion and abuse while providing significant net savings. Net savings were proposed to result from a reduction in drug expenditures and investigation costs.[29]

Several limitations of the above review limit the validity of its conclusions and the ability to generalize the findings to other jurisdictions, particularly those in Canada. For example, a section of the paper referred to as "success stories" does not provide a description of how the information provided was obtained. Consequently, it is likely that any program evaluations with limited positive or negative results are not representatively reported. As well, much of the information originates with program managers who may over report positive aspects of PMPs relative to negative aspects. Finally, the lack of universal physician payment and population drug databases (that are commonly used in Canada) may result in greater support for PMPs in the United States and less emphasis on potential alternative drug tracking measures.

Williams reported on the use of a limited triplicate PMP in Washington State that was implemented in 1987. The determination of which practitioners were required to participate was left to the disciplinary boards for the respective health professions. It was based on the disciplinary board's knowledge of suspected inappropriate prescribing by specific practitioners or the suspected inappropriate personal use of drugs by prescribers themselves. While there was some support for a full triplicate program with mandatory participation, the state was unable to provide sufficient funding. Unlike other PMPs, the responsibility for providing the program with a copy of the prescription under the limited program was assigned to the prescriber rather than the pharmacist. In essence, the respective dental and physician licensing board had the responsibility for operating its own program.[152]

The Washington State limited triplicate program was noted as having some problems including lack of security over blank forms, boards not reviewing prescriptions on a timely basis, lack of clarity of the completed forms, and what appear to be problems associated with the lack of a clear patient identifier. A limited survey of 13 physicians and two dentists determined that one physician's prescribing practices needed to be brought to the attention of the Medical Disciplinary Board. Williams believed that the program had been of value. He recommended all states adopt some type of PMP and that it be placed in an agency that does not have a vested interest in the practitioners.[152]

A 1994 study by Shapiro described various measures used internationally and in the United States to control illegal drug diversions. However, he cautioned that some of the controls might interfere with appropriate opioid prescribing for legitimate pain management. On the international side, governments were required from the 1912 International Opium Convention and other agreements to restrict the trade of opium to medical and scientific purposes. In the United States, federal legislation restricts manufacturing of opioids while many states restrict opioid prescribing through a variety of means such as limitations on prescribing to addicts, restrictions to a specific number of dosage units and PMPs. Shapiro reported that ten states had multi-copy prescription programs. As well, he cited Collins who noted that PMPs had been in existence as early as 1913 with millions of dollars spent annually to operate them while "...there has been no evaluation of their impact on drug diversion, cost savings or patient care."[153,154]

Shapiro reported that multi-copy prescription programs resulted in decreases in the prescribing of monitored drugs and increases in substitutes as discussed above. He also noted the reasons why some were critical of these programs. They included the regulation of all practitioners to identify a few instances of drug abuse or diversion thereby interfering with good medical practice by potentially shifting prescribing patterns to less safe or effective drugs;[147,153,155] their expense; and the appropriateness of the state scrutinizing prescribing practices.[153]

Shapiro articulated potential alternative means to monitor inappropriate and fraudulent prescribing and dispensing. Some of these include the better use of existing state and federal databases including Medicaid claims and the use of point of sale computerized pharmacy records with electronic data communication.[153] Additional articles referenced by Shapiro also examined American PMPs. One before-and-after study involved measuring the prescribing of Schedule II drugs for outpatients at a 1,200-bed teaching hospital in Texas. It examined the prescribing of 280 resident physicians on a six-month before and after basis. It found that the total number of prescriptions for these drugs decreased by 60.4% (while total prescribing increased) after the introduction of the triplicate prescribing law. As well, the number of similar prescriptions written by first year residents decreased by 44.5%. The authors concluded that the triplicate prescription law reduced the prescribing of Schedule II drugs and increased the prescribing of some substitutes.[155]

The U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Program's web site was reviewed for information regarding American prescription monitoring programs. One document entitled "A Closer Look at State Prescription Monitoring Programs" involved a compilation of interviews with state PMP program administrators and a minimum of one practitioner and pharmacist from each state with a program. The purpose of the study was to articulate the extent of the controlled substance diversion problem and to conduct an examination of state PMPs. It described PMPs in eighteen states. The paper was very supportive of PMPs and supported their continuance based on testimonials from health professionals and program administrators.[156]

The strength of the evidence supporting PMPs provided in the above-noted report would be considered relatively weak. It is anticipated that program administers may bias the reporting of PMP attributes that are more positive in comparison to potential negative attributes. Program administrators would be expected to have a vested interest in the continuation of these programs and, consequently, their reporting may not always be objective.

A 1992 report of the Canadian Centre on Substance Abuse entitled "Licit Drug Diversion In Canada" by Stew Clark summarized the impact of TPPs in Alberta, Saskatchewan and Manitoba. British Columbia was unable to provide information and the Nova Scotia program had just been implemented at the time.[94]

The Clark study referenced two unpublished studies completed by the Alberta Blue Cross. The first study noted a dramatic decline in prescriptions for drugs included in Alberta's triplicate program at the program's onset. In the first three months of the program, there was a 38% reduction and a 58% reduction in the second three months. It also stated there was a 17% increase in some other drugs that were not included in the triplicate program.[94]

The second Blue Cross study compared the number of prescriptions for a variety of program-included drugs and excluded drugs for the month of July in 1987, 1988 and 1989. This study found that there were large increases and decreases in the number of

prescriptions for a variety of program-included drugs and non-program included drugs. The study could not conclusively confirm that the changes in prescribing patterns were due to the implementation of a TPP.[94]

Clark was unable to provide specific conclusions about the effectiveness of the Alberta program. It appeared that the prescribing patterns of a wide variety of psychoactive drugs that were included and excluded from the TPP fluctuated dramatically. Clark suggested the second Alberta study revealed the importance of considering drugs excluded from the TPP when assessing program effectiveness.[94]

The Clark review noted that Saskatchewan had a dramatic increase in the number of people investigated as a result of its TPP. In its first two years, there were 667 patient profiles sent to the Bureau of Dangerous Drugs, 109 double-doctoring patients identified, 543 charges laid and 33 subsequent convictions for double doctoring. It appeared there was a 10% to 20% reduction in the number of prescriptions for program-included drugs. However, the study did not mention changes in the prescribing patterns of non-program drugs.[94]

The Clark paper also reported the results of The Manitoba Pharmaceutical Association's survey of purchases of two wholesale pharmacy companies. The survey was intended to determine the impact of the TPP; however, results were not published or written up. They compared the purchases for the same three-month period prior to and after the

program's implementation. They found that purchases of the program-included drugs decreased by 50% to 60%. However, the purchases of some comparable, less potent drugs increased dramatically. For example, purchases of acetaminophen containing 30 mg. of codeine increased by 104%.[94]

Clark referenced another survey of 23 Manitoba pharmacies that showed a decline of 40% to 60% in prescriptions filled for program-included drugs. Some commonly abused prescription drugs had declined in the 56% to 61% range. This study did not examine prescribing trends for drugs not included in the TPP.[94]

In summary, there was limited evidence regarding the impact of PMPs. The available evidence was narrowly focused on program-monitored drugs and their substitutes. Other potential outcomes such as the effect on the appropriateness of prescribing and multiple doctoring were not thoroughly studied. The evidence suggested that these programs dramatically reduced the number of prescriptions for program-monitored drugs ranging from a low of 30% to a high of 60%. As well, the number of prescriptions for alternative or substitute medications that were not monitored increased dramatically, from a low of 15% to a high of 136%.

4.7 EVALUATION OF PROVINCIAL PMPs

During the early planning stages (1996) of the Newfoundland and Labrador PMP and following its conclusion (2002), discussions were held with officials of other provinces that had PMPs to determine if unpublished evaluations had been undertaken. An official with the Nova Scotia program advised that a statistical analysis of data was completed between the first and second year of the program. The study was unavailable but it claimed to have positive results. A more recent review of statistics concerning "alert letters" demonstrated that the number of prescriptions to patients who were named on the letters dropped (on average) from 8 to 4 over a 90-day period and the number of different physicians visited also dropped. The self-policing nature of the program is credited with reducing the number of double-doctoring offences. The short time frame involved limits the conclusions that can be drawn. (Personal communication – C. Conway, Program Manager, PMANS, September 23, 2002.)

Despite a lack of formal evaluations, officials in three provinces that have PMPs felt that their programs have been successful. The pharmacist on staff with the Manitoba Department of Health noted that a detailed review of the TPP had not been completed. Despite this, they were pleased with the perceived benefits of the program. In its first year, the program was believed to have reduced prescriptions of controlled substances by approximately 35% and reduced double-doctoring billings by approximately $100,000. Overall financial benefits to the provincial government were crudely estimated at

$750,000 compared to the program's annual budget of $86,000. (Personal communication – D. Arenson, Manitoba Department of Health, September 20, 2002.) The College of Physicians and Surgeons of Alberta advised that a comparison of program effectiveness had also not been completed but felt that the benefits exceeded the costs. (Personal communication – C. McCann, Manager – Physician Prescribing Practices, College of Physicians and Surgeons of Alberta, September 25, 2002.) Officials of the Saskatchewan program advised that there had been no formal reviews of the program. (Personal communication – A. Lee, College of Physicians and Surgeons of Saskatchewan, September 20, 2002.)

4.8 SUB-EVALUATION

The policy-making stage according to the Lomas approach involves researchers collecting and synthesizing information to generate alternative policies. To achieve this, the project team should complete a comprehensive review of the research evidence for each alternative approach. A panel of stakeholder groups then reviews the evidence collected and is actively involved in choosing the policy to be implemented. The intent is to allow the stakeholders to use their values in selecting the appropriate policy; however, the chosen policy would be anchored to research evidence.[3]

Newfoundland and Labrador did not follow the policy process developed by Lomas in deciding to implement a pilot PMP to address inappropriate prescribing and

illicit use of narcotics and benzodiazepines. During the summer of 1996, the Deputy Minister of the DOHCS requested that the CEG at Memorial University complete a discussion paper regarding the merits of PMPs. The author met with local stakeholders to discuss anecdotal evidence regarding inappropriate narcotic and benzodiazepine prescribing and reviewed the characteristics of other provincial programs. In addition, the paper included a review of the limited academic evidence for PMPs. Following the completion of this document, a multidisciplinary working group under the leadership of the Registrar of the NMB was formed to pursue a pilot PMP for this province. There were no formal "terms of reference" for this group.

A review of the fall 1996 minutes of the PMP working group suggests that during the initial period when the Program was designed there was no discussion of alternative potential options for improving prescribing appropriateness of these drugs. In essence, the PMP was the only option considered. However, the minutes suggest that there was discussion between representatives of stakeholder groups regarding specific options within a PMP, such as the merits of a duplicate, triplicate, electronic PMP and real-time electronic PMP; the categories of medications to be included like narcotics and/or benzodiazepines; whether there should be an educational component to influence physicians who wished to change medications for those patients with substance abuse; and the appropriate methods or committees to establish threshold reports for determining excessive prescribing.

A preferred approach would have been for the discussion document to have reviewed the merits of potential alternative and complementary approaches for addressing inappropriate prescribing and the use of narcotics and benzodiazepines in the community. This could have been initiated through literature searches as described earlier in this chapter. In addition, national experts, such as those who have published extensively on prescribing interventions, could have been invited to meet with the advisory group to discuss alternative potential interventions. Only one meeting was held between the advisory group, drug dependency groups and the RNC in the early stages of program design to discuss the street use of these medications. The merits of other potential approaches were not discussed.

Most of the educational approaches described in this chapter were unlikely to have had a significant impact on improving prescribing practices for narcotics and benzodiazepines. This was because the policy problem was defined by key stakeholders as mostly limited to illicit use and inappropriate personal use of medications by a select number of patients. The educational initiatives were intended to increase physicians' knowledge of the appropriate clinical indications for prescribing. The policy problem analysis (as described in Chapter 3) also indicated, based on NLPDP data and discussions with the RNC, that a select number of physicians were suspected to be indiscriminately prescribing narcotics and benzodiazepines. However, it was reasonable to assume that they were aware of their actions and that an educational initiative would have been unlikely to address them. A legal or regulatory sanction would be most applicable in this

instance. As well, the rather narrow focus of the policy problem towards illicit use of these medications was likely responsible for the lack of consideration of potential alternative options such as educational interventions.

Academic detailing requires continuous effort by the detailer to reinforce the educational message. It is considered effective in changing prescribing patterns and explains why profit maximizing (cost minimizing) pharmaceutical manufacturers would continuously use this approach to market their products. It may have had some impact in this instance, since physicians targeted for the detail would have become aware that their prescribing patterns were being scrutinized. However, since participation in such exercises was normally voluntary, some physicians suspected of indiscriminately prescribing might decline to participate.

Large group education initiatives were not effective in improving prescribing patterns according to the literature and, thus, unlikely to be effective in addressing the issue at hand. Again, this was because of the illicit nature of the narcotic and benzodiazepine use targeted. As well, in most instances participation in educational interventions was voluntary. Those physicians intentionally involved in providing prescriptions for inappropriate purposes would be unlikely to attend, while those physicians who were inadvertently duped into prescribing would also not gain from such an intervention since they were prescribing for fictitious indications.

Providing written information to prescribers on the volume of their prescribing in relation to their peers offered some potential towards decreasing excessive prescribing. The Anderson study confirmed its success, but only for those physicians with large numbers of prescriptions.[109] It was believed that this was in part because the physicians became aware that they were being monitored. In addition, a prescription monitoring type program was necessary to gather the necessary data to determine prescribing profiles. The NLPDP could have undertaken this role but only for prescriptions provided for their claimants. As well, data was only available where claimants requested payment by NLPDP. It was conceivable that some patients who sought prescriptions for illicit purposes were not seeking public reimbursement.

Unfortunately, there were limited individual physician prescribing data to determine if the potential alternative approaches could have been successful. NLPDP data were available; however, they only included seniors and social assistance claimants and it was conceivable that patients involved in the illicit use of narcotics and benzodiazepines were doing so outside of the NLPDP. Supplying written information to prescribers is predicated on having accurate, specific information regarding individual prescribing patterns.

Prior to implementing the PMP, stakeholders were actively involved in discussing the various features to be included in the Program consistent with the approach proposed by Lomas. However, there was no discussion of potential alternative or complementary

approaches to the PMP as proposed by Lomas. Since the RNC and other stakeholders had described the policy problem as being mostly attributed to patients believed to be duping physicians into prescribing, and the suspected indiscriminate prescribing by a limited number of general practitioners, it may have been implicitly understood that alternative approaches would have been ineffective. Given the popularity of PMPs in other provinces, and the lack of formal evidence on their effectiveness, stakeholders felt that introducing a pilot PMP complemented by a clinical evaluation was the best choice.

The preferred approach would have involved all stakeholder representatives having an opportunity to engage in a thorough, explicit discussion of all potential options for addressing the illicit and inappropriate personal use of narcotics and benzodiazepines. In addition, if PMPs remained the chosen policy option, a more explicit determination of the type of PMP to be implemented may have alleviated some post-implementation problems. The minutes of the initial stakeholder meetings suggested there was a thorough discussion of the components of a PMP. However, the pharmacy association's contention that a "real-time" PMP be implemented was not fully appreciated. To facilitate this process, provincial focus groups could have been established involving pharmacists and physicians to discuss their values with respect to the policy options.

Table 4.3

Summary of the Policy Options and Evidence of their Effectiveness Stage

- Ideally, the policy-making stage should involve researchers collecting and synthesizing information to generate alternative policies.
- In this instance, a PMP was the only policy option considered to address the policy problems. Potential alternatives and complementary approaches to a PMP should have been explored and reviewed with stakeholders.
- Academic detailing, small group education, specific written information to prescribers, PMPs and regulatory interventions offer some merit to address the policy problems under consideration.

CHAPTER 5

IMPLEMENTATION OF THE PRESCRIPTION MONITORING PROGRAM

The Newfoundland and Labrador Pilot PMP for narcotics and benzodiazepines was officially implemented on June 19, 2000. It operated for approximately 22 months and was discontinued in March 2002. The program was terminated because of the relatively poor outcomes, which will be discussed in more detail in the next chapter, and the belief that more specifically targeted interventions would have been more effective in addressing the policy problem.

The PMP implementation process began a number of years prior to the start date, but work on the process escalated during the months immediately preceding commencement. The initial section of this chapter describes the implementation process that began some months before the start date and the results of a physician survey that was commissioned to assist in implementation. However, the majority of the chapter describes difficulties in the implementation. These difficulties fall under the categories of: (1) budget considerations; (2) legal considerations; (3) confidentiality of prescription information; and (4) participation by pharmacists. The latter part of this chapter includes a sub-evaluation that describes how the policy implementation stage compares with the approach discussed by Lomas.

Information for this chapter was obtained through an exhaustive review of program files from various officials within the DOHCS and PMP. Confirmation of the

appropriate access to and disclosure of this information was obtained through an official Freedom of Information request to the DOHCS (Appendix A). Much of the information was repeated across sources, suggesting that the majority of the PMP implementation issues were captured. However, it is recognized that there may be some omissions due to the number of years over which issues occurred, the number of stakeholder groups involved, and the sometimes private, confidential correspondence between individual stakeholders and their legal counsel.

Participation in the pilot PMP was mandatory for physicians and pharmacists where prescriptions were dispensed at community-based pharmacies. The Program issued special personalized prescription pads to prescribers. However, the use of existing pads was permitted provided that all relevant information was included. Information on the prescription was required to be transmitted electronically by the pharmacy in batch format to the Program on a regular basis. The Program also issued "alert" and "explain" letters to prescribers to address individual cases. Alert letters were intended to inform prescribers of their specific patients who may be receiving monitored drugs from multiple physicians in a relatively short time period. Explain letters informed prescribers of patients who may be receiving monitored drugs exceeding recommended dosages. A detailed description of the actual PMP is provided in the "Handbook for Prescribing and Dispensing Health Professionals" (Appendix B).

5.1 IMPLEMENTATION PROCESS

The dissemination of information about the PMP to the public and stakeholders took place gradually over a number of years and escalated in May 2000, the month immediately preceding the actual start date and the hiring of the Program Director. The Program Director was a registered nurse with experience in treating patients with addictions.

The public were notified of the Program through various media reports and two scheduled news conferences. One was initiated by the Minister well in advance of the start date, while the second one was held by the NMB on June 8, 2000.

A PMP advisory group was formed in the fall of 1996 following the release of the PMP discussion document. The purpose of the advisory group was to design a suitable program for Newfoundland and Labrador. This group was chaired by the Registrar of the NMB and consisted of members of various stakeholder groups including: the Executive Director of the NLMA, the Secretary-Registrar of the NPA, the Director of Drug Programs for the DOHCS, a Health Economist and PhD student from the Patient Research Centre ("PRC"), Health Care Corporation of St. John's ("HCCSJ"), and a Director from Atlantic Data Systems ("ADS"). The latter group was a local computer consulting firm that was subsequently contracted to provide computer programming and data collection services to the Program.

Physicians' and pharmacists' professional associations were periodically updated on the status of the PMP through board meetings while their membership was updated through regularly published bulletins and newsletters. The NLMA included update articles in its newsletter, the "Communique," while the NPA did the same in its newsletter, the "Apothecary."

The January/February 2000 edition of the "Apothecary" contained an article that generally informed pharmacists about the PMP. It also outlined the specific information required under the Program and the methods and frequency for transmitting information.

In early May 2000, the PMP distributed to all prescribers and pharmacists a document entitled "Handbook for Prescribing and Dispensing Health Professionals" (Appendix B). The purpose of the handbook was to provide specific detail on how the Program would function. Accompanying the handbook was a memo from the PMP Director. The May 1, 2000 memo provided a proposed timeline for introducing the PMP and contained a sample copy of the new prescription form. In addition, this memo indicated that the Program would forward to individual physicians and pharmacists posters, brochures and bulletins to be displayed in their offices, waiting areas and pharmacies. This information was intended to inform patients about the Program.

On May 26, 2000, the Program Director forwarded an additional memo to all pharmacists. This memo was in response to the Pharmacy Association's concern that

many pharmacists did not have the necessary computer upgrade in place and/or the computer capability to permit them to transmit data to the Program. This memo provided the implementation status of PMP software as noted by the six individual computer software vendors that service all Newfoundland and Labrador pharmacies. It indicated that software upgrades ranged from fully implemented in most stores to being implemented by early June 2000 for the remainder.

On May 29, 2000, the Program Director issued a third memo to pharmacists encouraging them to install their computer upgrades as soon as possible and noting that the PMP was expected to commence in early June 2000. A fourth memo was issued to pharmacists by the Program Director on June 8, 2000 advising them that the Program would be implemented on June 19, 2000. This memo also advised pharmacists that physicians would be required to issue prescriptions for monitored drugs on personalized PMP prescription forms, or to provide all the required information on their office prescription forms. It also advised pharmacists of procedures in the event that a prescriber had not properly or fully completed the prescription form.

Physicians were periodically informed of the PMP through a variety of means. These included regular updates in the "Communique" in addition to the mail-out of personalized prescription pads in April/May 2000. The status of the Program was also discussed at the NLMA's annual general meeting.

5.1.1 Physician Survey

During the winter of 1998, I undertook with the financial support of the PRC of the HCCSJ and the NMB a physician survey (Appendix C). The purpose of the survey was to determine: (1) which Program features physicians considered worthwhile; and (2) the most appropriate way to inform and educate physicians about the PMP. Unfortunately, this survey was limited to doctors and the implications of this are discussed in the sub-evaluation of this chapter.[157]

The survey involved a random sample of 300 physicians throughout the province. Their views were requested on: (1) the potential inclusion of a toll-free phone line for physicians to obtain patient prescribing information; (2) the potential inclusion of additional categories of drugs such as antibiotics; (3) how they would like to receive introductory information about the Program; and (4) their desire to receive feedback reports from the Program describing their prescribing patterns in comparison with their peers. The response rate was 48.3%. The demographic characteristics of the survey respondents were similar to the physician population as a whole suggesting that the respondents were representative of the physician population.[157]

The relatively limited time frame to complete the study did not allow for follow-up questionnaires to be mailed in order to increase the response rate. As well, the use of physician focus groups prior to developing the questionnaire and pre-testing could have

better ensured that the questions more accurately reflected physician's concerns about prescription medication abuse. In addition, it could not be determined if all respondents had the same understanding of the problem of prescription medication abuse. The survey was not subjected to a test and re-test to ensure reliability. Also, since the survey was anonymous, rather than confidential, there was no way to obtain information on the non-respondents to determine if they were different from respondents.[157]

The survey revealed (Table 5.1) that physicians were very supportive of the Program providing a toll-free phone line in order for them to obtain up-to-date information regarding a patient's previous prescriptions. In addition, they were supportive of the PMP providing them with information concerning the prescribing patterns of classes of drugs to be included in the Program. It also became apparent that the preferred manner of receiving introductory Program information was by correspondence, or in conjunction with personal contact from Program administrators. However, physicians were less supportive of including other categories of drugs such as antibiotics in the Program. The survey material forwarded to physicians described problems with narcotic and benzodiazepine prescribing but not problems associated with other categories of drugs.[157]

Table 5.1
Results of the 1998 Physician Survey[157]

Question	Number of Respondents	Response; number and (percent)		
		Yes	*No*	*Uncertain*
1. Would you like the proposed PMP to include a toll-free phone line?	143	130 (90.9)	6 (4.2)	7 (4.9)
2. Would you like to see antibiotics included in the proposed PMP?	144	40 (27.8)	74 (51.4)	30 (20.8)
3. Would you like to see other classes of drugs included in the proposed PMP?	143	35 (24.5)	63 (44.1)	45 (31.5)
4. Would you like to see the proposed PMP produce peer prescribing reports?	143	118 (82.5)	19 (13.3)	6 (4.2)

In general, the 1998 physician survey found physicians to be supportive of the PMP. Only 13.8% of respondents indicated any additional comments or concerns related to aspects of the Program. They were categorized across a wide variety of matters including the need to ensure patient confidentiality; not distributing prescribing patterns to pharmaceutical manufacturers; the status of locum physicians; the need for punitive measures for physicians who inappropriately prescribe; the potential negative clinical effects on patients who are appropriately receiving monitored drugs; the need to ensure fair peer comparisons are made; and the added physician effort required to write explain letters and compensation for this effort.[157]

5.2 IMPLEMENTATION CONSTRAINTS

The implementation of the PMP encountered several difficulties. These difficulties are categorized as: (1) budget considerations; (2) legal considerations; (3) confidentiality of prescription information; and (4) participation by pharmacists.

5.2.1 Budget Considerations

While preparing the PMP discussion document in 1996, researchers contacted officials who administered similar programs in other provinces. At that time, officials with Maritime Medical Care ("MMC") who administered the Nova Scotia PMP expressed an interest in administering the proposed pilot program for Newfoundland and Labrador. It was believed that the administration of a pilot PMP by an adjacent province (which already had its own PMP) would be cost-effective since some start-up costs could be avoided and there would be operating economies of scale.

During the fall of 1996 and early in 1997, the NMB initiated discussions with MMC of Nova Scotia with regard to contracting them to administer the pilot PMP for Newfoundland and Labrador. In late February 1997, MMC submitted a formal proposal to the NMB to undertake these responsibilities for the first year for $173,000. Consequently, the original resource commitment from government reflected the estimated costs proposed by MMC.

The MMC proposal assumed that the prescription data associated with monitored drugs would be submitted by pharmacies to a central location in Newfoundland and forwarded to MMC by a local computer vendor. The fees of the local computer vendor were estimated at $18,000 annually. MMC suggested that second year costs be estimated following the first year of operation. Correspondence of July 24, 1997 between the NMB and the DOHCS indicated that the NMB accepted MMC's offer as well as having ADS provide the necessary local computer support.

In early December 1997, MMC informed the NMB that they were unable to fulfil their commitment to administer the pilot PMP. They indicated that the Government of Nova Scotia had decided to evaluate the Nova Scotia Prescription Monitoring Program with respect to upgrading the supporting computer system. They expected these matters to be resolved within a few months. The MMC was not, however, subsequently able to administer a pilot PMP for Newfoundland and Labrador.

Following the MMC's inability to administer the Newfoundland and Labrador PMP, the NMB engaged a local chartered accounting firm to provide an estimate of the costs associated with administering a two-year program locally. The accountants estimated the two-year cost of the Program to be $810,000. This amount included approximately $230,000 for local computer support services. This estimated budget was approximately double the initial projection by the MMC and there was concern that Treasury Board would not approve the incremental resources requested.

The DOHCS expressed concern with some of the estimates provided by the chartered accountant. Specifically, there were considerable estimated expenses related to printing and distributing prescription pads, professional fees and salaries. The Department was unable to provide the resources budgeted by the accountant. Consequently, in November 1998, the DOHCS requested the Director of the PRC of the HCCSJ to review the proposed budget.

The Director of the PRC had two primary responses to the proposed budget: (1) the exclusion of potentially avoidable contingency fees in both the operating and capital estimates; and (2) some expenditures which may be unnecessary or could be scaled back with alternative approaches. The inclusion of contingency fees was felt by the Director of the PRC to be necessary only if the NMB assumed the risk of cost overruns with the Program. However, the cost of the Program was significant compared to the NMB's total budget. Consequently, the NMB was unable to accept the risk associated with cost overruns and, therefore, reasonably included significant contingency allowances in their estimates. The Director of the PRC suggested that alternatively, Government should accept the risk of cost overruns allowing the estimated budget to be reduced.

While the Director of the PRC questioned the accountant's estimates under most categories of expenditures, the primary disagreement was related to the costs of prescription pads and their delivery. The Director of the PRC suggested that the Program

use generic pads and that they be delivered by regular mail as opposed to personalized pads delivered to physicians' offices by courier. The Director of the PRC estimated that the pilot program could be implemented for two years at $431,150 or 18 months at $344,688.

The NMB subsequently revised the proposed PMP budget with respect to most of the minor expenditures. They estimated that the Program could then be administered for $492,800 for a two-year period. This amount assumed the use of single generic prescription pads that would be distributed to prescribers via regular mail.

However, within the following month, both the NLMA and NPA rejected the idea of using generic prescription pads. The NLMA believed that the Program would lead to significant savings to the subsidized drug program and that Government should absorb the costs of personalized prescription pads. The pharmacists noted that the current use of generic prescription pads by hospitals caused them much frustration. They stated that on numerous occasions they are required to consult the prescribing physician concerning a prescription and the consultation is made difficult if the prescriber's information is not included with the prescription. The physician's signature is illegible in some instances. The NPA suggested several alternative measures aimed at addressing the budgetary shortfall. They included: (1) the use of generic prescription pads imprinted with an individual physician stamp; (2) the use of pre-printed generic stickers that could be attached to a physician's regular personalized prescription pad; or (3) the continued use

of a physician's own prescription form with the mandatory use of the patient identifier number on all prescriptions.

Based on the negative response of stakeholders to the idea of generic prescription pads, the DOHCS revised the budget for the Program. They subsequently committed $600,000 towards the implementation of the two-year pilot PMP based on a March 30, 1999 budget estimate of $611,650. The revised amount was intended to permit the use of personalized prescription pads as requested by stakeholders and the delivery of pads to providers via courier. The Department also requested that the NMB fund the evaluation from Program resources, if sufficient resources permitted. The NMB agreed with the Department's request and provided initial evaluation start-up funds of $15,000 to the CEG.

5.2.2 Legal Considerations

The PMP discussion paper prepared in August 1996 included a preliminary assessment of the legal implications of introducing a PMP. While PMPs fall under provincial jurisdiction, they are intended to deal with federal offences. The Newfoundland and Labrador PMP was intended to address the problem of double doctoring which is considered an offence by the patient. At that time, two federal laws prohibited double doctoring. They included Section 3.1(1) of the Narcotic Control Act and Section 38.1(1) of Part III of the Food and Drugs Act. These Acts described double

doctoring as "seeking or obtaining a narcotic or a prescription for a narcotic from a practitioner unless that person discloses to the practitioner particulars of every narcotic or prescription for a narcotic issued to that person by a different practitioner within the preceding thirty days." Currently, double doctoring is an offence under the federal Controlled Drugs and Substances Act and also includes medications such as benzodiazepines.

Preliminary legal advice obtained during the summer of 1996 indicated several issues to consider when implementing a PMP. They included: (1) confidentiality of patient information; (2) abuse of services and conditions of insured services; and (3) mandatory use of PMP forms and the dispensing of drugs. The legal advice suggested that there were several provincial Acts respecting these activities. They included sections of the Medical Care Insurance Act, the Medical Act and the Pharmaceutical Association Act.

The Medical Care Insurance Act requires MCP officials to preserve confidentiality and has numerous subsections that address the abuse of services by patients and conditions for payment of insured medical services. The Medical Act provides authority to the NMB, with the Minister of Health's approval, to impose regulations requiring physicians to issue triplicate prescription forms when prescribing some medications. The Pharmaceutical Association Act provides the Minister of Health with broad powers with respect to the dispensing, selling and handling of drugs. The preliminary

opinion suggested that any program that monitors the prescribing of drugs would have to be grounded in law to protect professionals in the event of a breach of confidentiality.

In August 1997, the NMB wrote Government to begin the process of obtaining the appropriate regulatory authority in order to implement the Program. The NMB raised the following issues that they felt would require regulatory consideration:

1. Pharmacists must be restricted to dispensing monitored drugs to prescriptions written on fully completed, special prescription forms;
2. Pharmacists must electronically submit the prescribing information for monitored drugs on a periodic basis;
3. Physicians wishing to prescribe monitored drugs must use the special prescription forms and the form must be fully completed;
4. A patient's MCP number must be usable as a patient identifier;
5. Authority is required for the Program administrators to require physicians to provide a written explanation of the clinical circumstances where the prescribing of monitored drugs appears inappropriate; and
6. Authority is required for the Program administrators to provide physicians with patient information when patients are seeing multiple physicians for monitored drugs.

The DOHCS felt that most of the above matters could be addressed under existing legal authority. However, they requested during the spring 1998 session of the legislature that the Medical Act be amended to permit the NMB to carry out the functions necessary for a pilot PMP. Specifically, the amendments provided authority to the NMB to require physicians to provide patient information and/or explanations of prescribing practices and

to allow the NMB to release patient information to physicians where patients were seeing multiple physicians for monitored drugs.

The Newfoundland Pharmaceutical Association had two objections to the amended Medical Act.[158] Firstly, there were no provisions for the Board to provide Program information to pharmacists. Secondly, the means of ensuring physicians use the special prescribing pad rested with pharmacists through amended regulations in their Act that prohibited them from dispensing these medications unless written on the appropriate form. They argued that pharmacists were inappropriately being used to ensure physicians complied with the Medical Act.

During the fall of 1999, there were proposed changes to the Medical Act by the NMB. The initial amendment was requested to clarify that the NMB had the authority to require a physician to provide patient medical charts and health and drug records to satisfy the objectives of the PMP. The additional proposed amendment was intended to give the NMB full investigative powers upon receipt of a complaint against a physician prior to a disciplinary hearing. These amendments were passed by the provincial legislature in December 1999.

Also during the fall of 1999, the DOHCS held discussions with the NMB and NPA to explore additional concerns related to the implementation of the pilot prescription monitoring program. Some of the additional issues raised included:

1. Additional approval of regulations by the Minister;
2. Clarification of terms in the Pharmaceutical Association Regulations to protect pharmacists from professional misconduct charges;
3. The need for pharmacists to have protection against legal actions for providing information under the PMP (similar to physicians);
4. The need for unique PMP prescription forms to be described in regulations for both professional groups; and
5. Issues of confidentiality related to the Privacy Act, Bill C-6 and the Personal Information Protection and Electronic Documents Act.

Legal advice received by the DOHCS concurred with the NPA that the Pharmaceutical Association Act be amended (similar to the Medical Act) to ensure that pharmacists would not have an action for damages laid against them for simply providing information under the PMP. The DOHCS also agreed with the NMB and NPA regarding the inclusion of a requirement in the regulations for the use of the unique prescription forms.

During the fall of 1999, both the NPA and NMB made formal requests to the DOHCS to have sections of their Acts amended. The NPA required their Act be amended to reflect previous changes made to the Medical Act for physicians. Specifically, they requested the Act be revised to ensure that a civil action for damages against a pharmacist not proceed solely because the pharmacist disclosed information related to the dispensing of a drug to a third party in the furtherance of the PMP, a lawful investigation, or to a health care professional involved in the patient's care. The DOHCS agreed with the NPA's request and the legislation was subsequently passed on

May 12, 2000. The NMB's proposed amendment was intended to preclude claims against the Board for invasion of privacy or breach of confidentiality for disclosures of personal prescription medication information in furtherance of the purposes of the PMP.

During the spring of 2000, the NMB also submitted draft regulations to the DOHCS for consideration to be enacted under the authority of the Medical Act.[158] The purposes of the draft regulations were to define terms used in the Act; describe the role of the Program's handbook and schedule of monitored drugs; describe the requirement for practitioners to fully complete the prescription forms for monitored drugs; state the Program's start date; and describe the repercussions due to a breach of these regulations.

