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SYNTHESIS SERIES

Pharmaceutical Issues

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This report is one in a series of 10 syntheses of HTF project results covering the following topics: home care, pharmaceutical issues, primary health care, integrated service delivery, Aboriginal health, seniors' health, rural health/telehealth, mental health, and children's health. The tenth document is an overall analysis. All are available electronically on the HTF website (**www.hc-sc.gc.ca/htf-fass**), which also contains information on individual HTF projects.

Executive Summary

The Health Transition Fund (HTF), a joint effort between federal, provincial, and territorial governments, was created out of the 1997 federal budget to encourage and support evidence-based decision making in health care reform. Between 1997 and 2001, the HTF funded approximately 140 different pilot projects and/or evaluation studies across Canada. In order to communicate research evidence from the projects to decision-makers, experts were employed to synthesize the key process and outcome learnings in each of nine theme or focus areas: home care, pharmaceutical issues, primary care/primary health care, integrated service delivery, children's health, Aboriginal health, seniors' health, rural health/telehealth, and mental health. This document summarizes the key learnings from 25 projects in the pharmaceutical issues theme area. It has been prepared by Wendy Kennedy, PhD, and Robert Goyer, PhD, Faculty of Pharmacy, Université de Montréal.

Pharmaceutical Issues in Canada

A number of the HTF projects addressed issues of pharmacotherapy (used loosely in this context as any aspect of health care involving pharmaceuticals). The main theme was improvement in the use of pharmaceuticals. A secondary theme was the make-up and population coverage of prescription drug insurance programs.

Because of the increasing cost of prescription drugs, pharmacotherapy remains the focus of attention for many health care decision-makers and was the first of four key areas on which the Fourth Annual Premiers' Conference decided to focus its energy and resources (News Release, August 2, 2001). The chief drivers for this increase are change from older to newer treatments and increases in the use of existing treatments. Non-optimal use of drugs is certainly responsible for part of the increased cost of pharmacotherapy. All stakeholders play a role in this non-optimal use: patients, prescribers, pharmacists, manufacturers, and government authorities. The other health care sectors must also bear the burden of the non-optimal use of drugs; inappropriate prescriptions and inadequate adherence to treatment regimens can cause increased use of physician, emergency, and hospital services.

Both patients and health professionals require easy access to credible, pertinent, understandable information from sources other than the media and the pharmaceutical manufacturers, which are too often marketing-driven rather than information-driven. This problem has been complicated by the recent increase in direct-to-consumer advertising, which is also marketing-driven. Physicians and pharmacists could profit from the development of uniform clinical practice guidelines (CPGs), which lay out the best therapy and management of a given disease or condition.

Even if CPGs are of optimal quality, they alone do not ensure a positive change in prescribing. HTF studies show that interactive forms of intervention, such as audit, feedback, academic detailing, and a team approach between physicians and pharmacists, appear to be effective in influencing some types of pharmacotherapy, albeit to a limited extent. Because physicians in the community have little communication with the pharmacists treating the same patients, facilitation of team care would require some attitude and system changes, which should start during the training process. A team care approach also improves patient adherence to prescribed medicines; again, this requires proper coordination between professionals, including familiarity with the appropriate treatment of the disease and the recommendations given to patients. Prescribing practices for some types of drugs (e.g.,

benzodiazepines and antibiotics) and conditions are more difficult to influence than others, as some HTF studies demonstrated. The more difficult areas may require intensive remedial work, incentives, or changes to reimbursement policy.

Affordability is a major issue in pharmacotherapy. In all Canadian programs, eligibility for public drug insurance coverage tends to be based on age or socio-economic circumstances: senior citizens, status Aboriginals, and unemployed individuals tend to be covered. Private drug insurance coverage largely depends upon employment status. Programs differ in terms of which drugs they will cover and the amount that insured individuals must pay out of their own pockets (cost-sharing). Underinsurance affects 10 per cent of Canadians, and the rate of underinsurance varies by province of residence. Canadians working full time are less likely to be underinsured: the group most at risk earns less than $10,000 per year.

Insurance programs for prescription drugs and population coverage vary across Canada because the provision of pharmacy products and services was never part of the original concept of universal public health insurance coverage in Canada. Theoretically, provincial pharmacare programs should ensure cost-effective health care (i.e., the best level of care for the least cost possible) for their residents. However, provincial governments must balance population access to needed pharmaceuticals with cost-containment for the pharmacare and health care programs, which in turn must be balanced with the promotion of industrial development for the pharmaceutical industry, autonomy of prescribing for physicians, and increased cost-sharing for consumers. The tendency has been to reduce public costs by increasing consumer cost-sharing. However, deregulation of the pharmaceutical market by injecting more private funding would take Canada further away from the model of largely public financing of pharmaceuticals that exists in most developed countries (generally less expensive and more equitable) and closer to the U.S. model (more expensive and less equitable).

Focusing on the drug program budget can also backfire: cost savings seen in drug programs are not necessarily reflected in savings in total costs to the society. Costs may be shifted to other areas, resulting in an increase in the use of other health services or a shift of the burden to patients or caregivers. Other methods to contain pharmaceutical sector costs may be worthy of exploration: price management by actively negotiating or setting drug prices or profits; limiting the benefits packages of their insurance programs for drugs; restricting conditions under which newer, more expensive pharmaceuticals can be prescribed in place of older, less expensive medicines; assessing the added value of a new drug; setting drug budgets for physicians; contracting with industry so that the manufacturer shares the financial risk if higher-than-expected expenditures are incurred. Jurisdictions outside Canada using these policies generally set them centrally, and Canada could profit by promoting common provincial efforts to establish and negotiate policies to contain pharmaceutical sector costs and influence professional practice.

In general, the HTF studies have confirmed, using Canadian research, a number of approaches to improving pharmacotherapy in other jurisdictions, as well as exploring a few new ideas. We have a number of good directions to travel in the future and some better road signs.

Preface

In recent years, Canada's health care system has been closely scrutinized with a view to quality improvement and cost-effectiveness. Fiscal pressures and changing demographics are resulting in initiatives to explore how the efficiency of the health care system can be increased while ensuring that high-quality services are affordable and accessible. Within this context, there has been a need for more research-based evidence about which approaches and models of health care have been working and which have not. In response to this requirement for evidence, and on the recommendation of the National Forum on Health, the Health Transition Fund (HTF) was created out of the 1997 federal budget to encourage and support evidence-based decision making in health care reform.

A joint effort between federal, provincial and territorial governments, the HTF funded 141 pilot projects and/or evaluation studies across Canada between 1997 and 2001, for a total cost of $150 million. Of that, $120 million supported provincial and territorial projects and the remaining $30 million funded national-level initiatives. The HTF targeted initiatives in four priority areas: home care, pharmaceutical issues, primary health care, and integrated service delivery. Various other focus areas emerged under the umbrella of the original four themes, including Aboriginal health, rural health/telehealth, seniors' health, mental health, and children's health.

The HTF projects were completed by the spring of 2001. In order to communicate the evidence generated by the projects to decision-makers, experts were employed to synthesize the key process and outcome learnings in each theme area. This document summarizes the key learnings in the pharmaceuticals issues theme area. It has been prepared by Wendy Kennedy, PhD, and Robert Goyer, PhD, Faculty of Pharmacy, Université de Montréal.

Unique Nature of the HTF Projects

The HTF was quite different from other organizations that fund health-related research in this country, such as the Canadian Institutes for Health Research and its predecessor the Medical Research Council.

- It was a time-limited fund, which meant that projects had to be conceived, funded, implemented, and evaluated all in four years – a very short time in the context of system reform.
- It was policy-driven; policy-makers were involved in the project selection process, and wanted to focus on some of the outstanding issues in the four theme areas in the hope that results would provide evidence or guidance about future policy and program directions.

In order to encourage projects to address issues and produce results that would be relevant to decision-makers, the HTF developed an evaluation framework consisting of six elements (access, quality, integration, health outcomes, cost-effectiveness, and transferability). Each project was required to have an evaluation plan addressing as many of these elements as were relevant. In addition, all HTF projects were required to include a dissemination plan (for which funding was provided) in order to ensure that results were effectively communicated to those best able to make use of them. In addition to these individual dissemination plans, the HTF Secretariat is implementing a national dissemination strategy, of which these synthesis documents are one element. This emphasis on evaluation (systematic learning from the experience of the pilot initiatives) and dissemination (active sharing of results) was unique on this scale.

Most national projects were selected by an intergovernmental committee following an open call for proposals, while provincial/territorial initiatives were brought forward by each individual jurisdiction for bilateral approval with the federal government. At both levels, applications came not just from academics in universities, or researchers in hospital settings, but also from non-traditional groups such as Aboriginal organizations, community groups, and isolated health regions. Groups that had rarely, if ever, thought in terms of research, evidence, evaluation, and dissemination began doing so, and these developments bode well for improved understanding and collaboration among governments, provider organizations, and researchers. The role of federal, provincial, and territorial governments in the selection process ensured that the projects delved into the issues that were of high concern in each jurisdiction. By the same token, there was considerable scope in the range of project topics, and the body of projects was not (and was never intended to be) a definitive examination of each theme.

This unique focus and selection process imparts specific features to the HTF body of projects. The projects that were funded represent good ideas that were put forward; they do not represent a comprehensive picture of all the issues and potential solutions in each of the theme areas. The relatively short time frame meant that many researchers struggled to complete their work on time and the results are preliminary or incomplete; some pilot projects might take a number of years to truly show whether they made a difference. This must be left to others to carry forward and further investigate. Perhaps the greatest value in the large body of HTF projects comes from the lessons we can learn about change management from the researchers' struggles and challenges as they undertook to implement and evaluate new approaches to longstanding health care issues.

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1. Setting the Context

Drug costs account for the Canadian health care system's second-highest expenditure (Canadian Institute of Health Information, 2001). Since the early 1980s, their annual growth rate has been approximately 20 per cent. This rate of increase is expected to continue in the future, which puts at risk the viability of the existing public (pharmacare) and private prescription drug insurance programs.

The level of waste and inefficiency in the system has been the subject of much study, consistently showing that the quality of pharmacotherapy can be improved and drug costs could be better managed and controlled. "The conditions for successful control of pharmaceuticals are: system-wide (well managed formularies so that pharmacists have access to effective drugs at the lowest possible cost), patient-provider interface (treatment guidelines to assist the prescribing physician in choosing the most effective drug for the patient; drug utilization management so that the prescribing physician and the pharmacist are informed systematically about all the drugs being used and can advise the patient on ways to avoid adverse reactions) and research (to identify situations where pharmaceuticals are a cost-effective substitute for other interventions such as surgery)" (Angus, Auer, Cloutier, & Albert, 1994, p. 15).