Also during the spring of 2000, the NMB formally requested the DOHCS to amend the Medical Act for two additional reasons. Firstly, they desired the Act to clearly state that the NMB could not disclose personal information to peace officers without the consent of the individual(s) involved and/or provide such information to the Minister who could in turn disclose it to peace officers. Secondly, the NMB desired amendments to the Act to further detail indemnity provisions for the Board, Registrar, members and employees for actions taken or not taken in carrying out the duties prescribed by the Act.

Internal correspondence to senior DOHCS officials from the Legislative and Regulatory Affairs Division during March 2000 disclosed (departmental) frustrations regarding the most recent legal requests made by the NMB and the lack of appropriate

time to address them. It noted that the Board had verbally requested that the current subsection of the Act (that required the Board to report to police) be repealed because the NMB felt that reporting to police brings the Board into the public arena, beyond its core function. Furthermore, the Board indicated that they might not implement the PMP unless this matter was resolved. They also desired that this proposed amendment be put before the current session of the House of Assembly.

With regard to the NMB's request for additional indemnity provisions for the Board, its Registrar, members and employees, DOHCS officials felt that Section 2.8 of the Act was sufficiently broad to protect the Board, including the Registrar, in carrying out their responsibilities. They noted that the Board's request added more detail to the Act, but not any more or less protection for members acting in good faith. DOHCS officials noted that as a distant second preference, the Board would consider implementing the Program under current legislation if the Department provided the Board with a letter of indemnification against financial liability associated with reporting blatant misuse to peace officers. Despite some reservations, the Department agreed as an interim measure to accept the Board's request that they report a member of the public who breaches the Controlled Substance Act to the Department who might in turn disclose it to police. Through additional correspondence, the Department acknowledged that Board members were indemnified; however, its employees and agents were not. The DOHCS then agreed to amend Section 2.8 of the Medical Act to rectify the situation.

The DOHCS believed that the Medical Act adequately protected a medical practitioner from an action for damages when providing information to the PMP. Consequently, the DOHCS would not extend indemnity for medical practitioners beyond the protection already provided. In addition, the DOHCS also responded unfavourably to the NMB's request for a letter of indemnification to the NMB with respect to any liability incurred in relation to the Program.

During the summer of 2000, the Regulatory Affairs Division of the DOHCS indicated to the NMB their frustration with the frequency of requests for legislative amendments to accommodate the PMP. They suggested that three changes had already occurred, and now consideration was being given to including dentists in the Program (because illicit drug seekers may subsequently target dentists). They suggested that the implementation committee review the current requests from the NPA and the Dental Board, as well as perform a comprehensive review of the legislation as it stands. They asked that any requests for legislative changes should be accompanied by a rationale for the requested change and supporting documentation.

The solicitors for the NMB responded by enclosing copies of immunity liability provisions from the governing acts for Nova Scotia, New Brunswick, Ontario, Manitoba and British Columbia. They noted that the liability provisions in those jurisdictions all confer protection on the licensing authority and its members. They suggested that Nova Scotia's wording was closest to that already found in the Medical Act.

Despite the DOHCS concerns with the NMB's request to have the Medical Act amended to avoid them having to report a suspected offence contrary to the Controlled Substances Act to a peace officer, the Department did seek a legal opinion from the Department of Justice on this issue. No formal response from the Department of Justice was found; however, the DOHCS Legislative Affairs Division advised that the Medical Act was not amended to accommodate this request.

In early November 2000, the NMB's legal counsel informed the DOHCS that a pharmacist who was not submitting information to the PMP intended to challenge the Program as being contrary to the Charter of Rights and Freedoms. The correspondence indicated that the pharmacist did not provide any information regarding the factual or legal grounds for such a challenge. However, the NMB requested a rapid implementation of proposed amendments to the Medical Act to protect the Board and its employees and agents (and that it have a retroactive effect); and secondly, Government indemnify the Board with regard to all costs and any damages arising from the Charter challenge. The DOHCS denied the NMB's solicitor's request indicating that there was little or no detail concerning the basis for a potential court challenge against the Program.

5.2.3 Confidentiality of Prescription Information

During the fall of 1999, the NMB requested its legal counsel to review the proposed PMP with regard to: (1) any concerns in respect of Newfoundland privacy legislation; and (2) the ability of a pharmacist to refuse to fill a prescription if the prescriber failed to complete the prescription on the proper form.

The legal opinion suggested that the proposed PMP would not likely contravene the Privacy Act because the intent of the Program was to monitor drug utilization patterns rather than invade privacy. However, the opinion stated that the exchange of information should be limited to the NMB, physicians and pharmacists. It did not specify if this meant the Board itself or Board officials as part of their PMP administration role. In addition, the legal opinion indicated that Section 5(1)(C) of the Privacy Act would provide a complete defence for limited disclosure since it was authorized or required under a law in force in the province. The legal opinion did not discuss the issue of the PMP providing information to the police.

The opinion also stated that the Medical Act and the Pharmaceutical Association Regulations (1998) indicated that providing prescription information to the NMB did not imply professional misconduct. However, they cautioned that while the Medical Act provides statutory defences to the Board and medical practitioners for actions for damages based on the disclosure, there was no such provision contained in the

pharmaceutical legislation. Consequently, pharmacists could be exposed to claims in this regard. It suggested that the Pharmaceutical Act and Medical Act be amended accordingly to ensure that no claims for damages arising from sharing information under the PMP were possible against pharmacists, the NMB or medical practitioners.

The second issue related to the appropriateness of pharmacists refusing to fill a prescription if not completed on the proper form. The legal opinion suggested that the courts would take an unfavourable view of failing to dispense medications in instances where the patient had no control over the prescription form used by physicians, or on its completion by the physician. The opinion advised that a more appropriate manner to address this issue would be to impose the obligation to complete prescription forms on medical practitioners under the Medical Act. In this instance, the Board could sanction those who failed to properly complete the prescribed forms.

In January 2000, the Newfoundland and Labrador Centre for Health Information ("NLCHI") in conjunction with the Policy Development Division of the DOHCS produced a guideline document entitled "Privacy, Confidentiality and Access Standards, Guidelines, Policies and Procedures."[159] The document is intended to ensure adequate protection of an individual's privacy with regard to health related information. The NLCHI further stated that the standards contained in the guideline document should become the basis on which all Health Information Network participants will act with respect to privacy, confidentiality and access.[159]

Shortly after the release of the NLCHI guidelines, the Centre advised the DOHCS that they believed the proposed PMP involved practices that were not in keeping with the standards proposed by the NLCHI or the policy framework under consideration by the Department. Consequently, the NMB met with the executive of the NLCHI to review their concerns and commissioned their legal counsel to review the guideline document referenced above.

In the opinion of the NLCHI, there were two main points where the PMP was deficient in regard to confidentiality requirements. These were: (1) the patient's right to know how information collected about them will be used; and (2) the patient's right to refuse the release of information to a third party. The NLCHI acknowledged that the NMB's response to the second point would be addressed through legislation and regulations before implementation of the Program. They also suggested to the NMB that a public information campaign be conducted prior to the Program's introduction. This was to consist of advertisements in provincial newspapers and signs to be posted in physicians' offices and pharmacy outlets.

The NLCHI also forwarded, at the NMB's request, a two-page summary of their guidelines for information systems under development. It listed eleven areas of concern ranging from accountability, purpose, consent, collection, uses, accuracy, security, openness, access, compliance and ownership of information. The following is a summary of the legal opinion obtained by the NMB regarding the NLCHI

recommendations. The legal opinion was stamped confidential; however, its contents appeared straightforward and the NMB followed its advice.

In regard to the information collected, the legal opinion contained two aspects of guidance for the NMB. The first suggested that the information collected must be rationally connected to the objectives of the Program. Secondly, the legal opinion recommended that in the absence of a patient's expressed consent, access to information must be required by law. It further continued to suggest specific wording in the Medical Act to accommodate this concern.

In terms of the accountability issues raised by the NLCHI, the NMB's legal opinion provided the Board with three recommendations. The first suggested that the NMB undertake an advertising campaign to explain to the public: the purpose of the PMP; the information that the NMB may access; and the uses for which the Board can employ the information such as the reporting of possible violations of law relating to misuse or abuse of the controlled drugs. The document did not specify that the term "Board" implies just the NMB or its officials acting as administrators of the PMP.

The second recommendation suggested that the NMB provide a detailed explanation of the Program to all physicians and pharmacists. Again, this information should detail the purpose of the program, obligations of physicians and pharmacists, uses of the information, and the consequences for failure to comply.

The third recommendation advised the Board to keep all PMP related information separate from other information. In addition, the Board should ensure that only designated individuals have access to PMP information. As well, detailed records should be maintained of persons authorized to access information, information received and modifications to this information.

The NMB's legal counsel also reviewed the summary document provided by the NLCHI and commented that most of the other issues raised were administrative in nature and would impose additional burdens on the NMB's resources. The legal opinion did not support the majority of the NLCHI suggestions and concluded that the guidelines could only impose administrative burdens and inconveniences on the Board.

5.2.4 Participation by Pharmacists

Over several years, throughout the development period for the PMP, the Secretary-Registrar of the NPA actively participated as a member of the PMP Advisory Committee chaired by the NMB. Despite this, the NPA through correspondence from the Secretary-Registrar officially notified the Minister of Health and Community Services on June 14, 2000 (less than one week before the Program's start date) that they would prefer a real-time, on-line PMP capable of providing feedback to pharmacists prior to dispensing prescriptions. The NPA argued that such a system would allow for more efficient administration of the NLPDP, provide a source of data for research and

evaluation, and improve information to pharmacists to assist in avoiding drug interactions and inappropriate duplication of therapy. They stated their reason for continuing to participate in the PMP development was their anticipation that the proposed Program would justify the future establishment of a real-time system.

The June 14, 2000 correspondence also informed the Minister of the following:

1. the NPA no longer supported the Program because of its inability to provide feedback information to pharmacists;
2. the NPA believed there was significant outstanding computer software and hardware problems that pharmacists requested be corrected at no cost to them;
3. the NPA would not request the necessary regulatory changes to the Pharmaceutical Association Act until their outstanding concerns were addressed; and
4. the NPA advised that compensation for other services provided to government-funded programs needed consideration and that additional services would not be provided without additional compensation.

In relation to the above, while the PMP "Handbook for Prescribing and Dispensing Health Professionals" (Appendix B) indicated a pharmacist might receive alert letters in some instances, the legislation governing the PMP did not allow this. Consequently, the Program did not provide patient specific information to pharmacists.

It is also noted that some pharmacy software vendors had committed to providing necessary upgrades at no cost to pharmacies. However, that commitment was contingent on the respective pharmacies having the latest version of the vendors' software. Unfortunately, some pharmacists did not have the latest version.

Immediately following the implementation of the PMP on June 19, 2000, it became apparent that a minority of independent pharmacists was failing to submit data to the PMP. However, not so apparent was the fact that there were two types of non-compliance. In addition to those failing to submit any information, it was retrospectively determined that a small group of pharmacists was submitting incomplete data to the Program despite having received the appropriate information from the prescriber. While the precise number of pharmacists involved was unattainable from Program administrators, incomplete information being forwarded by pharmacists involved approximately fifty prescribers. Through additional research by PMP officials, it was determined that 95% of physicians were compliant with PMP regulations when it came to completing prescription forms at the onset of the Program.

On September 11, 2000, approximately three months after the introduction of the PMP, the NPA sent correspondence to the NMB in an attempt to provide a rationale for those pharmacists who remained non-compliant with the Program. The areas of concern which prompted their non-compliance could be summarized as: (1) the potential effectiveness of the Program; (2) the financial and time expense associated with updating computer programs; and (3) the restoration of reduced compensation needed for government-subsidized prescriptions generally and work associated with the PMP. The NPA also informed the NMB that a resolution had been approved by the NPA's Council. The resolution was that pharmacists not be considered in breach of professional conduct for not providing information to the PMP until the NMB addressed the following:

information to be encrypted prior to transmission; pharmacists to receive information from the Program; software and hardware problems to be addressed; and that pharmacists receive necessary training.

The NMB reacted with strongly worded correspondence to the NPA regarding the non-compliance of some pharmacists with the PMP. The NMB noted that as of October 2, 2000, approximately 70% of pharmacists were cooperating with the Program in a full and timely manner. However, a number of negative observations were also made. In summary, they included: (1) a minority of pharmacists had not provided any Program requested information; and (2) some had omitted to submit patient's MCP numbers despite the physician providing them on the prescription. The NMB suggested that the majority of non-compliant cases were seen as deliberate and related to financial expenses, confidentiality concerns or just mere refusal to cooperate.

The Board stressed that the non-compliance of some pharmacists undermined the integrity of the Program and jeopardized the goodwill and further cooperation of the complying pharmacists and medical practitioners. Furthermore, they believed that these pharmacists were in contravention of the Pharmaceutical Association Act and possibly guilty of professional misconduct. The NMB requested that the NPA take all reasonable steps to have the non-compliant pharmacists cooperate. Failing this, the Board indicated that they might consider lodging a formal complaint with the NPA by October 16, 2000. Immediately following receipt of the NMB's correspondence, the NPA Secretary-

Registrar wrote to all Pharmacists-in-Charge informing them of the NMB's concerns. Pharmacists-in-Charge are accountable to the NPA for all professional activities occurring within a pharmacy and ensuring that the pharmacy complies with the Pharmaceutical Association Act and its regulations.[160]

During the fall of 2000, there were a number of meetings between officials of the NMB and the ALPHA Group (a consortium of independent pharmacies) regarding the non-compliance of some of their members. In correspondence dated November 6, 2000, the Registrar of the NMB responded to the ALPHA group's concerns. The response dealt with three main points: (1) the security of information transmitted; (2) the extent of patient information requested; and (3) the use of the MCP database. They indicated that the information used by the ALPHA Group to support their non-compliance was inaccurate. With regard to the security of information transmitted, the NMB advised that: Blue Cross currently does not have the capability to accept encrypted information; the PMP system is not easily "hacked in to;" and the PMP had policies to ensure the security and confidentiality of information. With respect to the patient information that the PMP requested (patient's full name and MCP number), the NMB confirmed that both were necessary to determine if a patient was using more than one MCP number. As well, the NLPDP currently received the patient's full name. The NMB suggested that the idea of pharmacists submitting only the MCP number (and the NMB accessing the patient's name using the MCP database) was cumbersome. This would require the NMB having

access to the MCP database (which requires Cabinet approval) and would be impractical since it is not always kept up to date.

The NMB also dispelled the myths regarding the lack of security of prescription information and the perception that the PMP data collection and storage capabilities and procedures were below industry standards. The NMB added towards the conclusion of their correspondence that they believed that they had addressed the "non-monetary concerns of the representatives of ALPHA." The reference to remuneration was also noted in previous correspondence from the NMB to the NPA. On June 12, 2000, the Registrar of the NMB indicated to the Secretary-Registrar of the NPA his sympathy with the economic pressures of pharmacy practice; however, the Board was not in a position to remedy these.

The stand off between non-compliant pharmacists and the NMB had continued since June 2000. In early January 2001, the NMB held meetings with the executive of the DOHCS to inform them of the political sensitivities of pursuing professional misconduct charges against the non-compliant pharmacists. The Department agreed with the NMB's analysis and concurred that a delay of a few weeks would reduce the likelihood that the non-compliant pharmacists would instigate a political debate about the PMP during the provincial Liberal leadership campaign. However, the NMB did not immediately pursue professional misconduct charges against the non-compliant pharmacists following the three-week delay. The NMB then indicated, through

correspondence dated May 3, 2001 to the DOHCS, that legislative amendments were again needed to protect the Board and its officials from legal action. In addition, the NMB requested the Government to reimburse any of the Board's potential legal expenses associated with court challenges to the Program. Amendments were made to the Medical Act in the Spring of 2001 and the NMB commenced professional misconduct allegations with the NPA regarding the non-compliant pharmacists, with the understanding of the NPA that the allegations would be dropped if those pharmacists became compliant.

Correspondence of October 25, 2001 to the DOHCS from the NMB confirmed that the Board lodged a complaint with the NPA with respect to the non-compliance of thirteen pharmacists with the PMP. The NMB advised that a hearing was tentatively set for November 24, 2001. The Board also outlined to the DOHCS their understanding of the grounds for the non-compliant pharmacists' failure to participate. They related to the Program's request for "personal information" on the basis that: (1) there were concerns regarding the lack of security of the personal information; (2) the excessively broad nature of the personal information requested; (3) the present availability of the personal information from other government institutions under existing legislative authority; (4) their potential exposure to claims arising from the unauthorized disclosure of personal information by third parties; and (5) principles of privacy law, law of confidentiality, and the Charter rights of both patients and pharmacists. The NMB also predicted in this correspondence that the non-compliant pharmacists would be taking the position that it should be sufficient for pharmacists to provide solely the patient's MCP number and,

with that information, the Program could obtain the corresponding names from the DOHCS.

In early November 2001, the NPA informed the Minister that the non-compliant pharmacists, through their legal counsel, had indicated that their reason for non-compliance was because the Program requested personal information that infringed upon "principles of privacy law, the law of confidence, and the Charter rights of both patients and pharmacists." The NPA argued that this challenge was not a typical case for the Association. They accepted the responsibility for administering the Pharmaceutical Association Act and the Pharmaceutical Association Regulations. However, they believed that their members should not shoulder the financial burden of defending the Program or the legislation under which it operated. They argued that it would be equitable for Government to assist the NPA financially in dealing with the complaints against the non-compliant pharmacists.

In early November 2001, the NMB again requested that the DOHCS assume their legal expenses associated with pursuing the complaints against the non-compliant pharmacists. As well, they requested that an application be made to the courts to limit the public discussion of computer specifications and capabilities of the PMP. The NMB believed that public discussion of the computer capabilities and specifications of the Program could potentially compromise the security aspects of the Program.

In mid-November 2001, prior to the proposed public disciplinary hearing, one of the non-compliant pharmacists made a repeat suggestion to the DOHCS for a compromise solution to their non-participation in the Program. It was suggested that their non-participation was due to confidentiality reasons and that if the Program were to accept patient MCP numbers without the patient's names, they would participate in the Program. It would involve the Program having to obtain the corresponding patient names from MCP.

The NMB strongly opposed the compromise solution proposed by the non-compliant pharmacists. They stated that MCP numbers were frequently inaccurate and that the Program required patient names to verify patient identification. As well, ensuring the accuracy of personal identifiable information was necessary to adhere to the NLCHI guidelines. They also argued that their current approach was consistent with the Canadian Pharmaceutical Association's Standards for the electronic transmission of data and the proposed approach would require reconfiguring current pharmacy software. Finally, they argued the practical implications (for those patients involved in inappropriately accessing prescriptions) of only certain pharmacies submitting MCP numbers to the PMP without the corresponding names.

During the fall of 2001, the DOHCS offered to participate in another potential compromise solution with the non-compliant pharmacists. The Department offered to fund an independent review of the PMP's data security system (in addition to the external

audit already conducted by XWave) with the notion that, if satisfactory, the dissenting pharmacists would participate. However, if security concerns were identified they would be corrected. On this basis, the NMB advised the NPA that an arrangement had been reached with the non-compliant pharmacists and the disciplinary proceedings were no longer necessary. Unfortunately, while there was agreement on the process, both parties could not agree on the appropriate organization to review the security matter. The cost of the review was estimated to exceed $25,000 and was to be paid by the DOHCS. However, because the PMP was discontinued, the security review was never commissioned.

5.3 SUB-EVALUATION

Under the Lomas approach, the policy implementation stage involves three steps. The first is to disseminate and publicize the chosen policy to relevant stakeholders and the public, if necessary. In Lomas' example, policymakers sent personal letters and bulletins to individual stakeholders such as physicians and administrators and then presented the policy at various conferences. Secondly, they had additional consultation with opinion leaders within the discipline of obstetrics in their case. The third step was to monitor and, if necessary, revise the policy. This involved the committee of stakeholders appointed by the Minister of Health proposing revisions based on newly available research. The proposed revisions were determined using a similar process to that used to

identify the original policy. Consequently, this could be interpreted as a second iteration of the policy-making process.[3]

5.3.1 Implementation Process

The dissemination of information surrounding the introduction of the PMP was very thorough. The initial section of this chapter discussed the multiple news conferences, media reports, letters to stakeholders such as physicians and pharmacists, publication in professional associations' newsletters, the introduction of a handbook for physicians and pharmacists, and memos directly from the PMP Director to physicians and pharmacists during the introductory period. The NMB followed the suggestions and advice of the NLCHI and the Human Rights Commission in propagating information about the PMP to the public.

Stakeholder surveys in general are a reasonable tool for identifying respondents' values and to receive input with respect to specific policy initiatives. The use of a physician survey as described at the beginning of this chapter as a means of obtaining a better understanding of physician values was consistent with the approach proposed by Lomas. If policymakers had expanded the survey to include pharmacists, it might have yielded information that could have averted some of the implementation problems associated with this group. As well, the NMB chose not to implement potential components of a PMP that physicians generally supported as identified in the survey.

These components were: (1) a toll free phone line to provide prescribers with up-to-date information regarding a patient's previous prescriptions; (2) peer prescribing reports; and (3) punitive measures for physicians who inappropriately prescribed. The use of peer prescribing reports and punitive measures for physicians who inappropriately prescribed might have increased the effectiveness of the pilot PMP. The most recent proposal by the PMP for continuing the Program beyond the pilot phase included the need for peer prescribing reports.

An October 2001 report prepared by PMP staff for Government's consideration regarding the future of the PMP acknowledged the medical profession's interest in receiving peer prescribing reports and indicated the NMB's desire to distribute such reports if the PMP proceeded beyond the pilot phase.[161] A detailed discussion of the possible reasons the NMB never investigated physicians suspected of indiscriminate prescribing, which might have led to disciplinary actions, is provided in Chapter 7.

The lack of participation by eleven pharmacies (by the end of the Program) did not appear to be attributed to their lack of knowledge of the implementation requirements of the Program. If it were due to possible shortcomings in the implementation process, one would expect the non-participating pharmacies to be randomly located throughout the province. However, these pharmacies did not appear to be randomly distributed. Some were located in the downtown area of St. John's (where the police and NPA had identified suspected concern over illicit drug use) and were also members of one

consortium. Some of these and other non-participating pharmacies were located near high volume prescribing physicians of monitored drugs as identified through NLPDP data.

During the dissemination process, it became apparent that some pharmacy stores were experiencing difficulties in getting their computer programs functional. Many pharmacies associated this with the PMP. However, Atlantic Data Systems (who provided computer support for the pilot PMP) had repeatedly forecasted that there would be some problems during the early design stage of the PMP because of inadequate computer services provided by large international computer vendors. The same computer vendors were tardy in implementing software changes to accommodate other provincial programs. As predicted, most pharmacies experienced few difficulties while others reported excessive problems.

Upon review of the policy implementation phase of the PMP, it became apparent that there were underlying problems. The NMB may not have had the financial or the political capacity to endure the level of risk that the PMP required. Secondly, while they had regulatory power to ensure physicians participated in the Program, they were not able to ensure, through their relationship with the NPA, the full participation by pharmacists. In retrospect, it appeared that regulatory power over stakeholders was a rather "blunt" instrument in ensuring compliance with their respective legislation. As shall be

discussed, a financial intervention such as the ability to withhold reimbursement to delinquent parties may have been more effective.

Physician and pharmacy professional groups both argued that legal action against their members had become more common in recent years and was expensive to defend. It also appeared that the mere threat of legal action by a provider or patient had led to professional regulatory groups becoming more conservative for fear that such action would result in financial difficulty for the professional organization. This raised the question of whether these provider organizations under their current structure were able to adequately protect the public's safety and interests in this instance. An indication that the current arrangement was less than adequate in this application was the NMB's and NPA's repeated requests for changes to their respective legislation to protect them from liability and for financial assistance from Government (to assist with their legal defences) should some party initiate legal action for administering their respective legislation. In both instances, the provider regulatory groups had insufficient financial capabilities to shoulder the expenses associated with a legal challenge, or the threat of a legal action, despite their confidence in being successful. While if successful, the losing party would assume the association's legal expenses, this appeared to be insufficient assurance. Additionally, the professional regulators might encounter political repercussions within their professions should they be required to increase membership premiums to shoulder the additional financial burden.

The ability of some pharmacists to successfully avoid submitting PMP data contrary to the Pharmaceutical Association Act throughout the tenure of the pilot PMP also raised concerns about the effectiveness of professional self-regulation in this instance. The problem may have been compounded since the NPA at that time assumed a dual role as both an advocacy group on behalf of its member pharmacists and as a regulatory body. Consequently, the literature regarding self-regulation was reviewed for further guidance regarding possible mechanisms to address the current problems.

Self-regulation in the health economics literature is a response to a specific market failure known as "asymmetry of information" between providers of health care and patients. University of British Columbia's Health Economics Professor, Robert Evans[158] described a market failure in health care as a situation where the organization of production and distribution of outcome through unregulated markets was unsatisfactory to most members of society.

Evans noted several sources of market failures in the Canadian health care system as well as "institutional structures" in place to address each. One of the market failures included "asymmetry of information" between providers and consumers of health care. This occurs when health care providers have more information about the value of a medical service to the consumer such that they can unfairly influence the consumer's consumption. Compared to the patient, physicians, for example, have a greater understanding of the potential impact of a newly prescribed drug or medical procedure on

the health outcome and eventual health status of the patient. Evans noted that the primary institutional structure to address this market failure in Canada is professional self-regulation. The role of self-regulation is to control entry to these occupations, the conduct of those in the occupation and to ensure public safety. Unfortunately, there are side effects with such interventions. With self-regulation, there is tremendous power to control markets for certain health provider services, resulting in increased costs to consumers and increased incomes for those providers.[162] Despite this, society values this approach compared with the alternative, potentially unregulated, lower cost model.

The literature further discussed some of the shortcomings of self-regulation. Firstly, it focused on the monopoly powers provided to regulatory groups noting that any occupation seeking self-regulation status will attempt to restrict entry, define its scope of practice, and put in place plans (scopes of practice) to maximize the benefits it may achieve while maintaining public confidence in its ability to regulate its members.[163] It is argued that self-regulating professions can raise prices through two means. They include anti-competitive behaviours and secondly, through over-training and their failure to permit para-professionals or auxiliaries to undertake duties that do not require professional education and training. Governments have preferred self-regulation because it typically does not require any public resources; it creates an understanding of protection to the public; and it confers a valuable property right on a relatively small occupational group (which may be politically desired). Arguments to change self-

regulation in the economics literature are typically based on reducing the economic power of such organizations.[163]

Another weakness of self-regulation described in the medical literature related to the inability to adequately protect the public's safety in specific circumstances. However, it would appear that self-regulation only becomes an issue for widespread discussion when there is a high profile media case involving members of the public suffering serious harm due to inadequate medical practice. The situation is further compounded if the regulatory body is possibly aware of ongoing suspected inappropriate activity or if the suspected inappropriate activity involved the same health professionals but also occurred in another jurisdiction in the past. At this point, the public becomes alarmed, will likely call for a public inquiry, and openly questions the merits of self-regulation. Government, too, may become the target of criticism since they have sanctioned these regulatory bodies. One example repeatedly discussed in the medical literature involved a case in Bristol, England between 1989 and 1995 where several dozen infants and small children died during or following cardiac surgery. Internal hospital reviews were inadequate and when the self-regulatory body subsequently reviewed the case it found all three physicians involved guilty of serious professional misconduct.[164-167] Other, similar extreme cases have been described in the United Kingdom and Canada. One author described such cases as having similar themes, some of which included the absurd behaviour of the limited number of individual practitioners involved; constant and critical

media attention regarding the merits of self-regulation; and the slow response of medical regulatory groups to address the problem.[164]

This literature was further examined for options to improve self-regulation in order to address the shortcomings described above. However, complete discontinuation was argued to be impractical since, once self-regulation is in place, revoking it would inflict severe economic costs on the respective profession resulting in strong resistance.[163] Some options proposed in Ontario to address potential shortcomings were, in summary:

1. Maintaining the current system but provide greater public information;
2. Increasing the number of public representatives on governing councils;
3. Changing the responsibilities of the regulatory body such that they retain authority over registration while policing and adjudicative authority is moved elsewhere, or even combined with other health professions; and
4. Changing the regulatory structure such that a government agency fulfils part of the regulatory function.[164]

This research identified that professional regulatory groups may have been reluctant to accept the required legal, political and financial risks necessary to achieve the full benefits of the PMP. However, option number four listed above could be considered as a means to address this. For example, if the DOHCS administered the PMP, they could take responsibility for investigating suspected inappropriate dispensing and prescribing and, where necessary, lay formal complaints with the regulatory body. The

regulatory body, in this instance, would be obliged to take the necessary disciplinary action as required by their respective legislation. In retrospect, the DOHCS had done this on an ad hoc basis in the past by lodging formal complaints with the NPA and NMB in instances where suspected inappropriate activity was detected using the NLPDP and MCP databases.

5.3.2 Budget Considerations

Many of the problems associated with determining a suitable budget for the PMP were related to the administrative financial risk that the NMB had to undertake. While the Program would have involved a prospective budget being transferred from Government to the Board, the NMB perceived that any budget overruns would place them at risk financially. Consequently, when the Board devised a budget for Government's consideration, it contained significant contingency items. This was a reasonable assertion on their behalf. The NMB had annual revenues in the vicinity of $800,000 annually. The PMP was expected to cost as much as $350,000 annually with many uncertain budget items. This was because such a program had never been administered in this province and there were potentially unanticipated start-up expenses and expenses associated with prescription volumes.

A preferred approach from the outset would have been for a more conservative estimate of the PMP budget leaving the Government to assume the potential additional

costs. Any additional expenses would have been small in comparison to the DOHCS's budget, but significant in terms of the NMB's annual budget. Alternatively, Government could have chosen to administer the PMP itself to accommodate the financial risk. The financial implications of expanding the NLPDP to achieve this were never explored.

Much of the predicted contingency expenses were associated with the estimated printing costs of personalized prescription pads. As well, the Program was delayed awaiting additional resources from Treasury Board for the personalized pads. However, once implemented, the NMB decided that prescribers were not required to use the personalized pads and, as such, many pharmacists indicated that about half of the narcotic and benzodiazepine prescriptions were written on conventional forms. (Personal communication – St. John's area pharmacies, Fall 2001.) Unfortunately, more precise data were unavailable. The decision, not to utilize personalized prescription pads, contributed to serious logistical difficulties with the Program, since many prescribers who used the conventional pads failed to include the specific patient and physician identification information necessary for Program administration. Consequently, as of October 2001 (approximately 16 months after the Program commenced), approximately 21% of all prescriptions in the PMP database did not have MCP numbers.[161] It was also informally estimated that only 25% to 30% of physicians used PMP forms on a regular basis. The NMB has since proposed that any extension of the Program require the mandatory use of personalized prescription forms.

5.3.3 Legal Considerations

Initial legal considerations suggested that the introduction of a PMP required changes to specific legislation. However, there were multiple requests for additional changes, mostly by the NMB, that were not always mutually agreed to by all stakeholders. The disagreeing party was usually Government. The mere number of requests may have demonstrated the preference of the medical regulatory groups not to undertake or accept risk in this instance. Government, by its financial capacity, has the ability to assume greater risk compared to these groups. Consequently, they may not have fully appreciated the necessity for the requested changes in liability provisions from the professional regulatory bodies' perspective.

It became apparent through discussions with the regulatory groups that the threat of legal action was cause for concern. In all of the examples provided, the regulatory groups were confident of their success should a legal action commence; however, the legal expenses associated with defending the respective Board, its registrar and employees would be significant. As well, it was conceivable (and came to reality with the non-participating pharmacists) that many members could jointly collude in a legal action causing an even greater financial risk to the regulatory body. The idea that such pursuits might be based on ideological grounds suggested that the legal battles could be expensive. In retrospect, a more expedient process could have involved legal representatives for the various stakeholder groups, including Government, meeting to

discuss their risk perspectives and to jointly determine the necessary legislation changes. This process could have reduced the tremendous time lags associated with considering legislation changes on a consecutive as opposed to concurrent basis.

It is conceivable that the DOHCS could have played a stronger leadership role in coordinating the repeated requests from stakeholder groups for additional resources and legislation to implement the PMP. This may have helped to streamline the process and reduce the multiple exchanges of correspondence between the parties. At one juncture, the DOHCS successfully convened such a meeting to discuss the repeated requests for financial resources for the Program. This meeting allowed the stakeholder representatives to openly discuss their rationale for their requests. A similar process may have assisted in reducing the number of consecutive requests for changes to legislation (and the subsequent exchanges of correspondence).

There were some plausible reasons why the DOHCS did not assume a stronger leadership role with respect to the implementation of the PMP. For example, the requests for legislation changes from the stakeholder groups occurred in a consecutive (vs. concurrent) fashion and Departmental officials may have felt that each request was the final one prior to the implementation. In addition, several departmental officials from several branches were involved with the Program and sometimes they may have been unaware of the extent of the requests on a timely basis. Consequently, a holistic viewpoint was not readily apparent. As well, during the years immediately preceding the

PMP, there were considerable personnel changes at the senior levels within the DOHCS. Accordingly, this turnover resulted in senior officials only being familiar with the file for short durations. However, the precise contribution of each perceived factor is uncertain.

5.3.4 Confidentiality of Prescription Information

The stakeholders involved with the development and implementation of the PMP were cognizant of the security requirements necessary to undertake a successful program. A review of the minutes of meetings of the steering committee during the PMP formation stage and in the latter stages of its development noted continuous references to confidentiality requirements and the Program's ability to meet them. As reported above, the NMB instructed its legal counsel in the fall of 1999 to review the proposed PMP with respect to Newfoundland privacy legislation. In addition, there were confidentiality agreements in place between the PMP and ADS. The NMB also, according to a report produced by the PMP, developed policy guidelines for data collection and the day-to-day operation of the Program. Finally, the Board commissioned an internal review of the database's security by the Information Technology Division of the DOHCS. A local computer firm, XWave, also conducted an external audit of the system.

Many of the privacy concerns raised by the NLCHI were, or had been, adequately addressed by the Program's policies or through legislation. Some suggestions, such as patient consent being obtained prior to releasing prescribing information to the PMP, may

have rendered the Program less effective. It is unlikely that those patients involved in illicit drug activity would have concurred with allowing their prescription information to be submitted to a third party for monitoring purposes. The NMB chose the approach of having such requirements grounded in legislation. However, the thorough review of confidentiality requirements by the NLCHI made all stakeholders more aware of the need for stringent standards in this area.

5.3.5 Participation by Pharmacists

Since the inception of the PMP, at least eleven pharmacies refused to submit data to the PMP contrary to the Pharmaceutical Association Act. Through NPA correspondence to the DOHCS, they proposed a number of reasons for their non-participation including: (1) the inability of the Program to provide feedback; (2) computer software and hardware problems; (3) the financial expenses associated with the Program; and (4) the fee associated with dispensing services provided to government-subsidized drug claimants in general. After retaining legal counsel, it appeared that the stated grounds for dissident pharmacists' refusal to participate (according to NPA correspondence to the DOHCS) moved to concerns about the validity of the Program and the security of personal patient information rather than the requirements of the Pharmaceutical Association Act. In addition, through individual meetings with in excess of sixty pharmacists by this researcher, including some of those non-participating (while conducting other aspects of this research), it appeared that their refusal to participate may

have been primarily based on financial reasons. Coincidentally, the non-participating pharmacists were not randomly located throughout the province as would be expected if they were opposed to the PMP only on the grounds stated. They were primarily affiliated with one consortium. It appeared to this researcher that the NMB and Government had adequately addressed their non-monetary concerns and that any continued non-participation was more likely rooted in monetary issues. Although a formal qualitative study may have further explored the pharmacists' views, it is unlikely they would have been totally candid in formal interviews about such matters.

Recent changes in the market structure of the retail pharmacy business in the St. John's area may have indirectly contributed to the lack of participation by some pharmacists in the PMP. The retail pharmacy business in urban Newfoundland and Labrador had experienced increased competition over the decade prior to the PMP's existence and many independent pharmacies had been adversely affected. Pharmacies have recently been established in traditional, large retail chain stores and supermarkets, mostly in urban centres. As well, these new entrants advertised greatly reduced dispensing fees in the vicinity of $1.99 per prescription or 30% of the standard subsidized rate of $6.50. During the spring of 1996, the Government of Newfoundland and Labrador, in search of all available cost savings to minimize the budget deficit, abruptly announced that it would only provide reimbursement of $3.50 per prescription (it has since been reinstated through small increments to $6.50). However, immediately following the reduced rate policy, some pharmacists began a public feud with

Government that resulted in even greater public attention to the fact that large retail chains and supermarkets were offering substantially reduced dispensing fees. This response may have compounded the reduction in revenues for many independent and associate pharmacies in the urban centres. Ironically, many independent pharmacists directed their bitterness towards Government as opposed to the new entrants who initiated the reduced dispensing rates.

The NPA had regulatory authority to address those pharmacists who did not comply with the Pharmaceutical Association Act. The NMB had submitted formal complaints against the dissident pharmacists with the caveat that the complaints would be withdrawn if the pharmacists were to comply. This approach may have prolonged the non-participation by these pharmacists. As well, it also caused further legal and administrative problems for the Program and additional legal expenses on behalf of stakeholders.

The ability of the NMB and the DOHCS to influence the status of disciplinary proceedings against non-complying pharmacists had potential adverse financial implications for the NPA. Regulatory bodies such as the NPA recover the expenses of disciplinary investigations from members if they are found guilty. When allegations of pharmacists' wrongdoing were withdrawn or deferred at the last moment at the request of the NMB and DOHCS, the NPA had already assumed the full costs of investigating the

complaints. The NPA subsequently asked the DOHCS to reimburse these expenses. Government reimbursed the majority of the NPA's legal expenses.

It appears that all stakeholders may have overestimated the deterrent effect of regulatory power in addressing pharmacists' non-compliance with the PMP. This exercise illustrated that regulatory powers were relatively limited in addressing the non-participation by some pharmacists. The mere process of pursuing regulatory sanctions provided an opportunity for the non-participating pharmacists to further "game," resulting in increased effort for the regulatory bodies and Government.

In retrospect, it is conceivable that a financial penalty might have been a more effective option. Government could have considered the legal implications of limiting the non-participating pharmacists' participation in the NLPDP during the time period they were refusing to submit data to the PMP. This would have caused some inconvenience for NLPDP claimants if the non-participation continued; however, it is conceivable that this intervention might have had an immediate effect on pharmacists' participation. MCP has successfully used a similar approach by withholding payments to physicians who have not submitted required information under the physician payment program.

Table 5.2

Summary of the Policy Implementation Stage

- The dissemination of information regarding the introduction of the PMP was very thorough.
- The physician survey completed in April 1998 should have been expanded to include pharmacists.
- The NMB did not appear to be able to accommodate the legal, financial and political risk necessary to effectively administer the PMP.
- Regulatory power over stakeholders was seen as a "blunt" instrument in ensuring compliance with their legislation. Consideration should have been given financial sanctions.
- The ability of some pharmacists to successfully avoid submitting PMP data contrary to legislation throughout the tenure of the PMP raised concerns about the effectiveness of professional self-regulation in this instance.
- Options from the literature to strengthen self-regulation may include providing greater public information or having a government agency fulfill part of the regulatory function.
- Government should have ensured that the financial risk associated with administering the Program was not transferred to the NMB.
- The incomplete use of personalized prescription pads contributed to serious logistical difficulties for the Program.
- Legal representatives for the various stakeholder groups and government should have met to discuss their risk perspectives and then jointly determined the necessary legislative requirements for the Program. The DOHCS could have played a greater leadership role in this regard.
- Privacy of information concerns appeared adequately addressed by the Program's policies or through legislation.
- The non-participation by some pharmacists in the PMP and the reluctant participation by others was attributed, in part, to the 1996 reduction in the pharmacy dispensing fee for government-subsidized prescriptions.
- The soft approach in addressing complaints against the non-compliant pharmacists was problematic.
- The influencing of pharmacists' disciplinary proceedings had adverse financial implications for the NPA and eventually government.

CHAPTER 6

EVALUATION OF THE PRESCRIPTION MONITORING PROGRAM

The NMB in co-operation with the Provincial Government and professional stakeholder groups implemented, through legislation, a two-year pilot PMP on June 19, 2000 to test its effectiveness in addressing the abuse of narcotics and benzodiazepines.

There is currently limited empirical evidence regarding the effectiveness of PMPs. Consequently, the CEG of Memorial University was assigned the responsibility for designing and implementing a full clinical evaluation of the pilot PMP. This chapter describes the methodology for and the results of a clinical assessment of the Program.

A before/after study design was used to evaluate the impact of the PMP. This design was chosen because the intervention was legislated to include all prescriptions dispensed for monitored drugs, precluding the use of a concurrently controlled study within the province. The clinical evaluation attempted to determine if the pilot PMP in Newfoundland and Labrador resulted in clinically important changes in appropriate and inappropriate therapeutic uses of monitored drugs, their substitutes and the illicit use of monitored drugs and illegal substances.

This evaluation provides an assessment of the PMP by examining: (1) IMS Health, Canada and NLPDP data on the volume of PMP monitored drug prescriptions

filled over time; (2) IMS Health, Canada and NLPDP data on trends in the use of a selected group of non-monitored but potential substitute medications; (3) trends in potentially illicit monitored drug use measured by changes in the incidence of suspected double doctoring; (4) the illegal access to PMP monitored drugs through theft and break and enters at pharmacies; (5) the potentially inappropriate therapeutic prescribing of PMP monitored drugs measured by surveys of patient medical records; and (6) the potentially inappropriate underutilization of PMP monitored drugs for therapeutic purposes measured by interviewing patients whose medication(s) of program-included drugs were discontinued immediately following the introduction of the PMP.

The Human Investigation Committee, Faculty of Medicine, Memorial University of Newfoundland approved all aspects of the clinical evaluation protocol for the PMP in August 1999.

6.1 METHODS

The clinical evaluation of the pilot PMP involved six measurements of which five were measured on a before and after basis. These measurements are summarized in Table 6.1 and described in more detail following the table.

Table 6.1
Summary of Methodology for the PMP Evaluation

Measure	Study Period(s)	Methods	Data Source(s)	Population
PMP monitored drugs dispensed	1997-2001	Calculate number of PMP prescriptions dispensed by drug class and total drug class dose equivalent.	IMS Health, Canada, NLPDP	Newfoundland and Labrador (n = 521,000)
PMP substitute drugs dispensed	1997-2001	Calculate number of PMP substitute prescriptions dispensed by drug class.	IMS Health, Canada, NLPDP	Newfoundland and Labrador (n = 521,000)
Multiple doctoring	1997-2001	Calculate number of patients visiting three or more, four or more and five or more different fee-for-service GPs/month.	DOHCS (MCP)	Newfoundland and Labrador (n = 521,000)
Theft of PMP monitored drugs	1998-2001	Determine number of break and enters and armed robberies at pharmacies.	RNC, NPA	St. John's area (n = 171,870)
Appropriateness surveys	Fall 1999, Winter 2000 & Summer/Fall 2001	Randomly selected prescriptions for PMP monitored drugs assessed for clinical appropriateness by specialist panels.	Community-based pharmacies and physicians	St. John's area (n = 171,870)
Discontinuation survey	Summer/Fall 2001	Discontinued long-standing prescriptions of NLPDP beneficiaries assessed for clinical appropriateness.	NLPDP, St. John's and CBN* pharmacies, NLPDP beneficiaries	NLPDP beneficiaries residing in St. John's/CBN*

* Conception Bay North

The indicators to evaluate the PMP were chosen, in part, based on previous research by Weintraub who evaluated the 1989 New York State TPP for benzodiazepines.[146] I expanded on the approach used by Weintraub based on criticisms of PMPs by Schwartz who argued that they had a profound negative impact on legitimate prescribing of Program monitored drugs.[148] Consequently, my research includes an assessment of the clinical

appropriateness of prescriptions and an examination of the circumstances where patients' medications were abruptly discontinued coinciding with the introduction of the Program. An analysis of the theft of monitored drugs from pharmacies was based on concerns expressed by some local pharmacists.

6.1.1 Prescriptions of PMP Monitored Drugs

IMS Health, Canada is a private sector international research company. The data they provide originate from their IMS Health "Compuscript" database which is drawn from their panel of over 4,700 Canadian pharmacies. This represents approximately two-thirds of all retail pharmacies in Canada. The sample is stratified by province, store type (chain or independent) and store size and is representative of all the retail pharmacies in Canada. Records are collected electronically each month from the pharmacies.

For Newfoundland and Labrador, the IMS Health, Canada data is derived from data provided by 27 of 174 retail pharmacies. Of these, 13 of 60 large chain pharmacy stores were represented, 2 of 10 large independent pharmacies represented, 5 of 42 small pharmacy chains represented, and 7 of 62 small, independent pharmacies represented. IMS Health, Canada requires specific criteria to be met prior to including individual pharmacy data in the sample. For example, the individual pharmacy must dispense a minimum number of prescriptions per time period; there must be a minimum ratio of new to repeat prescriptions dispensed; the mode of pharmacy payment must be consistent with

provincial norms; and the pharmacy must consistently provide data for a minimum of six months. IMS Health, Canada officials advised that if the desired sample design is not achieved, statisticians would make adjustments to limit bias. Due to confidentiality reasons, IMS Health, Canada will not disclose the identity of participating or non-participating pharmacies. It is uncertain if the same pharmacies were sampled each year and how data inaccuracies were addressed by IMS Health, Canada. Therefore the accuracy of the data cannot be completely verified. (Personal communication – D. Rhodes, Senior Analyst, IMS Health, Canada, July 2, 2003.)

In August 2000, IMS Health, Canada voluntarily provided an Excel file containing estimated monitored drug dispensing data for Newfoundland and Labrador for 1997, 1998 and 1999. The data described the dispensing patterns for 150 different types or strengths of benzodiazepines and 227 different types or strengths of narcotics. A list of these medications is contained in the Newfoundland and Labrador Prescription Monitoring Program (PMP) Handbook for Prescribing and Dispensing Health Professionals (Appendix B). The information contained estimates of the number of prescriptions dispensed, number of units dispensed and the total value of the products as dispensed to the consumer including the dispensing fee. The estimates were provided for each strength of each formulation for each product containing a specific active ingredient. The units represent the smallest unique measurable quantity of the specific formulation. For example, oral solids are measured as tablets or capsules, liquids (oral, injectible or

nasal) as millilitres and patches (e.g., duragesic) and suppositories (systemic rectals) are measured in single units (e.g., 1 mg.).

The IMS Health, Canada data were provided in terms of units as opposed to WHO ATC defined daily dose. The latter measurement is defined as the assumed average maintenance dose per day for a drug product when taken for its major indications in every day practice. It allows for a standardized measurement of drug utilization within and between drug entities. It may also be used to describe drug utilization patterns across a population and as a measure of intensity.[168] However, the WHO ATC defined daily dose may vary by indication, for example, in the use of benzodiazepines to treat anxiety or insomnia. Since the IMS Health, Canada data were not provided by indication, the drug class dose equivalent was considered the appropriate measure for comparison in this instance.

In December 2001, IMS Health, Canada provided comparable data for 2000 and January to October 2001 from which annual 2001 estimates were then projected.

In September 2000, the investigators met with two pharmacists with specialty practices in disciplines where PMP monitored drugs are frequently prescribed. One was employed at the Newfoundland and Labrador Cancer Treatment Research Foundation and the other was an instructor with the School of Pharmacy, Memorial University of Newfoundland. The pharmacists provided appropriate conversion tables enabling the

IMS Health, Canada benzodiazepine data to be converted into 1 mg. lorazepam oral equivalents and the narcotics data into 10 mg. morphine IM equivalents (Appendix D). The drug class dose equivalent was then calculated using these conversion tables. There were six opium products for which no conversion factor could be found but their volume of sale was very low.

In December 2001, the NLPDP provided data regarding the number of claims and expenditures for PMP included drugs in comparison to the total NLPDP claims and expenditures for six-month intervals from March 1999 to September 2001.

The IMS Health, Canada and NLPDP prescription data over time were plotted and visually assessed for changes in trends coinciding with the introduction of the PMP. A linear regression was then undertaken to determine if a single line would fit the yearly data including pre/post PMP periods. If the PMP caused a change in prescribing patterns, a single line would not fit the data points well, and consequently, the R square value would be low. The slope of the fit line (if a good fit) would show if any temporal trends were occurring irrespective of the PMP. The more negative the slope (and especially if statistically significant) the greater the ongoing decline over time (or by converse if the slope was positive). Time-series analysis was not done due to the scarcity of data points.

6.1.2 Prescriptions of Substitute Medications

During the fall of 2000, individual discussions were held with pharmacists at the DOHCS, Newfoundland Cancer Treatment and Research Foundation and the School of Pharmacy at Memorial University to identify potential non-PMP monitored medications that might be substituted by prescribers for narcotics and benzodiazepines. Based on these discussions, 23 narcotic and three benzodiazepine substitutes were analyzed. As well, three additional anti-inflammatory COX-2 selective inhibitors introduced in 1999/2000 could be considered narcotic substitutes. These potential substitute medications are listed in Appendix E. The criteria used by the pharmacists to identify a potential substitute required the drug to provide a similar action or side effect as a PMP monitored drug but not to be included in the panel of monitored drugs. Substitute medication data were provided by IMS Health, Canada in the same form as described above for PMP included drugs. Comparable NLPDP data were also analyzed.

Similar to the above analysis, the PMP substitute medication data over time were plotted and a linear regression was used to assess if there was a single linear relationship between the quantity of PMP substitute drugs dispensed per year over time. The R square value was interpreted as a measure of goodness of fit.

6.1.3 Multiple Doctoring

Data regarding the suspected incidence of multiple doctoring were obtained from MCP upon specific request of the Minister of Health and Community Services. MCP provided data regarding the number of recipients who visited: (1) three or more; (2) four or more; and (3) five or more different fee-for-service ("FFS") general practitioners and/or emergency room physicians within each month from September 1997 to September 2001. A block funding arrangement was introduced for reimbursing St. John's area emergency room physicians in May 1999. As such, MCP does not have patient specific information for services provided by St. John's area emergency room physicians beyond May 1999.

The multiple doctoring data was provided on a monthly basis and the yearly average was used to even the time series. A more reliable analysis would require having access to individual monthly data over a longer time series.

As discussed in the previous analyses, the multiple doctoring data over time was also plotted and a simple linear regression was used to assess if there was a single linear relationship between the number of individuals visiting multiple different general practitioners per month over time. The R square value was interpreted as a measure of goodness of fit.

6.1.4 Theft of PMP Monitored Drugs

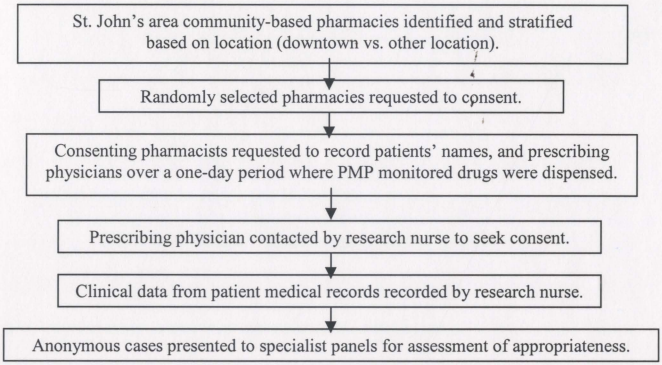
Information pertaining to the theft of monitored drugs from 1998 to 2001 was obtained from two sources: the NPA and the RNC. Officials of the RNC provided information on the incidence of break and enter crimes and thefts where monitored drugs were stolen, based on: (1) a manual review of files prior to April 1999; (2) a computerized search in later years; and (3) through personal contact with officers who investigated such crimes. The NPA permitted researchers to review records of reports by local pharmacists of break and enters, armed robberies and prescription forgeries for several years before the pilot PMP. However, available data sources were not comprehensive over the study period. Pharmacies from whom monitored drugs are stolen are obliged to submit records of such to Health Canada on a special form entitled "Narcotic/Controlled Drug Loss/Theft Report." A copy of this report is then forwarded to the NPA. However, the NPA advised that not all thefts are reported.

The RNC computer system was not able to electronically search its database prior to April 1, 1999. However, officers assigned to investigating armed robberies and break and enters at pharmacies noted that increased efforts to apprehend responsible individuals have, historically, dramatically reduced the number of robberies in subsequent time periods. There were some inconsistencies between the data sources. For example, some crimes were documented in one source but not in the other. As such, the highest number recorded from either source was used.

6.1.5 Appropriateness of Prescribing of PMP Monitored Drugs

A random sample of St. John's area physician prescribing practices was taken by this researcher to estimate the rate of appropriateness and reasons for prescribing monitored drugs for therapeutic purposes before and after the PMP. For the baseline measurement, a random sample of St. John's area pharmacies was identified from a list of all provincial retail pharmacies provided by the NPA during the fall of 1999 (Figure 6.1). The pharmacies were stratified based on actual physical location using a city map (downtown vs. other areas) following the suggestion of the NPA that a disproportionate amount of drugs destined for illicit use was dispensed at downtown pharmacies. Identified pharmacies were chosen by random numbers and the Pharmacists-in-Charge were contacted by the principal investigator or research nurse and requested to sign a consent form indicating their willingness to and the conditions under which they would participate in the study and the measures used to ensure confidentiality of information (Appendix F). Following consent, pharmacists were requested to disclose to the principal investigator or research nurse for cases where PMP monitored drugs were dispensed, the names of patients, prescribing physicians and the drug dispensed over a one-day time period. The Human Investigation Committee, Faculty of Medicine, Memorial University of Newfoundland did not require patient consent for this survey. Additional details of the prescriptions were not disclosed.

Figure 6.1
Summary of Methodology for Pre- and Post- PMP Appropriateness Surveys



The identified physicians were contacted by the research nurse and requested to sign a consent form indicating their willingness to and the conditions under which they would participate in the study (Appendix G). Following consent, the nurse extracted clinical information from patient medical records for each prescription and also had a brief interview with the prescribing physicians (Appendix H). The research nurse separated the clinical data into two groups - narcotics and benzodiazepines. Individual anonymous case data were then presented to two panels of physicians with expertise in treating patients in each category. The baseline narcotic panel was proposed to include two pain management specialists and a general practitioner. The benzodiazepine panel included the same physicians except that a psychiatrist was substituted for the pain management specialists.

The data extraction form was developed and agreed to by the panels. To enhance patient confidentiality, the patients', pharmacists' and physicians' identification information was not recorded on the data extraction form. For the pre-PMP appropriateness surveys, the NPA and NLMA individually wrote their respective members who were chosen for the study to encourage their participation.

Similar follow-up surveys were initiated approximately one year following the introduction of the PMP to determine the rate of appropriateness and reasons for monitored drug prescribing for therapeutic purposes. For the post-PMP appropriateness surveys, the remaining pharmacies that had not been randomized to participate in the baseline surveys and were not affiliated with the non-participating pharmacies (identified from the baseline surveys) were requested to participate. This approach was used to avoid potential changes in prescribing behaviour associated with physicians knowing in advance that their prescribing appropriateness would be re-evaluated in the post survey. As well, to improve the efficiency of data collection, pharmacies participating in the post-PMP appropriateness surveys were requested to identify patient and physician information from prescriptions of PMP monitored drugs dispensed over a two-day period.

General guidelines for narcotic use were unsuccessfully sought through computerized library searches and through contact with the American Pain Society. Specific guidelines for narcotic use for some indications such as cancer pain were provided by a pain management specialist.[169-177] The Canadian Medical Association provided

guidelines produced by the College of Physicians and Surgeons of Alberta entitled "Guidelines for Management of Chronic Non-Malignant Pain."[178] For the purposes of these surveys, it was suggested that the Alberta appropriateness guidelines be used and, in consultation with the panel, lack of appropriateness be defined under the categories of: (1) lack of indication; (2) incorrect dosage; (3) inappropriate duration; and (4) lack of trial of more appropriate alternative therapy. Incorrect dosage occurred when medications were prescribed at sub-therapeutic doses or with dosing intervals too long to control continuous symptoms. Inappropriate duration occurred when the specific prescription was written for too long a time period (E.g., greater than one month for a short-term problem). A similar approach was used for determining the appropriateness of benzodiazepine use. However, the panels never referred directly to the guidelines during their assessments because of time constraints for assessing the information. As well, panel members provided their time voluntarily and their schedules did not permit detailed pre-assessment debate.

In an effort to estimate the sample size for the appropriateness surveys, the literature was initially reviewed for an indication of the likely rate of inappropriate prescriptions of PMP monitored drugs for therapeutic purposes. No data comparable to the current application were found. There were studies identified that measured rates of potentially inappropriate prescribing of benzodiazepines in the elderly, in nursing homes and in a specific aboriginal population and are described in Chapter 3, Section 3.2.3. These studies described wide-ranging rates of potential inappropriate prescribing between 14% and 75%.[65-68,70,73] Consequently, an inappropriateness rate of 30% was assumed

reasonable for the pre-PMP period in calculating the sample size. To detect a decrease to 15% after the PMP, a sample size of 94 cases per survey was estimated using the formula $n/group = 2[(Z_\alpha + Z_\beta) / (2\sin^{-1}\sqrt{\pi_1} - 2\sin^{-1}\sqrt{\pi_2})]^2$. This sample size if repeated in the post-PMP survey would be likely to detect a fall in the inappropriateness rate to 15% with statistical significance, eight times out of ten. This sample size also allows estimation of baseline inappropriateness rates within 10% of a true value of 30%, 19 times out of 20.

A Kappa statistic is defined as the proportion of actual to potential agreement beyond chance that is achieved between raters independently assessing the same information.[179] In this instance, Kappa statistics were calculated to determine the level of agreement beyond chance that was actually achieved between the independent physician panels assessing the same prescription information. This also provided an indication of the reliability of the data. A Chi-squared analysis was used to assess the statistical impact of the PMP.

Data were analysed using SPSS software. Ethical aspects for this survey were considered according to "Guidelines on Research Involving Human Subjects 1987."[180] For ethical reasons and because the study intentionally focused on prescriptions dispensed at community-based pharmacies, patients who were residents of nursing homes or in acute care institutions were excluded from this survey.

6.1.6 Appropriateness of PMP Monitored Drug Discontinuation

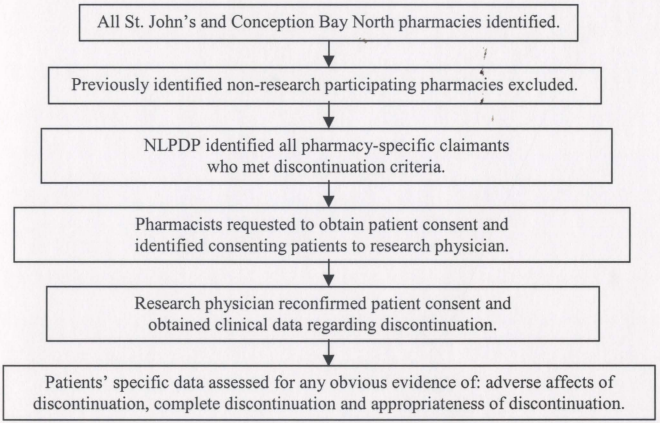
During the spring of 2001, a random sample of St. John's and Conception Bay North area physician prescribing patterns was undertaken to measure the potential inappropriate under-utilization of monitored drugs following the PMP's introduction. This involved telephone interviews by a research physician with patients whose medication(s) were suddenly discontinued coinciding with the introduction of the PMP.

To obtain the sample, pharmacies that had initially agreed to participate in the baseline appropriateness surveys were approached and requested to voluntarily participate in this aspect of the research (Figure 6.2). Following this, the remainder of pharmacies in the St. John's area that had never been contacted (and were not affiliated with a consortium of pharmacies not participating in the PMP) were also requested to participate. In addition, to increase the sample size, all pharmacies in the Conception Bay North area were invited to participate.

Officials of the NLPDP identified all patients for each consenting pharmacy from its database that met specific criteria. The criteria included patients who had been continuously receiving a prescription for a monitored drug(s) for a minimum of three months prior to the PMP of which at least one was abruptly discontinued once the Program was implemented.

Figure 6.2

Summary of Methodology for Discontinuation Survey



Pharmacists who consented to participate in this survey were requested to contact, by phone, their respective patients whose dispensing patterns corresponded with the study's criteria as identified by NLPDP officials. The purpose of the initial patient contact was to inform the patient about the research and to seek their permission for their name to be forwarded to a physician investigator who would then contact them for participation in a survey designed to measure the impact of the PMP on prescribing patterns (Appendix I).

If the patient agreed, a physician investigator contacted the patient by phone to reconfirm their consent and to discuss their previous use of monitored drug(s) and the possible reason(s) for discontinuation (Appendix J). Specifically, the physician investigator was attempting to determine if the indication still existed according to guidelines for narcotic and benzodiazepine use or if an effective alternative therapy for the indication was substituted. Possible reasons for discontinuing the PMP monitored drug(s) included: (1) potentially inappropriate under-utilization following the PMP; (2) potentially inappropriate over-utilization for therapeutic reasons prior to the PMP; (3) illicit use of monitored drugs prior to the PMP; or (4) the patient's condition had improved and the medication was no longer indicated. This survey was attempting to measure only the initial reason for discontinuation.

A Professor of Medicine reviewed the patient participants' information. It was assessed for any obvious reported evidence of: (1) adverse consequences of the discontinuation; (2) complete discontinuation of a drug class (all narcotics and/or all benzodiazepines); and (3) appropriateness of the discontinuation. A discontinued case was assessed as appropriate if there was no ongoing medical indication and/or a preferred alternative treatment was provided.

The literature was unable to provide an indication of the rate of inappropriate discontinuation. Consequently, an assumed inappropriate discontinuation rate of 30% was considered reasonable for calculating the sample size. Using the formula $n = p(1-p)$

x (1.96/desired half width of CI)^2 where p equals the expected proportion, the sample size for this survey was estimated at 81 cases. This estimate assumed the inappropriate discontinuation rate of 30% with a desired confidence interval of +/-10% around the estimate.

Measures to ensure validity and reliability of this survey were limited because: (1) this was not the main focus of the research; (2) budget restrictions; and (3) ethical and consent considerations. Reliability testing of this survey instrument was not feasible since this would have involved taping or repeating patient phone interviews.

Data for this survey were summarized using SPSS software. Ethical aspects of this survey were considered according to "Guidelines on Research Involving Human Subjects 1987."[180] Patients who were residents of nursing homes or in acute care institutions were also excluded from this survey. In addition, patient participants who were legally or mentally incompetent (as identified by the pharmacist) were excluded from this survey. As mentioned, the Human Investigation Committee, Faculty of Medicine, Memorial University of Newfoundland approved all aspects of the clinical evaluation protocol for the PMP in August 1999.

6.2 RESULTS

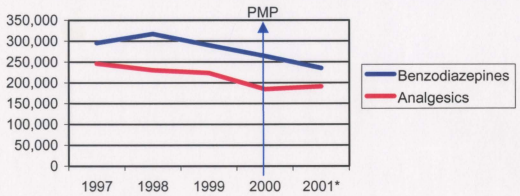
6.2.1 Prescriptions of PMP Monitored Drugs

The annual number of benzodiazepine prescriptions dispensed in Newfoundland and Labrador fell from 294,996 to 234,742 (-20.4%) from 1997 to 2001 (Figure 6.3). The corresponding per capita rate fell from 0.54 to 0.45 prescriptions per year from 1997 to 2001, respectively. Despite a small increase in 1998, there was a general downward trend in prescribing over the five-year period. There was no noticeable change in the rate of decline of benzodiazepine prescribing between the years 2000 and 2001. The total provincial drug class dose equivalent (1 mg. lorazepam oral) from 1997 to 2001 followed the same general trend as the number of prescriptions for benzodiazepines (Figure 6.4). The average drug class dose equivalent (1 mg. lorazepam oral) per benzodiazepine prescription in 1997 was 75.2 units compared with 80.8 units in 2001. NLPDP pharmacists advised that there were no specific formulary or other changes for these two classes of drugs during the time period of study. The number of general practitioners in the province increased by approximately 4.7% from 1998 to 2001. Other potential confounding interventions are discussed further in Section 6.4.2. A time-series analysis of these data would have been preferred, but there were too few data points.

Wagner proposed that data in this instance would ideally be analyzed using segmented regression analysis of interrupted time series. Such an analysis allows the

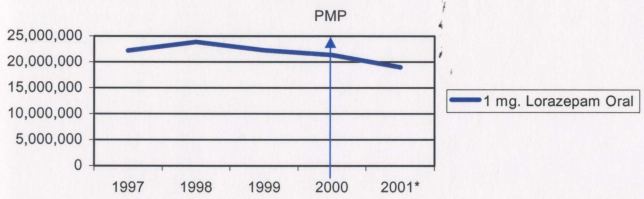
researcher to use statistics in assessing how much an intervention influences a particular outcome on an immediate basis and over time and if confounding factors could be involved. This analysis involves an assessment of both the level and trend of the data both before and after the intervention. To conduct such an analysis requires a sufficient number of time points before and after the intervention. It is generally recommended that there be a minimum of twelve data points before and twelve data points after the intervention. Using monthly measures allows for adequate evaluation of seasonal variations. Wagner advised, as was done in this research, that as an initial step researchers take a visual inspection of the series over time and assess if the time series pattern has changed in relation to the pre-intervention period. He also acknowledged some limitations of the segmented regression analysis approach. They included the data following a linear trend within each segment, a minimum required number of data points and the potential for individual-level covariates that may predict the outcome.[181]

Figure 6.3
Total Prescriptions Dispensed
Newfoundland and Labrador
1997 to 2001



Source: IMS Health, Canada
* Projected based on January-October

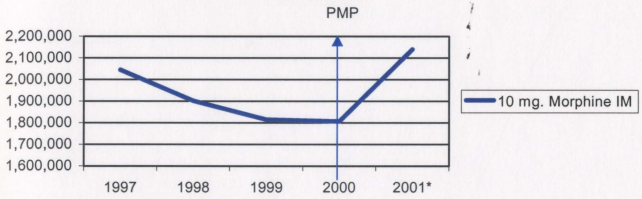
Figure 6.4
Benzodiazepine Drug Class Dose Equivalent
Newfoundland and Labrador
1997 to 2001



Source: IMS Health, Canada
* Projected based on January-October

The annual number of narcotic prescriptions decreased from 246,161 to 190,771 (-22.5%) between 1997 and 2001 (Figure 6.3). The corresponding per capita rate fell from 0.45 to 0.37 prescriptions per year from 1997 to 2001, respectively. There was a general downward trend in the number of prescriptions from 1997 to 2000 and a slight increase from 184,401 to 190,771 (+3.5%) prescriptions from 2000 to 2001. The total analgesic drug class dose equivalent (10 mg. Morphine IM) followed a similar trend as the number of prescriptions dispensed from 1997 to 2000 (Figure 6.5). However, it increased by 18.4% in 2001 compared with 2000. This suggested that the average potency or quantity of drug per prescription rose in 2001. In fact, the average drug class dose equivalent (10 mg. Morphine IM) per analgesic prescription was 11.2 units in 2001 compared with 9.8 units in 2000 (+14.3%). The comparable figure for 1997 was 8.3 units. Thus, the 2001 value was 34.9% greater than the 1997 value.

Figure 6.5
Analgesic Drug Class Dose Equivalent
Newfoundland and Labrador
1997 to 2001



Source: IMS Health, Canada
* Projected based on January-October

Except for the total prescriptions of analgesics over time analysis, the confidence interval for the estimated slope of the regression line included zero in each instance (Table 6.2). While the small number of data points limited the interpretability of the regression analysis, it suggested that prescribing patterns did not change significantly with the introduction of the PMP. The relatively high R square value for most of the analyses also supported this conclusion. However, the extremely low R squared value for the analgesic drug class dose equivalent (and corresponding per capita) analysis indicated that a single line did not describe the data. In this instance, the slope post-PMP changed sharply upwards. Consequently, if the PMP influenced this variable, it did so in a manner that was inconsistent with the objectives of the Program.

Table 6.2

Simple Linear Regression Results
Total Prescriptions and Drug Class Dose Equivalent of PMP Monitored Drugs Dispensed*

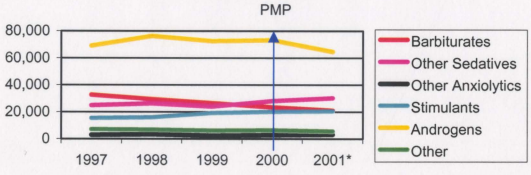
	Dependent Variable	Independent Variable	R Square	Estimated Slope of Regression Line	*p* Value
1.	Total Rx of benzodiazepines (Figure 6.3)	Year	0.757	-17,330.7	0.055
2.	Total Rx of analgesics (Figure 6.3)	Year	0.879	-15,657.1	0.019
3.	Rx of benzo-diazepines per capita	Year	0.644	-2.700×10^{-2}	0.102
4.	Rx of analgesics per capita	Year	0.809	-2.400×10^{-2}	0.038
5.	Benzodiazepine drug class dose equivalent (Figure 6.4)	Year	0.636	-893,959.2	0.106
6.	Analgesic drug class dose equivalent (Figure 6.5)	Year	0.011	9,643.5	0.868
7.	Benzodiazepine drug class dose equivalent per capita	Year	0.417	-1.215	0.239
8.	Analgesic drug class dose equivalent per capita	Year	0.140	6.500×10^{-2}	0.535

* Using IMS Health, Canada data.

Total prescribing for other categories of drugs included in the PMP was relatively small compared with narcotics and benzodiazepines (Figure 6.6). Except for androgens, the total number of prescriptions was below 35,000 annually for each category over the entire time period. There was a gradual decline in the number of scripts for barbiturates over the study period. A number of other sedatives and some stimulants showed a slight

increase over the period of the study. Only the volume of androgens prescribed decreased from 73,055 in 2000 to 64,442 (-11.8%) specifically in 2001 corresponding with the introduction of the PMP in 2000.