However, the multitude of issues surrounding prescription drugs has many facets: the industry that makes the drugs, the doctors who prescribe them, the pharmacists who provide them, the patients who use (and sometimes request) them, and the public and private insurance programs that pay for them (in whole or in part).

1.1 Pharmaceutical Industry

The industry plays a major role in the discovery of drugs. From 1988 to 2000, 1,020 new patented medicines appeared on the Canadian market (Patented Medicines Prices Review Board [PMPRB], 1991-2001). However, only 65 of them were considered as "breakthroughs" or significant improvements. The others (955, or 94 per cent) consist of new active ingredients showing no or modest gains compared with existing medicines ("me-too" drugs) or new dosage forms or strengths of existing medicines (line extensions). Too often, health professionals and consumers assume that a new drug is somehow "better" than an older one, even though its effectiveness is not superior, its risk profile is still uncertain, and its price is often higher.

Companies generally protect and expand their share of the market through patents, which give the companies exclusive rights to their drugs for a period of 20 years from the time the drug is discovered.[1] Considering the time required from discovery to marketing, the residual period of exclusivity (or market exclusivity) for the patented drug generally varies from eight to 12 years. The industry views such a period as insufficient, thus requesting additional benefits (such as patent extension, freedom to set prices, and more rapid access to market).

When the patent expires, the exclusivity ends and other manufacturers can sell a generic version of the drug having the same chemical composition, dosage form, and clinical efficacy. Thus the competition becomes one of price. Therefore, the length of the exclusivity period, the rate of introduction of new patented drugs, and the level of popularity they achieve will have an effect on the market share of the patented versus the generic drugs: between 1990 and 2000, the proportion of total drug sales accounted for by patented

1. Changes to legislation in Canada in 1987 and 1993 have restored full patent protection.

drugs rose from 41 to 63 per cent, while the market share of generics fell to under 9 per cent (Federal/Provincial/Territorial Task Force on Pharmaceutical Prices 1999).

Pharmaceutical companies promote sales of their drugs to both consumers and professionals. In Canada, direct-to-consumer advertising (DTCA) is not legal for prescription drugs; however, there is some spillover effect from American advertising, which has grown from $0.1 billion to $2.5 billion between 1993 and 2000 (Schommer and Hansen 2001). Medical promotion (which cost pharmaceutical companies $13.9 billion in the United States in 1999) includes physician detailing,[2] drug samples, gifts, entertainment, and the financing of educational conferences and seminars for health care professionals (Bero and Lipton 2001).

Such promotional activities have major impacts on drug use and expenditures. Indeed, the recourse to a new, often more expensive, drug may be justified in therapeutic and economic terms. But in many instances it is not, in which case there are important negative consequences for prescription drug insurance programs, including reducing accessibility and increasing user charges.

1.2 Patients

Population increase and aging accounted for only 10 per cent of the growth in prescription drug expenditures in the 1980s; the other 90 per cent was attributed to the rising cost of drugs per patient due to inflation, high prices of new medicines, and increase in use (increase in quantity of a medicine and of number of medicines per patient) (Angus et al., 1994).

Patients' attitudes and values have a tremendous impact on optimal, cost-efficient pharmacotherapy, influencing the correct use (in contrast to inappropriate use, overuse, or underuse) of medicines, whether prescribed or not. For example, it has been estimated that, in Canada, the direct and indirect costs of non-compliance (e.g., failure to follow directions of use, including unfilled or unrenewed prescriptions, changes in dosages, use of non-prescription drugs) range from $7 billion to $9 billion, excluding social costs (Coambs et al. 1995).

To facilitate patients' participation in their pharmacotherapy, they need credible, pertinent, and understandable information. Too often, health professionals do not have available the appropriate information leaflets, or they lack the time or facilities for confidential discussions with the patient. In contrast, patients have easy access to a multitude of information sources – via the Internet, the pharmaceutical companies' publicity, and the media – which may be of questionable quality and which the patient is ill equipped to evaluate.

The increase in direct-to-consumer advertising (DTCA) of prescription drugs is of particular concern with respect to its effect on the use of medicines and on the patient-physician relationship and its consequent impact on public health. "While DTCA may alert consumers to new information and facilitate treatment of their medical problems, it also may confuse consumers and adversely impact the relationship between patients and their health providers.… DTCA could affect health outcomes and health services utilization via multiple decisions and multiple behaviours by both consumers and physicians" (Schommer and Hansen 2001).

But even assuming the best patient attitudes and values, optimal pharmacotherapy is not achievable if these attitudes and values are not shared by health care professionals or if there are no appropriate regulations allowing access to necessary medicines.

2. Detailing is a technique used by pharmaceutical companies to promote the sale of their products. It combines marketing and the professional education of prescribers (usually physicians). The pharmaceutical company representatives are generally university graduates and are conversant in the attributes of the products they promote. They meet the physicians in their offices face-to-face.

1.3 Health Care Professionals

Although patients are often considered to be the principal cause of inappropriate medication use – they must provide their clinicians with the information needed to make optimal decisions and subsequently follow the clinicians' instructions – health professionals are responsible for ensuring patients receive the right medicine, at the right dosage, in the best manner and at the least cost. They must also pass on to patients the skills and information needed to take the medication in the manner prescribed.

In reality, the physicians who prescribe the drug, the pharmacists who supply it, and the patients who use it are bombarded by advertising and promotion, and too often a physician visit terminates with a prescription, even though neither health professional is fully informed of the patient's potential drug risks. Both professions operate in circumstances where communication between physician and pharmacist about their common patient is difficult.

Making appropriate medication choices requires knowledge, skills, and tools. Academia should assume full responsibility for providing knowledge and skills in all aspects of pharmacotherapy, not forgetting the importance of the team approach, communication, and health economics. It should be the source of independent, credible information about new treatments and of the best ways to incorporate these treatments in order to optimize practice. Promotional information about drugs should not be confused with objective information, training, or continuing education in pharmacotherapy. Regulatory bodies and professional associations should ensure that their members maintain their level of competence, taking into account the tools that government should provide.

1.4 Governments

The federal government controls the testing of new drugs on humans; reviews all the evidence on quality, safety, and efficacy, including the information that must be available about the drug (i.e., product monograph and patient information leaflet) before it can be marketed in Canada; and oversees many aspects of drug commercialization (e.g., adverse drug reactions, advertising and promotion, price of patented drugs).

The Patented Medicines Prices Review Board (PMPRB) reviews the price of patented drugs from the date they are first sold on the market until the patent expires. Essentially, the introductory price of a new, patented drug cannot be higher than that of comparable products unless it brings significant therapeutic improvement over existing drugs.[3] Afterward, until the patent expires, annual price increases are tied to the consumer price index (CPI). Since 1987, the PMPRB has profoundly influenced both the introductory price of new patented drugs and their evolution.

Provincial drug insurance programs also have a major impact on the prices of drugs (whether patented or not) sold in community pharmacies by limiting annual increases or by negotiating with manufacturers on the basis of price as a condition for listing a drug (including generics[4]) on their formulary. Other strategies used to limit costs are:

- pharmacists substituting a generic version of a drug for a prescribed patented drug;
- governments limiting the reimbursement to the cost of a given drug in a therapeutic class (therapeutic reference-based pricing) or the cost of the generic drug;
- governments reimbursing pharmacists on the basis of real acquisition cost or best available price in Canada; and

3. In the case of significant therapeutic improvement, the price is limited to the median international price of the drug itself in seven countries.

4. Ontario controls generic drug prices as part of its policy, placing a ceiling of 70 per cent of the price of the brand-name (formerly patented) drug on the introductory price of the first generic to be marketed.

- governments ensuring through special access programs that costlier drugs are provided only if absolutely needed.

Increasing the uniformity of policies among provinces could generate major additional savings.[5] However, "cost-effective health care requires more than global budget controls at the centre. It also requires a regulatory regime that encourages providers and patients to choose the most appropriate treatment – taking into account both costs and outcomes" (Angus, Auer, Cloutier, and Albert 1994). By providing and integrating training programs, on-line access to patients' files and drug information centres, appropriate guidelines, feedback on practice profiles, and accountability, health professionals and governments could ensure cost-efficient, continuous, seamless care.

Prescription drug insurance programs differ greatly across the country. Generally, beneficiaries of public insurance programs tend to be persons on social assistance and senior citizens who pay a charge per prescription or periodically bear a percentage of the total costs. These costs to patients, varying among provinces and beneficiaries, have been established to reduce the overall budget of the pharmacare program and to influence the level of prescription drug use. Although reducing prescription drug use can limit the pharmacare budget, it may also have an impact on other health sector costs – such as physician visits, emergency services, and hospital or long-term care facilities – that must be considered.

2. Overview of the Health Transition Fund (HTF) Studies

The 25 HTF pharmacotherapy studies were varied in their scope and focus. Not all the issues discussed above were addressed, but several were. The main theme of the majority of the studies was improving the use of pharmaceuticals by targeting patients and health care professionals. A secondary theme, the subject of some studies, was the make-up and population coverage of prescription drug insurance programs, including publicly funded ones. One study touched on the pharmaceutical industry, exploring its role in DTCA (NA250). The studies provided background information for these themes, explored or developed tools to better measure the use of pharmaceuticals or identify problems, or evaluated interventions aimed at improving pharmaceutical use. Five studies were reviews of existing information pertinent to the discussion:

- NA236 examined international examples of pharmaceutical policy on which Canada could draw.
- NA202 provided an overview of the different prescription drug insurance systems and looked at the extent of insurance coverage (public and private) for prescription drugs in the Canadian population.
- NA203 evaluated the quality of clinical practice guidelines, including those dealing with prescribing.
- NA246 examined the process of cost-effectiveness evaluation in provincial drug programs.

5. For 1997, savings would have been achieved by implementing a best-available-price policy in all provinces ($60 million) and extending the median international price limit to non-patented single-source drugs ($64 to $87 million) (Federal/Provincial/ Territorial Task Force on Pharmaceutical Prices, 1999).

- NA250, a three-part study, reviewed direct-to-consumer advertising of prescription drugs.

Two projects looked at variations in citizens' coverage associated with the differences in pharmacare programs:

- NA227 examined how differences in drug costs affect drug use in general.
- NA228 looked at how differences in drug costs affect the use of antibiotics.