Figure 6.6
Total Prescriptions Dispensed
Other PMP Monitored Drugs
Newfoundland and Labrador
1997 to 2001



Source: IMS Health, Canada
* Projected based on January-October

Table 6.3 outlines the additional drugs included in the PMP by Category.

Table 6.3

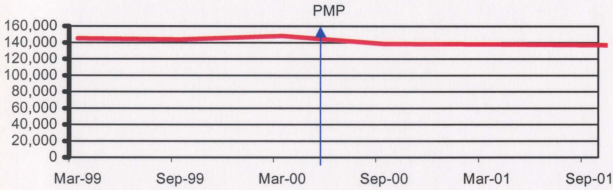
Additional Drugs* Included in the PMP by Category

Barbiturates	Other Sedatives	Other Anxiolytic	Stimulants	Androgens	Other
Amobarbital	Chloral Hydrate	Buspirone	Dextroamphetami	Fluozymesterone	Diphenoxylate
Pentobarbital	Ethchlorvynol		Diethylproplon	Methyltestoster	Homatropine
Phenobarbital	Zopiclone		Mazindol	Nandrolone	Naltrexone
Secobarbital			Methylphenidate	Testosterone	Primidone
Butabarbital			Modafinil	Testosterone Ben	Theophylline
Butalbital			Pemoline		
			Phentermine		
			P-Hydroxyephedri		

* Other than analgesics and benzodiazepines.

Total NLPDP prescriptions of PMP monitored drugs over six-month periods decreased slightly from 144,842 to 135,571 (-6.4%) between March 1999 and September 2001 (Figure 6.7). There was also a slight reduction from 147,938 to 138,624 (-6.3%) between the six-month period ending March 2000 and September 2000. This offset a slight increase in the six-month period immediately preceding March 2000.

Figure 6.7
NLPDP Prescriptions of PMP Monitored Drugs
Each six months
March 1999 to September 2001



Source: NLPDP

The estimated slope of the regression line was small for each analysis (relative to the scale on the vertical axis) and the confidence interval for the estimate included zero when the analysis was undertaken on a per eligible beneficiary basis (Table 6.4). Again, the small number of data points limited the interpretability of the regression analysis. However, the positive estimated slope of the NLPDP prescriptions of PMP monitored drugs per eligible beneficiary analysis was inconsistent with the objectives of the Program. As well, a low R square value for this variable indicated that a single straight line did not closely fit the data. However, a review of the individual data points

suggested that one slightly elevated data point prior to the introduction of the Program (March 2000) may have contributed to this result. Overall, the per eligible beneficiary rate varied by a maximum of 4.3% over the entire time period.

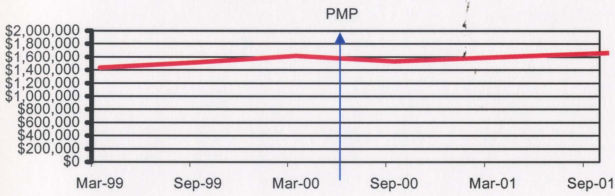
Table 6.4

Simple Linear Regression Results
NLPDP Prescriptions of PMP Monitored Drugs Dispensed

	Dependent Variable	Independent Variable	R Square	Estimated Slope of Regression Line	*p Value*
1.	NLPDP Rx of PMP monitored drugs (Figure 6.7)	Time	0.661	-2,046.886	0.049
2.	NLPDP Rx of PMP monitored drugs per eligible beneficiary	Time	0.198	5.143×10^{-3}	0.376

Total NLPDP expenditures on PMP-monitored drugs increased steadily from $1,434,571 to $1,766,617 (+23.2%) from the six-month period ending March 1999 to September 2001 (Figure 6.8). There was a slight decline in expenditure between March 2000 and September 2000. While no detailed cost analysis was undertaken, a variety of factors such as price effects, volume effects, entry of new drugs, exiting drugs may contribute to the expenditure increases.[182] However, I concur with NLPDP program administrators who indicated that the increases in expenditure corresponded with periodic increases in the pharmacy-dispensing fee.

Figure 6.8
NLPDP Expenditures on PMP Monitored Drugs
Each six months
March 1999 to September 2001

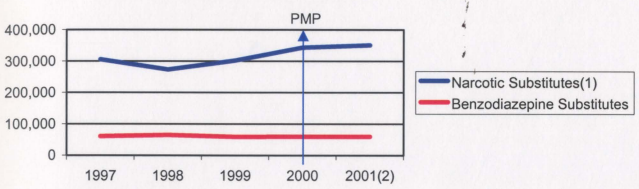


Source: NLPDP

6.2.2 Prescriptions of Substitute Medications

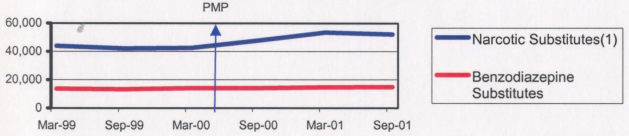
Total prescribing of benzodiazepine substitute medications as reported by IMS Health, Canada was relatively static from 1997 to 2001 and averaged approximately 60,655 prescriptions per year (Figure 6.9). Total prescribing of narcotic substitutes had increased since 1999. However, the increase was attributed to the introduction of new COX-2 selective inhibitors. NLPDP data showed similar trends as the IMS Health, Canada data for both benzodiazepine and narcotic substitutes (Figure 6.10).

Figure 6.9
PMP Substitute Drugs Dispensed
Newfoundland and Labrador
1997 to 2001



Source: IMS Health, Canada
(1) Includes COX-2 selective inhibitors introduced in 1999
(2) Projected based on January to October

Figure 6.10
NLPDP Prescriptions of PMP Substitute Drugs
Each six months
March 1999 to September 2001



Source: NLPDP
(1) Introduction of COX-2 selective inhibitors beginning in September 1999.

Using IMS Health, Canada data, the estimated slope of the regression line for the benzodiazepine substitute drugs dispensed analysis (and corresponding per capita estimate) had a negative slope that was opposite to what might have been expected (Table 6.5). As well, the R square value was low. However, a review of the individual

data points indicated only a 1.4% drop in total benzodiazepine substitute prescribing over the time series. There was a negligible drop in the corresponding per capita rate.

Table 6.5

Simple Linear Regression Results
PMP Substitute Drugs Dispensed*

	Dependent Variable	Independent Variable	R Square	Estimated Slope of Regression Line	*p* Value
1.	Benzodiazepine substitute drugs dispensed. (Figure 6.9)	Time	0.227	-708.5	0.418
2.	Analgesic substitute drugs dispensed. (Figure 6.9)	Time	0.632	16,016.8	0.108
3.	Benzodiazepine substitute drugs dispensed per capita.	Time	0.125	-1.0×10^{-3}	0.559
4.	Analgesic substitute drugs dispensed per capita.	Time	0.733	3.6×10^{-2}	0.064

* Using IMS Health, Canada data.

The estimated slopes of the regression lines for the NLPDP benzodiazepine and analgesic substitute drugs dispensed analysis (and corresponding per eligible beneficiary estimate) had positive slopes consistent with what would be expected (Table 6.6). As well, the R square values were high indicating that a straight line fits these data relatively well. However, as discussed, the increase in the number of analgesic substitute prescriptions (beginning prior to the introduction of the PMP) was attributed to the introduction of COX-2 selective inhibitors. It was also noted that the estimated slope of

the NLPDP benzodiazepine substitute regression line was statistically significant; however, it was very small in relation to the scale on the vertical axis. The small number of data points limited the interpretability of the analysis.

Table 6.6

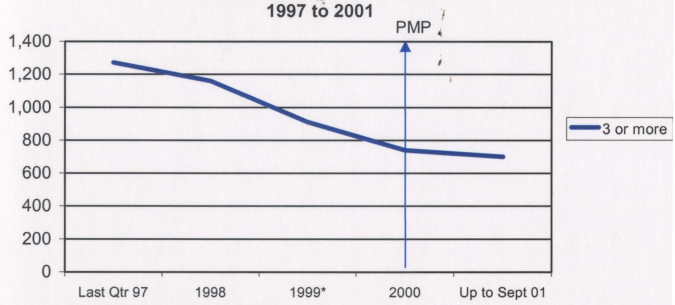
Simple Linear Regression Results
NLPDP Prescriptions of PMP Substitute Drugs Dispensed

	Dependent Variable	Independent Variable	R Square	Estimated Slope of Regression Line	*p* Value
1.	NLPDP Rx of benzodiazepine substitutes (Figure 6.10)	Time	0.862	276.914	0.007
2.	NLPDP Rx of analgesic substitutes (Figure 6.10)	Time	0.751	2,291.029	0.025
3.	NLPDP Rx of benzodiazepine substitutes per eligible beneficiary	Time	0.914	4.571×10^{-3}	0.003
4.	NLPDP Rx of analgesic substitutes per eligible beneficiary	Time	0.814	3.0×10^{-2}	0.014

6.2.3 Multiple Doctoring

The average number of individuals who visited three or more general practitioners ("GPs") and/or emergency room ("ER") physicians per month decreased steadily from 1,271 in the last quarter of 1997 to 698 (-45.1%) in 2001 as measured up to September 2001 (Figure 6.11).

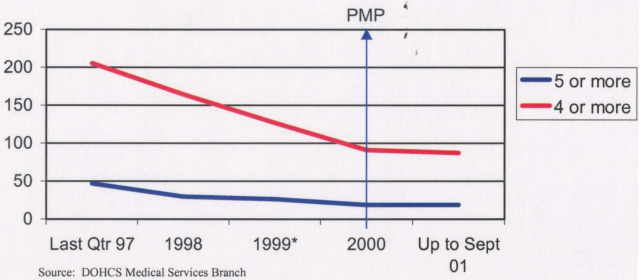
Figure 6.11
Average Number of Patients Visiting Multiple Fee-for-service GPs and ER Physicians per month Newfoundland and Labrador 1997 to 2001



Source: DOHCS Medical Services Branch
* May 1999 – Introduction of Block Funding Program

The average number of individuals who visited four or more GPs showed a similar decline from 205 to 87 (-57.6%) between 1997 and 2001 (Figure 6.12). The comparable reduction for those visiting five or more GPs was from 46.5 to 18.6 (-60%) over the period 1997 to 2001. Thus, the greatest reductions were seen in those visiting the greatest number of physicians. From 1997 to 2001, MCP staff also corresponded with patients and physicians who appeared to be grossly overusing insured medical services based on fee-for-service claim data. Such policy initiatives are discussed further in Section 6.4.2.

Figure 6.12
Average Number of Patients Visiting Multiple Fee-for-service GPs and ER Physicians per month
Newfoundland and Labrador
1997 to 2001



Source: DOHCS Medical Services Branch
* May 1999 – Introduction of Block Funding Program

The rate of reduction of all three multiple doctoring indicators decreased only slightly during the final year of comparison suggesting no specific impact of the PMP on this indicator.

The slopes of the regression lines for all of the analyses summarized in Table 6.7 have negative coefficients indicating that the conditions influencing these variables had improved over time. The high R square values indicated that a straight line fits these data well and that it was unlikely that the introduction of the PMP significantly influenced the pre-existing trend.

Table 6.7

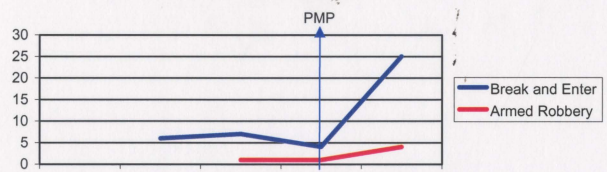
Simple Linear Regression Results
Patients Visiting Multiple GPs

	Dependent Variable	Independent Variable	R Square	Estimated Slope of Regression Line	*p* Value
1.	Average number of patients visiting three or more GPs/month (Figure 6.11)	Time	0.957	-156.6	0.004
2.	Average number of patients visiting four or more GPs/month (Figure 6.12)	Time	0.950	-30.96	0.005
3.	Average number of patients visiting five or more GPs/month (Figure 6.12)	Time	0.846	-6.63	0.027

6.2.4 Theft of PMP Monitored Drugs

No data was available on the number of armed robberies at local pharmacies involving theft of PMP monitored drugs prior to 1999. One armed robbery was recorded each year from 1999 to 2000, increasing to four in 2001 (Figure 6.13). The number of break and enters was six in 1998 and seven in 1999. These decreased to four in 2000, but increased dramatically to twenty-five in 2001. The specific cause was unknown, but the trend was compatible with increased difficulty in obtaining monitored drugs from physicians. The large increase in 2001 corresponded in time to when an effect of the PMP might have been expected.

Figure 6.13
Break and Enter/Armed Robberies at
St. John's Area Pharmacies
1997 to 2001



Source: NPA, RNC

6.2.5 Appropriateness of Prescribing of PMP Monitored Drugs

The appropriateness surveys were time consuming and administratively cumbersome to undertake due to a lack of participation of stakeholders (following consultation) and scheduling difficulties. Unfortunately, pharmacists employed by some large drugstore chains did not participate in the baseline surveys because changes to their governing legislation were not in place or because their employer disapproved of their participation. However, the majority of the independent pharmacies randomly selected did participate. Consequently, the sample of pharmacies included a disproportionate share of independent pharmacies. Approximately 39 (75%) of physicians contacted agreed to participate in the initial baseline appropriateness survey. One physician who prescribed a significant proportion of the sample of monitored drug prescriptions was not

contacted because it was assumed he would not participate based on past hostile responses to MCP audits.

Unfortunately, due to scheduling problems, the entire physician panel for the baseline surveys was not able to meet simultaneously. Consequently, it was agreed that the cases be reviewed by the available physicians and any difficult or indeterminate cases would be referred to the absent members for their opinion. The remaining panel members deemed that only three narcotic cases required this consideration.

The initial narcotic panel met on May 10, 2000 (Table 6.8). They reviewed 42 data extraction forms. The panel decided that 15 (35.7%) were appropriate while 27 (64.3%) were potentially inappropriate. The potentially inappropriate prescriptions were further categorized as: dependency present and no other treatment provided 12 (44.4%); unclear diagnosis 5 (18.5%); no indication 8 (29.6%); multiple opioids 1 (3.7%); and unclear diagnosis and no indication 1 (3.7%).

Table 6.8

Appropriateness of Narcotic Prescriptions

	Pre-PMP		Post-PMP
	Panel 1 (n = 42)	**Panel 2 (n = 42)**	**Panel 2 (n = 52)**
Appropriate	15 (35.7%)	23 (55%)	38 (73.1%)
Potentially inappropriate	27 (64.3%)	19 (45%)	14 (26.9%)
Reasons for potential inappropriateness			
Dependency present and no other treatment provided	12 (44.4%)	1 (5.3%)	2 (14.3%)
Unclear diagnosis	5 (18.5%)	2 (10.5%)	-
No indication	8 (29.6%)	4 (21.1%)	3 (21.4%)
Multiple opioids	1 (3.7%)	-	1 (7.1%)
Wrong dose and/or duration	-	4 (21.1%)	4 (28.6%)
Multiple reasons	1 (3.7%)	8 (42.1%)	4 (28.6%)

Level of agreement beyond chance between the two pre-PMP panels assessing same cases, Kappa = 0.536 (moderate).
Proportion of potentially inappropriateness decreased by 0.18 from 0.45 prior to PMP to 0.27 after PMP.
Chi squared = 2.6643 (p = 0.1026; C.I.: -0.01 to 0.38)

The initial benzodiazepine panel met on June 6, 2000 (Table 6.9). They reviewed 61 data extraction forms. They deemed that 20 (33%) were clinically appropriate while 41 (67%) were potentially inappropriate. The potentially inappropriate prescriptions were further subdivided into the following categories: dependency present and no other treatment provided 9 (22.0%); unclear diagnosis 4 (9.8%); no indication 11 (26.8%); wrong dose and/or duration 6 (14.6%); no indication and wrong dose and/or duration 2 (4.9%); unclear diagnosis and no indication 1 (2.4%); dependency present and no other treatment provided and unclear diagnosis 2 (4.9%); dependency present and no other

treatment provided and multiple sedatives 5 (12.2%); and multiple sedatives and wrong dose and/or duration 1 (2.4%).

Table 6.9

Appropriateness of Benzodiazepine Prescriptions

	Pre-PMP			Post-PMP
	Panel 1 (n = 61)	**Panel 2 (n = 61)**	**Panel 3 (n = 61)**	**Panel 3 (n = 69)**
Appropriate	20 (33%)	56 (92%)	38 (62%)	48 (69.6%)
Potentially inappropriate	41 (67%)	5 (8%)	23 (38%)	21 (30.4%)
Reasons for potential inappropriateness				
Dependency present and no other treatment provided	9 (22%)	-	5 (21.7%)	8 (38.1%)
Unclear diagnosis	4 (9.8%)	1 (20%)	3 (13%)	1 (4.8%)
No indication	11 (26.8%)	-	3 (13%)	-
Multiple sedatives	-	1 (20%)	2 (8.7%)	-
Wrong dose and/or duration	6 (14.6%)	1 (20%)	5 (21.7%)	6 (28.6%)
Multiple reasons	11 (26.8%)	2 (40%)	5 (21.7%)	6 (28.6%)

Level of agreement beyond chance between the three pre-PMP panels assessing the same cases, Kappa = Panel 1 and 2, 0.083 (slight); Panel 2 and 3, 0.092 (slight); and, Panel 1 and 3, 0.395 (fair).
Proportion of potential inappropriateness decreased by 0.07 from 0.38 prior to the PMP to 0.30 after the PMP.
Chi squared = 0.4741 (p = 0.4911; C.I.: -0.10 to 0.24)

The research team met with officials of the NMB, NLMA and the DOHCS on September 7, 2000 to discuss the results of the initial panel surveys. Due to the extent of the potentially inappropriate prescribing as determined by these panels, the stakeholders requested that two additional independent panels be established to review the identical

cases. The membership of these panels was based on the recommendation of the stakeholder groups.

The second baseline narcotic panel met on October 10, 2000 (Table 6.8). They reviewed the same 42 cases as the first narcotic panel. They decided that 23 (55%) were appropriate while 19 (45%) were potentially inappropriate. The potentially inappropriate prescriptions were further categorized as: dependency present and no other treatment provided 1 (5.3%); unclear diagnosis 2 (10.5%); no indication 4 (21.1%); wrong dose and/or duration 4 (21.1%); no indication and wrong dose and/or duration 2 (10.5%); unclear diagnosis and wrong dose and/or duration 3 (15.8%); dependency present and no other treatment provided and no indication and wrong dose and/or duration 1 (5.3%); unclear diagnosis and multiple opioids 1 (5.3%); and no indication and multiple opioids 1 (5.3%).

The second baseline benzodiazepine panel met on October 16, 2000 (Table 6.9). This panel reviewed the same 61 benzodiazepine cases as the first panel. They decided that 56 (92%) of the benzodiazepine prescriptions were appropriate while 5 (8%) were potentially inappropriate. The potentially inappropriate prescriptions were further described as: unclear diagnosis 1 (20%); multiple sedatives 1 (20%); wrong dose and/or duration 1 (20%); unclear diagnosis and no indication 1 (20%); and dependency present and no other treatment provided and no indication and multiple sedatives and wrong dose and/or duration 1 (20%).

It was subsequently proposed that the two panels in each category meet to further discuss those cases on which they disagreed. Unfortunately, the psychiatrist participating on the first benzodiazepine panel became ill and was unable to continue this research. Consequently, she was replaced with another psychiatrist and the revised panel reviewed the entire 61 benzodiazepine cases for the third time. Again, due to scheduling problems the two panels were unable to meet to discuss cases of disagreement.

The third baseline benzodiazepine panel met on May 1, 2001 (Table 6.9). This panel reviewed the same 61 benzodiazepine cases as the first and second panels. They decided that 38 (62%) of the benzodiazepines prescriptions were appropriate while 23 (38%) were potentially inappropriate. The potentially inappropriate prescriptions were further described as: dependency present and no other treatment provided 5 (21.7%); unclear diagnosis 3 (13%); no indication 3 (13%); multiple sedatives 2 (8.7%); wrong dose and/or duration 5 (21.7%); dependency present and no other treatment provided and unclear diagnosis 1 (4.3%); dependency present and no other treatment provided and incorrect dose and/or duration 1 (4.3%); dependency present and no other treatment provided and multiple sedatives 2 (8.7%); and unclear diagnosis and incorrect dose and/or duration 1 (4.3%).

In an effort to expedite data collection for the post-PMP appropriateness survey, the NMB was requested in May 2001 to permit PMP officials to provide to researchers the names of patients (and prescribing physicians) who received monitored drugs on randomly

chosen days. This would have avoided the involvement of and follow-up with dozens of pharmacies. Unfortunately, the request was declined because the NMB's legal opinion suggested that legislation governing the Program did not specify that the information be used specifically for this purpose. Furthermore, the NMB did not want to risk the potential negative reaction from a minority of pharmacists who were non-compliant with the PMP.

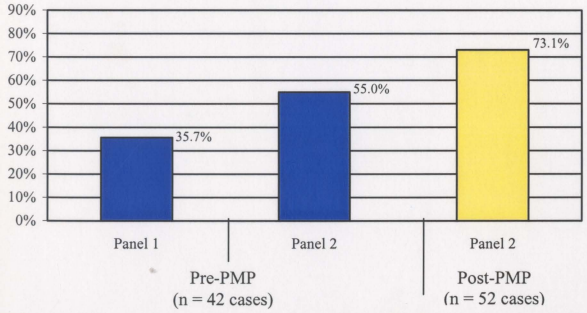
Eleven independent pharmacies and seven pharmacies of a major chain of pharmacies were requested to participate in the post-PMP appropriateness surveys. These were the remaining pharmacies that had not participated in the pre-PMP appropriateness survey and were expected not to be hostile to the Program or the evaluation. The head office of the major chain had since approved of their associates participating in the post-evaluation as revised legislation was in place (since the pre-PMP survey). They requested that their associates' participation be voluntary and remunerated. Seven of the eleven independent pharmacies and four of the seven associate pharmacies agreed to participate. Fifty-eight (54.7%) of the 106 physicians identified by pharmacy records participated.

A psychiatrist who was recommended by the medical stakeholder groups participated on the panel to assess benzodiazepine prescriptions prior to the PMP implementation. However, following repeated attempts, researchers were unable to contact him for participation on the panel to assess post-PMP benzodiazepine prescriptions. Consequently, the post analysis was limited to two of the original five panels that assessed the baseline information. As well, the post-PMP panels sub-

categorized some of the cases deemed potentially inappropriate differently from the baseline analysis.

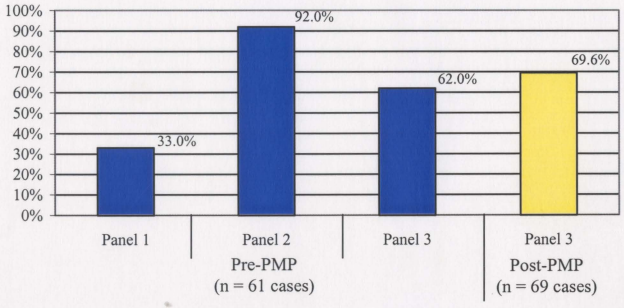
The post-PMP narcotic panel met on March 1, 2002 and jointly reviewed 47 data extraction forms (Table 6.8). Six additional cases were reviewed individually by panel members in the following weeks. One of the 53 cases contained insufficient information to assess appropriateness. The panel decided that 38 (73.1%) of the 52 prescriptions were appropriate and 14 (26.9%) were potentially inappropriate (Figure 6.14). The potentially inappropriate prescriptions were further categorized as: dependency present and no other treatment provided 2 (14.3%); lack of indication 3 (21.4%); multiple opioids 1 (7.1%); wrong dose and/or duration 4 (28.6%); dependency and no other treatment provided and lack of indication 2 (14.3%); lack of indication and wrong dose and/or duration 1 (7.1%); and lack of indication and multiple opioids 1 (7.1%).

Figure 6.14
Proportion of Narcotic Prescriptions Assessed as Appropriate



The post-PMP benzodiazepine panel met on April 9, 2002 (Table 6.9). They reviewed 70 data extraction forms, but one was found to have insufficient information to assess appropriateness. The panel determined that 48 (69.6%) were clinically appropriate while 21 (30.4%) were potentially inappropriate (Figure 6.15). The potentially inappropriate prescriptions were further subdivided into the following categories: dependency present and no other treatment provided 8 (38.1%); unclear diagnosis 1 (4.8%); incorrect dose and/or duration 6 (28.6%); no indication and incorrect dose and/or duration 2 (9.5%); dependency and no other treatment provided and no indication and multiple sedatives 1 (4.8%); dependency present and no other treatment provided, and unclear diagnosis, and no indication and multiple sedatives, and incorrect dose and/or duration 2 (9.5%); and unclear diagnosis and no indication and incorrect dose and/or duration 1 (4.8%).

Figure 6.15
Proportion of Benzodiazepine Prescriptions Assessed as Appropriate



The three independent pre-PMP benzodiazepine panel cases were then re-categorized as either appropriate or potentially inappropriate and assessed for the potential level of agreement beyond chance using a Kappa statistic. A similar process was used for the two pre-PMP narcotic panels.

The calculated Kappa statistics between the three independent pre-PMP benzodiazepine panels were 0.083 (Panel 1 and 2), 0.092 (Panel 2 and 3) and 0.395 (Panel 1 and 3). Sackett described the first two Kappa results as indicating a "slight" level of agreement beyond that expected by chance and the latter as a "fair" level of agreement beyond that expected by chance.[179] The corresponding Kappa statistic between the two pre-PMP narcotic panels was 0.536. Sackett described this level of agreement beyond that expected by chance as "moderate."

The proportion of benzodiazepine prescriptions deemed potentially inappropriate by the same panels on a pre/post basis reduced by 0.07 from 0.38 prior to the PMP to 0.30 following the Program. The Chi squared was calculated to be 0.4741 ($p = 0.4911$; C.I.: -0.10 to 0.24). Consequently, there was a non-statistical difference between the proportion of benzodiazepine cases assessed as potentially inappropriate before and after the PMP.

Similarly, the proportion of narcotic prescriptions deemed potentially inappropriate by the same panels on a pre/post basis reduced by 0.18 from 0.45 prior to

the PMP to 0.27 following the Program. The Chi squared statistic was calculated to be 2.6643 ($p = 0.1026$; C.I.: -0.01 to 0.38). As well, there was a non-statistical difference between the proportion of narcotic prescriptions assessed as potentially inappropriate prior to and following the PMP.

6.2.6 Appropriateness of PMP Monitored Drug Discontinuation

There was a ten-month delay between the introduction of the PMP and the commissioning of the discontinuation survey. The rationale for this time lag is discussed in Section 6.4.6.

To improve the efficiency of accessing data for the discontinuation survey, researchers contacted the same pharmacies that had consented to participate in the pre-appropriateness survey (because they were known to be supportive of this research) and those under consideration for the post-appropriateness survey (to permit data collection for two surveys simultaneously). This exhausted the available pharmacies in the St John's area that would potentially participate in this component of the research. To increase the sample size, all 17 pharmacies in the Conception Bay North area were also invited to participate. Overall, 30 of 50 pharmacies (60.0%) contacted participated in the discontinuation survey.

NLPDP officials identified 256 patients from the 30 participating pharmacies who met the criteria for this survey (Table 6.10). These patient's names were provided to the respective participating pharmacists. Of these, 92 patients (35.9%) consented to participate and 164 (64.1%) were excluded because: the patient declined 34 (20.7%); the patient was deceased 33 (20.1%); the patient was a resident of a nursing home 5 (3.0%); the patient moved or changed pharmacies 49 (29.9%); or other 43 (26.2%). The latter category included patients who were subsequently incarcerated, mentally challenged, hard of hearing or whose phone number was no longer in service.

Table 6.10

Summary of Consent Status of Pharmacists and Patients For Discontinuation Survey

Pharmacies contacted	50
Agreed to participate	30 (60%)
Total number of NLPDP beneficiaries meeting discontinuation survey criteria	256
• Agreed to participate (provided consent to pharmacist)	92 (35.9%)
• Excluded	164 (64.1%)
Reasons for excluding	
• Declined	34 (20.7%)
• Deceased	33 (20.1%)
• Resident of nursing home	5 (3.0%)
• Moved or changed pharmacies	49 (29.9%)
• Other	43 (26.2%)

Of the 92 patients who consented to participate to their pharmacist, the research physician was unable to obtain data regarding 12 (13.0%) (Table 6.11). In some

instances, the patient withdrew their consent while most non-participants did not respond to repeated attempts by the research physician to reach them.

Table 6.11

Summary of Demographic and Baseline Characteristics for Discontinuation Survey Patients

Patients providing consent to pharmacist	92
Patient confirming consent with research physician and data provided	80
Sex	
• Male	28 (35%)
• Female	52 (65%)
Age	
• 20-45	30 (37.5%)
• 46-64	36 (45.0%)
• 65+	13 (16.3%)
• Age unavailable	1 (1.3%)
Receiving multiple narcotics and benzodiazepines	36 (45%)
Receiving single or multiple prescriptions for benzodiazepines only	24 (30%)
Receiving narcotics only	19 (23.8%)
Ritalin (methylphenidate) only	1 (1.3%)

Overall, data was collected regarding 80 patients (Table 6.11). The majority were females 52 (65.0%) compared to males 28 (35.0%). They were mostly in the middle age group (46-64 years) 36 (45.0%) compared to young adults (20-45 years) 30 (37.5%) and seniors (65 years and older) 13 (16.3%). One patient's age was not included on the data extraction form and was not available from the NLPDP database.

Thirty-six of the 80 cases (45.0%) involved patients who were receiving multiple narcotics and benzodiazepines concurrently prior to the introduction of the PMP

(Table 6.11). A further 24 (30.0%) cases were receiving singular or multiple prescriptions for benzodiazepines only, while 19 (23.8%) were receiving narcotics only. One patient's long-standing prescription for Ritalin (methylphenidate) was discontinued following the introduction of the Program.

The completed data extraction forms were reviewed and evaluated by a Professor of Medicine. He had overseen but did not participate on the panels assessing the appropriateness of prescriptions. Upon a preliminary review of approximately a dozen data extraction forms, the physician evaluator determined that many lacked the necessary information for a thorough clinical assessment. Consequently, he decided that each case should be assessed for any obvious reported evidence of: (1) adverse consequences of the discontinuation; (2) a complete discontinuation of a drug class (e.g. all benzodiazepines, all narcotics); and (3) appropriateness of the discontinuation. For the latter category, the discontinuation was deemed appropriate if there was no ongoing medical indication and/or preferred alternative treatment was given. The limitations of this methodology, particularly those related to not contacting the prescribing physician, are described in detail in Section 6.4.6.

In 5 (6.3%) cases, there was insufficient information for the physician evaluator to make a determination with respect to adverse clinical consequences of the discontinuation (Table 6.12). However, he determined that 60 (80.0%) of the remaining 75 cases demonstrated no evidence of any adverse clinical consequences of the

discontinuation. The remaining 15 (20.0%) cases did demonstrate evidence of some adverse clinical consequences associated with the discontinuation.

Table 6.12

Results of Discontinuation Survey

Evidence of Adverse Consequences Following Discontinuation	n = 80
Cases with sufficient information for assessment	75 (93.8%)
• Yes	15 (20%)
• No	60 (80%)
Evidence of Complete Discontinuation of a Drug Class	n = 80
Cases with sufficient information for assessment	50 (62.5%)
• Yes	25 (50%)
• No	25 (50%)
Appropriateness of Discontinuation	n = 80
Cases with sufficient information for assessment	49 (61.3%)
• Appropriate	48 (98%)
• Potentially inappropriate	1 (2%)

For 30 (37.5%) of the 80 cases, the physician evaluator was unable to determine if there was complete discontinuation of a drug class based on the information provided (Table 6.12). For the remaining 50 cases, he determined that half, or 25, showed evidence of a complete discontinuation of a drug class while the remaining half did not.

Thirty-one (38.8%) of the total 80 cases could not be assessed for appropriateness of discontinuation because the data extraction forms contained insufficient clinical information (Table 6.12). However, the physician evaluator determined that 48 (98.0%)

of the 49 remaining cases demonstrated clinical evidence of appropriate discontinuation of the PMP monitored drug(s). Only 1 (2.0%) case demonstrated evidence of a potentially inappropriate discontinuation.

6.3 ANALYSIS OF INFORMATION PROVIDED BY THE PRESCRIPTION MONITORING PROGRAM

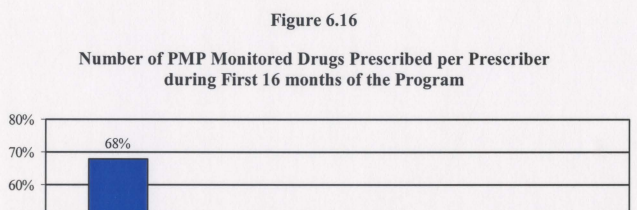
A report prepared by PMP staff[161] indicated that during the first 16 months of the Program approximately 2,200 letters were issued to physicians regarding approximately 850 individuals. Some were receiving PMP monitored drugs from several physicians, in higher than usual amounts or over extended periods of time. The report noted that 91% of patients reduced the number of physicians they visited following alert letters being sent to the respective physicians. By contrast, 9% of patients for whom alert letters were issued showed no reduction or actually increased the number of physicians they visited. Some patients merely switched physicians.

The PMP report indicated that the prescribing of PMP monitored drugs by most physicians was very modest during the first 16 months of the Program (Figure 6.16). Approximately 68% of an estimated 1,061 physicians wrote less than 100 prescriptions for these medications during this initial time period. However, 2% of physicians wrote in excess of 2,500 prescriptions, while eight physicians (1%) wrote in excess of 5,000 during this initial time period. The high prescribers were community-based general practitioners with an unlikely clinical rationale for these prescribing patterns. For

example, one would expect palliative care specialists (including general practitioners who provide palliative care services) and psychiatrists to possibly have a higher proportion of patients with clinical needs for these medications while their overall patient volume may be low. The PMP report also noted that oncologists and other specialists accounted for only 17% of all prescriptions for PMP monitored drugs.[161]

Figure 6.16

Number of PMP Monitored Drugs Prescribed per Prescriber during First 16 months of the Program



Source: PMP Report[161]

Additional information in the PMP report suggested that high rates of prescribing might be directed to specific patients. For example, 1% of physicians received alert letters on eleven or more patients and 1% of physicians received explain letters regarding eleven or more patients.[161] Although possible, additional analysis was not reported by the PMP on whether a small cluster of patients received frequent prescriptions for monitored drugs from a small cluster of physicians and had them dispensed at a small

cluster of pharmacies. Such a pattern would also have led to a cluster of "alert" and "explain" letters, the response to which could be judged from PMP data. The PMP report indicated that lack of data completeness limited the ability to perform in-depth statistical analysis. However, for the above analysis, the bias would be to underestimate the scope of the problem and thus would not lead to any patient or prescriber being unfairly targeted for further scrutiny. My research supervisor and I requested that such analysis be done, as the results would clearly identify whether the system of "alert" and "explain" letters had any impact on a potential "hard-core" of physicians and patients potentially involved in abuse of monitored drugs. As indicated in the PMP report, such a pattern would demand a more thorough and focused investigation of both prescriber and patient behaviour to determine the cause of the problem and the appropriate solution. This analysis could not be done externally by this researcher, as there was no access to patient or physician specific data even using anonymous non-identifying data.

6.4 DISCUSSION AND INTERPRETATION

6.4.1 Prescriptions of PMP Monitored and Substitute Medications

There is limited empirical evidence regarding the effectiveness of PMPs in other jurisdictions. However, the available evidence suggests that such programs should lead to an immediate and significant reduction in the prescribing of program-included drugs ranging from 30% to 60%.[94,146] Studies that tracked substitute drugs suggested there

should also be a noticeable increase in the prescribing of these medications. The data reported in this analysis indicated that the Newfoundland and Labrador PMP did not significantly influence the overall prescribing of Program monitored drugs or identified substitutes. The increase in prescriptions for narcotic substitutes beginning in 1999 was attributed to the introduction of new COX-2 selective inhibitors. These COX-2 selective inhibitors were only permitted under open access policy for seniors (under the NLPDP) in September 2000. There was a corresponding increase in NLPDP narcotic substitute prescriptions at that point. In retrospect, this research could have been strengthened by undertaking inter-provincial and national comparisons of the prescribing trends for both PMP monitored and substitute medications.

Claims that the PMP may have impacted the incidence of multiple doctoring were also not supported by the evidence, which rather suggested that factors external to the PMP had been responsible for a substantial decline in this problem over a period beginning long before the introduction of the PMP.

IMS Health, Canada data indicated that from 1997 to 2001 there was a continuous reduction in the prescribing of benzodiazepines and analgesics in Newfoundland and Labrador of approximately 20% and 22% respectively over the four-year period. A proportion of this reduction may be due to a 4.9% decrease in the provincial population over that time. Since the population decline was not distributed evenly across all age and sex categories, the analysis was further limited by not comparing age/sex standardized

rates over time. IMS Health, Canada had provided data for only the first ten months of 2001 and researchers projected these estimates for the year 2001. However, this was not expected to significantly influence the results.

The data indicated that the total analgesic-equivalent prescribed in Newfoundland and Labrador in 2001 was the highest over the entire study period despite a reduction in the number of prescriptions since 1997. There was a 35% increase in the average quantity of analgesic per prescription between 1997 and 2001. There were two plausible explanations for this. The NMB suggested that this might be attributed to increased marketing efforts by a limited number of pharmaceutical manufacturers to convince physicians to increase their prescribing for non-malignant pain. Alternatively, physicians may have increased the quantity of analgesic per prescription because they perceived that the PMP was monitoring the frequency of prescribing. NLPDP officials also advised that there were no changes in the average number of days supplied approved on patient co-payments.

In retrospect, a comparison of the prescribing trends of monitored drugs and substitute medications in relation to those of other provinces (including those with and without a PMP) and the country, generally, would have been preferred. This would have provided an indication of the potential impact of the Newfoundland and Labrador PMP compared to overall prescribing trends of these medications.

6.4.2 Potential Confounding Interventions

The continuous reduction in prescribing from 1997 to 2001 may have been due to alternate interventions prior to the introduction of the PMP. Interviews with officials of local stakeholder groups such as the RNC, MCP, NLPDP and NMB were held to determine the extent of any such interventions. Each stakeholder introduced initiatives in the years immediately preceding the PMP that may have contributed to the decline in prescribing of Program-included drugs. MCP frequently corresponded with patients and physicians who appeared to be grossly overusing insured medical services based on fee-for-service claim data. They corresponded with the principal offending physician and patient requesting a written explanation for the level of insured services provided. While there were several levels of thresholds used to initiate these letters, MCP officials claim that this resulted in an immediate reduction in services rendered to individuals who saw multiple general practitioners within short time periods. This MCP initiative continued despite the introduction of the PMP. (Personal communication – Dr. B. Fleming, Assistant Medical Director, DOHCS, January 17, 2002.)

The NLPDP identified claimants who received narcotics and benzodiazepines from two or more pharmacies within a three-month period. When this occurred, the prescribing physicians and respective social worker were provided correspondence advising them of the patient's claim information. The NLPDP then limited reimbursement to one pharmacy. However, patients may have continued to

inappropriately see multiple physicians and pharmacies if they paid for these drugs privately. While NLPDP officials acknowledge that some recipients continued to pay for these medications privately, approximately 200 claimants within each three-month period are restricted to one pharmacy for public reimbursement. The number of restricted recipients has varied by approximately 10% per period while the initiative has been in effect for approximately 15 years. There are approximately ten physicians writing prescriptions for these claimants. This NLPDP initiative also continued uninterrupted despite the introduction of the PMP. (Personal communication – J. Downton, Director of Drug Programs, DOHCS, January 2002.)

NLPDP officials also corresponded with the NMB to express general concerns with the prescribing patterns of a select group of physicians. Approximately six physicians have been reported over the past decade. The NMB advised that they initiated three separate disciplinary proceedings against three physicians immediately prior to 1997. All three physicians agreed to restrict their prescribing to avert potential disciplinary action. Consequently, the NLPDP/NMB's actions just prior to 1997 may have contributed to the decline in subsequent prescribing. (Personal communication – Dr. R. Young, Registrar, NMB, January 11, 2002.)

The NMB periodically received unsolicited phone calls regarding patients who may have been inappropriately receiving narcotics and benzodiazepines. Many of these calls were from relatives of the suspected abuser who refused to identify themselves. The

Board was reluctant, in most instances, to contact the identified physician because of the potential frivolous circumstances of the complaint. In instances where the Board contacted the physician, they changed their prescribing patterns. The Board continued to track the prescription rates over a six-month period of a limited number of physicians using NLPDP data records. The quantity of their prescriptions declined and remained at a reduced level over time. The NMB reported that since the PMP had commenced they had not received any calls regarding patients inappropriately receiving narcotics and benzodiazepines. (Personal communication – Dr. R. Young, Registrar, NMB, January 11, 2002.)

The RNC reported that they also initiated specific efforts to reduce double doctoring beginning in 1997. At that time, MCP provided them with information that assisted their criminal investigations against individuals who visited multiple physicians and a select number of physicians who were suspected of indiscriminately prescribing narcotics and benzodiazepines. The police were successful in obtaining criminal convictions against a number of individuals. The RNC complained that they were not being provided with information by the PMP or MCP regarding individuals believed to be involved in criminal activity. The RNC had curtailed their investigative and enforcement efforts in this area when the PMP began because of their expectation that the Program would deal with the issue. (Personal communication – Superintendent R. Shannahan and members of Break and Enter Unit, RNC, January 17, 2002.)

There are limited reasons why patients may visit multiple general practitioners and emergency room physicians within a one-month period. These include varying hours of service by different clinics, location of clinics, potential locum physician replacements, no one physician monitoring the patient's overall care, or potential drug seeking. It is likely that a significant proportion of the patients visiting four or five different general practitioners per month are seeking drugs. Letters from MCP to patients and prescribers would be expected to reduce all categories of overuse.

6.4.3 Multiple Doctoring

The data illustrated a general downward trend in the number of patients visiting multiple GPs and/or ER fee-for-service physicians per month from 1997 to 2001. This trend coincided with the reduction in the quantity of prescribing for narcotics and benzodiazepines, but showed no noticeable change with the introduction of the PMP. During May 1999, MCP initiated a block funding arrangement for general practice/ER services provided at St. John's hospitals. This arrangement does not require these physicians to report individual patient data for payment. Consequently, MCP data was likely to represent an even greater underestimate of actual patient visits from this period onward.

6.4.4 Theft of PMP Monitored Drugs

The theft of PMP monitored drugs by break and enters from St. John's area pharmacies increased substantially in the year following the introduction of the PMP. However, due to the relatively low number of cases involved, changes in the incidence of this crime appeared dramatic in percentage terms. The substantial increase suggested that the PMP (or the other confounding interventions discussed above) may have reduced the access to, or was perceived to reduce access to, Program monitored drugs through double doctoring. Alternatively, the RNC advised that while the number of break and enters increased dramatically, many of them might have been committed by the same individuals.

6.4.5 Appropriateness of Prescribing of PMP Monitored Drugs

The Kappa statistics calculated as part of the appropriateness surveys determined that there was only a "slight" or "fair" level of agreement beyond that expected by chance between the various baseline benzodiazepine panels examining the same data. This result may be attributed to multiple factors such as the variation in the characteristics of physicians on the panels and the lack of clinical guidelines for the prescribing of these medications. For some cases, all panels clearly indicated them as appropriate or potentially inappropriate. However, many cases were considered in the "grey" area where there was clearly some discretion on interpreting appropriateness. As expected,

the greater the proportion of cases in the grey area, the less chance of agreement between the evaluators.

The practice characteristics of the physician evaluators and their mode of medical practice differed between the various benzodiazepine panels. The initial benzodiazepine panel included a psychiatrist practising in a psychiatric hospital and having considerable past experience working with patients incarcerated in large federal prisons. This professional appeared to have a very conservative view of the appropriateness of patients receiving long-term low dosages of sedatives. However, practising in such "controlled" settings as psychiatric hospitals and prisons would better enable prescribers to initiate alternative non-prescription therapies compared with prescribers practising in a community setting. Patients in a community setting can seek medications from multiple prescribers. Alternatively, practising in a controlled setting provides a more favourable opportunity for prescribers to gradually withdraw medications over time. With the illness of this physician, another psychiatrist became involved who also provided psychiatric coverage to a local penitentiary along with a general practitioner who practiced in a geriatric/academic setting. Their views on the appropriateness of benzodiazepine prescribing appeared slightly more liberal compared with the original physician evaluator. However, a subsequent panel that included a psychiatrist practicing in a busy fee-for-service community-based setting along with a general practitioner with a similar practice style resulted in a higher ratio of these cases being deemed appropriate. As expected, many of the cases leading to disagreement were those considered in the "grey"

zone. For example, the community-based physicians commented that given the busy nature of their practices and the general acceptance that many of these patients had been functioning normally on low dose sedatives for extended periods, there was no clinical rationale to change their therapy. In evaluating several grey cases, they indicated that while the patient was not given the ideal treatment, it was clinically acceptable.

The lack of published clinical guidelines for appropriate benzodiazepine prescribing may suggest there is a lack of agreement within the medical academic community regarding the appropriateness of prescribing these medications. This would also elevate the proportion of grey cases and, therefore, the likelihood of less agreement between panels. Alternatively, guidelines for narcotic prescribing were readily available from multiple sources. Consequently, as expected, the Kappa statistics indicated a higher level of agreement beyond chance for the narcotic panels compared with the benzodiazepine panels.

The practice characteristics of the physicians participating on the two pre-PMP narcotic panels appeared more similar than between the benzodiazepine panels. This may explain the "moderate" level of agreement beyond chance between the narcotic panels. The initial narcotic panel included a general practitioner practicing in a geriatric/academic setting and a palliative care specialist. Due to scheduling difficulties, the palliative care specialist had limited influence as she reviewed only three cases deemed uncertain by the general practitioner. Both, however, by the nature of their

practices were accustomed to prescribing narcotics for pain management and less likely to encounter patients seeking these medications for street use. The second narcotic panel included a general practitioner with special training and practice in palliative medicine and a senior community-based fee-for-service general practitioner with a practice operating at full capacity. Both of these physicians spoke of the need to adequately prescribe narcotics to appropriately manage a patient's pain and appeared to have philosophical views similar to those of the initial narcotic panel members. Consequently, both panels were more likely to rank the "grey" cases as appropriate.

In addition, for narcotics the availability of alternate treatments and providers (e.g., physiotherapy, occupational therapy) as well as the ability to more clearly determine chronic conditions appear to have made the determination of "appropriateness" more straightforward. Finally, evidence from the data extraction forms that prescribers had gradually increased analgesic dosages implied that the cases were actively being managed and the panels may have been more likely to categorize such cases as appropriate. This likely reduced the proportion of "grey" cases relative to the benzodiazepines, contributing to a greater probability of agreement between the narcotic panels.

The Chi-squared analysis demonstrated a non-statistically significant difference between the proportion of pre-PMP cases deemed potentially inappropriate and the proportion deemed potentially inappropriate following the Program for both

benzodiazepines and narcotics. Due to the low sample size, the confidence interval surrounding the difference between the two proportions was fairly wide ranging to a high of 0.24 for benzodiazepines and 0.38 for narcotics. However, a potential decrease in the proportion of potential inappropriateness of greater than 0.20 could have clinical significance since the baseline measurement was 0.38 and 0.45 for benzodiazepines and narcotics respectively. While the likelihood was remote, in both instances, the upper range of the confidence interval would indicate that the PMP could have had a clinically important impact on reducing the proportion of potentially inappropriate prescribing. Consequently, it was concluded that the sample size was insufficient to exclude the PMP having a positive clinically significant impact on the rate of potentially inappropriate prescribing.

The appropriateness surveys contained various sources of bias that, when combined, likely resulted in an overestimate of the ability of the PMP to reduce potentially inappropriate prescribing. The strongest source of bias may have been related to the sample selection. The sampling of pharmacies was limited in two ways. Firstly, some pharmacies refused to participate. It was suspected that the non-participating pharmacies differed from those that participated which would have influenced the specific physicians who were invited to participate. Secondly, some non-participating pharmacies (in the PMP) participated on the pre-evaluation but, once their opposition to the Program was better organized, they refused to participate in the post aspect of the evaluation. Many of the pharmacists who refused to participate in the post-PMP portion

of the appropriateness surveys were known to be opposed to the PMP and some dispensed much higher volumes of PMP monitored drugs. It would be expected that pharmacists and physicians aware of potentially inappropriate prescribing would be less likely to participate. This would lower the proportion of cases pre and post deemed potentially inappropriate. Further evidence of the non-random nature of the non-participating pharmacies occurred through analysis of the NLPDP database. For example, following the discontinuation of the PMP, the NLPDP database was analyzed to identify the top four prescribers of PMP monitored drugs for further scrutiny by MCP's Audit Division. These high prescribing physicians were all in the same physical building, or in the same small community as pharmacies that had refused to participate in the PMP. This added further evidence to the idea that those pharmacies (and physicians) that declined to participate in the post-PMP evaluation were not representative of the larger population of pharmacies and physicians.

Some of the non-participating PMP pharmacies participated in the pre-PMP appropriateness surveys. As mentioned, once their non-participation became better organized they refused to participate in the post surveys. As well, in the pre-study, their involvement led to some of the highest prescribing community-based physicians (also identified by police) agreeing to participate. However, these pharmacists' lack of participation in the post surveys resulted in disproportionately less prescriptions from high prescribing physicians being sampled. This may have explained why a smaller

proportion of prescriptions in the post surveys were assessed as potentially inappropriate, thus overestimating the true effect of the Program.

It is believed that a measurement bias was also present in the post-PMP panel appropriateness surveys. Almost all of the panel members for both narcotics and benzodiazepines had commented that they believed the PMP was effective in addressing potentially inappropriate access to monitored drugs. They had cited several anecdotal cases of instances where they or their colleagues had been alerted by Program correspondence about patients who were suspected of double doctoring. Since many "grey" cases required considerable debate between panel members, it was conceivable that they may have been more likely to rate those post cases as appropriate whereas previously they may have been considered potentially inappropriate.

Another form of measurement bias related to the consistent, predetermined attitude of panel members towards the prescribing of PMP monitored drugs. The effect of this bias likely marginally underestimated the effect of the PMP on appropriateness of prescribing. Due to the clinical backgrounds of each panel member, they would have a certain predisposition towards prescribing these medications. Certainly, where there were blatant cases of potentially inappropriate prescribing (such as prescribing multiple opioids or sedatives) they would be expected to provide "true" measures. However, many cases fell into "grey" areas where clinical experience would influence their decision to label the case. For example, as previously discussed, the busy, community-

based physicians appeared more accommodating towards providing these medications for those with dependency problems. They commented that there was insufficient time for counseling in relatively short office visits and the patient, if initially refused a prescription, would seek the medication from another prescriber. Consequently, they were more likely to rate the prescribing of conservative levels of a monitored drug to such patients as appropriate. In contrast, those physicians accustomed to prescribing in controlled settings such as geriatric centres and correctional institutions appeared less likely to rank such practices as appropriate. Consequently, the panel members were not independently judging each case on its own merits and would appear to have a consistent predetermined view towards similar cases. This systematic bias (for the grey cases) may have led to the true measurement of the effect of the PMP on the appropriateness of prescribing being underestimated. In essence, the physicians' predetermined attitude towards prescribing for grey cases could result in a greater likelihood of the results displaying a particular pattern independent of the effect of the Program. For the Chi-squared statistic to provide meaningful results, independent random samples that measured appropriateness in an unbiased manner were required. Consequently, the effect of the biases that were outlined could have compromised the assumptions of the statistic and, therefore, its validity.

Finally, bias may have occurred in the collection of clinical information for the appropriateness surveys. The research nurse who collected the clinical information for the pre-PMP appropriateness survey was unavailable for the post survey. She was

replaced with a research physician who subsequently was replaced with another research nurse. Some measurement bias may have resulted since the researcher can influence the manner in which clinical information is collected. However, the magnitude and direction of this potential bias could not be determined.

6.4.6 Appropriateness of PMP Monitored Drug Discontinuation

The discontinuation survey was delayed following the introduction of the PMP because it was anticipated that Government would increase the pharmacists' dispensing fee for prescriptions dispensed under the NLPDP. This would, in turn, increase the proportion of pharmacists who would participate in the Program. The fee increase (from $5.00 to $6.50) was granted in April 2001 and this component of the research commenced shortly afterwards. Based on subsequent discussions with pharmacists, it is believed that the increase in the dispensing fee had a marginal positive impact on their rate of participation. The delay probably negatively contributed to a patient's ability to recall the circumstances surrounding the discontinuation of their medication(s).

The majority of patients identified for potential participation in the discontinuation survey were receiving multiple prescriptions for PMP monitored drugs. As this aspect of the study was being designed, it had been anticipated that the sample would mostly comprise of patients receiving only one PMP monitored drug for an extended period that was abruptly discontinued following the introduction of the

Program. However, because of the multiple prescriptions in place for various time periods, it became difficult to determine from the data which medication(s) (if any) were actually discontinued. Consequently, to test the accuracy of the data set, NLPDP officials manually reviewed approximately seven cases from the computer-generated list of potential participants. They confirmed that at least one of the long-standing PMP monitored medications was indeed discontinued coinciding with the introduction of the PMP (for each case manually reviewed). However, based on a review of patient responses, it became evident that many could not recall the discontinuation. This led researchers to question the ability of patients to accurately recall the circumstances surrounding the discontinuation of their medication(s). However, one might hypothesize that if the discontinuation coincided with adverse health effects for the patient, they would likely have had a better recall rate.

It would appear that some patients' medications were coincidentally discontinued with the introduction of the PMP. While it was not possible to determine how often this happened, it is believed that this occurred since some patients stated that they had initiated the discontinuation themselves because they found the medication(s) ineffective.

The study sample for the discontinuation survey was not representative of the provincial population. It was a subsection of a provincial population that included only patients receiving social assistance or senior citizens who were in receipt of the Old Age Supplement. Consequently, all were low-income recipients. In addition, due to the cut-

off criteria used, they were all receiving at least one PMP monitored drug for a minimum of three consecutive months. Consequently, it was expected that the sample would include a greater proportion of those with dependency/addiction problems than the general population. As expected, participating pharmacists were often familiar with the patients from whom they were asked to seek consent. Some pharmacists disclosed, in general terms, to investigators that many of the patients identified were known to be dependent on their medication(s). It was also anticipated that those patients who may have been obtaining medication(s) for illicit purposes and/or through multiple doctoring would have refused to participate. Consequently, the study sample was expected to include a higher proportion of patients who would have been anticipated to suffer adverse clinical consequences including withdrawal symptoms resulting from the interruption of their medication(s).

However, despite the sample including a disproportionately greater proportion of patients with dependency problems, the evaluator assessed, where sufficient information was provided, only one (out of 49) discontinued case as potentially inappropriate. However, it is important to note that in a substantial proportion of cases, 31 (38.8%), there was insufficient information to provide an assessment. The one case that the evaluator assessed as potentially inappropriately discontinued involved a young female who was receiving multiple benzodiazepines and a narcotic. These medications were taken for insomnia and headaches respectively which the patient reported continued following the discontinuation.

The patient discontinuation survey form (Appendix J) did not contain specific questions that would allow for the identification of potential withdrawal symptoms. Therefore, according to the criteria for assessing appropriateness (no ongoing indication and/or preferred alternative treatment provided), a case of abrupt discontinuation could conceivably be incorrectly considered as clinically appropriate. Eight cases required reconsideration where the patient reported adverse consequences following discontinuation and the prescriber's judgment was considered appropriate. However, in only one case was the physician evaluator unable to reasonably conclude that the patient's reported adverse consequences were not associated with potential withdrawal symptoms. In this instance, the patient was receiving a benzodiazepine (which was abruptly discontinued) for depression that had been substituted with an anti-depressant. The evaluator deemed this substitution appropriate while the patient reported feeling worse. However, it is unclear if a potential withdrawal symptom contributed to the patient's reported adverse effects following discontinuation. Alternatively, there may have been a lag effect between the introduction of the anti-depressant and the onset of its clinical effect. In the remainder of these cases, the change in prescribing was considered appropriate as it was due to significant side effects from the initial medication, the substitution of a stronger analgesic for continued pain, consolidation of multiple benzodiazepines or the patient initiated the discontinuation themselves.

The accuracy and reliability of the data from the discontinuation survey are questionable because they all originate from the patient's recall. As well, they were

collected approximately one year after the discontinuation. There were no efforts to test for accuracy and/or reliability by discussing the cases with the prescribing physicians or by reviewing the respective medical charts.

It was hypothesized that the PMP would negatively impact some patients who had been continuously receiving a PMP monitored drug because it was expected that the prescribing physician would abruptly discontinue their medication(s) or substitute them with less effective ones. This did not appear to occur. As discussed, this survey found only one (of a sample that included many patients receiving multiple prescriptions) that appeared to be potentially inappropriately discontinued. As well, many patients could not recall the discontinuation while pharmacists in many instances confirmed that if a medication was discontinued it was either substituted by another within the same class or reinstated in the immediate future. Consequently, it was concluded that the PMP did not adversely impact this group. On the contrary, the physician evaluator assessed (for cases where sufficient information was available) that in 48 (98.0%) of 49 cases, the discontinuation was clinically appropriate.

6.4.7 Internal PMP Data Analysis

The PMP report (prepared by the Program's staff)[161] indicated that a small minority of physicians were involved in prescribing large quantities of PMP monitored drugs. This finding was based solely on data provided by the compliant pharmacies. A

further analysis of the PMP data would have helped to clarify whether a PMP-based intervention using the "alert" and "explain" letter system had any impact on this problem. Some of these analyses were undertaken; however, a condition of the NMB in providing these data, was that the results of these analyses not be reported publicly or in this thesis. Despite this, the results reported by the PMP itself suggested that specific measures such as peer prescribing review, academic detailing and regulatory investigation should have been initiated immediately for this select group of prescribers and patients.

This research attempted to evaluate the overall effectiveness of the pilot PMP by measuring its effect on various outcomes. Some outcomes could not be measured in this study. These included the number of individuals who switched from the illicit use of prescription medication to illegal drugs such as marijuana and cocaine.

Table 6.13

Summary of the Evaluation of the Prescription Monitoring Program

- The clinical evaluation of the PMP determined that it did not impact the volume of prescribing of Program monitored drugs, identified substitutes, and the incidence of multiple doctoring as was expected. It is believed that interventions by the DOHCS and other stakeholder groups over several years preceding the Program may have led to an apparent decline in these variables.

- The increase in break and enters at retail pharmacies coinciding with the Program suggested that these medications may have been more difficult to access, or there was a perception that they were more difficult to access. Alternatively, the increase in these crimes may have been due only to a spate of activity by a small number of individuals.

- The appropriateness surveys indicated that the PMP may have positively impacted the appropriateness of prescribing of PMP monitored drugs. However, the presence of various biases and a small sample size limited the ability to accurately determine the magnitude of the effect of the PMP on this indicator.

- The discontinuation survey demonstrated that the PMP did not appear to adversely impact legitimate patient access to these medications.

- Combined with the positive anecdotal information provided by individual physicians and the favourable responses to Program-issued alerts as discussed in the PMP report prepared by Program staff, this research concluded that the PMP had a marginal positive impact on the policy problem it was intended to address.

CHAPTER 7

DISCONTINUATION OF THE PRESCRIPTION MONITORING PROGRAM

In February 2002, CEG researchers presented the findings of the clinical evaluation of the PMP (as described in Chapter 6) to the senior executive of the DOHCS. Following a thorough review of this information and additional analysis of internal PMP data, the DOHCS decided to discontinue the Program at the end of March 2002. Information for this chapter was obtained from PMP program records within the DOHCS where it is filed. Confirmation of the appropriate access to and disclosure of this information was obtained through an official Freedom of Information request to the DOHCS (Appendix A).

On March 27, 2002, the Minister of Health and Community Services officially informed the NMB, NPA, NLMA, RNC and the media[183] of the rationale for discontinuing the PMP. Through individual correspondence to each group, she proposed alternate interventions to address the continuing problems that the PMP had been intended to address. Stakeholders were informed that the evaluation of the PMP demonstrated that the Program had a positive impact on prescribing for some patients who were the subject of correspondence from the Program to their prescribing physicians. However, overall the Program did not achieve the desired results. For example, a number of patients appeared to circumvent the Program and continued to obtain medications inappropriately. As well, a select number of physicians continued to prescribe very significant quantities of PMP monitored drugs. The Minister

acknowledged that the full potential of the Program was also compromised because of the incomplete reporting of prescription information by pharmacists and physicians.

The Minister explained to stakeholders that based on research from other PMP jurisdictions, evaluators expected the PMP to have a sudden, dramatic impact on the prescribing of Program monitored drugs. This did not occur. However, when researchers reviewed historical prescribing data, and through further investigation, they determined that alternate specific interventions by several stakeholder groups in the years immediately preceding the introduction of the PMP may have contributed to the measured decline in monitored drug prescribing. As described in the previous chapter, such interventions included: (1) the NLPDP policy to limit some of its beneficiaries to only one pharmacy; (2) MCP's utilization reviews that requested explanations from patients and physicians when there appeared to be excess visits; and (3) the RNC targeting individuals involved in double doctoring (based in part on information obtained from MCP through subpoena). Stakeholders were advised that the NLPDP and MCP initiatives would continue.

The Minister advised the stakeholders that based on the above information, the Department would like to replace the broad-based PMP with more specific policy measures to address inappropriate access to and prescribing of narcotics and benzodiazepines. Academic detailing and peer prescribing reports were mentioned as two potential examples. It was also proposed that the NLPDP database could be used as

a potential data source for such initiatives. However, the Minister specifically noted that these interventions would not likely be effective for those prescribers with excessive levels of prescribing. Consequently, she formally requested the NMB to investigate the prescribing practices of a select number of general practitioners in the Province. Evaluators concluded that existing data from the PMP would identify the physicians involved.

The Minister also informed the stakeholders and the media that in addition to the above specific measures, the Department intended to propose specific legislative changes. This would permit the Department to report to police the names of individuals visiting excessive numbers of general practitioners for the suspected purpose of inappropriately accessing narcotics and benzodiazepines.

As a long-term measure, the Minister advised that the development of an electronic real-time Newfoundland and Labrador Pharmacy Network by the Newfoundland and Labrador Centre for Health Information should permanently address these problems. The Provincial Government intended to begin financing the further planning of this system in 2002-2003.

The Minister responded to issues about the PMP raised by the President of the NPA in correspondence to her dated February 13, 2002. The NPA had solely attributed the increase in break and enters at St. John's area pharmacies to the PMP and the lack of

addiction treatment facilities. In addition, the NPA asserted that they had warned the Department of the potential shortcomings of the PMP prior to its implementation.

The Minister shared the NPA's concern with respect to the apparent increase in the incidence of break and enters at pharmacies for the purposes of obtaining medications monitored by the PMP. She confirmed that the clinical evaluation demonstrated that the number of break and enters had increased in recent years. However, the evaluation also confirmed that the total number of prescriptions for monitored drugs did not change as a result of the Program. As well, the Minister noted that there continued to be a select number of general practitioners who prescribed high volumes of these medications. She informed the NPA that researchers surmised that the existence of the PMP may have led some to believe that these medications were more difficult to obtain through traditional means, but it is not certain this perception resulted in the increased number of break and enters.

The Minister questioned the idea that the apparent lack of addictions treatment facilities were partly responsible for the break and enters. She stated that treatment programs are one plausible option for addressing such problems, but cautioned that these programs are voluntary. Those involved in pharmacy break and enters would be unlikely to voluntarily participate in treatment programs.

The Minister also responded to the NPA's assertion that they had warned the Department through various correspondences of the potential shortcomings of the PMP prior to its implementation. She stated that, unfortunately, these correspondences were sent just days and weeks prior to the Program implementation date. At that late date, the Program was in its latest state of implementation with appropriate legislation in place. Program staff had been hired, prescription pads mailed to prescribers and office space rented. She further related her disappointment considering the NPA had participated in the working group that designed the PMP for approximately four years prior to its implementation. She did acknowledge that the NPA had strongly preferred a "real time" system from the outset; however, it was her understanding that all stakeholders would support the current PMP and be guided by its evaluation for subsequent initiatives.

The Minister concluded her correspondence to the President of the NPA by advising him that researchers, in conducting the PMP evaluation, had met with more than sixty pharmacists in eastern Newfoundland. She indicated that researchers had advised her that some pharmacists were hostile to the Program and its evaluation while others were extremely supportive and demonstrated to researchers that it took only a few minutes per week to electronically forward the necessary information. She also noted that some pharmacists refused to participate in the evaluation despite being offered reimbursement for their effort.

Following the ministerial correspondence to stakeholders, the NMB responded (correspondence dated July 12, 2002 to the DOHCS) to the Minister's request that they investigate the prescribing practices of a select number of general practitioners in the Province. This letter initiated some additional legal considerations. It indicated that the current status of the PMP needed to be clarified so that the NMB could respond to the Minister's request. The NMB also stated that the PMP was operated at "arm's length" from other Board functions and that it did not lodge with the NMB any complaints regarding high prescribing physicians. They hypothetically added that if the PMP had continued and been given an opportunity to further monitor and investigate prescription patterns, such complaints might have been made by the Program to the NMB over time.

This correspondence also outlined a number of important considerations with respect to the NMB's perception of their mandate and authority to monitor and investigate prescription patterns. It noted that prior to the joint establishment of the Program, the Board did not have the mandate or authority to receive patient prescribing data or to monitor and investigate prescription patterns. The NMB now questioned whether it had the lawful authority to use the prescription data already collected, or to receive additional prescription data, now that the Program had been discontinued.

The NMB further stated that the statutory power to investigate the prescribing of prescription drugs by a medical practitioner is, according to the Medical Act, "in connection with a prescription drug monitoring program established jointly by the Board

and the Minister." They articulated their concern that their authority to receive prescription data from the non-compliant pharmacists or to further investigate the prescribing of prescription drugs by a medical practitioner could be challenged. This could be based on the grounds that such actions could no longer be considered to be "in connection with" a prescription drug monitoring program since the Program had been discontinued by the Minister.

The ability of the PMP/NMB to adequately address suspected inappropriate prescribing during the tenure of the PMP was also discussed in the PMP report (prepared by PMP staff).[161] The document identified this as a significant issue; however, there appeared to be inconsistent statements between different versions of the report. The October 2001 version of the PMP report contained 16 policy statements numbered in increments of 10 from 10 to 160. Policy statement number 120 stated that PMP information is confidential and will not be transferred between committees of the NMB. It added that the PMP could lodge a formal complaint with the NMB if there is evidence of professional misconduct. The procedure section for this policy directive indicated that physicians would be advised in writing when there is evidence that they are prescribing over the established thresholds for particular drugs or drug groups. This letter would also advise them of their prescribing practices in relation to their peers and would require a response. The policy statement also included a procedure where, if the findings by the PMP indicated that there may be an issue related to prescribing practices, the matter would be forwarded to the NMB. However, page twelve of this report stated that the

PMP had no authority to conduct even a preliminary investigation to determine whether such practices may be inappropriate. It added that the only recourse was to lodge a formal compliant with the NMB. This version acknowledged that the authority for the formal investigation of a physician practice lies with the Board. It also argued the need for a process to determine the relevance of the information on which a complaint was being considered.

Another version of this paper (undated) produced by PMP staff during the tenure of the PMP stated that the Program should exercise its investigative authority in cases where questions were raised by the Program regarding a physician's or group of physicians' prescribing patterns. It argued that an investigation may include a review of patient records and should precede a formal complaint to the NMB. It then stated that the ability of the Program to conduct this type of review was limited due to lack of available resources.

DOHCS officials were unaware of the legal and/or financial shortcomings of the PMP with respect to its investigative abilities. Chapter 5 of this thesis outlined the numerous requests by the NMB over several years to enhance the PMP's budget and to provide legislation changes prior to implementation to allow the Program to fulfill its core objectives. The DOHCS assumed this was sufficient. Undoubtedly, the effectiveness of the PMP was limited because it did not sufficiently investigate and address those physicians with excessive prescribing patterns.

The July 12, 2002 correspondence (from the NMB to the DOHCS) also included a copy of a May 2, 2002 letter from the NPA to the NMB. The purpose of this letter was for the NPA to obtain clarification of a number of matters in order to seek resolution of the formal complaint lodged by the Program against a number of pharmacists. It posed seven questions related to: the potential subsequent compliance of the previous non-compliant pharmacists; any potential arrangements between them and the Program; any evidence of attempts to submit data at the time of discontinuation; the status of the Program security review; any reasonable grounds to believe that the Program's security was inadequate; and any possible exemptions provided to pharmacists to submit information and the current requirement for it given that the Program had been discontinued.

The NPA correspondence also indicated some of the circumstances surrounding the complaints against the non-compliant pharmacists. Upon the initial complaint from the PMP, the NPA delegated the investigation of the complaint to a screening committee of the Discipline Committee of the Association and to a hearing of the Discipline Committee. However, the hearing of the complaint by the Discipline Committee was rescheduled on three occasions and postponed on three occasions.

This correspondence also suggested the need for clarification surrounding the NMB's most recent withdrawal of complaints (January 17, 2002) against the non-compliant pharmacists. The NMB's notification to the NPA indicated that there had been

a satisfactory solution to their previous complaint. It was apparently based on the agreement to conduct a PMP computer security review and for the dissident pharmacists to comply with the requirements of the Program. However, the NPA were never advised whether those pharmacists had subsequently complied. The NPA Discipline Committee indicated that if a complaint was withdrawn and a pharmacist had subsequently complied with the requirements of the Program then the case would not proceed further. However, the PMP had not indicated when they withdrew the complaint that the remaining eleven pharmacists had submitted the necessary prescription information, a requirement of the NPA Discipline Committee. The NMB declined to respond to the NPA's correspondence until the DOHCS commented on the current status of the Program.