The majority of the projects examined the effects of various methods to improve medication use in the community setting. SK221 targeted improvement in physician prescribing and patient compliance by looking at academic detailing,[6] prescribing practices feedback, and patient compliance reminders. Patient behaviours were explored by using:

- a health care team approach (AB301-27);
- patient-oriented, disease-specific, information guides (NA204);
- community involvement programs (BC201-03); and
- an asthma education program (BC201-06).

Physician prescribing practices were targeted by continuing medical education strategies such as academic detailing, provision of feedback on prescribing profiles (NA221, BC201-01, BC201-02), and regulatory changes in drug reimbursement policy (BC201-05). The influence of the community pharmacist on physician prescribing and patient behaviours was explored by several studies (ON221, BC201-04, BC201-07, BC201-08).

A number of studies developed and refined research tools as part of an evaluation or as the primary study objective:

- BC201-01 to -08 generally incorporated methodologies to take advantage of British Columbia's new centralized prescription drug database.
- NA201 and NA235 explored the feasibility of creating a national database containing drug utilization data and cost data that would allow drug use review studies to be carried out on a national basis.
- ON222 evaluated, on a province-wide basis, the dissemination of guidelines and the implementation of an educational strategy for antibiotic use.
- NA228 evaluated the use of DDDs (defined daily doses) to enable a comparison of rates of drug use at national and international levels, choosing antibiotics as an initial example.
- BC201-05 looked at a study design to test the implementation of a regulatory policy changing reimbursement for medications.

Funding for these 25 projects totalled $7.6 million. The amount of funding for individual studies varied from $88,800 for NA250 to $3,165,600 for BC201 (comprising eight separate studies). A complete list of the HTF studies appears in Appendix A.

6. Academic detailing is a technique similar to the detailing used by pharmaceutical companies, but, as used by health insurance plan providers, the objective is to promote appropriate and cost-effective prescribing (usually in one or two therapeutic classes or for one or two specific indications) rather than the promotion of specific products.

3. Discussion of Significant/ Relevant Findings

3.1 Quality of Pharmacotherapy

3.1.1 Patient Satisfaction

Patients want more information and more input into their treatment. This was demonstrated in several studies, which also showed that physicians and pharmacists are sometimes reluctant to provide as much information and involvement as the patients would like. In *An Evaluation of a Randomized Controlled Project on Asthma Education in B.C.* (BC201-06), professional asthma educators taught individual asthma patients how to better monitor and control their disease. Unfortunately, problems were noted with many of the patients' physicians, who did not seem to be familiar with the appropriate treatment of the disease and did not endorse the recommendations of the education sessions given to patients.

One message that came clearly out of *Canada Drug Guide: A Pilot Study* (NA204) was the public's interest in credible and understandable information about treatment choices and health problems. A large proportion of patients who received patient-friendly treatment guides found them very useful. The majority of interviewed patients reported using the information in their decisions about their treatment. However, "focus group findings revealed a disparity between the kind of drug and therapy information consumers say they want and what their clinicians [physicians and pharmacists] seemed willing to give them. While there was a strong patient preference for information on treatment options, benefits and risks, including side effects of medications, some clinicians raised concerns about the feasibility and impact such disclosure might have on patient care" (p. 10).

These messages regarding public interest in information and the importance of public understanding of health issues were emphasized in two projects: *Partners for Appropriate Anti-Infective Community Therapy – Development of a Guideline Dissemination Infrastructure* (ON222) and *Women's Health in the Mid-Life Years* (BC201-03). "Project feedback … suggests that patients and the public feel that it is important that their opinions are represented during the course of development of any guidelines or reimbursement criteria that are to be distributed to physicians at a provincial or national level" (ON222, p. 23). In BC201-03, "a great number of women reported major change in the main areas of learning new knowledge … feeling more confident to make decisions … resolving to continue to learn more, and developing an intent to make lifestyle changes" (p. 21).

3.1.2 Improving Physician Prescribing Practices

For Canadian practitioners, it is important to develop nationally uniform, high-quality prescribing standards that have been created by relying on clinical expertise and experience. The *National Evaluation of Clinical Practice Guidelines (CPGs)* project (NA203), a review of the literature on interventions to improve prescribing involving CPGs, found improved prescribing in 77 per cent of the 35 studies published.

Some types of interventions are more effective than others in changing prescribing practices. Simply delivering written materials or presenting materials at a workshop or conference does not appear to be enough. An interactive form of intervention – such as audit, feedback, academic detailing, and a team approach between physicians and pharmacists – is more effective in producing a positive change in prescribing. If a desired prescribing change is from one medication to another, then discontinuing reimbursement for the targeted drug (allowing recourse to special exceptions upon the request of the

prescriber) appears to have the desired effect of reducing prescribing without harming the patient. Physicians are more amenable to change prescribing practices for some types of drugs. For example, it appears to be difficult to influence benzodiazepine (BC201-01, NA221) and antibiotic (SK221) prescribing, perhaps because these changes require more time or different expertise than is generally available to physicians.

3.1.2.1 Guidelines

Changing prescribing practices requires standards for such practices against which problem prescribing patterns can be identified, interventions designed, and improvements measured. This is the purpose of clinical practice guidelines (CPGs), which are systematically developed statements that help physicians make decisions about appropriate health care. According to ON222: "It is extremely important to differentiate [between] an 'evidence document' developed based on the literature and meta-analysis, and a 'guideline' which has gone through an external validation process and incorporates accepted approaches and clinician wisdom" (p. 23). The authors listed a number of requirements for the successful implementation of CPGs, including:

- high-quality materials developed with clinician involvement (professional materials) and patient involvement (patient materials);
- a feedback loop for improvement;
- intensive advertising and general mail-outs to recruit facilitators and educators in the primary care community and to raise awareness of the program;
- the training of medical residents; and
- the use of partnerships to disseminate patient materials.

There appears to be less evidence of improvement from interventions that presented physicians with literature alone or conference/workshop material alone. Interventions that involved audit, feedback, and academic detailing had, in general, a positive impact on prescribing.

Although guidelines can be useful, they have proliferated in recent years and their quality is not always assured. According to the *National Evaluation of Clinical Practice Guidelines* project (NA203), "It is estimated that [there] are some 2,500 CPG that have been developed in Canada with most having been produced in the last decade. With the exponential growth in CPG development, clinicians are increasingly being confronted with differing and sometimes contradictory recommendations. For example, in one study the recommendations from 20 practice guidelines on anticoagulant treatment in a trial fibrillation were applied to 100 consecutive patients. Depending on the guideline, anticoagulant treatment would have been recommended for 13 per cent to 100 per cent of the patients" (p. 6). Only 19 per cent of the guidelines reviewed by NA203 were recommended to be used in practice "as is"; another 56 per cent were acceptable with modifications.

3.1.2.2 Interdisciplinary Approach

The *Randomized Trial Evaluating Expanded Role of Pharmacists for Seniors Covered by a Provincial Drug Plan in Ontario* (ON221), which involved seniors living in their own homes and at high risk for drug-related problems,[7] found that expanding the role of pharmacists to identify and resolve these problems and make recommendations to the treating family physician had extremely positive results.[8] The pharmacists identified problems in 88 per cent of

7. Taking five or more medications, an average of eight drugs per day.

8. This is similar to the role of the clinical pharmacist in hospital pharmacy practice.

the seniors participating in the study; the family physicians agreed to implement 84 per cent of the recommendations made to them; and 57 per cent of these recommendations had been implemented within five months.

The importance of an interdisciplinary approach in development of guidelines emerged from the project *Partners for Appropriate Anti-Infective Community Therapy – Development of a Guideline Dissemination Infrastructure* (ON222). "The success of these guidelines has been attributed to the rigorous development process that was followed and the involvement of a multi-disciplinary consensus panel, including specialists, primary care physicians and pharmacists in addition to over 150 reviewers from across Canada" (p. 16).

3.1.2.3 Regulatory Change

In the *Evaluation of the Feasibility of a Randomized Controlled Trial of a Drug Reimbursement Policy Change During Implementation* project (BC201-05), a change in reimbursement policy resulted in the desired improvement in prescribing practices as well as reduced costs and no decrease in health outcomes. This study examined a regulatory change in reimbursement: coverage for costly nebulized forms of respiratory drugs (needing a machine) was eliminated, which should have resulted in replacement-prescribing of reimbursed inhalation forms of those medications. Unusually, a concomitant rise in the use of inhalers was not observed, which points to a previous questionable need for the nebulized medications or to an as-yet-unseen shifting to other resources.

A Controlled Study of Initiatives to Improve Antibiotic Prescribing and Adherence (SK221) showed that it was difficult to improve antibiotic prescribing through either academic detailing, profiling (sending a physician his or her prescribing pattern compared with those of colleagues or with a certain standard), or a combination of the two. Two studies that looked at changing benzodiazepine prescribing (whether by providing physicians with guidelines for the safe withdrawal of benzodiazepines and with patient-oriented materials to aid discontinuing, or by using academic detailing) also indicated that current benzodiazepine prescribing is not amenable to change by "educational" intervention. If change is desired, other more direct methods are needed, such as regulation or financial incentives.

Physicians seemed to be reluctant to participate in studies aimed at changing prescribing practices for benzodiazepine, and those who did participate did not improve. The participation rate of identified physicians in the *Benzodiazepine Use in the Elderly* project (NA221) was very poor, ranging from a low of 12 –17 per cent in Quebec to a high of 39 per cent in Newfoundland. The measured impact on prescribing was also disappointing; no changes were seen in Newfoundland and only minor changes occurred in Ontario. This was confirmed by the findings of the *Sleep and Anxiety Management Project* (BC201-01). More physicians increased rather than decreased their prescribing of benzodiazepines, in terms of number of patients, volume of benzodiazepines, and number of scripts. However, such results may have been complicated by a concurrent government policy change. The negative results of BC201-01 are particularly disappointing because it is expected that physicians who volunteer for a study like this one are likely to be those most amenable to practice change.

3.1.3 Improving Patient Adherence to Prescriptions

Patient adherence to prescribed medicines was improved by experts in patient education (asthma), pharmacists (asthma), and multidisciplinary teams of physician, pharmacist, and home care professional (in persons with complex medical needs[9]) (BC201-06, BC201-08, AB301-27). However, as shown by *An Evaluation of a Randomized Controlled Project on Asthma Education*

9. Persons who self-reported their health state as "poor" and were taking an average of five medications.

in B.C. (BC201-06), this adherence requires proper coordination among the professionals, including a familiarity with the appropriate treatment for the disease and with the recommendations given to patients.