The DOHCS referred the above legal matters to the Department of Justice. They notified the Department of Justice that they still wished the NMB to fulfill the Minister's request to investigate the prescribing practices of a select number of general practitioners in the Province as outlined in her March 27, 2002 correspondence. However, the DOHCS acknowledged that the NMB representatives had advised (at a meeting of June 4, 2002) that the Board felt that the relevant legislation was inadequate, there was a lack of funding and there was a perception by providers and the public that the Program had been discontinued.

The DOHCS specifically requested a response to a number of queries related to the proprietary rights to the PMP database; the potential of maintaining the database to be

used for future purposes related to the project goals; the potential legal use of this information by the NMB or DOHCS to permit the NMB to pre-investigate the prescribing practices of specific physicians; the ability of the NMB to accept outstanding data from the non-compliant pharmacists; and the proprietary rights to the software developed by ADS. As well, the DOHCS sought general guidance regarding the NMB's legal capabilities and responsibilities to undertake the Minister's request.

Legal advice was given in two separate correspondences. The first response (September 17, 2002) addressed the Minister's request that the NMB investigate the prescribing practices of a select number of general practitioners in the Province using the existing data from the PMP to identify the physicians involved. An opinion was given that the term "in connection with" was vague and an argument could be made that the prescription information, which was the basis of the concern, was collected as part of the Program. Consequently, a subsequent investigation could be considered "in connection with" the Program. It was noted that a court would likely accept the Board's argument that they had no statutory authority to comply with the Minister's request as the prescription drug monitoring program had been discontinued and that any investigation not yet commenced could not be considered to be "in connection with" the Program. The legal opinion also responded to the DOHCS' request for general guidance regarding the NMB's legal capabilities and responsibilities to undertake the Minister's request. It stated that they had no statutory authority to carry out the request.

In early January 2003, the DOHCS responded to the NMB regarding the further investigation of high prescribers of narcotics and benzodiazepines using PMP data. This correspondence commented on the potential risk to the public safety should these high levels of prescribing be potentially deemed inappropriate. It also recognized the NMB's legal opinion but focused on the vagueness of the term "in connection with." The correspondence also acknowledged the ambiguity in the wording of the current legislation and restated the DOHCS' position that they would like the NMB to proceed in undertaking the Minister's request of March 27, 2002. The DOHCS concluded that in the longer term it may be necessary to amend the current legislation to provide the NMB with more explicit authority to effectively address suspected inappropriate prescribing in the absence of a PMP. They argued that such authority is necessary since prescribing is a significant component of a medical practitioner's practice and inappropriate prescribing poses a risk to the public's safety. The DOHCS offered to work jointly with the NMB in proposing the necessary legislation.

Legal advice was also given in correspondence dated October 3, 2002. It addressed the remaining legal concerns raised by the NMB. The first related to the proprietary rights to the PMP database and the confidential information it contained. Since the NMB was the only body permitted to collect such information, it should likely remain in the control of the Board. The legal response concluded that since the PMP had been cancelled, it was questionable that the information could be used for any other purposes, even those related to furthering the Program's objectives. It further stated that

the DOHCS did not have authority to access this information despite funding the Program.

The October 3, 2002 legal response argued that the NMB was able to accept data from the non-compliant pharmacists for the time the PMP was functional since they had proper authority to collect it during this time period. Finally, the legal opinion advised that ADS likely owned the PMP computer software since they were an independent contractor to the Program and did not appear to assign their right of ownership to the software they developed.

Undoubtedly, most stakeholders assumed that the discontinuation of the PMP meant that there would be no further action against those pharmacists who had refused to participate, particularly since the NMB had withdrawn the complaints against them. The Secretary-Registrar of the NPA commented that because these pharmacists had allegedly practiced contrary to the Pharmaceutical Association Act for almost two years, the mere withdrawal of a complaint by the NMB did not imply that the NPA could not or should not pursue disciplinary action. He indicated that the NPA's Discipline Committee would determine the status of the disciplinary action against these pharmacists. (Personal communication – D. Rowe, Secretary-Registrar, NPA, April 15, 2002.) The NPA further advised the DOHCS in correspondence dated September 20, 2002 that the NMB provided no details of the "resolution" and no indications were given that the failure by these pharmacists to comply with the requirements of the PMP alleged in the original

complaint had been rectified. He confirmed that the NPA requested specific information about these pharmacists from the NMB but no response was provided, although apparently a draft response was provided to the DOHCS for uncertain reasons.

The NPA advised in this correspondence that they had acted in good faith in addressing this complaint and incurred significant expenses (approximately $34,000) in the process while the complainant abandoned the process at the last minute. Based on the fact that all expenses of the NMB related to this were paid from government funding for the Program, the NPA argued that they should be entitled to appropriate compensation of costs. The DOHCS subsequently agreed to reimburse the majority of the NPA's legal expenses associated with these complaints.

Attached to the NPA's September 20, 2002 correspondence were copies of: (1) the Request of Withdrawal of Complaint and Termination of Proceedings; (2) Order of the Disciplinary Committee; and (3) a copy of the notification letters to the non-participating pharmacies. The latter correspondence outlined the chronology of events in addressing the complaints of professional misconduct against pharmacists; the NPA's frustration associated with the withdrawal of complaints by the NMB; the current expense and uncertain future expense associated with this complaint; and the request to the NPA Discipline Committee that the complaint be terminated.

Following the announcement of the intent to discontinue the PMP, the Minister agreed to assume the incremental expenses associated with the discontinuation. These included items such as legal and accounting fees, computer processing fees and severance pay for PMP employees. However, the NMB, NPA and DOHCS agreed that it was unnecessary to undertake the PMP computer security review that had been agreed to between the dissident pharmacists, the NMB and the DOHCS.

Internal DOHCS meetings between officials of the Medical Services and the Support Services Branches were held following the discontinuation of the PMP to discuss the possible policy options and procedures to deal with the policy problems that the PMP was intended to address. These policy options included those suggested to stakeholders by the Minister and described above.

The discontinuation of the PMP and introduction of alternative policy options did not follow the approach articulated by Lomas. For example, the decision to discontinue the pilot PMP was made solely by the DOHCS based on the interim evaluation. The Lomas approach would suggest that stakeholders should have been involved in a review of the policy problem indicators. In this instance, some of these indicators may have been redefined based on the evaluation information provided in Chapter 6 of this thesis. As well, stakeholders should have been involved in choosing between the potential alternative policy measures. It is conceivable in this instance that the regulatory stakeholders may have been helpful in jointly implementing some of the alternative

policy measures and/or assisting in determining their effectiveness. For example, the identification, investigation and follow up of high prescribing physicians suspected of indiscriminately prescribing may have been successfully pursued jointly between the DOHCS and the NMB.

Brewer and deLeon described termination generally as the adjustment of policies and programs that may have become redundant, unnecessary or perhaps counterproductive. It most often involved the replacement of one set of practices with another because the policy problem that warranted the development of the policy in the initial instance may still exist. This was necessary because policy problems are dynamic. Policies themselves become dated, may become obsolete or continue to solve problems that have already been resolved. From an economic perspective, terminations may provide an opportunity to redeploy financial and other resources towards more pressing problems. Consequently, the authors suggested that the termination stage might be considered the beginning of the policy process as much as the conclusion.[10]

The termination examples cited by Brewer and deLeon involved large United States, federally based policies and programs with very significant budgets. However, they provided a number of criteria for consideration when program discontinuation is necessary and note that program termination is difficult without an adequate evaluation and consideration of the effects of its discontinuation. In general terms, they advised policymakers to consider who will be disadvantaged by the program's termination and in

what ways. They further advised policymakers to give particular consideration to those individuals disadvantaged or whose lives were adversely affected by the discontinuation. This can include consideration of issues related to due process, severance compensation and/or ethical and moral responsibilities. Also, the use of incentives to facilitate terminations should also be considered. Additional considerations should be provided to preserving the knowledge obtained from the discontinued program for use in future endeavours.[10]

Brewer and deLeon proposed that programs and policies could be more readily terminated or merged with other initiatives if the potential termination was contemplated as part of the initial policy planning process.[10]

Table 7.1

Summary of the Discontinuation of the Prescription Monitoring Program

- The feasibility of introducing potential substitute policy approaches to replace the PMP could have been further considered prior to discontinuing the Program.
- Complaints against the non-compliant pharmacists were dismissed following the discontinuation of the PMP.
- Further investigation using PMP data of high prescribing physicians was not undertaken.
- Stakeholders were not involved in the decision to discontinue the PMP.

CHAPTER 8

SUMMARY OF THE POLICY EVALUATION

The primary objectives of this research were to analyze the policy process used to develop and implement the pilot PMP, and to provide a thorough clinical evaluation of this initiative. The process for developing and implementing the Program lasted approximately four years because of many administrative, legal, budgetary and stakeholder participation problems. As well, pharmacist compliance problems, the lack of regulatory investigation and action to address suspected inappropriate prescribing and patient access to PMP monitored drugs during the pilot phase limited its potential effectiveness once introduced. However, data from the PMP illustrated a reduction in the number of prescriptions subsequently issued to a substantial number of individuals who were the subject of alert letters sent to their doctors.[161] As well, anecdotal prescriber feedback suggested that the Program positively impacted the identification and subsequent management of some patients who were dependent on these medications. Consequently, the evaluation concluded that the Program had a marginal positive impact on the problems it was intended to address. The purpose of this chapter is to summarize the findings from the sub-evaluations in the previous chapters.

The views of various health policy experts, as described in the introductory chapter, unfolded during the tenure of the pilot PMP. Ham argues that the process of public policy-making is not straightforward. He noted that decision-making is not a rational, logical linear process where information and research determine policy

decisions. Rather, it is a highly political process where power and vested interests are among the primary driving forces.[7] Some of the reasons why research has limited effectiveness in developing health care policies include policymakers having goals other than clinical effectiveness; lack of consensus about the evidence; sources of competing evidence; an environment not conducive to policy change; and inadequate knowledge by purveyors of the research.[5]

Some of these factors were operative during the tenure of the PMP. For example, while it is believed that the medical professions and Government were concerned about inappropriate drug use, there was also evidence of their inability or unwillingness to accept the necessary legal and financial risks associated with administering a monitoring program. Administrators did not act further with those patients who were repeatedly obtaining monitored prescriptions from numerous physicians, and physicians who were suspected of inappropriately prescribing. In addition, some pharmacists indicated that their uncooperative spirit resulted from Government's sudden decrease of the dispensing fee for prescriptions reimbursed under government-sponsored programs. This became evident through meetings with over sixty community-based pharmacists. This lack of co-operation required tremendous effort to address and directed attention away from the primary objective of the pilot PMP - to combat inappropriate drug access.

Lomas surmised that there were a number of common areas of misunderstanding between researchers and policymakers. Sometimes policymakers communicate with

researchers only late in the policy development process and this does not provide the researcher with time to incorporate additional components into the research. Likewise researchers arrive with findings too late in the decision-making process.[8] Lomas argued that once a policy has been implemented, research has a dual role to play in the monitoring of the policy and the measurement of outcome. Research also plays a role in determining whether the objectives of the policy have been achieved.[3] If the policy problem persists, policymakers can then use the results of research to determine if the existing intervention requires amendment to better address the policy problem or perhaps consider whether an alternative approach is required. Without adequate data, policymakers would have limited, perhaps biased, anecdotal information regarding the usefulness of the intervention.

In this instance, the NMB consulted researchers only when it became apparent that Government would be basing the decision to continue the PMP on the results of the clinical evaluation and the likely success of specific alternative options. If researchers had conducted interim analyses throughout the tenure of the pilot PMP, it may have been possible to address some of the shortcomings in time to salvage the true objective of the Program. The report prepared by the PMP staff acknowledged that these problems existed, but they proposed to address them after the pilot phase was concluded. CEG researchers had not proposed to the NMB that their research (e.g. the measurements described in Chapter 6 of this thesis) could be used as a monitoring tool.

The Lomas approach for policy-making proposes that the "definition of the policy problem stage" contain two important criteria: identifying the problem/issue and identifying stakeholders. He suggests that policymakers examine variations in practice utilization rates over time and between jurisdictions such as community and urban centres as a means of quantifying the policy problem.[3]

Unfortunately, the identification of the policy problem in this instance was limited to an ad hoc review by a number of stakeholders. Researchers and stakeholders used an informal unsystematic approach for collecting information related to the policy problem. Most of the information provided by stakeholders during the preparation of the discussion document was circumstantial. In the case of the RNC, the interview was limited to only one officer and there was no substantiation of the information provided. Information provided by the NPA and the NMB was anecdotal. MCP provided a copy of their 1988 Multiple Services Listing that documented the extent of inappropriate physician service use.[93] It was suspected to heavily involve those who were inappropriately obtaining drugs for non-clinical use. However, while this information was the most detailed, it was prepared eight years prior to the consideration of the PMP and twelve years prior to its introduction.

Many of the problems identified in the policy problem stage were relatively straightforward to address. More specifically, measurements of the baseline components of the protocol for the clinical evaluation of the PMP could have been initiated to provide

quantitative data to describe the policy problem. For example, two readily available data sources, IMS Health, Canada and the NLPDP could have been used to provide a baseline indication of the extent of narcotic and benzodiazepine prescribing in the Province over time. Specifically, IMS Health, Canada data could have enabled policymakers to determine if the extent of narcotic and benzodiazepine prescribing in this Province, measured by per-capita consumption, was greater than other provinces, particularly those with PMPs. Similarly, the same process could have been followed to determine the per-capita consumption of narcotic and benzodiazepine substitutes over time and in comparison with other jurisdictions with and without PMPs.

MCP physician claim information was available to allow policymakers to determine the number of individuals who had visited multiple fee-for-service general practitioners during thirty-day periods throughout the Province over time. A time-series analysis of this information could have provided an indication of the change in the number of individuals directly involved in obtaining inappropriate prescriptions by way of double doctoring over time.

It is plausible that if the policy problem stage of the policy-making process had been thoroughly undertaken, it may have led policymakers to conclude that the policy problem was limited to a relatively small number of patients suspected of multiple doctoring and a relatively small number of physicians suspected of indiscriminately prescribing. Consequently, policymakers may have concluded from the outset that a

broad-based PMP was not the preferred policy option. They may have favoured introducing more specific policy measures similar to those discussed in the previous chapter.

As well, if the appropriateness of prescribing surveys had been completed prior to introducing the PMP, it would have alerted policymakers to the extent that narcotics and benzodiazepines were inappropriately prescribed for clinical reasons. Examples of potentially serious inappropriate prescribing include using benzodiazepines for extended periods of time, inappropriate use of long acting benzodiazepines, and the use of two or more benzodiazepines and/or narcotics concurrently. Early completion of the appropriateness of prescribing surveys may have led stakeholders to consider a broader definition of the policy problem (other than illicit use). This in turn may have led policymakers to consider interventions other than or in addition to a PMP.

The policy development literature suggested that if stakeholders were actively involved in the formation of policy from the outset they would be more likely to modify their practice pattern in compliance with the policy. The huge majority of the stakeholders in this instance modified their clinical practices to accommodate the PMP. Those who refused were not representative of the general pharmacy and physician population and some were of concern prior to the PMP, suggesting that self-interested behaviour may have prevailed.

It appeared that two stakeholder groups had an interest in the activities of the PMP but were not included on the advisory committee. They were the RNC and local drug dependency groups. The RNC provided some of the information that initially led to the introduction of the PMP. The extent of the Program's success would have a direct impact on their requirement to deploy police resources in the community to address the "street use" of prescription medications. As well, they were familiar with the "street use" of prescription medications and possible means of circumventing the Program once introduced. In addition, they would be called upon to investigate potential break and enters into pharmacies that may occur as a result of the Program. Both the drug dependency groups and the RNC could have provided first hand knowledge of how illicit users of narcotics and benzodiazepines responded to the PMP. If the RNC had been formally involved, they could have put forward their views on the necessity to access information from the PMP in order to pursue investigations against those suspected of inappropriately obtaining PMP monitored drugs. They complained that the PMP did not have this latter capability.

The NPA participated on the advisory committee that developed the PMP. Despite this, the advisory group may have underestimated the strength of some pharmacists' opposition to the Program. Consequently, while stakeholder representation was necessary, it was also imperative that the opposing views to proposed policies be sufficiently addressed during the policy formation stage.

Under the Lomas approach, the policy-making stage of the iterative loop involves researchers collecting and synthesizing information to generate alternate policies. This involves the project team completing a comprehensive review of the research evidence for each alternative approach. Lomas proposed that stakeholder groups then review the evidence collected and be actively involved in choosing the policy to be implemented. The purpose of this approach is to permit the stakeholders to accommodate their values in selecting the appropriate policy; however, the chosen policy would be anchored to research evidence.[3]

The actual policy-making process followed in implementing the pilot PMP did not adhere to the suggestions proposed by Lomas. On request, the CEG had prepared a discussion paper regarding the merits of PMPs; however, it failed to address alternate policy approaches.[141] Following the completion of the discussion paper, a multidisciplinary working group under the leadership of the Registrar of the NMB was formed to pursue a pilot PMP for this Province. However, there were no formal "terms of reference" for this group. A review of the minutes of this group's meetings suggested that during the initial period when the Program was designed, there was no discussion of alternative potential options for improving prescribing appropriateness of these drugs. In essence, the PMP was the only option considered. However, there was discussion between representatives of stakeholder groups regarding specific options within a PMP.

Despite the lack of consideration of potential alternate approaches, it is believed that some of the educational approaches (such as group education) would have been unlikely to have had a significant impact on improving prescribing practices where PMP monitored medications were prescribed at levels that greatly exceeded ten times the average. Such educational initiatives are intended to increase the physician's knowledge of the appropriate clinical indications for prescribing. While there was a select number of physicians believed to be indiscriminately prescribing large volumes of narcotics and benzodiazepines, it is reasonable to assume that they were aware of their actions and that an educational initiative would be unlikely to address them. Consequently, a regulatory or financial sanction may be the most applicable. However, it might have been worthwhile to consider academic detailing and peer prescribing to complement the PMP for those physicians with slightly high prescribing levels, but not for those with extreme prescribing levels.

This research concluded that the preferred policy development approach would have seen all stakeholder representatives with an opportunity to engage in a thorough, explicit discussion of all potential options for addressing the policy problem. If a PMP was chosen as the final policy option, a more explicit determination was needed of the specific characteristics of the PMP to be implemented. This may have yielded better clinical outcomes from the Program.

Under the Lomas approach, the policy implementation stage involves three steps: disseminating and publicizing the chosen policy to relevant stakeholders and the public; additional consultation with opinion leaders; and monitoring. If necessary, revising the policy is also proposed.[3] Unfortunately, many serious problems were experienced by the PMP during the latter steps of the policy implementation stage.

The dissemination of information to stakeholders and the public regarding the introduction of the PMP was thorough. There were multiple news conferences, media reports, letters to stakeholders such as physicians and pharmacists, publications in professional association's newsletters, the distribution of a handbook for physicians and pharmacists, and memos directly from the PMP director to physicians and pharmacists during the introductory period. Also, the NMB appropriately followed the suggestions and advice of the Newfoundland and Labrador Centre for Health Information ("NLCHI") and the Human Rights Commission in propagating information about the PMP to the public.

The use of a physician survey,[157] as described at the beginning of the policy implementation chapter, as a means of obtaining a better understanding of stakeholder values was consistent with the approach proposed by Lomas. However, policymakers should have expanded the survey to include pharmacists. This might have yielded information that could have averted some of the implementation problems associated with this group. For example, including pharmacists in the survey may have provided

information regarding the extent to which they desired a "real time" PMP and their opposition to the Program that was eventually implemented.

The NMB chose not to implement components of a PMP that physicians generally supported as identified in the survey. These included: (1) a toll free phone line to provide prescribers with up-to-date information regarding a patient's previous prescriptions; (2) peer prescribing reports; and (3) punitive measures for physicians who inappropriately prescribed. The most recent proposal by the PMP for continuing the Program beyond the pilot phase included the need for peer prescribing reports. The concurrent use of peer prescribing reports and punitive measures for physicians who possibly indiscriminately prescribed might have increased the effectiveness of the Program.

The policy implementation chapter also concluded that the PMP experienced significant administration problems that could be considered "self-inflicted." For example, the Program was initially delayed awaiting additional resources from Treasury Board to accommodate the NLMA's and, to a lesser extent, the NPA's demands for personalized prescription pads for all prescribers. However, once the PMP was implemented, the NMB, following requests by some physicians, unilaterally decided that prescribers were not required to use the personalized pads. Consequently, many pharmacists verbally indicated that about half of the narcotic and benzodiazepine prescriptions were written on the conventional forms. This decision contributed to

serious logistical difficulties with the Program, since many prescribers who used the conventional pads failed to include the specific patient and physician identification information necessary for Program administration. Approximately 20% of all prescription information obtained by the Program was incomplete. The NMB later proposed that any extension of the Program would require the mandatory use of personalized prescription forms.

The NMB was appropriately concerned that the pilot PMP preserve the confidentiality of the information it collected. In that regard, they consulted with various groups and agencies with experience in this area. Many of the privacy concerns raised by the NLCHI were, or had been, adequately addressed by the Program's policies or through legislation. Some administrative procedures proposed by the NLCHI would have imposed an additional burden on the Program and were not supported by the NMB's legal council.

One of the most significant PMP implementation problems was the lack of participation by some pharmacists. Since the inception of the Program, at least eleven independent pharmacies refused to submit data to the PMP, contrary to the Pharmaceutical Association Act. Through correspondence from the NPA to the DOHCS, they initially proposed a number of reasons for their non-participation including: (1) the inability of the Program to provide feedback; (2) computer software and hardware problems; (3) the financial expenses associated with the Program; and (4) the fee

associated with dispensing services provided to government subsidized drug claimants. Over time, the stated grounds for the non-participating pharmacists' refusal to participate (according to NPA and NMB correspondence to the DOHCS) moved to concerns about the validity of the Program and the security of personal patient information rather than the requirements of the Pharmaceutical Association Act. Through individual meetings with more than sixty pharmacists by this researcher, including some of those non-participating (while conducting other aspects of this research), it is my opinion that the refusal to participate by some was based primarily on financial reasons. The non-participating pharmacists were not randomly located throughout the province as would be expected if they were opposed to the PMP only on the grounds stated. They were primarily affiliated with one consortium. As well, some of the non-participating pharmacies were located near high prescribing physicians of PMP monitored drugs (as identified by NLPDP data).

Anecdotal evidence suggested that many pharmacists intended to be uncooperative towards government-sponsored initiatives. Some advised that this resulted from the sudden reduction in their dispensing fee paid by Government for NLPDP claims. However, the circumstances for this appears to have originated in the pharmaceutical sector and related to the establishment of many new pharmacies in traditional large chain retail stores and supermarkets in recent years. These new entrants initially advertised greatly reduced dispensing fees of approximately $1.99 per prescription or 30% of the standard subsidized rate of $6.50. During the spring of 1996,

the Government, in an attempt to minimize the budget deficit, abruptly announced that it would only provide reimbursement of $3.50 per prescription (it has since been reinstated in small increments up to $6.50). However, immediately following the reduced rate policy, pharmacists who began a public feud with Government generated even greater public attention to the fact that large retail chains and supermarkets were offering substantially reduced dispensing fees. This response compounded the reduction in revenues for many independent and associate pharmacies in the urban centres. Many pharmacists attributed the 1996 dispensing fee reduction as their reason for being uncooperative with government-sponsored initiatives.

The policy implementation chapter indicated that the regulatory authority of the NPA was unable to assure the full compliance of their members in the PMP. However, this may have been compounded by the NMB's approach to submitting complaints against the non-compliant pharmacists. When the NMB submitted formal complaints against the dissident pharmacists, they stipulated that the complaint would be withdrawn if the pharmacists were to comply. It appears that this approach prolonged the disruptive behaviour of the non-participating pharmacists. It allowed them to exhaust every possible legal and administrative avenue to avoid participating in the Program. Some pharmacists who were non-compliant with the PMP suddenly participated when they realized that such practice limited their ability to obtain a letter of good standing from the NPA (to obtain employment elsewhere or to hire student assistants). One pharmacist

advised that he permitted one of his stores to submit data for these reasons while the second, in a downtown location, refused.

The ability of the NMB and the DOHCS to influence the status of disciplinary proceedings against non-complying pharmacists had adverse financial implications for the NPA and Government. Regulatory bodies such as the NPA recover the expenses of disciplinary investigations from individual members if they have committed professional misconduct. When allegations of pharmacists' wrongdoing were withdrawn, or deferred at the last moment, at the request of the NMB and DOHCS, the NPA had already assumed the full costs of investigating the complaints. The DOHCS has since reimbursed approximately 75% of the NPA's legal expenses. However, these actions substantially increased the legal expenses of the PMP and, consequently, Government since they accepted full responsibility for the PMP's expenses.

In retrospect, a financial penalty may have been the most effective option to address pharmacists' non-participation in the PMP. In other circumstances, Government has successfully withheld payments to providers pending the receipt of requested information. In this instance, Government would need to consider the legal implications of limiting the non-participating pharmacists' participation in the NLPDP during the time period they were refusing to submit data to the PMP. This would have caused some inconvenience for NLPDP claimants if the non-participation continued. However, it is

conceivable that this intervention might have had an immediate effect on their participation.

The policy implementation chapter attributed many of the implementation problems to the professional regulatory groups' lack of financial or political capacity to endure the level of risk that the PMP required. Physician and pharmacy professional groups argued that legal action against their respective members had become more common in recent years and was expensive to defend. As well, the mere threat of legal action may have led professional regulatory groups to become more conservative, for fear that such action would cause them financial difficulty. While the losing party in a disciplinary process would assume the association's legal expenses, this appeared to be insufficient assurance. This risk aversion raises the issue of whether the current structure of the regulatory regime enables these provider organizations to accept sufficient legal and financial risk to adequately protect the public's safety and interests with respect to the administration of a PMP. The symptoms of these groups' inability to accept risk was evidenced by both the NMB and NPA repeatedly requesting from Government: (1) changes to their respective legislation to protect them from liability; (2) letters of indemnification; and (3) full financial assistance for legal defences in the event of legal action for administering their respective legislation.

Professional regulatory groups were also concerned about the political repercussions within their professions should they be required to increase membership

premiums to shoulder the additional financial burden of legal proceedings. As well, it was conceivable (and came to reality with the non-participating pharmacists) that many members could jointly collude in legal action causing an even greater financial risk to the regulatory body.

The policy implementation chapter also discussed the problems associated with determining a suitable budget for the PMP. Many of these problems were associated with the administrative financial risk that the NMB had to undertake. Administration of the PMP involved a prospective budget being transferred from Government to the Board. However, the Board perceived that any budget overruns would place the NMB at risk financially. Consequently, when the NMB prepared a budget for Government's consideration, it contained significant contingency items. This was a reasonable response since the NMB was an organization with revenues in the vicinity of only $800,000 annually. The PMP was expected to cost as much as $350,000 annually with many uncertain budget items related to start-up expenses and prescription volumes. A preferred approach could have involved a more conservative estimate of the PMP budget leaving the Government to assume any potential additional costs. Alternatively, Government could have chosen to administer the PMP itself to accommodate the financial risk.

In concluding, the policy implementation chapter discussed examples where medical regulatory groups had difficulty accepting sufficient legal and financial risks.

This, combined with the ability of some pharmacists to avoid submitting PMP data contrary to the Pharmaceutical Association Act throughout the tenure of the pilot PMP, again raised concerns about the effectiveness of professional self-regulation with respect to this application. The chapter discussed the role of self-regulation as a response to a specific economic market failure known as "asymmetry of information" between providers of health care and patients. This occurs when health care providers have more information about the value of the service to the consumer and can therefore unfairly influence their consumption. In this case, the role of self-regulation is to control entry to these occupations, the conduct of those in the occupation, and to ensure public safety. Unfortunately, there are side effects with such interventions. With self-regulation, there is tremendous power to control markets for certain health provider services, resulting in increased costs to consumers and increased incomes for those providers.[162] Undoubtedly, society values this approach compared with the alternative, potentially unregulated, lower cost model. If the current form of self-regulation is unable to ensure adequate public protection in circumstances such as this, policymakers should consider options to possibly improve the current structure. At this juncture, I referred to the literature for further guidance regarding the effects of self-regulation and possible ways to address the current shortcomings.

The literature discussed shortcomings with respect to self-regulation. Firstly, it focused on the negative effects of monopoly powers provided to regulatory groups. Occupations seeking self-regulation status will attempt to restrict entry, define its scope

of practice and put in place plans to maximize the benefits it may achieve while maintaining public confidence in its ability to regulate its members.[163] It is argued that self-regulating professions can raise prices through anti-competitive behaviours and through their failure to permit para-professionals or auxiliaries to undertake duties that do not require professional education and training.[163]

The second weakness of self-regulation is further described in the medical literature as the inability to adequately protect the public's safety in specific circumstances. However, it would appear that self-regulation becomes an issue for widespread discussion only when there is a high profile media case involving members of the public suffering serious harm due to inadequate medical practice. The situation is further compounded if the regulatory body is possibly aware of ongoing suspected inappropriate activity or if the suspected inappropriate activity involved the same health professionals and occurred in another jurisdiction in the past. At this point, the public becomes alarmed, will likely call for a public inquiry, and openly questions the merits of self-regulation. Government, too, may become the target of criticism since they have sanctioned these regulatory bodies.[164-167] One author described the media being attracted to cases having similar themes: the absurd behaviour of the limited number of individual practitioners involved; constant and critical media attention regarding the merits of self-regulation; and the slow response of medical regulatory groups to address the problem.[164]

The literature was further examined for options to improve self-regulation in order to address the shortcomings described above. However, complete discontinuation is argued to be impractical since, once self-regulation is in place, revoking it would inflict severe economic costs on the respective profession resulting in strong resistance.[163] As well, governments prefer self-regulation because it typically does not require any public resources, it creates an understanding of protection for the public and it confers a valuable property right on a relatively small occupational group (which may be politically desired).[163]

One option for improving self-regulation described in the literature offered potential in this application. It involved changing the regulatory structure such that a government agency fulfils part of the regulatory function.[164] For example, if the DOHCS administered the PMP, they could take responsibility for investigating suspected inappropriate dispensing and prescribing and, where necessary, lay formal complaints with the regulatory body. The regulatory body in this instance would be obliged to take the necessary disciplinary action as required in their respective legislation. The DOHCS had done this in the past by lodging formal complaints with the NPA and NMB in instances where suspected inappropriate activity was detected using the NLPDP and MCP databases.

The data reported in the clinical evaluation chapter suggests that the PMP did not significantly influence the overall prescribing of Program monitored drugs or identified

substitutes. IMS Health, Canada data indicated that from 1997 to 2001 there was a continuous reduction in the prescribing of benzodiazepines and analgesics in Newfoundland and Labrador by approximately 20% and 22% respectively over the four-year period.

The increase in prescriptions for narcotic substitutes beginning in 1999 was attributed to the introduction of new COX-2 selective inhibitors. In addition, the PMP did not appear to impact the incidence of multiple doctoring that had been declining during the period immediately preceding the Program. However, the theft of PMP monitored drugs through break and enters from St. John's area pharmacies had increased substantially in the year following the introduction of the PMP, suggesting that the PMP may have reduced the access to Program monitored drugs through double doctoring. Alternatively, the RNC suggest that although the number of break and enters increased dramatically, they may have been committed during a spate of activity by the same small group of individuals.

PMPs in other jurisdictions have been subjected to limited evaluations. However, the available evidence suggests that they led to an immediate and significant reduction in the prescribing of program monitored drugs ranging from 30% to 60%. The levels of prescribing of substitute drugs did experience a noticeable increase.[94,146] However, the net benefit of these changes remains uncertain. The clinical evaluation of this PMP

indicated that the Program did not have any meaningful impact on levels of prescribing. The number of analgesic prescriptions increased slightly after 2000.

The data suggested that the total analgesic-equivalent prescribed in Newfoundland and Labrador increased after the introduction of the PMP, despite a reduction in the number of prescriptions since 1997. The average quantity of analgesic per prescription between 1997 and 2001 increased by 35%. This may have been due to increased marketing efforts by a limited number of pharmaceutical manufacturers towards physicians to increase their prescribing for non-malignant pain. (Personal communication – Dr. R. Young, Registrar, NMB, January 11, 2002.) Alternatively, physicians may have increased the strength of prescriptions because they perceived that the PMP was only monitoring the frequency of prescribing.

Overall, the clinical evaluation concluded that factors other than the PMP were more likely responsible for declines in prescribing and multiple doctoring from 1997 to 2001. The declines may have resulted from alternate interventions by several stakeholder groups during this period. For example, during this period MCP frequently corresponded with patients and physicians who appeared to be grossly overusing insured medical services based on fee-for-service claim data and requested a written explanation for the level of insured services provided. (Personal communication – Dr. B. Fleming, Assistant Medical Director, DOHCS, January 17, 2002.)

The NLPDP identified claimants who received narcotics and benzodiazepines from two or more pharmacies within a three-month period. The prescribing physicians and respective social worker were advised of the patient's claim information and NLPDP reimbursement was limited to one pharmacy. Also, NLPDP officials reported several physicians to the NMB and the Board initiated disciplinary proceedings against several physicians because of their prescribing patterns during this period. (Personal communication – J. Downton, Director of Drug Programs, DOHCS, January 2002.)

Beginning in 1997, the RNC initiated specific efforts to reduce double doctoring. Information provided by MCP assisted their criminal investigations against individuals who visited multiple physicians and a select number of physicians who were suspected of indiscriminately prescribing narcotics and benzodiazepines. (Personal communication – Superintendent R. Shannahan and members of Break and Enter Unit, RNC, January 17, 2002.)

The clinical evaluation also included two surveys of physician prescribing practices of PMP monitored drugs. One measured the appropriateness of prescribing for a sample of prescriptions on a before/after basis. The second assessed the circumstances surrounding the abrupt discontinuation of long-term prescriptions to patients that coincided with the introduction of the Program.

The appropriateness surveys indicated that the PMP might have positively impacted the appropriateness of prescribing of PMP monitored drugs. Unfortunately, the surveys were subject to various sources of bias that, when combined, likely provided an overestimate of the ability of the PMP to improve the appropriateness of prescribing. Some of the biases were related to the lack of voluntary participation of pharmacists and physicians in the surveys, the clinical backgrounds and experience of the physician evaluators, and the use of two research nurses and a research physician to collect the clinical data. Finally, the small sample size limited the ability to accurately determine the magnitude of the effect of the PMP on this indicator.

The discontinuation survey suggested that the PMP did not adversely affect legitimate patient access to PMP monitored drugs as was expected. The study sample in this case included a disproportionately higher proportion of patients receiving multiple PMP monitored drugs who were of low income and dependent on their medications. Despite this, only one of 49 discontinued cases (where sufficient information was available for assessment) was deemed inappropriate. Unfortunately, the accuracy and reliability of the data was questionable since it all originated with the patient and was collected one year after the discontinuation.