3.2 Access

Affordability is a major issue in pharmacotherapy because the lack of affordable access to prescription drugs may result in inadequate care and lead to an increased use of other health care resources. Asthma patients mentioned that one of the factors leading to compliance problems was their difficulty in affording their medications (BC201-06). Certainly asthma is an example of a chronic disease for which medications form the bulk of the costs of treatment for most patients; the more underused drugs (the anti-inflammatory and long-acting bronchodilator drugs) are the more expensive, and the more overused (the short-acting bronchodilator drugs) are the cheapest.[10]

3.2.1 Canada-Wide

In all Canadian programs, eligibility for public drug insurance coverage tends to be based on age or socio-economic circumstances; private drug insurance coverage largely depends upon employment status. Public drug insurance coverage tends to be provided for senior citizens, status Aboriginals, and unemployed individuals. Programs differ in terms of the drugs they cover and the amount that the insured individual must pay out of his or her pocket (cost-sharing). The *Canadians' Access to Insurance Coverage for Prescription Medicines* project (NA202) found that about 10 per cent of Canadians have no drug insurance or insurance only for expenses exceeding $1,000 annually.

Canada is far from unique in providing public funding for prescription drug costs. All of the seven countries[11] studied by the *International Experience with Pharmacare: Lessons for Canada* project (NA236) have extensive public insurance funding programs for prescribed drugs. They also require some level of cost-sharing from consumers, averaging 25 to 30 per cent of prescription costs. However, in all these countries, public expenditures account for a higher proportion of overall drug costs than they do in Canada. In 1997, public expenditures on drugs in Canada were roughly 31 per cent of overall drug costs, compared with about 65 per cent (average) in the seven countries studied (and 15 per cent in the United States).

Using the ability to pay index,[12] NA202 found that 2 per cent of Canadians would pay more than 4.5 per cent of their gross income[13] to meet a $1,000 drug bill (4.5 per cent is a cut-off assuming financial hardship and deemed equivalent to no insurance). Using this index, individuals would be considered underinsured if they paid 2.5 per cent or more of gross family income for this potential drug bill: 10 per cent of Canadians are exposed to this level of risk.

3.2.2 Regional Variation in Drug Insurance Coverage

Estimates of potentially inadequate drug insurance showed a regional difference by province of residence. Figure 1 presents in graphic form the findings of NA202 with respect to the proportion of the population in each province with no insurance according to the ability to pay index, or those at risk for a drug bill they could not afford (underinsured). Roughly 15 per cent of Atlantic provinces residents are exposed to this level of risk, compared with none in Manitoba.

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10. Underuse and overuse are in relationship to established guidelines for treatment of this disease, which in general calls for use of anti-inflammatory and long-acting bronchodilator medications at a level that keeps use of short-acting bronchodilator drugs down to twice a week or less.

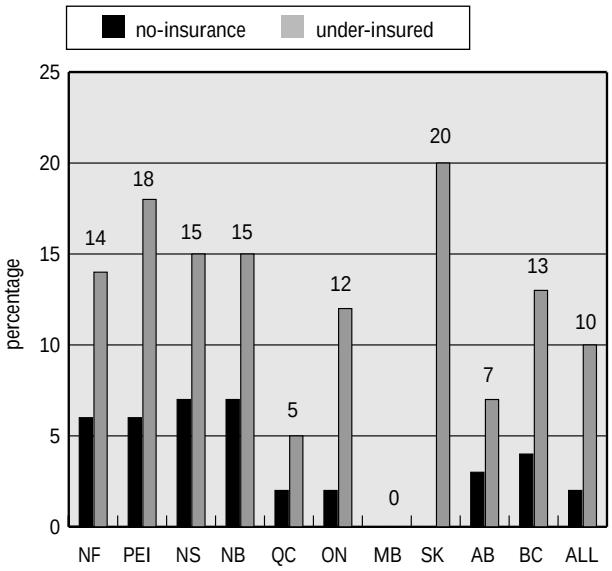
11. New Zealand, Australia, United Kingdom, France, Germany, Sweden, and the Netherlands.

12. The percentage of gross income an individual would pay if faced with a drug bill of $1,000 in a year.

13. This would apply to persons with a family income of $22,222 or less. Therefore, a $1,000 drug bill represents 10 per cent of gross income where the family income is $10,000, 5 per cent if it is $20,000, and so onforth.

Figure 1: Proportion of Individuals with No Insurance or Underinsured

According to the Ability to Pay Index, 1998, by Province (Data from NA202, p. 95)



3.2.3 Socio-Demographic Variation in Drug Insurance Coverage

According to ability to pay, risk differs by age group: 1 per cent of seniors, 7 per cent of 18- to 24-year-olds, and four per cent of 55- to 64-year-olds are at risk for a drug bill they could not afford. Persons working full time are less likely to be so exposed: only 1 per cent, compared with 4 per cent of those working part time or not at all. Those most at risk earn less than $10,000 per year. Registered Indians, eligible Inuit, and Innu are less likely to be at risk than non-Aboriginals, Métis, and non-status Indians (NA202).

3.3 Integration

Many drawbacks result from the variations in the Canadian health care system, particularly the multiplicity of prescription drug insurance programs, which complicate the measurement of national patterns of drug use. Information about national drug use must be obtained by survey. Insurance companies maintain databases of information about prescription claims reimbursed for beneficiaries, but patterns of prescribing and the use of prescription drugs can currently be analyzed only within the database created by each insurer. The *National Prescription Drug Information Model* (NA201) and the *Options for Prescription Drug Utilization Study (OPUS)* (NA235) tested the feasibility of establishing a national database. They found that many of the requirements could be met with relatively little effort, but the main stumbling block for usefulness was the inability of the database to link to other health data such as health status.

The several B.C. projects grouped under *British Columbia Pharmacare Health Transition Project* (BC201-01 to 08), using the PharmaNet database to identify and randomize potential study subjects, all found the system useful and were apparently able to deal successfully with issues of patient confidentiality. According to *The Patient Outreach Project: Community Pharmacy-Based Assessment of Patient Therapy* (BC201-07), identifying patients in this way did not involve a release of patient information outside the PharmaNet system. In addition, when questioned, the majority of patients found that pharmacists' use of the PharmaNet database to identify individuals with potential problems was acceptable from a privacy point of view (BC201-07).

3.4 Health Outcomes

It is often difficult to show an improvement in the health status of a group of patients even when the intervention has substantially improved their drug treatment. For example, the *Randomized Trial Evaluating Expanded Role of Pharmacists for Seniors Covered by a Provincial Drug Plan in Ontario* (ON221) demonstrated that a pharmacist may recognize drug-related problems and intervene successfully, causing a physician to make prescribing changes, but there may be no improvement in the quality of life of the

patients and no change in the number of patients reporting a medication problem. However, the *Primary Health Care Collectives: Improving the Quality of Medication Use in the Community* project (AB301-27) showed that when patients taking an average of five drugs improved their adherence to prescribed medication regimens, no further decline in their health status was observed, even though some of the patients had been identified as declining in health status at the outset of the study.

The Impact of Asthma Care Protocol, Administered by Trained Community Pharmacists, on Improving Outcomes in Adult Asthma project (BC201-08) resulted in better asthma control for patients receiving the intervention than for the control patients: symptoms decreased, pulmonary function increased, days off work or school decreased (not significantly), rescue inhaler use decreased, and quality of life improved.

When a change in pharmacotherapy regulation is imposed, it is important to ensure that little or no negative health impact results. To test the impact of a change, the *Evaluation of the Feasibility of a Randomized Controlled Trial of a Drug Reimbursement Policy Change During Implementation* project (BC201-05) used a sample of physicians (and all their patients) who were exempted from the implementation of the policy for a six-month period. The researchers wanted to see if there was any negative change in the health of the subjects who switched to the new treatment. Deteriorations in health can often be seen relatively quickly by an increased use of other, non-drug health services and would be reflected in an increase in the use of other rescue-type medications, physician services, or emergency or inpatient care. In other words, savings in drug costs can be shifted to another area of the health care system, resulting in no net savings or, in some cases, a net increase in health care costs. The evidence from the study about emergency visits and hospital stays is still unclear and awaits further analysis. However, few cost or health changes were seen, with the exception of some increase in the cost if not the frequency of physician services in the group subject to the substitution policy.

3.5 Cost-Effectiveness

There was little information on cost-effectiveness of the various interventions studied in the pharmacotherapy report series. Cost savings may be realized from policy changes, but not always to the extent predicted. In BC201-05, although savings of $3 million over a one-year period were projected, a review found savings of roughly $1 million.

Several provinces are placing increasing reliance on economic evaluation tools to increase the efficiency of their drug insurance programs. When a manufacturer seeks to have its drug included as a benefit, it generally provides the evidence upon which the assessments are made. This evidence is generally based upon data from clinical trials, not data from real-life use. This is not surprising, because in most cases the new drug has not been on the market long enough for real-life data to be gathered. The *Evaluation of Provincial Procedures for Drug Listing* project (NA246) found that most drug plans base their assessments of the cost impact of the new drug on their drug plan budget alone, without doing an overall evaluation of the potential costs to the overall provincial health care budget and without looking at the cost impact on patients.

The *International Experience with Pharmacare: Lessons for Canada* project (NA236) discussed the international use of economic evaluation. This type of assessment forms part of the process of product review for insurance subsidy in Australia and New Zealand. Other countries use these analyses on a more limited basis (United Kingdom, Sweden, France) or are just in the process of implementing them (the Netherlands).

NA246 points out that economic evaluation in Canada (by five provincial drug programs: British Columbia, Alberta, Ontario, Quebec, and New Brunswick) lacks

transparency. A lack of transparency also exists in international programs; only the United Kingdom body deems the information to be public (NA236). This lack of transparency, which is endemic in the Canadian review process for medications at all levels,[14] leads to inconsistencies in decision-making and inequalities in medication coverage for insured individuals in different programs. NA246 makes several recommendations, including:

- a joint review of prescription drugs' comparative efficacy, safety, and effectiveness;
- a national committee ensuring adequate cost-effectiveness analyses;
- the inclusion of experts in pharmaco-economic evaluation on provincial drug program review committees;
- requirements for Phase IV studies[15] of new medications after their introduction to determine real-life, population-based health outcomes and cost impact;
- the authorization to market being conditional on achieving desired levels of cost-effectiveness, and safety;
- the increased involvement of the public and health practitioners in the review process and decisions; and
- increased transparency in the review process.

3.6 Transferability/Generalizability

The positive effects of the body of HTF pharmacotherapy research will include the availability of research tools and educational materials that have been developed by the projects and can be used as is or adapted to other situations. Many of the patient and physician education studies have appropriate materials attached, together with relevance reviews from participants. For example, *The Better Prescribing Project* (BC201-02) and *An Evaluation of a Randomized Controlled Project on Asthma Education in B.C.* (BC201-06) prepared educational materials for physicians to improve prescribing practices and for patients with asthma to improve their disease control, respectively. The *How to Link Policy to Evidence* project (BC201-05, part 2) created a four-part manual that shows health bureaucrats how to link policy to research evidence.

Certainly the results of the studies cannot always be generalized to other settings, other groups, and other interventions. In patient education there may be difficulties in generalizing the results to all groups. Patient groups differ according to demographics, health status, attitudes, and medication adherence. In the *Women's Health in the Mid-Life Years* project (BC201-03), the special needs of certain groups were highlighted. In particular, First Nations women desired smaller groups organized in their own communities, and women with disabilities had specific needs related to the overriding difficulties associated with their conditions.

It is often easy to see a positive short-term impact of an education program on individuals who have participated in the program. The difficulty resides in maintaining that impact, which usually requires continuing effort and expense. *The Patient Outreach Project: Community Pharmacy-Based Assessment of Patient Therapy* (BC201-07) confirmed that the development and use of patient information is desirable and feasible, at least for patients and health professionals who participated in the study. However, even in these motivated individuals, areas of conflict arise, particularly with respect to the difference in the

14. Not just in Canada; in most countries the reviews of medications conducted prior to the approval of sale of prescription drugs are not transparent.

15. A Phase IV study is one that is conducted after a medication is approved for marketing. Generally the objective is to determine the risks and benefits of the medication under conditions of normal use.

amount of information the patient expresses interest in receiving (more) and the amount the physician and pharmacist are interested in providing (less).

On a national scale, NA221 demonstrated some important difficulties in accessing information and timeliness for research purposes. Problem prescribers of benzodiazepines could not be easily identified in five of the provinces. In two provinces, the information is considered confidential. Thus it appears that in two jurisdictions the confidentiality of data, inasmuch as it pertains to health professionals, outweighs the importance of the health of the public. Three provinces suffered from the delayed updating of their database sets (two to three times per year), making timely information difficult to access. Studies had not even started in two provinces because of extremely slow ethics approval processes.

3.7 Control of Pharmaceutical Spending

Deregulating the pharmaceutical market by injecting more private funding would take Canada further away from the model of largely public financing of pharmaceuticals found in most developed countries (generally less expensive and more equitable) and closer to the U.S. model (more expensive and less equitable). Expenditures on pharmaceuticals have been increasing in most developed countries at a rate exceeding that of other health care sectors, but Canada and the United States have been doing relatively poorly in controlling that increase.

According to the *International Experience with Pharmacare: Lessons for Canada* project (NA236), Canadian per capita spending on pharmaceuticals is less than that of France and the United States, but greater than that of Germany, Australia, the Netherlands, New Zealand, Sweden, and the United Kingdom. Leaving aside the U.S. model, most of these other countries set policies for drugs on a national basis, in contrast to Canada's regional policies. Public levels of financing drugs are all higher than in Canada. The role of private insurance is essentially non-existent in the United Kingdom and in Sweden and covers about 9 per cent of the population in Germany, one third of the Dutch population, and co-payments for the public insurance fund for about 80 per cent of the French populace.

As NA236 points out, governments attempt to balance their three roles of:

- promoter and guardian of the health of the population (reviewing drugs before they are allowed to be sold and regulating conditions of marketing);
- promoter of industrial growth and strength (through attracting and retaining research-intensive businesses); and
- payer of a certain portion of prescription drugs for consumers (through partial or complete reimbursement of prescription drug costs for particular groups).

As noted in NA236 and the *Canadians' Access to Insurance Coverage for Prescription Medicines* project (NA202), Canadian programs tend to focus on the following tools to control the cost of their public drug insurance programs:

- limiting the persons eligible for insurance coverage (senior citizens, social assistance recipients, and individuals with health conditions subject to high treatment costs generally qualify for public insurance program coverage, although this varies across the country);
- limiting the benefits available for reimbursement (most programs list the prescribed drugs that can be included; some plans attempt to influence prescribing practices by promoting prescribing guidelines);

- holding down the prices of the listed products (some drug plans negotiate prices with manufacturers); and
- requiring beneficiaries to share costs.

Other tools and other ways of controlling costs are possible. NA236 reviewed a number of the approaches used in other jurisdictions.

3.7.1 Direct Approaches to Controlling Spending

Countries can use price or cost management by actively negotiating or setting drug prices, reimbursement amounts, or profits. Limiting the benefits packages of their insurance programs for drugs is another technique; this restricts the conditions under which newer, more expensive pharmaceuticals can be prescribed in place of older, less expensive medicines. Germany, the United Kingdom, and Sweden all have national negative lists (a list of drugs that are not considered benefits). France, Australia, New Zealand, and the Netherlands all have positive lists (a list of drugs considered benefits), and Sweden is developing them on a regional basis. Other direct tools are also used:

- promotion of generic substitutes for off-patent products (United Kingdom, Germany, Netherlands, France);
- automatic substitution of generic products (Sweden, United Kingdom, Netherlands, France); and
- therapeutic reference-based pricing (Germany, Netherlands, New Zealand).

In most of these countries, pharmaco-economic analysis[16] is increasingly being used to assess the added value of a new drug. And, as mentioned earlier, only the United States and France have drug costs higher than Canada's.

3.7.2 Indirect Approaches to Controlling Spending

The United Kingdom, Germany,[17] and New Zealand use drug budgets for physicians as a spending control, but NA236 found that their overall health spending effects and health outcome effects have not been well studied. Increased cost-sharing has been shown to have negative impacts on health outcomes, particularly for low-income earners. France, Australia, and New Zealand contract with industry in a way that "renders the manufacturer vulnerable to financial risk should higher-than-anticipated expenditures be incurred" (NA236, p. 25). These risks involve some sort of payback or decrease in reimbursement if the price-volume agreements are exceeded.

3.8 Direct-to-Consumer Advertising (DTCA)

According to *An Assessment of the Health System Impacts of Direct-to-Consumer Advertising of Prescription Medicines* (NA250), policy-makers should be wary of allowing direct-to-consumer advertising (DTCA) for prescription drugs and on guard for the negative effects (in cost and health terms) on pharmacotherapy. Current Canadian law does not allow DTCA of prescription drugs; however, spillover advertising can be seen on American television stations, and it seems to have had an effect. "The 14 drugs [mentioned by drug name as having been requested in the past by three or more patients] represent 43 per cent of specified product requests. Most have been advertised

16. The economic evaluation of pharmaceuticals; includes the following types of analyses: cost-effectiveness (measure the consequences in natural units, such as individuals found symptom-free), cost-benefit (translates the consequences into money terms), or cost-utility analyses (sometimes considered a variant of cost-effectiveness analyses, the consequences are adjusted by utility or health state preference scores) (Drummond et al. 1997, 2nd edition).

17. Germany has not yet imposed financial penalties, though budgets have been exceeded on several occasions.

to the public, and half were among the 25 drugs with the highest DTCA budgets in the U.S. in 1999" (NA250 part 3, p. 20). A Vancouver survey found that only 10 per cent of the patients surveyed in physician offices had not seen a direct-to-consumer ad for a prescription drug within the previous year; 30 per cent had seen 10 or more products advertised (NA250, part 1). If advertising were to be beneficial, the result would be consumers who were more informed, using needed treatments, and more compliant to treatment. However, the reality of this type of advertising is that it contains more emotive than factual messages, and the factual components tend to be "selective, subjective and misleading" (NA250 part 2). Providing information that is just as accessible and is seen by as great a proportion of the public to balance this onslaught of promotion from the pharmaceutical industry would require considerable effort and expenditure.

4. Health Human Resources in Pharmaceutical Issues

When health care professionals from different disciplines work together, the result is increased satisfaction and understanding of the role of their colleagues. Family physicians participating in the *Randomized Trial Evaluating Expanded Role of Pharmacists for Seniors Covered by a Provincial Drug Plan in Ontario* project (ON221) expressed a more positive view of pharmacists and a greater appreciation for their potential role. The physicians felt that they had learned from the experience and the information gained could be used in the treatment of other patients, and both pharmacists and physicians indicated they would recommend increased collaboration to their colleagues. Health professionals (physicians, pharmacists, home care workers) involved in *Primary Health Care Collectives: Improving the Quality of Medication Use in the Community* (AB301-27) expressed a preference for this approach and a more positive view of their colleagues, whereas physicians and pharmacists developing patient-oriented guidelines in *Canada Drug Guide: A Pilot Study* (NA204) indicated a high degree of satisfaction with the quality of the materials produced (over 80 per cent), which they found useful and helpful for their patients (over 90 per cent).

In contrast, lack of collaboration may lead to a less generous view of the role of other professionals. Changes in current roles in the health care system, even when a positive impact can be predicted on health outcomes and cost-effectiveness, are not always easily accepted by other players. When physicians, pharmacists, and patients responded to questionnaires prepared by the *Potential Pharmacist-Directed Strategies and Reimbursement Mechanisms* project (ON 223), which explored the possibility of a changing role for pharmacists, the attitude of physicians was less than positive. "While patients recognized that pharmacists had a specialized set of knowledge, physicians were less convinced. This may reflect the relative amount of time spent in contact with the pharmacist. It may also reflect the different criteria and knowledge base that physicians apply in judging pharmacists' abilities" (p. 7).

The results of the HTF studies emphasize the importance of interdisciplinary collaboration and interaction among health care professionals if changes in currently defined roles are to be implemented smoothly.

5. Implications for Policy and Practice

5.1 Myriad and Separate Financing and Policy-Making Groups

A number of the HTF studies touched on the problems endemic to the plurality of the Canadian health care system, particularly in relation to pharmacare and pharmacotherapy. For example, there were regional differences in prescribing guidelines, in standards of drug insurance coverage, and in access to research data. There is considerable scope for reducing the duplication of effort, confusion, and inequity. Joint policies also would allow for considerably greater political, regulatory, and negotiating power when dealing with professional associations and international corporations.