The clinical evaluation chapter concluded that suspected inappropriate access to and prescribing of PMP monitored drugs might be limited to a relatively small proportion of the population and prescribers, respectively. A report prepared by PMP staff[161]

indicated that a small minority of physicians was involved in prescribing very large quantities of PMP monitored drugs. The NMB provided to researchers PMP data for further analysis on the basis that the results not be publicly disclosed. This analysis also concluded, as alluded to in the PMP report, that a small number of physicians had suspected excessive prescribing levels. In addition, there was a small proportion of patients who continued to see multiple, different physicians despite being the subject of alert letters to their prescribing physicians.

Table 8.1

Summary of the Policy Evaluation

Policy Problem	- Inadequate description of the policy problem. - Important stakeholders missing from the policy development process.
Policy Options	- Lack of consideration of alternate/complementary policies to the PMP.
Policy Implementation	- Dissemination of PMP implementation information to stakeholders was adequate. - Confidentiality of prescription information appeared adequate. - Pharmacists compliance was a major factor which limited the PMP's effectiveness. - Professional self-regulatory groups appear to lack the necessary financial, legal and political capacity to endure the level of risk that an effectively administered PMP would require.
Policy Evaluation	- The PMP did not significantly influence the prescribing of monitored or identified substitute medications or the incidence of multiple doctoring. Theft of monitored drugs appeared to increase corresponding with the programs introduction. - The average quantity of analgesic per prescription increased dramatically coinciding with the introduction of the Program. - Numerous interventions by stakeholders likely contributed to the decline in prescribing in the years preceding the Program. - Appropriateness of prescribing surveys and the appropriateness of discontinuation survey suggest that the pilot PMP did not result in any harm or reduce legitimate patient access to their medications. These surveys were limited by various biases.

CHAPTER 9

CONCLUSION AND FUTURE DIRECTION

The PMP was a broad-based intervention intended to address the suspected inappropriate access to narcotics and sedatives by a select number of patients through multiple doctoring. As well, it was intended to address the suspected excessive, indiscriminate prescribing by a select number of physicians. Three conditions are required for any such program to be effective. Firstly, the program must provide, or utilize, a sufficiently comprehensive data gathering system to permit identification of prescribing patterns that cause concern. The PMP did appear to be meeting this requirement since prescribing patterns that caused concern were being identified.

The second condition for an effective program is that it includes a mechanism to induce an effective investigation of the cause of the prescribing pattern of concern. The PMP in this province included such a mechanism via "alert" letters where the onus for investigation was on the prescriber and "explain" letters where the onus was shared between the prescriber and Program staff. One area where the PMP was not totally effective was in facilitating further investigation in cases where these preliminary mechanisms were insufficient.

The third requirement for an effective program is the existence and utilization of effective measures to deal with all instances of inappropriate prescribing patterns. The PMP as operated in this province did not meet this requirement adequately. The "alert"

and "explain" letters were not only an investigative tool but also a form of prescriber feedback intervention. The PMP data suggested that these interventions did have some positive impact. However, a significant deficiency in the Program was the failure to make use of existing regulatory or disciplinary channels to deal with prescribing patterns that failed to respond to the "alert" and "explain" letter interventions. In addition, since these channels are not always appropriate as interventions, the lack of use of other evidence-based targeted interventions, such as an academic detailing program, further limited the potential impact of the PMP in this province.

One might have expected a general reduction in the rate of prescribing of monitored drugs following the introduction of the PMP. It does appear that this happened; however, the time series data used in this analysis was limited,. Consequently, the PMP was not likely to be an effective means to target any broadly based overuse of sedatives and analgesics in this province. Information from the PMP shows a reduction in the number of prescriptions subsequently issued to patients who were the subject of alert letters sent to physicians in 91% of cases.[161] This, and the anecdotal prescriber feedback alluded to in the PMP report, does suggest that the Program may have had some positive impact on recognition and management of some patients dependent on these drugs. The increase in theft of monitored drugs from pharmacies following the implementation of the PMP was also consistent with some perceived impact on access to these drugs for purposes of abuse and illicit trade. It seems likely that the PMP was not completely successful in dealing with access by prescription to sedatives and analgesics

for abuse and illicit trade. A select number of physicians continued to prescribe PMP monitored drugs at rates that well exceeded ten times the provincial average (likely an underestimate as some pharmacies were failing to report and others were incompletely reporting data). This suggested that a risk to the general public persisted. The PMP could be viewed as successful if it had helped to identify this problem more clearly, although anecdotal information arising from stakeholder interviews with the evaluation team indicated that this problem was already clearly identified prior to the PMP. This is further attested to by the fact that multiple agencies had introduced measures targeting multiple doctoring and illicit trade in prescription drugs prior to the implementation of the PMP.

The PMP appears to have failed in that it did not facilitate efforts to deal with instances of likely abuse identified through Program data. The PMP report suggested that inaccuracies in Program data hindered the ability of the PMP to report suspected criminal activities to proper authorities.[161] This conclusion seems unfounded, as the inaccuracies alluded to would only lead to under- and not over-recognition of these problems. PMP data would also form only one source of information for authorities investigating instances of suspected criminal activity. The PMP report also suggested that the Program should be responsible for the preliminary investigation of prescribing patterns that raised concern. However, the "explain" letter system constitutes such an investigative tool. Prescribers who could reasonably justify their actions would not be subject to further scrutiny by responsible authorities. Conversely, prescribers failing to justify their actions

should rightly be reported to the NMB or other authority already having the mandate to deal with such issues.

Most pharmacies fully complied with the requirements of the PMP. However, following the implementation of the Program, a select number of independent pharmacies continued to refuse to participate by not submitting data as required under the Pharmaceutical Association Act. Initially, there were some 40 pharmacies not reporting; however, at the conclusion of the PMP, eleven were not reporting. These pharmacies were not randomly distributed throughout the province and some were located in the downtown area of St. John's. Discussions with the police and the NPA suggested that a disproportionate share of prescribing for illicit or non-medically-indicated purposes might be attributed to patients, physicians and pharmacies in this area. As well, a participating downtown pharmacist suggested that he lost customers to the non-participating pharmacies since the introduction of the PMP. The effect of these pharmacies' non-participation in the PMP on the availability of drugs for abuse and illicit purposes cannot be quantified. However, the lack of complete participation by pharmacies would be expected to limit the effectiveness of the PMP since some patients who inappropriately seek prescriptions may align themselves with the non-participating pharmacies. Disciplinary action against the non-compliant pharmacists had been terminated. A subsequent review of NLPDP data indicated that some of the highest-prescribing physicians of narcotics and benzodiazepines had practices that were located

in the same physical buildings or the same rural communities as the non-participating pharmacies.

The use of regulatory measures by the NPA against the non-participating pharmacies was time consuming and costly, but did entice some to commence reporting. The outcome of the efforts to induce compliance with the PMP by all pharmacies would have been highly relevant to any decision to continue, modify or abandon the Program. It would seem irrational to continue the Program in its existing form unless participation by all pharmacies could have been assured. The likely outcome of the efforts to induce compliance was difficult to judge as the approach being taken and the defence against it was legally based. Alternative measures to induce compliance may have been possible. These could have included the exclusion of pharmacies not participating in the PMP as dispensing sites for NLPDP reimbursed prescriptions. However, the legal ramifications of pursuing such an approach would have to be explored in advance. Such a measure would not likely excessively inconvenience patients since there were adjacent, substitute PMP participating pharmacies available. MCP has successfully used an analogous non-payment option in the case of health care providers who failed to remit information required under the Medical Care Insurance Act.

The pilot PMP cost in excess of $600,000 over two years and was projected to cost in excess of $350,000 annually to continue. As well, it placed an administrative burden on pharmacists, physicians and the NMB. There were no data on the

administrative burden of the Program for most parties. However, the NMB had estimated that approximately $40,000 of their executives' time was required each year to administer the Program which was significant in relation to the other core responsibilities of the Board. These other responsibilities continued without additional assistance throughout the tenure of the pilot PMP.

PMP staff recommended expansion of the Program to capture prescriptions dispensed by hospital pharmacies, nursing homes, and physicians and nurses in remote health stations. However, such an expansion would be costly and no data were available to suggest that such sources of prescription drugs were a source of concern with regard to abuse and illicit trade. An argument could be made to include prescriptions issued by dentists and veterinarians in the Program since some drug seekers may approach these alternate prescribers. However, it would seem more reasonable to initially rely on qualitative feedback from such prescribers, having warned them of the need to be vigilant, to identify if a problem was arising.

The PMP reported a number of additional administrative difficulties that potentially contributed to the limited effectiveness of the Program. Some of these included the lack of and irregular participation by some pharmacies, the use of outdated physician identification numbers and missing MCP numbers.

The PMP was shown to be of limited value in its existing form. Consequently, DOHCS decision makers were advised by CEG researchers to complement or replace it by implementing targeted evidence-based specific interventions such as peer prescribing reports and academic detailing to address the suspected indiscriminate prescribing by a limited number of physicians. Peer prescribing involves sending a comparison to specific physicians of their prescribing patterns compared to their peers with the intent that specific monitoring will deter extreme prescribing levels. Academic detailing involves having a trained pharmacist or physician visit targeted prescribers to re-educate them on the appropriateness of prescribing. Both interventions have been shown to be effective in some circumstances. Although academic detailing is costly on a widespread basis, there appears to be a limited number of prescribers to be targeted in this instance.

Peer prescribing reports and academic detailing require a data source, such as a PMP, to identify targets for intervention and to provide the necessary data to judge their effectiveness. To determine if a PMP is necessary in this province in the long term to support such interventions, one could compare the rate of prescribing of a select number of physicians with their comparable rate using NLPDP data. If the NLPDP data suffices to identify and track prescribing patterns, then the PMP may be providing duplicate information.

This research concluded that the pilot PMP had a marginal positive impact in achieving its desired objectives. As discussed, most patients who were the subject of

alert letters subsequently reduced the number of prescribers they visited and received a reduced number of prescriptions for monitored drugs. Ironically, the Program had the potential to achieve its objectives since it was supposed to monitor the prescribing activities of specific medications for all physicians, pharmacies and patients. However, various policy decisions throughout the Program's tenure limited its effectiveness. These policy decisions involved not effectively addressing: the non-participation by a limited number of pharmacists; the prescribing of a select number of physicians; and patients who did not reduce the number of general practitioners they visited despite being the subject of repeated alert letters to their physicians.

During the tenure of the PMP, a number of pharmacists failed to remit Program data as required under the Pharmaceutical Association Act. As well, there were a relatively small number of prescribers with very high levels of prescribing as measured by the NLPDP and PMP databases. Some others may have been undetected in the PMP database most likely because of their close physical location to the non-participating pharmacies. The respective regulatory organizations did not effectively address this issue despite a reasonable timeframe. These regulatory organizations' inability to accommodate the necessary financial, legal and political risk was attributed as the primary reasons. Since public safety may be compromised, policymakers should review current approaches with the idea of possibly strengthening the ability of these groups to endure the necessary risk or potential alternate arrangements. The use of an explicit approach is recommended.

The data collection process outlined in Chapter 6, specifically the tracking of prescribing patterns of monitored drugs, substitute medications, multiple doctoring and theft of monitored drugs from pharmacies included the period preceding and during the tenure of the Program. It is recommended that policymakers continue this data collection process as they contemplate introducing alternate interventions to address the policy problems that led to the introduction of the PMP. Consequently, the data analysis could include time periods before, during and after the PMP as well as periods where subsequent interventions are introduced. This could allow a better assessment of the impact of such interventions on general prescribing trends over a longer period of time.

The policy problem of inappropriate access to monitored drugs has been ongoing since the late 1980s. There have been multiple interventions prior to the PMP and likely additional ones to follow. Such an ad hoc approach to policy development is believed to underline the continuation of the policy problem for approximately 15 years which is inefficient. The approach has consumed significant financial resources and time by officials of all stakeholder groups including government.

The lack of an explicit approach for policy development, implementation and evaluation permitted the pilot PMP to continue with its limited effectiveness undetected. If the Program had not been fully evaluated, it may have been continued indefinitely at the request of stakeholder groups. This may have masked the continuing suspected illicit drug behaviour since the police, for example, had directed their efforts towards other

initiatives assuming that the PMP was fulfilling its objectives. The use of an explicit approach for policy-making proposed by Lomas assisted policymakers in their decision to reallocate the Program's resources.

The Lomas[3] framework for analysis was invaluable in assessing the policy implications of the pilot PMP. Undoubtedly, if policymakers had used this or a similar approach from the onset of the decision to pursue an intervention to address the policy problem, it is conceivable that the PMP may have been implemented in a more orderly fashion. However, there appears to be one area where the Lomas approach was inadequate in this application. For example, the Lomas approach strives at great length to accommodate stakeholder values when attempting to change practice patterns. However, in the example that they cited, the extent of opposition to the initiative (clinical practice guideline for caesarean section) was limited in comparison to the formal and organized opposition to the PMP (despite the existence of legislation in the latter instance). In the Lomas application, it appears that policymakers would accept and even anticipate some non-adherence to the chosen policy; however, in the case of a PMP, full compliance was necessary to achieve the Program's objectives. Less than full compliance could possibly have been tolerated for short durations provided that it was random and those seeking monitored drugs for inappropriate reasons were unaware of the non-compliance.

I believe that the Lomas approach could be strengthened whereby specific categories of stakeholders who may be opposed to the policy are identified in advance, as

well as measures to address each category of non-compliance. In this application, the non-compliance by some pharmacists was attributed to technical problems, financial reasons and resentment towards government-sponsored programs. Policymakers could have established different thresholds for the full participation of stakeholders. For example, the allowable time for participation by those experiencing technical difficulties could have been more liberal than those refusing for unsubstantiated reasons. As well, stakeholders could have agreed in advance on the process for submitting formal professional misconduct complaints and the required timelines. In retrospect, the resolve of certain pharmacists to continue, allegedly, to practice contrary to the Pharmaceutical Association Act was underestimated.

Table 9.1

Summary of the Conclusions and Future Direction

- An effective PMP must have a sufficient data gathering system, mechanisms to further investigate prescribing patterns of concern, and effective measures to deal with all instances of suspected inappropriate prescribing concerns.
- The current PMP did identify prescribing patterns of concern. However, further investigation of suspected problematic cases did not occur and there were a lack of measures to address all instances of suspected inappropriate prescribing.
- In most instances, patients who were the subject of alert letters reduced the number of physicians they visited. However, a small number increased their visits. There was no further action taken against those who responded unfavourably to the alert letters.
- The potential effect of the PMP was compromised by the lack of participation by some pharmacists. The use of regulatory measures was time consuming and costly, but did encourage some non-participating pharmacists to commence reporting.
- The broad-based PMP should be complemented or replaced with more specific measures such as academic detailing, peer prescribing and disciplinary action.
- The use of an explicit approach for policy development, implementation and evaluation assists in accommodating stakeholder values in the policy-making process and linking decisions to research evidence.

Since the policy problems that the PMP was intended to address remain, I propose the following recommendations and policy options.

9.1 RECOMMENDATIONS

- It is imperative that patients or prescribers suspected of criminal activity be identified to the RNC for investigation. It is recommended that the necessary legislative/regulatory changes be made to permit MCP, NLPDP and any PMP to initiate the sharing of information regarding individuals suspected of criminal activity with the police. A multi-stakeholder Working Group on Medication Abuse/Misuse (which included many of the PMP stakeholder groups) commissioned a pertinent legal review in 1999. It recommended minor changes to the Medical Care Insurance Act. Following these proposed changes and as an initial measure, MCP should immediately report information to the police regarding individuals who consistently visit five or more different general practitioners per month.

- The self-policing nature of the current PMP failed to curtail the suspected excessive prescribing by a select number of physicians. If the PMP were to continue, it is recommended that instances of inadequate response to "explain" letters be referred to the NMB for a complete investigation and disciplinary action, if warranted. It is also recommended that targeted peer prescribing, academic detailing or regulatory interventions be implemented immediately, singularly or in combination (depending

on the extent of suspected excessive prescribing), using either the PMP or NLPDP program databases to identify those for intervention and to track responses. As well, MCP should initiate medical services and financial audits of suspect prescribers because it is believed that they may be partly motivated by the financial compensation they receive for the services provided to patients seeking these medications.

- Regulatory measures have not to date successfully dealt with the non-participation by a select number of pharmacists in the PMP contrary to the Pharmaceutical Association Act. If a PMP were to continue in any form, it is recommended that Government seek a legal opinion regarding the implications of discontinuing participation by these pharmacies in the NLPDP pending their full participation in the PMP.

9.2 PMP POLICY OPTIONS

The interim evaluation of the PMP included an option for the NMB to continue to administer the Program. However, since that time the policy evaluation component of this research was completed. This research, as discussed above, concluded that the self-regulating groups, because of their limited resources, might not be able to endure the risk necessary to effectively administer a prescription monitoring program. Consequently,

unless measures are introduced to strengthen their ability to endure the necessary risk, it is not recommended that they continue to administer the Program.

Consequently, two options are proposed regarding the furtherance of the PMP, each with advantages, disadvantages and cost implications. Continuing the PMP (option 2) is proposed only where the above recommendations are implemented.

9.2.1 Option 1 – Discontinue the PMP

This option would permit the redistribution of the annual estimated program cost of $356,000. It would also avoid the continuing legal opposition to the Program by non-complying pharmacists. However, the problem of PMP monitored drug misuse remains. Consequently, the RNC, MCP and NLPDP would presumably have to reinitiate/continue with past interventions to address blatant inappropriate drug use.

Unfortunately, discontinuing the PMP would result in losing any potential benefit that the Program provided. Specifically, there appears to be a number of individuals (patients and physicians) who responded positively following the issuing of alert and explain letters.

9.2.2 Option 2 – Department of Health and Community Services to Administer the PMP

A proportion of the projected expenses such as office rent, business taxes, bank charges, legal fees, insurance and contingency fees could be avoided by having the DOHCS administer the Program since they already administer the NLPDP. This could reduce the projected cost to approximately $300,000 annually. As well, depending on the nature of prescription pads utilized, the Program could be administered for less than $300,000 annually.

The DOHCS could immediately impose (assuming a favorable legal opinion) financial disincentives for pharmacists and physicians not complying with the Program. Also, they could immediately report to police those individuals suspected of being involved in criminal activity. This option would involve the Department assuming the administrative burden of the Program.

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APPENDIX A

RESPONSE TO FREEDOM OF INFORMATION REQUEST

APPENDIX B

NEWFOUNDLAND AND LABRADOR

PRESCRIPTION MONITORING PROGRAM (PMP)

HANDBOOK FOR PRESCRIBING AND DISPENSING

HEALTH PROFESSIONALS

Newfoundland and Labrador
Prescription Monitoring Program
(PMP)

Handbook for Prescribing and Dispensing Health Professionals

Overview

General. The Newfoundland Medical Board (NMB) has implemented a province-wide prescription monitoring program for narcotics, benzodiazepines and other controlled drugs dispensed by community pharmacies. The **Newfoundland and Labrador Prescription Monitoring Program (PMP)** is a two year pilot project, funded by the Government of Newfoundland and Labrador and established in co-operation with the Newfoundland and Labrador Medical Association (NLMA), the Newfoundland Pharmaceutical Association (NPhA), and the Patient Research Centre of the Health Care Corporation of St. John's. The licensing bodies for the participating health professions endorse the PMP and have ensured the necessary regulations exist to support the program.

Prescription monitoring serves two important purposes. First, by providing accurate data on prescribing patterns for certain drugs to prescribers and pharmacists, these health professionals are able to maintain the best possible standards of practice. Licensing bodies for their professions are also able to make informed decisions about continuing education programs or to detect conditions that require other regulatory intervention.

Second, the PMP is part of a concerted effort by health professionals and other authorities to deter double doctoring and inappropriate prescribing. Drug abuse/misuse is aided by the lack of shared information among prescribers and pharmacists. Evidence from police forces indicates the problem of prescription drug diversion has grown in recent years, with narcotics and benzodiazepines being the most frequently abused drugs. Drug abuse creates tangible costs to health care and society as a whole. It produces unnecessary physician visits, hospital stays, laboratory tests and drug costs, in addition to the very real havoc that substance abuse causes in the lives of those directly affected.

Prescription monitoring programs are currently in place in British Columbia, Alberta, Saskatchewan, Manitoba and Nova Scotia, as well as many states in the United States. Many private drug insurance companies also provide a form of prescription monitoring limited to their clients.

Objectives. The PMP is a two-year pilot project to confirm the effectiveness of prescription monitoring in combating abuse and misuse of monitored drugs and to assist prescribers and pharmacists in improving their practice. Specifically, the PMP will assist in:

- providing the best possible health care to the people of Newfoundland and Labrador by sharing information among health professionals on patients they are treating in common;
- providing information on prescribing and dispensing practices;
- identifying persons who are double doctoring so that appropriate action may be taken; and,
- providing licensing authorities with accurate information regarding any inappropriate prescribing or dispensing practices.

Evaluation. The Clinical Epidemiology Group, Faculty of Medicine, Memorial University of Newfoundland will complete a thorough evaluation to determine the effectiveness of the PMP.

How the PMP works

General. Participation in the PMP is mandatory. Prescriptions for drugs listed in the *Schedule of Monitored Drugs* should be completed according to the example contained in this handbook. Prescriptions may be written on existing prescription pads or they may be transmitted verbally or electronically to the pharmacy where permitted.

Regardless of the format, **all information required on the approved prescription form must be sent to the community pharmacy.** Once filled, information on the prescription will be transmitted electronically on a regular basis from the community pharmacy to a central database where it will be assessed to determine any patterns or trends. The PMP will produce regular reports on general prescribing patterns, in addition to *alert letters* and *explain letters* to deal with individual cases.

There is no doubt that the PMP will require extra effort from prescribers and pharmacists, however, it is believed that the potential benefits far outweigh the inconvenience.

Confidentiality, Security and Use of Information. Patient and prescriber confidentiality will be preserved and protected by the PMP. Transmission of information will only occur through secure connections that meet industry standards. Information will be held securely, and will be used solely for the purposes of the PMP.

Schedule of Monitored Drugs. All drugs specified in the *Schedule of Monitored Drugs* should be prescribed using the approved prescription form. **Note that while orders for certain monitored drugs, including some narcotic medications, may be transmitted to a pharmacy in verbal or electronic form, prescribers must provide all information required on the PMP prescription form.** Prescribers are therefore strongly encouraged to use the PMP prescription form for all monitored drugs.

The drug list provided with this handbook is complete for the active ingredients being monitored. Given changes in the marketplace, drug brand names may vary from time to time and the list should not be considered exhaustive. Periodic updates will be issued to advise prescribers and pharmacists of additions to the *Schedule of Monitored Drugs*. Software vendors will also be provided with regular updates of the drugs being monitored and lists of those authorized to prescribe the monitored drugs.

Alert Letters. The PMP issues two types of letters to prescribers and pharmacists as part of its assessment process. The PMP prepares an *alert letter* about each patient who, within a thirty-day period, has received a prescription for monitored drugs from two or more prescribers. The *alert letter* details the patient's use of the drugs and shows the total number of prescribers involved. The purpose of the *alert letter* is to keep prescribers and pharmacists informed of their patient's drug consumption. Pharmacists may not receive *alert letters* in all cases.

Issuance of an *alert letter* does not necessarily mean that a patient is acting inappropriately. The information contained in an *alert letter* is intended primarily to enable a prescriber or pharmacist to make more informed decisions in providing therapy to patients.

Double doctoring is an offence contrary to federal statutes. As such, the PMP may report an individual suspected of double-doctoring narcotics to the Royal Newfoundland Constabulary or the Royal Canadian Mounted Police. However, such a referral will occur only after the PMP has obtained persuasive evidence that the patient may have been double doctoring and has consulted with the prescribers involved.

Explain Letters. The PMP also issues *explain letters* to prescribers regarding patients who receive prescriptions for monitored drugs that exceed recommended dosages. On receipt of an *explain letter*, prescribers are required by legislation to provide a written explanation of the medical indications that have caused the quantity of medication to be prescribed. In some cases, pharmacists may also receive *explain letters*. Responses will be reviewed by a committee of the PMP. Prescribers and pharmacists will receive a reply. These *letters* may not signify wrongdoing; however, responses give the PMP a better understanding of the prescribing data. The goal of *explain letters* is the maintenance of the best possible standards of care.

Peer pattern reports. The PMP will issue regular reports to all prescribers on general prescribing patterns for narcotics, benzodiazepines and other controlled drugs arranged by peer group. These reports will assist prescribers by providing meaningful comparisons with other prescribers having similar practices. Other reports on both prescribing and dispensing patterns will be prepared and distributed to members of the participating health professions.

Refills and part fills. Refills are not permitted for narcotic prescriptions. For part fills, the time intervals between fills must be specifically indicated both on the prescription and in the pharmacist's patient files. The intervals will be assessed by the PMP.

MCP Numbers. Each prescription must include the patient's Medical Care Commission (MCP) number. Out-of-province residents, as well as members of the Canadian Forces and the Royal Canadian Mounted Police, do not have MCP numbers. For patients from another province, prescribers should enter the appropriate provincial health insurance number on the prescription form. For members of the Royal Canadian Mounted Police, prescribers should enter the member's regimental number. For members of the Canadian Forces, prescribers should enter the member's service number. For others without an MCP number, such as out-of-country residents, enter identifying information such as a driver's license number or social insurance number. **Pharmacists should leave the MCP field blank for these persons.**

Prescription Pad Ordering and Security

Prescription pad ordering. Prescription pads may be ordered by telephoning the PMP at 709-726-5175, or by writing the Prescription Monitoring Program, 139 Water Street, Unit 6, St. John's Newfoundland, A1C 1B2. Please allow one week for processing and delivery. Most prescribers will receive an initial supply of two prescription pads of the PMP prescription forms. Each pad contains 75 sequentially numbered prescription forms, each of which includes the prescriber's name and license number.

New registrants and *locum tenens* may receive an initial supply of generic prescription pads from the PMP while their personalized prescription pads are being produced. On each generic prescription, prescribers must legibly print their name and license number. New registrants and *locum tenens* cannot use forms assigned to another prescriber.

Prescription pads should be kept in a secure location, preferably under lock and key.

Personalized prescription pads cannot be transferred between prescribers.

Loss or theft of prescription pads must be reported immediately to the PMP at 709-726-5175. Regular reports on lost/stolen prescription pads will be issued by the PMP to prescribers and pharmacists.

Completing a Prescription

Prescriptions should be written on the approved form, but may be written on personal prescription forms or transmitted to pharmacies electronically or verbally. ***All information required on the approved form must be transmitted to the pharmacy in order to have a prescription filled.*** Failure to complete all sections of the prescription entirely and accurately will normally cause the pharmacist to reject the prescription.

Quantities must be entered in both alpha and numerical format. (e.g. forty and 40) This is a good practice on all written prescriptions. The PMP prescription form requires the quantity be written separately from the other instructions as a safeguard against tampering.

Include the patient's MCP number on all prescriptions. For out-of-province patients, use their provincial health insurance plan number. For members of the Canadian Forces and the RCMP, use their service number or regimental number. Pharmacists should enter only the MCP number in their computer files.

The approved prescription form is required for the purchase of narcotics and controlled drugs that are to be used by the prescriber in the normal conduct of his/her practice. The prescriber should complete the prescription in his/her own name and use his/her license number in place of the MCP number. The form should be annotated "For Office Use".

Schedule of Monitored Drugs	
Drug Name (active ingredient)	**Some common trade names**
Androgens	
Fluoxymesterone	Halotestin tabs
Methyltestosterone	Metandren tabs
Nandrolone Decanoate	Deca Durabolin inj
Testosterone Cypionate	Depo-Testosterone inj
Testosterone Enanthate	Climacteron • Delatestryl
Testosterone Propionate	Malogen in oil
Testosterone Undecanoate	Andriol caps
Barbiturates	
Amobarbital Sodium	Amytal • Tuinal
Butabarbital Sodium	Butisol tabs
Butalbital	Fiorinal C ¼ • Trianal • Tecnal
Pentobarbital	Cafergot PB
Pentobarbital Sodium	Nembutal sodium inj • Nova Rectal supp
Phenobarbital Sodium	Phenobarb • Combinations-Donnatal, Bellergal Spacetabs
Secobarbital Sodium	Seconal • Tuinal
Benzodiazepines	
Alprazolam	Xanax
Bromazepam	Lectopam
Chlordiazepoxide HCL	Librium • Combinations - Librax, Chlorax, Corium
Clobazam	Frisium
Clonazepam	Rivotril
Clorazepate Dipotassium	Tranxene
Diazepam	Valium • E Pam • Vivol
Flurazepam HCL	Dalmane • Somnol
Lorazepam	Ativan
Nitrazepam	Mogadon • Nitrazadon
Oxazepam	Serax
Temazepam	Restoril
Triazolam	Halcion
Zopiclone	Imovane • Rhovane

Schedule of Monitored Drugs	
Drug Name (active ingredient)	**Some common trade names**
Miscellaneous Anxiolytics	
Chloral Hydrate	Noctec
Meprobamate	Equanil • 282 MEP
Opiate Agonists	
Anileridine(Anileridine HCL)	Leritine tabs
Anileridine(Anileridine Phosphate)	Leritine inj
Butorphanol Tartrate	Stadol NS
Codeine and salts	Many products
Dextropropoxyphene HCL	692
Dextropropoxyphene Napsylate	Darvon-N
Droperidol	Droperidol inj
Fentanyl	Duragesic
Fentanyl Citrate	Fentanyl Citrate inj
Hydrocodone Bitartrate	Many products, including Hycodan, Tussaminic DH• Tussionex
Hydromorphone HCL	Dilaudid • Hydromorph Contin
Meperidine HCL(Pethidine)	Demerol
Morphine (Opium)-see also 'Opium'	Opium Tincture
Morphine HCL and Sulfate	Many products, including MS Contin,MS IR
Opium- see also 'Morphine (opium)'	Donnagel-PG • Diban • Paregorique • Opium Tincture
Oxycodone HCL	Many products, including Oxycontin • Percocet • Endocet
Oxymorphone HCL	Numorphan
Opiate Partial Agonists	
Pentazocine HCL	Talwin tabs
Pentazocine Lactate	Talwin Inj

Schedule of Monitored Drugs	
Drug Name (active ingredient)	**Some common trade names**
Respiratory and Cerebral Stimulants	
Dextroamphetamine	Dexedrine
Diethylpropion HCL	Tenuate
Mazindol	Sanorex
Methylphenidate HCL	Ritalin • Riphenidate
Phentermine resin	Ionamin
Antidiarrheal Agents	
Diphenoxylate HCL	Lomotil
Antitussives	
Normethadone HCL	Cophylac •Cophylac expectorant
Unclassified Therapeutic Agents	
Modafinil	Alertec
Nabilone	Cesemet

Newfoundland and Labrador Prescription Monitoring Program

A project of the

Newfoundland Medical Board

in co-operation with the

Newfoundland and Labrador Medical Association

Newfoundland Pharmaceutical Association

Patient Research Centre, Health Care Corporation of St. John's

with funding from

The Department of Health and Community Services
Government of Newfoundland and Labrador

APPENDIX C

A PHYSICIAN SURVEY TO OBTAIN INPUT CONCERNING THE CONTENT AND IMPLEMENTATION OF A PROPOSED PRESCRIPTION MONITORING PROGRAM

Michael Doyle

Patient Research Centre

April 1998

Abstract

Background: Prescription monitoring programs (PMPs) are primarily intended to reduce the diversion of prescription medications to illicit purposes. The Newfoundland Medical Board is considering sponsoring a pilot PMP in this Province for narcotics, benzodiazepines and other controlled drugs. To help minimize the cost and administrative burden of providing the program, the primary purpose of this study was to determine: (1) which program features physicians consider worthwhile; and (2) what is the best way to inform and educate physicians about the proposed program.

Methods: A two page self-administered questionnaire and information sheet was mailed to a random sample of 300 of 1,034 physicians licensed to practice in Newfoundland and Labrador. The questionnaire contained five close-ended questions; space to provide information regarding additional classes of drugs they would like to see included in the program; and space to provide comments or concerns they may have.

Results: There were 145 (48.3%) respondents to the 300 questionnaires mailed. Respondents had similar baseline characteristics as the physician population except that they were more likely to be Canadian medical school graduates. It is not believed that this biased the results.

Among the respondents, 90.9% felt that the proposed program should have a toll-free phone line to provide physicians with information regarding a patient's previous prescriptions for monitored drugs. Only 27.8% felt that antibiotics should be included in the proposed program while 24.5% felt that other classes of drugs should be included. Approximately 82.5% supported receiving reports, which describe their prescribing patterns of monitored drugs in comparison with their peers.

Conclusions: Physicians were strongly supportive of the proposed program having a toll-free phone line and providing them with peer prescribing reports. Physicians are less supportive and somewhat uncertain of including other classes of drugs and including antibiotics in the proposed program. To enhance support for other classes of drugs being included, program sponsors should consider educating physicians on the extent and repercussions of inappropriately prescribing these substances. Finally, physicians prefer to receive written introductory information about the program.

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Introduction

Over the past several years, local medical and pharmaceutical professional associations, drug dependency groups, the Royal Newfoundland Constabulary (RNC), and provincial health agencies have noted an increase in the inappropriate use of prescription medications. Some prescription medications are being diverted to illicit uses or inappropriately prescribed for therapeutic purposes. Narcotics and benzodiazepines appear to be the most commonly abused substances. The RNC have estimated that over 600 people in the St. John's area are involved in obtaining and trafficking prescription medications. Many of the people involved are high school students and young adults in the community.

Prescription monitoring programs (PMPs) are primarily intended to reduce the diversion of prescription drugs to illicit purposes. Such programs are also credited with reducing inappropriate prescribing and educating the public, physicians, and pharmacists about various drugs. In addition, PMPs help in identifying: (1) patients who are abusing prescribed drugs; (2) any physicians who may be inappropriately prescribing; and (3) trends of drug use which may require intervention in terms of re-education or other public policy intervention.

With appropriate regulatory approval, a PMP involves physicians using special prescription pads when prescribing from a defined list of narcotics, benzodiazepines, and

other controlled drugs. Once a prescription for a monitored drug is dispensed, the pharmacist forwards the prescription information electronically to a central database. Information in the database is used to examine prescription trends. The program automatically generates "Alert Letters" to physicians informing them about patients who have received prescriptions for monitored drugs from two or more prescribers within a thirty-day period. Alert letters include details of the patient's drug use and the number of prescribers involved. "Explain Letters" are sent to physicians who have prescribed monitored drugs which exceed recommended dosages or manufacturer's instructions. Physicians are required to respond to explain letters with a rationale.

A PMP could also be used as a patient drug information source for physicians. It can provide prescribers with a toll-free phone line to obtain information regarding the patient's previous prescriptions for controlled substances. Information could include: the drugs prescribed, quantities, and where the prescription was provided and dispensed. It is also plausible that the toll-free line could also be used as a drug information source for physicians.

PMPs change the prescribing patterns of program-included drugs and their substitutes. They provide the physician with a partial escape from being intimidated to inappropriately prescribe. Unfortunately, they can adversely influence the appropriate prescribing of program-included drugs, since physicians may change their prescribing patterns when being monitored. As well, break and enter crimes may increase as a means

to access the monitored drugs and there may be an increased use of substitute illegal substances. Current research is considered insufficient to demonstrate the overall net benefits of PMPs.[1-4]

PMPs are normally implemented by the provincial government in cooperation with medical and pharmacy licensing and regulatory bodies. British Columbia, Alberta, Saskatchewan, Manitoba, and Nova Scotia as well as numerous states in the United States use some form of a PMP for controlled substances. The annual cost of PMPs across Canada ranges from $86,000 to $3 million.[4]

The Newfoundland Medical Board in cooperation with the Newfoundland and Labrador Medical Association, the Newfoundland Pharmaceutical Association, the Department of Health, and the Patient Research Centre is considering implementing a two-year pilot PMP to test its effectiveness in combating prescription medication abuse of narcotics, benzodiazepines, and other controlled drugs. To help minimize the cost and administrative burden of providing the program, the primary purpose of this study was to determine: (1) which program features physicians consider worthwhile; and (2) what is the best way to inform and educate physicians about the proposed program. Specifically, a short survey was sent to physicians asking their views on: (1) the inclusion of a toll-free phone line; (2) including additional classes of drugs to the program; (3) how they would like to receive introductory information about the program; and (4) receiving feedback

reports which describe their prescribing patterns in comparison with their peers. No similar surveys were found in the literature.

Methods

A two page, self-administered questionnaire was developed and tested with three physicians at the Health Sciences Centre and the Newfoundland Medical Board. It was mailed to a random sample of 300 physicians throughout Newfoundland and Labrador who were identified from a list of 1,034 physicians registered with the Newfoundland Medical Board. The list included all physicians licensed to practice medicine in the province. A response rate of 10% of the total provincial physician population was desired. Knowing that physicians have a particularly poor response rate to mailed questionnaires and there was insufficient time to send follow-up questionnaires, we chose a conservative sample of 300 in anticipation that a minimum of 100 would be returned.

A covering letter, PMP information sheet, and a stamped return envelope accompanied the questionnaire. The covering letter provided a rationale for the program, indicated its sponsors, and assured participant confidentiality. The information sheet provided additional details of how the proposed program could function. It included details of how the proposed program would notify physicians of patients suspected of double doctoring and where prescriptions may be inappropriately prescribed. It also explained: the merits of a toll-free phone line to allow physicians to obtain up-to-date

patient prescription information and disciplinary reporting procedures. A contact person was also suggested for individual contact. Due to the relatively short time frame to complete the study, there was no further follow-up. The study was approved by the Human Investigation Committee, Faculty of Medicine, Memorial University of Newfoundland in March 1998.

Demographic information concerning the Newfoundland and Labrador physician population was obtained from the Newfoundland Medical Board[5] and the Newfoundland and Labrador Medical Association.[6] The Medical Board information included the physician's: name, mailing address, specialty, country of training, and year of graduation. The Medical Association provided some information concerning method of physician payment (salary, fee for service or mixed).

The questionnaire contained five close-ended questions; space to provide information regarding additional classes of drugs they would like to see included in the program; and, space to provide comments or concerns they may have. The close-ended questions provided for answers under the categories of yes, no, and uncertain.

The data were analyzed using the computer package SPSS.[7] Descriptive statistics were compiled for the answers to the physician questionnaire and demographic characteristics. Chi-square analysis was used to assess differences in group proportions.

Results

There were 145 (48.3%) respondents to the 300 questionnaires mailed. Only one questionnaire was returned by the post office because of an incorrect address. Demographic information was obtained on the total Newfoundland and Labrador physician population from the master list provided by the Newfoundland Medical Board. Table 1 provides a baseline comparison of physician characteristics.

Table 1: Baseline Comparison of Physician and Respondent Characteristics

Physician Characteristics	Physician Population[a]	Respondents
% Male	75.3	74.5
% Urban Based	59.2[b]	54.2[c]
% Family Practitioner	50.3[d]	53.5
% Canadian Medical School Graduate	54.9	72.7
Year of Graduation from Medical School		
% Before 1970	19.5	14.5
% From 1970-79	27.6	28.3
% From 1980-89	35.0	37.9
% After 1990	18.1	19.3

(a) Source: Newfoundland Medical Board Update Report. February 1998.
(b) These physicians had either a St. John's, Mount Pearl or Corner Brook mailing address. It is expected a small proportion may practice on the outskirts of these centres, but maintain an urban postal address.
(c) 19% of respondents did not answer this question.
(d) Of the 1,034 total provincial physician population, 86 were listed as "residents" while 477 (50.3%) of the remaining 948 physicians were listed as "general practitioners."

The baseline comparison suggests that the survey respondents had similar characteristics as the physician population except that they were more likely to be Canadian medical school graduates.

About two thirds of the respondents (62.8%) indicated that they are paid by fee-for-service while the remainder are divided almost equally between salary and a mix of fee-for-service and salary. Information from the Medical Association suggests that approximately 70% of physicians are paid by fee-for-service and 30% by salary.[6] There was no information available on the mixed category.

Table 2 provides a summary of the physician responses to the primary questions of the survey.

Table 2: Number and Percentage Response for Questions Concerning the Proposed PMP.

Question	Number of Respondents	Response; number and (percent)		
		Yes	*No*	*Uncertain*
1. Would you like the proposed PMP to include a toll-free phone line?	143	130 (90.9)	6 (4.2)	7 (4.9)
2. Would you like to see antibiotics included in the proposed PMP?	144	40 (27.8)	74 (51.4)	30 (20.8)
3. Would you like to see other classes of drugs included in the proposed PMP?	143	35 (24.5)	63 (44.1)	45 (31.5)
4. Would you like to see the proposed PMP produce peer prescribing reports?	143	118 (82.5)	19 (13.3)	6 (4.2)

Although 35 respondents would like to see additional classes of drugs included in the proposed program, only 26 (17.9%) provided suggestions. Their responses to this question were divided into four drug categories and summarized in Table 3.

Table 3: Classes of Drugs Physicians Would Like to See Added to the Proposed PMP.

Class of Drug	Number of Respondents (%)
Stimulants	12 (8.3)
Pain Medications	5 (3.4)
Psychotropic and Antidepressant Medications	6 (4.1)
Other Classifications	3 (2.1)

Approximately 32 (22.1%) respondents indicated additional comments or concerns they had with the proposed program. Their responses were classified into three categories and summarized in Table 4.

Table 4: Classification of Comments/Concerns Physicians Have About the Proposed PMP.

Comment/Concern	Number of Respondents (%)
1. Concern over aspects of the program.	20 (13.8)
2. General support for the program.	8 (5.5)
3. Program not applicable to their practice.	4 (2.8)

The majority of respondents (71.5%) wanted to receive written introductory information only about the program. A modest amount (26.4%) wanted both written and personal communication while only 2.1 % indicated they would like to receive this information through personal contact alone with program administrators.

After receiving the questionnaires, two physicians wrote personal letters outlining their concerns about the proposed program. One expressed concern over possible unnecessary work that explain letters would cause for oncologists and palliative care physicians while the other referred to the need for guidelines for narcotic prescribing.

Discussion

The survey showed that physicians in general were very supportive of having a toll-free phone line in order to obtain up-to-date information regarding a patient's previous prescriptions for controlled substances. As well, they were very supportive of the proposed program providing them with detailed information regarding their prescribing patterns of narcotics and benzodiazepines in comparison with their peers. These peer prescribing reports are considered helpful in facilitating physicians buying into and using the data to improve practices.[8] It was also clear that physicians would like to receive introductory information upon program implementation either by correspondence or in conjunction with personal contact from program administrators as opposed to personal contact only.

Physician support of various components of the program was seen to reflect their general views towards responsible measures to combat prescription medication abuse of narcotics and benzodiazepines. It is believed that the covering letter and enclosed information sheet adequately served to inform physicians about the extent of prescription drug abuse of these substances in the community. In addition, publications from groups such as the Newfoundland and Labrador Medical Association as well as numerous media stories and interviews with the RNC and Medical Board officials on this subject within the past two years have heightened concern. Due to the impending implementation of the

proposed PMP in Newfoundland and Labrador, it was deemed inappropriate to query physicians regarding their general attitudes towards the program.

The disproportionate number of respondents who had graduated from a Canadian medical school had the potential to bias the survey results. However, the results of cross tabulations between respondents who had graduated from a Canadian medical school and the response to the main survey questions indicated there was a very small absolute difference in the type of response. As well, the difference was not statistically significant. Consequently, it is not likely that the survey results were biased.

The inappropriate use of antibiotics is a contributing factor in the increasing emergence and dissemination of antibiotic-resistant organisms on a global basis. Canada is considered one of the greatest per capita users of antibiotics in the industrialized world. Most are prescribed by primary care physicians.[9] At least two local studies have shown that a similar problem exists in Newfoundland and Labrador. One study suggests that fee-for service physicians have a significantly higher antibiotic prescribing rate than salaried physicians.[10] Another local study determined that only 42% of ciprofloxacin (an expensive antibiotic) prescriptions were deemed appropriate by an academic panel and 62% deemed appropriate by an industry panel.[11] Based on this evidence, the questionnaire used in this study was amended to include a question regarding physician attitudes towards including antibiotics in the proposed program.

The survey showed, however, that physicians were less supportive of including antibiotics and other classes of drugs in the proposed PMP. This may in part be due to the lack of general knowledge about the level of inappropriate prescribing of antibiotics and other classes of drugs. It is likely that if the covering letter had been expanded to describe antibiotic prescribing problems and an additional information sheet included on this topic, physician support may have been greater.

Only 26 (17.9%) respondents specified any additional classes of drugs they would like to see included in the program. This suggests that physicians may not perceive that other classes of drugs are inappropriately used. Most of the suggestions for additional classes of drugs to be included are substances, which were always intended to be covered. The most notable example was Ritalin (methylphenidate). The pain medication category included analgesics and anti-inflammatory substances, of which, those containing narcotics are also proposed to be included. The psychotropic and mood altering medications category referred mostly to antidepressant medications. The "other" category referred to medications such as anti-migraine medications and steroids.

The physician characteristics of respondents who answered "no" to either: (1) having antibiotics included in the program, and (2) having the program provide them with peer prescribing reports were compared with the base line characteristics of those who responded "yes" and "uncertain." This was undertaken to determine if there were any physician characteristics that were unique to these physicians. However, the results

of the chi-square analysis suggested that there were no statistically significant differences in baseline characteristics between the respondents for either group.

Many of the respondents who expressed concern over aspects of the program referred specifically to the need to ensure patient confidentiality. This also included not allowing outside agencies such as drug companies access to prescribing information. Other concerns referred to the: status of physicians undertaking locums; the need for punitive measures for physicians who inappropriately prescribe; potential negative clinical effects on patients who are appropriately receiving monitored drugs; ensuring fair peer comparisons are made; and, the additional time required to produce explain letters and appropriate compensation for this work.

Although the questionnaire did not solicit physicians' attitudes towards the program directly, some comments indicated general support for the program. One emergency room physician at a pediatric acute care facility stated that although she rarely prescribes narcotics or benzodiazepines, she does care for a significant number of young people brought to the facility under the influence of these substances. As well, she added that the number of cases appears to be increasing. Only three physicians indicated that the program was not applicable to their practice.

There were some limitations to this study. The relatively limited time frame to complete the study did not allow for follow-up questionnaires to be mailed in order to

increase the response rate of 48.3%. Another physician survey in Newfoundland received a response rate of 44.8% with one mailed survey and 59.1% with a follow-up survey.[12] As well, it cannot be determined if all respondents had the same understanding of the problem of prescription medication abuse. Also, since the survey was anonymous, rather than confidential, there was no way to obtain information on the non-respondents to determine if they were different from respondents. Finally, if sufficient time had been available, the use of a physician focus group prior to developing the questionnaire could have better ensured that the questions more accurately reflected physicians' concerns about prescription medication abuse.

In conclusion, this survey found that physicians were strongly supportive of the proposed PMP having a toll-free phone line to obtain up-to-date patient drug information. As well, they support receiving peer prescribing reports, which describe their prescribing patterns in relation to their peers. Physicians were less supportive and somewhat uncertain of including classes of drugs other than narcotics and benzodiazepines in the proposed program. To enhance support for other classes of drugs being included, program sponsors should consider educating physicians on the extent and repercussions of inappropriately prescribing these substances. Finally, they prefer to receive written introductory information about the program rather than having program administrators contact them.

Acknowledgments: This study was supported jointly by the Newfoundland Medical Board and the Patient Research Centre, Health Care Corporation of St. John's.

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APPENDIX D

BENZODIAZEPINE AND ANALGESIC CONVERSION TABLES

Analgesic Conversion Table

Opioid Analgesics: Approximate Analgesic Equivalences			
Drug	Equivalent Dose (mg.) (compared to morphine 10 mg. IM)		Duration of Action (hours)
	Parenteral	Oral	
Strong Opioid Agonists:			
Morphine	10	60	3-4
Oxycodone	15	30	2-4
Hydromorphone	1.5	7.5	2-4
Anileridine	25	75	2-3
Levorphanol	2	4	4-8
Meperidine	75	300	1-3
Oxymorphone	1.5	4 (rectal)	3-4
Methadone	-	–	-
Heroin	5-8	10-15	3-4
Weak Opioid Agonists:			
Codeine	120	200	3-4
Propoxyphene	50	100	2-4
Mixed Agonist-Antagonists:			
Pentazocine	60	180	3-4
Nalbuphine	10	-	3-6
Butorphanol	2	-	3-4

Reprinted in part from: Cancer Pain: A Monograph on the Management of Cancer Pain, Health and Welfare Canada, 1984. Foley, K.M., New England Journal of Medicine. 313: 84-95, 1985. Arnoff, G.M. and Evans, W.O., In Evaluation and Treatment of Chronic Pain, 2nd Ed, G.M. Arnoff (Ed.), Williams and Wilkins, Baltimore, pp.359-368, 1992. Cherny, N.I. and Portenoy, R.K., In: Textbook of Pain, 3rd Ed., P.D. Wall and R. Melzack (Eds.), Churchill Livingstone, London, pp. 1437-1467, 1994.

Benzodiazepine Conversion Table

Generic Name	Comparative Dose (mg.)	Activity	Principal Use
Alprazolam	0.5	Intermediate Acting	Anxiolytic
Bromazepam	3	Intermediate Acting	Anxiolytic
Chlordiazepoxide	25	Long Acting	Anxiolytic
Clonazepam	0.25	Long Acting	Anti Convulsant, Anxiolytic
Clorazepate	10	Long Acting	Anxiolytic
Diazepam	5	Long Acting	Anxiolytic
Flurazepam	15	Long Acting	Hypnotic
Lorazepam	1	Intermediate Acting	Anxiolytic, Hypnotic
Nitrazepam	2.5	Long Acting	Hypnotic
Oxazepam	15	Intermediate Acting	Anxiolytic, Hypnotic
Temazepam	10	Intermediate Acting	Hypnotic
Triazolam	0.25	Short Acting	Hypnotic

Reprinted in part from: Bezchlibnyk-Butler, K., Jeffries, J.J., eds. Clinical Handbook of Psychotropic Drugs. Toronto: Hogrefe and Huber, 2000.

APPENDIX E

POTENTIAL NARCOTIC AND BENZODIAZEPINE SUBSTITUTE MEDICATIONS

Potential Narcotic Substitutes		
Molecule		
Carisoprodol	Ibuprofen	Naproxen
Celecoxib	Indomethacin	Piroxicam
Cyclobenzaprine	Ketoprofen	Rofecoxib
Diclofenac	Ketorolac	Salsalate
Diflunisal	Mefenamic Acid	Sulindac
Etodolac	Meloxicam	Tenoxicam
Fenoprofen	Meprobamate	Tiaprofenic Acid
Floctufenine	Methocarbamol	Tolmetin
Flurbiprofen	Nabumetone	

Potential Benzodiazepine Substitutes		
Molecule		
Amitriptyline	Methotrimeprazine	Trazodone

APPENDIX F

CONSENT FORM FOR PHARMACISTS' PARTICIPATION

IN THE APPROPRIATENESS SURVEYS

FACULTY OF MEDICINE
MEMORIAL UNIVERSITY OF NEWFOUNDLAND
ST. JOHN'S, NEWFOUNDLAND A1B 3V6

CONSENT TO PARTICIPATE IN BIO-MEDICAL RESEARCH

(Pharmacist for First Survey)

TITLE: Evaluation of the Newfoundland and Labrador Pilot Prescription Monitoring Program (PMP) for Narcotics and Benzodiazepines.

INVESTIGATOR(S): Mike Doyle, Patient Research Centre, HSC
Dr. Patrick S. Parfrey, Patient Research Centre, HSC
Dr. Brendan J. Barrett, Patient Research Centre, HSC

SPONSOR: Department of Health and Community Services, Government of Newfoundland and Labrador.

You have been asked to voluntarily participate in a research study. You may decide not to participate or withdraw from the study at any time. Confidentiality of patient and physician information will be carefully maintained by the investigator.

Purpose of the Study

Prescription monitoring programs (PMPs) are primarily intended to reduce the diversion of prescription drugs to illicit purposes. They are also credited with reducing inappropriate prescribing and educating the public, physicians, and pharmacists about various drugs. In addition, they help in identifying: patients who are abusing prescribed drugs; physicians who are inappropriately prescribing; and, trends of drug use which may require intervention in terms of re-education or other public policy intervention.

A Prescription Monitoring Program (PMP) for narcotics, benzodiazepines, and other controlled drugs was implemented in Newfoundland and Labrador at the request of local medical and pharmaceutical professional associations, drug dependency groups, the Royal Newfoundland Constabulary (RNC), and provincial health agencies.

Due to the additional administrative burden that the PMP places on physicians and pharmacists; and, the cost of the program, it is necessary to evaluate its effectiveness. Other jurisdictions have found that PMPs have both favourable and unfavourable effects on

prescribing patterns. They reduce the diversion of prescription medication to illicit purposes but, patients who may be legitimately prescribed monitored drugs could have their medications discontinued or substituted for less effective ones. The PMP may reduce both appropriate and inappropriate drug use.

The Clinical Epidemiology Group, Memorial University of Newfoundland has designed a study to evaluate the overall effectiveness of the pilot PMP. You have been invited to voluntarily participate in the component of the study which is intended to assess the reasons for narcotic and benzodiazepine prescribing before/after the PMP.

Description of the Study

It is proposed that a random sample of information abstracted from patient medical records be reviewed by a panel of physicians for appropriateness of narcotic and benzodiazepine prescribing. The panel would include a general practitioner, specialist in pain management, and a psychiatrist. Your participation would involve identifying several patients (and the prescribing physicians) who were dispensed narcotics and benzodiazepines by your pharmacy over a specified two-day period. The investigator will be responsible for maintaining the confidentiality of this information. The investigator would then contact the prescribing physician to seek their participation in the study. Physician participation would involve allowing a nurse researcher to extract information from patients' medical record for review by the panel as well as a short interview. To ensure confidentiality, patient and physician names would not be forwarded to the panel.

The panel will be attempting to determine the appropriateness of the prescription based on guidelines for appropriateness. These guidelines have been developed by the panel in accordance with published literature. A similar, follow-up survey will be completed in approximately one year.

Patient participants who are residents of nursing homes and patients of acute care institutions will be excluded from the study.

Benefits

You will be paid a small stipend for your participation.

Liability Statement

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate. In

no way does this waive your legal rights nor release the investigators, sponsors, or institutions from their legal and professional responsibilities.

Other Relevant Information

Your identity and the identity of your patient will remain confidential unless required by law.

Resource People

The investigator or his designate is available to answer all your questions. If you have additional questions during the course of this study about the research or your rights as a research participant, you may address them to **Human Investigations Committee** at **737-6762**. In the event problems arise, please contact Mike Doyle at 729-0338.

Voluntary participation in the study

Your participation in this study is voluntary. You may refuse to participate or may withdraw at any time during the study. You will be provided a copy of the signed consent form.

I, _____, the undersigned, agree to my participation in the research study described until December 31, 2003.

Any questions I had, have been answered and I understand what is involved in the study. I realize that participation is voluntary and that there is no guarantee that I will benefit from my involvement. I acknowledge that a copy of this form has been given to me.

_____
(Signature of Participant) (Date)

_____
(Signature of Witness) (Date)

Participant's initials _____

To be signed by investigator

To the best of my ability I have fully explained to the participant the nature of this research study. I have invited questions and provided answers. I believe that the participant fully understands the implications and voluntary nature of the study.

_____

(Signature of the Investigator) (Date)

Phone Number

APPENDIX G

CONSENT FORM FOR PHYSICIANS' PARTICIPATION IN THE APPROPRIATENESS SURVEYS

FACULTY OF MEDICINE
MEMORIAL UNIVERSITY OF NEWFOUNDLAND
ST. JOHN'S, NEWFOUNDLAND A1B 3V6

CONSENT TO PARTICIPATE IN BIO-MEDICAL RESEARCH

(Physician for First Survey)

TITLE: Evaluation of the Newfoundland and Labrador Pilot Prescription Monitoring Program (PMP) for Narcotics and Benzodiazepines.

INVESTIGATOR(S): Mike Doyle, Patient Research Centre, HSC
Dr. Patrick S. Parfrey, Patient Research Centre, HSC
Dr. Brendan J. Barrett, Patient Research Centre, HSC

SPONSOR: Department of Health and Community Services, Government of Newfoundland and Labrador.

You have been asked to voluntarily participate in a research study. You may decide not to participate or withdraw from the study at any time. Confidentiality of patient and physician information will be carefully maintained by the investigator.

Purpose of the Study

Prescription monitoring programs (PMPs) are primarily intended to reduce the diversion of prescription drugs to illicit purposes. They are also credited with reducing inappropriate prescribing and educating the public, physicians, and pharmacists about various drugs. In addition, they help in identifying: patients who are abusing prescribed drugs; physicians who are inappropriately prescribing; and, trends of drug use which may require intervention in terms of re-education or other public policy intervention.

A Prescription Monitoring Program (PMP) for narcotics, benzodiazepines, and other controlled drugs was implemented in Newfoundland and Labrador at the request of local medical and pharmaceutical professional associations, drug dependency groups, the Royal Newfoundland Constabulary (RNC), and provincial health agencies.

Due to the additional administrative burden that the PMP places on physicians and pharmacists; and, the cost of the program, it is necessary to evaluate its effectiveness. Other jurisdictions have found that PMPs have both favourable and unfavourable effects on

prescribing patterns. They reduce the diversion of prescription medication to illicit purposes but, patients who may be legitimately prescribed monitored drugs could have their medications discontinued or substituted for less effective ones. The PMP may reduce both appropriate and inappropriate drug use.

The Clinical Epidemiology Group, Memorial University of Newfoundland has designed a study to evaluate the overall effectiveness of the pilot PMP. You have been invited to voluntarily participate in the component of the study which is intended to assess the reasons for narcotic and benzodiazepine prescribing before/after the PMP.

Description of the Study

Pharmacists who have consented to participate in the study have randomly identified several of your patients who have been dispensed prescriptions for monitored drugs prescribed by you over a specific two day period. Your participation in the study would involve permitting a physician or nurse researcher to abstract information from these patients' medical records for subsequent review by a panel of physicians. The panel would include a general practitioner, specialist in pain management, and a psychiatrist. To ensure confidentiality, anonymous patient and physician case numbers will be used, no names will appear. The panel will attempt to determine the appropriateness of the prescription based on guidelines. These guidelines have been developed by the panel in accordance with published literature. The physician or nurse researcher will also briefly interview you regarding the information abstracted to verify that the chart data accords with your thoughts on the prescription and patient involved.

Duration of Participation

Your voluntary participation is strictly limited to allowing the physician or nurse researcher access to a limited number of patient records and a brief interview.

Benefits

You will be paid a small stipend for your participation.

Liability Statement

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate. In no way does this waive your legal rights nor release the investigators, sponsors, or institutions from their legal and professional responsibilities.

Other Relevant Information

Your identity and the identity of your patient will remain confidential unless required by law.

Resource People

The investigator or his designate is available to answer all your questions. If you have additional questions during the course of this study about the research or your rights as a research participant, you may address them to **Human Investigations Committee** at **737-6762**. In the event problems arise, please contact Mike Doyle at 729-0338.

Voluntary participation in the study

Your participation in this study is voluntary. You may refuse to participate or may withdraw at any time during the study. You will be provided a copy of the signed consent form.

I, _____, the undersigned, agree to my participation in the research study described.

Any questions I had, have been answered and I understand what is involved in the study. I realize that participation is voluntary and that there is no guarantee that I will benefit from my involvement. I acknowledge that a copy of this form has been given to me.

_____
(Signature of Participant) (Date)

_____
(Signature of Witness) (Date)

To be signed by investigator

To the best of my ability I have fully explained to the participant the nature of this research study. I have invited questions and provided answers. I believe that the participant fully understands the implications and voluntary nature of the study.

_____
(Signature of the Investigator) (Date)

Phone Number

Participant's initials _____

APPENDIX H

CLINICAL DATA EXTRACTION FORM FOR THE APPROPRIATENESS SURVEYS

Data Extraction Form

Use of Monitored Drugs in the Community

Demographic Data

Date (of patient visit; m/d/y) _____/_____/_____ Physician # _____

Date of Birth (m/d/y) of Physician _____/_____/_____ Gender of Physician 1.Male 2.Female

Location 1. St. John's, Mount Pearl

2. Other

Monitored Drug Prescribed	Dose	Duration	Reason for Monitored Drug Selection

Use of Monitored Drugs In the Community

Clinical Data

Patient #_____

Age(years)_____ of Patient

Gender 1.Male 2.Female of Patient

New patient 1.Yes 2.No

Presenting Complaint _____ Code_____

History of Present Illness(as per chart)

Describe symptom pattern, severity, duration. _____

Was a specific diagnosis made? _____

Is there supporting evidence from laboratory, clinical findings or consultants? _____

Pregnant 1.Yes 2.No

Relevant Past Medical History(recent injury or surgery, cancer, arthritis, headache, anxiety, sleep disorder, depression, dependency/abuse)

Treatments tried to date for presenting problem.

(1) **Drugs.** Is there evidence of:

(1) Use of co-interventions (e.g., antidepressants, anticonvulsants, anti-inflammatory steroids). _____

(2) Prescriptions to prevent side effects (e.g., opiods, laxatives, anti-emetic). _____

(3) Stepwise progression in drug potency or dose? _____

(2) **Non-pharmacological**; e.g. behavioral therapy, psychotherapy, non-traditional therapy. _____

Has the patient been prescribed this monitored drug previously? _____

If yes, provide details. _____

How long has the patient been using this monitored drug? _____

When was this medication last prescribed? _____

Have there been other treatments that could be used which were contraindicated by allergy/intolerance/co-morbidity? _____

Is patient being helped by therapy? _____

Is there a lack of community resources impeding appropriate therapy? _____

Is this patient expected to live longer than one year? _____

Is this patient your ongoing patient? _____

Factors influencing decision to prescribe monitored drug.

1. Was there a clear diagnosis in this instance?
   Uncertain 1 2 3 4 5 Very Clear

2. Was there some patient intimidation/expectation or demand?
   No Influence 1 2 3 4 5 Strong Influence

3. Did you feel that the patient would visit another physician if they did not receive monitored drug?
   No Influence 1 2 3 4 5 Strong Influence

APPENDIX I

CONSENT FORM FOR PHARMACISTS' PARTICIPATION IN THE DISCONTINUATION SURVEY

FACULTY OF MEDICINE
MEMORIAL UNIVERSITY OF NEWFOUNDLAND
ST. JOHN'S, NEWFOUNDLAND A1B 3V6

CONSENT TO PARTICIPATE IN BIO-MEDICAL RESEARCH

(Pharmacist for Second Survey)

TITLE: Evaluation of the Newfoundland and Labrador Pilot Prescription Monitoring Program (PMP) for Narcotics and Benzodiazepines.

INVESTIGATOR(S): Mike Doyle, Patient Research Centre, HSC
Dr. Patrick S. Parfrey, Patient Research Centre, HSC
Dr. Brendan J. Barrett, Patient Research Centre, HSC

SPONSOR: Department of Health and Community Services, Government of Newfoundland and Labrador.

You have been asked to voluntarily participate in a research study. You may decide not to participate or withdraw from the study at any time. Confidentiality of patient and physician information will be carefully maintained by the investigator.

Purpose of the Study

Prescription monitoring programs (PMPs) are primarily intended to reduce the diversion of prescription drugs to illicit purposes. They are also credited with reducing inappropriate prescribing and educating the public, physicians, and pharmacists about various drugs. In addition, they help in identifying: patients who are abusing prescribed drugs; physicians who are inappropriately prescribing; and, trends of drug use which may require intervention in terms of re-education or other public policy intervention.

A Prescription Monitoring Program (PMP) for narcotics, benzodiazepines, and other controlled drugs was implemented in Newfoundland and Labrador at the request of local medical and pharmaceutical professional associations, drug dependency groups, the Royal Newfoundland Constabulary (RNC), and provincial health agencies.

Due to the additional administrative burden that the PMP places on physicians and pharmacists; and, the cost of the program, it is necessary to evaluate its effectiveness. Other jurisdictions have found that PMPs have both favourable and unfavourable effects on

prescribing patterns. They reduce the diversion of prescription medication to illicit purposes but, patients who may be legitimately prescribed monitored drugs could have their medications discontinued or substituted for less effective ones. The PMP may reduce both appropriate and inappropriate drug use.

The Clinical Epidemiology Group, Memorial University of Newfoundland has designed a study to evaluate the overall effectiveness of the pilot PMP. You have been invited to voluntarily participate in the component of the study which is intended to measure the rate of inappropriate discontinuation of monitored drugs following the introduction of the PMP.

Description of the Study

It is proposed that a physician or nurse investigator conduct telephone interviews with patients who had been receiving a prescription for a monitored drug(s) for a minimum of three months before the PMP was introduced and who were taken off this drug or substituted to a non-monitored agent once the PMP was implemented. (Prescribing physicians would also be interviewed by telephone where necessary.)

If you agree to participate, officials from the Newfoundland and Labrador Prescription Drug Program will identify directly to you and only to you the names of several of its clients which meet the criteria described above and whose monitored medication(s) were dispensed at your pharmacy.

Your participation would involve contacting these patients to request that their name be forwarded to a physician or nurse investigator who would seek their consent to participate in a study designed to measure the impact of the PMP on prescribing patterns. The principal investigator will be responsible for maintaining the confidentiality of this information.

If the patient agrees, a physician or nurse investigator would phone the patient to seek their consent and to discuss their previous use of monitored drug(s), and the possible reasons for discontinuation. Specifically, the investigator would attempt to determine if the indication still exists according to guidelines for the monitored drug use; or, if there is an effective alternative therapy for the indication. Possible reasons for discontinuing the monitored drug may include: (1) inappropriate under-utilization following the PMP; (2) inappropriate over-utilization for therapeutic reasons prior to the PMP; (3) illicit use of monitored drugs prior to the PMP; or, (4) the patient's condition has changed and the monitored drug is no longer indicated. This survey is attempting to measure only the initial reason for discontinuation.

Patient participants who are deemed to be legally or mentally incompetent, minors, residents of nursing homes and patients of acute care institutions will be excluded from the study.

Duration of Participation

Your voluntary participation is strictly limited to: contacting several patients to request that their name be forwarded to a physician or nurse investigator.

Benefits

You will be paid a small stipend for your participation.

Liability Statement

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate. In no way does this waive your legal rights nor release the investigators, sponsors, or institutions from their legal and professional responsibilities.

Other Relevant Information

Your identity and the identity of your patient will remain confidential. Unless required by law or other regulatory body, only the physician or nurse investigator will have access to data identifying subjects by name.

Resource People

The investigator or his designate is available to answer all your questions. If you have additional questions during the course of this study about the research or your rights as a research subject, you may address them to **Human Investigations Committee** at **737-6762**. In the event problems arise, please contact Mike Doyle at 729-0338.

Voluntary participation in the study

Your participation in this study is voluntary. You may refuse to participate or may withdraw at any time during the study. You will be provided a copy of the signed consent form.

I, _____, the undersigned, agree to my participation in the research study described.

Participant's initials _____

Any questions I had, have been answered and I understand what is involved in the study. I realize that participation is voluntary and that there is no guarantee that I will benefit from my involvement. I acknowledge that a copy of this form has been given to me.

_____
(Signature of Participant) (Date)

_____
(Signature of Witness) (Date)

To be signed by investigator

To the best of my ability I have fully explained to the subject the nature of this research study. I have invited questions and provided answers. I believe that the subject fully understands the implications and voluntary nature of the study.

_____
(Signature of the Investigator) (Date)

Phone Number

APPENDIX J

PATIENT INTERVIEW SCRIPTS AND DISCONTINUATION SURVEY

Interview Script (Pharmacist) for Discontinuation Survey

Hello, may I please speak with (name of proposed participant). My name is (Name of Pharmacist). I am a pharmacist who works at (Name of Pharmacy and Location) where some of your prescription medication is dispensed.

I am assisting the Medical School at Memorial University who are researching the use of various prescription medications. Your name was selected by chance as a possible study participant. The purpose of my call is to seek your approval for a physician or research nurse directly involved in the study to call you. This study is voluntary and you may choose not to participate. If you choose to take part a physician or research nurse will call you at a later date to ask some questions on the phone about some of your prescription medications.

Would you be interested in helping in this study?

If yes } Indicate approximate time that a physician or research nurse would be best to call.

If no } Thank the person and finish the call.

Interview Script (Physician or Research Nurse) for Discontinuation Survey

Hello, may I please speak with (name of proposed participant). My name is (name of physician/research nurse). I am a research assistant with the Medical School at Memorial University. I understand that (name of pharmacist and location of pharmacy) has been in contact with you recently and that you agreed that I may call you to ask some questions over the phone regarding your use of some prescription medications.

If you decide to participate, your answers will be written down and combined with others who also take part. Your name will not be associated with your answers and information will be kept confidential. It may take up to 10 minutes to answer all the questions. Participation in the study is voluntary. You may decide not to participate or may stop answering questions at any time.

Would you be interested in helping in this study?

If yes and convenient	}	Go to questionnaire.
If yes and not convenient	}	Arrange a time to call back.
If no	}	Thank the person and finish the call.

Discontinuation Survey

Pharmacy records indicate that you were receiving a prescription each month for (name of drug) that was stopped around June 2000.

1. Can you tell me why your doctor prescribed this medication in the first instance? (Request description of diagnosis/symptoms)

2. Have you tried other treatments/therapies/medications for this condition before (name of drug) was stopped? If yes, were they effective?

3. Why do you feel your physician stopped prescribing this medication?

4. Can you tell me what happened once the medication was stopped?
   a. Did the condition continue?
   b. Did your physician restart the medication at a later date?
   c. Were there any substitute medications/therapy prescribed?

5. Are you Male _____ Female_____

6. Age bracket 20-45 _____ 46-64 _____ 65+ _____

Thank you for participating in this research.