It would be useful, initially, to implement specific, generally accepted, sure-win policies, achievable in the short term, that would address interprovincial cooperation. The resolution of more complex issues could be built on these successes.

5.2 Professionals Working Together

The HTF projects do not give credence to one old saying: among health care professionals, familiarity does not breed contempt. Professionals from different backgrounds, working together, increase their satisfaction and understand better their colleagues' strengths. It is interesting, albeit not surprising, that this positive appreciation, obtained in real working conditions, contrasts with observations from surveys that collect judgments and impressions not based on concrete common endeavours.

These HTF studies demonstrate that barriers can be broken and that mutual respect, a team approach, and "sharing" the patient (so the patient's "many parts" become a "whole") can be achieved by working together, and this can be facilitated by health professionals training together as early as possible in their respective curricula.

Future policy directions helping to bring professionals closer together in a real sense should therefore receive a high priority. Special emphasis should be given to projects in the community; this environment certainly appears to be the most difficult in which to create links of mutual co-operation and understanding. The ambulatory care community is the least familiar with the changes in training and practice that pharmacists have been undergoing during the last decade. Projects that facilitate earlier encounters of physicians and pharmacists (and nurses and inhalotherapists and …) at the training level should therefore also be given special attention.

5.3 Information About Drugs: Patients and Professionals' Perspectives

The HTF studies dealing with improving patients' understanding of the nature of their disease and pharmacotherapy seem to show disparities between the perceptions of patients and professionals, and even among professionals. In general, given appropriate information, patients adapt to changes in their therapy or are motivated to better control their disease status; they feel more confident in making appropriate decisions about their medication, changes in lifestyles, and so on. However, patients want more than to be given appropriate information: they want to contribute to its elaboration (e.g., the development of guidelines and of criteria for reimbursement). The participatory approach seems to be a requirement for the successful implementation of guidelines. Patients want to be assured that the information they receive is credible and understandable and that it includes options, benefits, and risks.

Under the same circumstances, this is exactly what health professionals would ask for. However, they still show concerns about the impact of the disclosure of full information (even if many of their patients can get it from the internet!). Future projects and policies should look at bridging gaps not only among professionals, but also between professionals' perceptions and patients' expressed needs for pertinent and usable information. It would be interesting to know whether the concerns of the professionals relate more to outcome issues or to perceived difficulties with increased requests for more of their time.

Patients need credible, pertinent, and understandable sources of information, just as health professionals do, because they are increasingly involved in choosing treatment. The pharmaceutical industry cannot be expected to play the role of provider of this information because detailing to health practitioners may be informative but is not formative. The U.S. experience shows that direct-to-consumer advertising (DTCA) distorts the physician–patient relationship; it also distorts the health care system by increasing drug volume and total sales ($5 of sales for every $1 invested) for the advertised patented or single-source products to the detriment of non-drug interventions and generic products. Future directions could include:

- identifying options for collecting, preparing, and disseminating unbiased and pertinent information;
- identifying the benefits to be derived from intra- and inter-professional linkages in the pursuit of seamless care; and
- identifying options for their financing.

Furthermore, regulators should put the burden of proof of DTCA benefits exclusively on the pharmaceutical industry, if that industry wants to force changes to present legislation in Canada.

5.4 Quality of Professional Practice

Competency and the quality of practice of health professionals, as well as the tools to support them, should be the responsibility of academia, licensing bodies, and governmental authorities, whose objectives should be similar: optimal knowledge, skills, and attitudes for optimal care at optimal costs. Although there are many approaches to achieve this, the HTF studies indicate that they should include good clinical practice standards (guidelines in some areas, but regulatory changes in areas difficult to affect by guidelines), feedback (prescribing/dispensing profiles), and academic detailing.

Not only was there a low participation of physicians in the HTF projects addressing benzodiazepine use (does this reflect a lack of interest and concern?), but there were also no changes seen, even in the province where the rate of enrolment was the highest. Worse, one intervention resulted in an increase of benzodiazepine prescribing (from a group theoretically most amenable to change!).

Judging from the previous studies, academic detailing using good clinical practice guidelines appears to be an important avenue for influencing prescribing, albeit limited in effect. One of the factors preventing greater impact could be the multiplicity and inconsistency of such guidelines. Another factor could be that many guidelines do not result from a rigorous development process, do not represent a multidisciplinary consensus panel, did not include patients' participation, and do not include incentives for their use. It would be appropriate to improve what we have and do now before adding anything. Is this not the right time for the provinces to jointly mandate an overall strategic plan for developing and implementing pertinent and credible guidelines? Commenting on the findings of NA203, Steven Lewis summed up the CPG issue succinctly:

"[Clinical practice guidelines], even great CPGs, are ignored because there is neither reward for following them nor penalty for ignoring them…. It is inevitable that the production of multiple CPGs on the same topic will be confusing, will lead to selective adoption of practices that reflect preferences and prejudices rather than evidence-based judgment and will create yet another excuse to do nothing about practice variations and perverse incentives. If we are to persist in the CPG business, there should be one Canadian guideline for each area, nationally produced, federally funded and compatible with the criteria contained in the Appraisal Instrument for Clinical Guidelines. If practitioners are going to ignore CPGs, they might as well ignore the best." (Lewis 2001, 165:180-181)

Overall, the results of educational initiatives influencing professional practice using CPGs and academic detailing were of limited effectiveness. Other policies, such as regulatory change and financial incentives, could be explored, as the costs of matching industry efforts to influence prescribing may be high, and the results modest.

5.5 Accessibility

It is surprising to realize that 10 per cent of Canadians are underinsured for prescription drugs. Four main predictors for lack of drug insurance have been identified: income, occupational category, education, and province of residence. Among the economically disadvantaged, increased charges for prescription drugs have the effect of lowering prescription drug use, which in turn may have deleterious effects on their health and increase their use of other health services.

The fact that some groups and individuals are not covered by the drug insurance programs may have "beneficial" impacts on the various insurance plan budgets, but what about budgetary impacts from non-drug components? There is a correlation between decreased accessibility to drugs and increased use of other medical services, so overall health costs may be increased. Is it tolerable that individuals are provided full access to medical services but limited access to drugs, whose purpose in many cases is to decrease the recourse to such medical services?

An unfortunate aspect of the HTF studies was the short time period for their completion, with the result that many of the researchers were unable to complete impact evaluations on health care resource use. Future research should focus on the impacts of policies on health care resource use to evaluate whether economic considerations (if ethical ones do not prevail) might be an additional incentive to eliminate the discriminatory access to prescription drug insurance.

5.6 Control of Pharmaceutical Spending

The government roles of ensuring optimal pharmacotherapy for the population, controlling health care budgets, and creating an atmosphere conducive to pharmaceutical industry research and development (R&D) investment are in conflict. Is it the role of health care policies or that of taxation policies to encourage R&D? We are not recommending increased cost-sharing from consumers. Although injecting more money from private sources into the medicines sector of health care will help contain pharmacare budgets and satisfy the manufacturing industry, it will also bring Canada closer to the U.S. system model, the most inefficient and inequitable of the systems studied. Judging from international examples, there is no reason to believe that additional funds will increase health outcomes. Instead, we should explore international examples of budget controls for pharmacare programs, such as negotiation with industry to share the risk of program cost increases and drug budgets for physicians. These policies would be easier to implement if the provinces were able to use a joint approach. Joint policies and regulations by the administrative bodies responsible for

pharmacotherapy policy and pharmacare programs would decrease duplication and confusion and allow for greater negotiating power with professional associations and industry. (This might, however, be seen as reducing the autonomy of these bodies.)

6. Conclusion

In general, the HTF studies have confirmed, using Canadian research, a number of approaches to improving pharmacotherapy that have been used in other jurisdictions. In addition, a few new ideas were explored and new tools were developed.

Interventions leading to better pharmacotherapy generally require some structural change. Teams of health care professionals working together can improve pharmacotherapy and increase professional satisfaction. Since team care is not common in current community practice for physicians and pharmacists, programs occurring during formative and continuing education should focus on co-operation. Academic detailing seems to work best to improve physician prescribing, but it requires time and financial investment from pharmacare programs and may not work in areas of prescribing or drug utilization that are difficult to change. What we need to know is what works in recalcitrant cases, such as patients who are unable to learn to control their asthma or unable to stop taking benzodiazepines; physicians and pharmacists who are unable or unwilling to change improper prescribing or dispensing practices; and health professionals unable or unwilling to communicate appropriate medication management practices to their patients. For these individuals and in these areas, education does not work; if change is seen to be beneficial and necessary, incentives, special remedial programs, or regulations are needed.

International experience indicates that increasing the current level of private funding in pharmacotherapy is not an option to help manage costs. Ten per cent of the Canadian population is still without adequate insurance. Policies such as negotiation with industry to share the risk of program cost increases and drug budgets for physicians could be explored as budget control options. Joint provincial policies and regulations with these goals would not only decrease duplication and confusion, but would also allow for greater negotiating power.

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Appendix A: List of HTF Projects Relevant to Pharmaceutical Issues

This appendix provides summary information on the HTF projects which were reviewed in the preparation of this document. For further information, please refer to the HTF website (www.hc-sc.gc.ca/htf-fass).

(NA201) National Prescription Drug Information Model: Phase I (High Level) Feasibility Study

Recipient: British Columbia Ministry of Health and Ministry Responsible for Seniors

Contribution: $183,000

This project sought to determine whether a database of national drug use practices and costs might help to contain escalating drug costs and assist public drug plan managers in policy development and program administration. Participants included provincial and federal pharmacare programs, provincial and federal drug insurers, and government and non-government organizations with an interest in drug use. The project succeeded in building a pilot database and in using the database to test the ability to answer stakeholders' questions. Researchers concluded that a national drug use model would be valuable and would be easier to construct than they first thought. Another project (NA235) built on these results and studied the feasibility of compiling claims data into a national prescription drug use database (the OPUS project).

(NA202) Canadians' Access to Insurance Coverage for Prescription Medicines

Recipient: Health Policy and Communications Branch, Health Canada

Contribution: $300,000

This project reviewed Canadians' access to insurance coverage of prescription drugs. This project also analyzed those who had no or inadequate prescription drug coverage. Volume I of the study describes the features of the various plans as well as relevant circumstances, such as province of residence, socio-economic status, and drug needs. Volume II determines the number of Canadians who, during 1998, had no or inadequate coverage. One of this project's major findings is that certain groups have a greater portion of out-of-pocket expenses than others do. Those who are particularly vulnerable are young people aged 18 to 24, schizophrenics and others with mental health problems, those whose illness makes them less employable or leads to disability, and those who have a disease requiring new, often costly drug therapies. A key finding was that while 90 per cent of Canadians have some coverage for routine drug expenses, about 10 per cent do not and another 10 per cent are underinsured.

(NA203) National Evaluation of Clinical Practice Guidelines (CPGs)

Recipient: University of Toronto

Contribution: $170,000

This project evaluated the quality of Canadian clinical practice guidelines (CPGs) that deal with drug prescribing practices and reviewed strategies to implement CPGs in clinical settings. CPGs are systemically developed statements that help physicians make appropriate decisions about health care. The study found that only 19 per cent of the guidelines were recommended for use as they are; another 56 per cent were recommended for use with changes; and 25 per cent were not recommended at all. Researchers concluded that while it is indeed possible to rate CPGs using a valid appraisal instrument, more research is needed to improve prescription practices through CPGs and other cost-effective measures.

(NA204) Canada Drug Guide: A Pilot Study

Recipient: British Columbia Ministry of Health and Ministry Responsible for Seniors

Contribution: $400,000

This pilot project is an extensive study of how physicians, pharmacists, and consumers use and are affected by drug information. The two-year study developed and evaluated patient-friendly drug guides concerning three medical conditions: sore throat, osteoporosis, and heartburn. The product was unique because no independent and authoritative source of drug information for patients exists. Patients reported that the guides were easy to understand and influenced their decisions. Also, patients wanted to know reasons for taking a particular drug, treatment options, possible side effects, length of treatment, and costs. Physicians

and pharmacists said they were concerned about information overload, confusion, and patient non-compliance but that the guides helped clarify treatment issues for patients.

(NA221) Benzodiazepine Use in the Elderly

Recipient: Association of Canadian Medical Colleges

Contribution: $618,455

This national project tested the feasibility of a Canada-wide drug utilization review as well as a continuing medical education (CME) component for primary care physicians concerning appropriate benzodiazepine prescribing. The inappropriate prescribing of benzodiazepines in the elderly has been well documented. All eight provinces with medical schools have adopted their own approach to the issue. Ontario and Quebec were able to identify physicians with potentially inappropriate patterns of prescribing and to tailor education efforts to these individuals on a confidential basis. Interventions in the provinces included seminars, the mailing of written material, and patient education handouts. Four provinces also used academic detailing. Two provinces used interactive small-group CME. The thrust of the initiative in all locations was non-coercive and educational. At the time of reporting, follow-up analysis had been completed only in Newfoundland and Ontario; Newfoundland showed no major change in group prescribing data, and Ontario showed a very modest decline in individual prescriptions to seniors.

(NA227) Do Drug Plans Matter? Effects of Drug Plan Eligibility on Drug Utilization Among the Elderly, Social Assistance Recipients, and the General Population

Recipient: Centre for the Evaluation of Medicines, St. Joseph's Hospital, Hamilton

Contribution: $122,372

This study illuminated the debate over a national pharmacare program by using data from two population health surveys in 10 provinces to predict the influence a national pharmacare program would have on the use of prescription drugs, physician services, and the health status of Canadians. The project identified variations in the extent of prescription drug coverage among the general population and differences in how provinces share costs with seniors and social assistance recipients. The project then constructed a range of indicator variables and estimate models of prescription drug use for tracking the impact of various types of drug insurance plans along with several socio-economic, demographic, and health variables. It concludes that variations in the extent of drug coverage do not appear to affect drug-use patterns among people of average socio-economic and health status, which suggests that pharmacare would not encourage most Canadians to use substantially more drugs or professional resources. On the other hand, shifting costs from consumer to government could encourage greater medication use by low-income and sick people for whom prices are a barrier to care, which could in turn lead to improved health status.

(NA228) Interprovincial Comparison of Medication Use in Pharmacare—Anti-infective Drugs in Seniors and the General Population

Recipient: Dalhousie University, Halifax

Contribution: $105,300

This study tested and evaluated a new way of comparing drug use between Canadian jurisdictions – a method that makes adjustment for drugs that come in different strengths, recommended dosages, and formulations. Researchers tested the efficacy of the World Health Organization's defined daily dose (DDD) system for making comparisons on an entire class of drugs, in this case anti-infective agents for oral use (e.g., amoxicillin). They identified individual medications used in three provinces (Nova Scotia, Manitoba, Saskatchewan) in three fiscal years, manually coded them into anatomical therapeutic chemical (ATC) codes, then calculated the number of DDDs of each medication that were filled per 1,000 beneficiaries per year. This allowed them to describe use by province, by drug, and by patient subgroup within both the general population (Manitoba, Saskatchewan) and senior citizen population (Manitoba, Saskatchewan, Nova Scotia). They found that the use of anti-infective agents decreased in Saskatchewan, increased in Nova Scotia, and went down, and then up again, in Manitoba during the three-year study period.

(NA235) Options for Prescription Drug Utilization Study (OPUS)

Recipient: British Columbia Ministry of Health and Ministry Responsible for Seniors

Contribution: $381,000

This study evaluated the feasibility of compiling claims data from federal and provincial insurers into a national prescription drug use database. Researchers found that a meaningful, secure dataset would be achieved even if all insurers did not contribute data. Although the database would allow insurers to compare their jurisdiction's performance and plan rules with those in other parts of the country, defining the value of national data was more difficult. The only monetary savings would come from reducing decentralized and/or external data analysis and from policy decisions stemming from data in the repository; all participating insurers would expect to continue their regular analytical practices. However, non-insurer organizations such as working groups, pharmaceutical groups, and CIHI would find value in national drug use data and analysis tools. The authors recommend that the next step should include confirming the participation of insurers and performing a detailed cost-benefit analysis.

(NA236) International Experience with Pharmacare: Lessons for Canada

Recipient: Centre for the Evaluation of Medicines, St. Joseph's Hospital, Hamilton

Contribution: $93,204

This study evaluated the drug expenditures of seven western industrialized countries in order to draw lessons about balancing the need to contain the costs of public health insurance programs while ensuring access to pharmaceuticals. The project noted that in wooing pharmaceutical research and development, governments also face corporate demands for concessions to policies designed to manage pharmaceutical expenditures. This broad-ranging study covered economic policies, pharmaceutical industry practices, world trade organization policies, public health insurance programs, and price management strategies. Key findings include the fact that in all countries studied, expenditures on pharmaceuticals are growing at a greater rate than are overall health care expenditures. The report concludes that the challenges facing Canadians regarding pharmaceuticals will be ethical and political. As a result, there will be a need for setting priorities so as to balance public and private interests, for defining the role of cost-sharing, and for deciding the limits of insurability.

(NA246) Evaluation of Provincial Procedures for Drug Listing Specifically Focused on the Approaches to Cost-Effectiveness

Recipient: Memorial University of Newfoundland

Contribution: $99,000

This project evaluated the current processes for listing medications in provincial formularies, paying particular attention to the drug's cost-effectiveness as it applied to the process of acceptance of five new drugs in five provinces (Alberta, British Columbia, New Brunswick, Ontario, and Quebec). A drug was chosen for each of the following five categories: innovative, innovative but somewhat controversial, expensive on a daily basis, expensive on the basis of a large number of patients, and expensive, for uncommon conditions. The evaluation was a cross-sectional observation survey of government and drug company representatives. The survey instruments were four questionnaires in two categories: general objectives about organization, procedures, and data; and drug-specific questions about the experience with the index drugs. The surveys included open-ended questions. The report found that the approach to listing drugs on the provincial formularies is rather unscientific, not evidence-based, not transparent, and inconsistent across the provinces. It makes many recommendations to improve the manner in which provinces list drugs on their formularies.

(NA250) An Assessment of the Health System Impacts of Direct-to-Consumer Advertising of Prescription Medicines

Recipient: Health Policy and Communications Branch, Health Canada

Contribution: $88,800

This project had three components examining the impacts of the pharmaceutical industry's advertising of prescription drugs directly to consumers, a practice that is illegal in Canada but common in the United States. Part one of this project explored economic theories to predict the benefit to consumers and the cost consequences of drug advertising and concluded that advertising is not geared to providing objective, verifiable health information but to increasing profit.

In part two, researchers conducted an opinion survey of experts on the impact of direct-to-consumer advertising in Canada, the United States, and New Zealand. They found that advertising, media, and pharmaceutical respondents viewed advertising in a positive light, whereas representatives of other sectors across the health care spectrum did not. In part three, a pilot project was undertaken to compare patient/physician information and attitudes regarding prescription drugs in Vancouver and Sacramento. Its early results indicate that direct-to-consumer advertising has an impact in physicians' offices in Vancouver. More than 30 per cent of those surveyed had seen U.S. advertisements for at least 10 drug products in the previous year, and doctors indicated that they were directly asked to prescribe advertised medications by 6.1 per cent of patients, while 9 per cent either requested a new prescription or raised the possibility of receiving a prescription for medicine they were not already taking.

(NA408) Addressing Prescription Drug Misuse in First Nations Communities

Recipient: First Nations and Inuit Health Branch, Health Canada

Contribution: $165,200

The Red Bank First Nation initiated this two-year pilot project to deal with prescription drug misuse for drugs like Tylenol 3®, cough syrup with codeine, and Ritalin®, which are free, easy to access, and acceptable because they are doctor-prescribed. The project generated a process by the community itself, with the commitment of its political leadership, to address the problem. It devised a non-judgmental team approach, viewing prescription drug misuse as a problem belonging to the entire community. The project staged several focus groups with service providers, community members, and youth; in-depth interviews with community and health representatives exploring factors leading to, and perpetuating, the prescription drug misuse problem; informal meetings; a case study; many workshops; and a video tape. However, the report notes that the undertaking suffered from the absence of a concrete implementation model and from some community resistance.

(AB301-27) Primary Health Care Collectives: Improving the Quality of Medication Use in the Community (Pharmacy)

This project attempted to improve the quality of medication use and medication management by patients and care providers alike. It hoped to achieve these goals by establishing community-based teams, called "collectives," comprised of a physician, a pharmacist, and a home care nurse. The project selected high-risk patients who were, on average, taking five medications, were about 66 years old, and self-reported their health status as poor. The project had mixed results. Patients did access home care services that were previously unavailable to them, and they significantly improved their compliance with medication regimes. In addition, data suggested a trend toward fewer physician and hospital visits, although this finding was not statistically significant. However, the patients' health status did not significantly improve.

(BC201) British Columbia Pharmacare Health Transition Project (PharmaNet)

Recipient: British Columbia Ministry of Health and Ministry Responsible for Seniors

Contribution: $3,165,600 – eight substudies

(BC201-01) Sleep and Anxiety Management Project

This project provided family physicians with materials to help them manage sleep and anxiety disorders in older patients in the hope that such material would reduce the prescribing of benzodiazepines, a class of tranquillizers and sleeping pills. The project also examined whether the use of a telephone support line would result in changes in drug prescribing practices. Prescribing of these drugs during the six months prior to the project was compared with prescribing six months after the initiation of project interventions. On the whole, this study found that its hypothesis was not supported.

(BC201-02) The Better Prescribing Project

Helping physicians to improve their drug prescribing practices was the central focus of this project, which sought to use data from two programs to achieve that goal: a national practice-based learning program and PharmaNet, British Columbia's on-line pharmacy database. The project evaluated the impact of education on prescribing for four health conditions: hypertension,

type II diabetes mellitus, otitis media, and congestive heart failure. Researchers developed two educational aids that were given to randomly selected family physicians whose prescribing practices were compared with those of colleagues who were receiving different materials. The study's findings are complex and at times contradictory. The hypertension trial, for example, led to a significant increase in prescriptions for first-line drugs, but other health conditions showed no change. Less than 5 per cent of participants said they intended to improve their prescribing in all four health conditions. Nonetheless, PharmaNet proved to be a powerful tool for providing physicians with individualized prescribing feedback on certain conditions.

(BC201-03) Women's Health in the Mid-Life Years

This project aimed to empower women aged 45 to 65 in five B.C. communities in making key mid-life health decisions through education and community involvement. The project focused on bone health and heart health as well as lifestyle changes and illness prevention strategies related to menopause. Each community tailored its program to its own needs. Some communities used discussion groups, others held conferences; yet others set up newsletters, magazines, and Web pages to inform and involve women. Participants said they gained new knowledge about coping with menopausal symptoms, felt more confident in making decisions, and intended to make major lifestyle changes. Some women, however, felt more confused about the range of options for therapy. A key benefit was the opportunity to socialize and learn about menopause from other women in mid-life. First Nations women did not feel comfortable in larger forums and preferred small groups that they could organize in their own communities.

(BC201-04) Community-Based Asthma Self-Management Program

This study evaluated the impact of specially trained community pharmacists on the health of patients with asthma. Researchers compared the health outcomes of two groups: those who received educational and monitoring services from specially trained pharmacists and those who received services from traditional pharmacists. Researchers followed 350 patients with asthma for at least one year and examined their health outcomes using patient self-reports, pharmacist reports, and government databases. This was a randomized, controlled trial in which community pharmacists monitored and managed the drug therapy of patients with asthma. Results were expected at the end of 2001.

(BC201-05) Evaluation of the Feasibility of a Randomized Controlled Trial of a Drug Reimbursement Policy Change during Implementation

This two-part pilot project sought to evaluate drug benefits programs in order to make them more evidence-based. Researchers used a B.C. Pharmacare decision in 1999 that introduced a change in coverage for respiratory drugs. In part one, they offered a randomized set of physicians a six-month exemption from Pharmacare's drug policy change and then measured outcomes by assessing the differences in health care utilization and quality of life between patients immediately affected by the policy and the randomized control group of patients served by physicians who were given the optional six-month exemption. Findings indicated that the policy was effective at saving Pharmacare money (an amount estimated at about $600,000 over the six months, and more than $1 million over the full year after the policy began). Part two developed a four-part "how-to" manual that set out steps for directors, managers, evaluators, and data systems managers to link policy to evidence in the field of pharmacare issues.

(BC201-06) An Evaluation of a Randomized Controlled Project on Asthma Education in B.C.

This project evaluated the effectiveness of a community-based asthma education program in British Columbia. The project's goal was to assess the feasibility of the education program and to measure the outcomes, including the number of hospitalizations, emergency visits, and physician visits. The study randomly selected community groups, and patients were randomized into education groups to learn self-monitoring, the role of medications, signs of poor asthma control, and so on. Detailed outcomes of this project were not expected until the summer of 2001. Early indications were that enrolled patients benefited from participation. The project recommends that all patients with asthma be encouraged to obtain education regardless of the severity of their condition and that asthma educators be recognized as part of the health care team.

(BC201-07) The Patient Outreach Project: Community Pharmacy-Based Assessment of Patient Therapy

This pilot project used the PharmaNet system in British Columbia to alert pharmacists to patients who may not be taking their prescribed drugs correctly. The project designers flagged patients taking a minimum of five or more concurrent medications. Once alerted, the pharmacist chose a range of intervention options to educate the patient about the medication and its use, including training, reinforcement, and physician contact. The project examined the feasibility and acceptability of the "alerting" system and the feasibility of the outreach program. Key findings indicate that the PharmaNet Alerting System is effective and feasible in a community pharmacy environment and that it is not disruptive to regular work practices. Future analyses will examine the cost-effectiveness of the program.

(BC201-08) The Impact of Asthma Care Protocol, Administered by Trained Community Pharmacists, on Improving Outcomes in Adult Asthma

This project sought to improve the health of asthma patients by giving them better pharmaceutical care. The study was offered to all pharmacists from the Health Outcome Pharmacies co-operative in British Columbia. Participating pharmacists were trained and certified in asthma care, and participating pharmacies were provided with separate counselling rooms. Participants were divided into three groups: those who received basic asthma education, those who received scheduled asthma self-management training sessions, and a control group who received pharmacists' normal level of care. Researchers found that patients in the enhanced care group used 50 per cent less of the medication (inhaled beta-agonists); had 50 per cent fewer symptoms, had a 10 per cent increase in lung function, and benefited from a greater improvement in asthma knowledge than did those receiving a normal level of care. There were no changes in emergency or physician visits or in hospitalizations but asthma-related visits decreased in the enhanced care group. Patient satisfaction with services was very high in both groups. Although pharmacists were pleased with their patients' improved health status, they were unhappy about the demands on their time and resources and by some patients' non-compliance.

(ON221) Randomized Trial Evaluating Expanded-Role of Pharmacists in Seniors Covered by a Provincial Drug Plan in Ontario – Seniors Medication Assessment Research Trial (SMART)

Recipient: McMaster University, Hamilton

Contribution: $677,860

The study evaluated a five-month program that linked family physicians with pharmacists trained to provide cognitive, clinical, patient-based care (known as "expanded role pharmacists" or ERPs) in an attempt to optimize drug therapy for seniors. The study used a "cluster randomized control trial design" that involved 889 senior patients, each using five or more medications, in 48 family practices in urban and rural Ontario. The SMART project twinned pharmacists with family physicians in the intervention group, provided access to medical records and patient interviews, facilitated recommendations on identified drug-related problems, and determined over the next five months which recommendations would be implemented. The report notes that the experiment was successful, effective, and reproducible: drug-related problems were identified in 88 per cent of the patients in the intervention group; physicians agreed to implement 84.2 per cent of the recommendations they received; and after five months, 56.5 per cent of those changes had been implemented successfully. The study found no significant differences between the intervention and control groups in terms of mean number of daily medications or medication units, proportions of appropriate or inappropriate drug use, the proportion of patients reporting a problem with their medications, or quality of life. Both physicians and pharmacists said they would recommend the method of collaboration to colleagues.

(ON222) Partners for Appropriate Anti-Infective Community Therapy – Development of a Guideline Dissemination Infrastructure

Recipient: University of Toronto

Contribution: $150,000

This study looked at the feasibility of extending an education strategy called PACCT (Partners for Appropriate Anti-infective Community Therapy), which had proven effective in a 1996 pilot, to the whole province in order to combat antibiotic resistance. The project had six objectives: to establish a provincial

network for disseminating evidence-based guidelines and educational materials; to empower family physicians to play a leadership role in improving the use of antibiotics; to contribute to decreasing regional and national bacterial resistance; to promote the appropriate use of anti-infectives; to improve patients' understanding and use of anti-infectives; and to provide an opportunity for enhanced physician-patient-pharmacist communication about drug-related issues. The project developed a provincial network of trained facilitators and supplied them with materials as well as program and evaluation support to give training to primary care providers in their communities. The project was not designed to measure changes in antibiotic prescribing and use. The report draws out the lessons learned and extends their application to suggest that this information dissemination approach could be extended to other primary care best-practice guidelines over a wide geographic area.

(ON223) Potential Pharmacist-Directed Strategies and Reimbursement Mechanisms

Recipient: Centre for Evaluation of Medicines, St. Joseph's Hospital, Hamilton

Contribution: $97,992

This project tested the premise that expanding the role of the pharmacist could improve drug therapy and reduce drug-related morbidity and costs. Researchers first deconstructed drug-related decision-making models – which range from paternalistic (decisions made entirely by the physician) to informed (the physician telling the patient what is happening and why) to shared (decisions made jointly by physician and patient) – to arrive at a list of eight potential roles a pharmacist could play. Then they interviewed key stakeholders about drug therapy decision-making and the role and reimbursement of pharmacists. Finally, they devised questions seeking reactions to five possible pharmacist roles, such as providing drug information to physicians, doing personal comprehensive medication assessments, and serving as an independent practitioner. They found that while all three groups generally support the principles of collaborative practice and a more integral role for pharmacists, physicians have more conservative opinions than do patients and pharmacists about the roles that would be acceptable, and they are less comfortable with the possibility of pharmacists having access to medical histories and charts. No strong concerns were expressed that the provision of any additional or enhanced services would conflict with the pharmacist's business role or would cost the health care system too much money.

(SK221) A Controlled Study of Initiatives to Improve Antibiotic Prescribing and Adherence

Recipient: Saskatchewan Pharmaceutical Association

Contribution: $309,804

This study sought to determine the most effective combination of physician prescribing and public education initiatives to ensure the best use of antibiotics and to increase adherence to the drug therapy. The researchers targeted family physicians with visits from pharmacists informed about antibiotics ("academic detailing") and used profiling feedback reports on antibiotic prescribing. Researchers also used written and oral communication (through letters and telephone calls) to determine prescribing patterns for community-acquired respiratory-tract infections and to inform patients filling prescriptions about the necessity for compliance. The results of the project indicated little or no significant impact from the interventions. This was a community-based project that faced several challenges, including insufficient physician participation, but researchers said academic detailing was a positive move that enhanced the role of pharmacists.