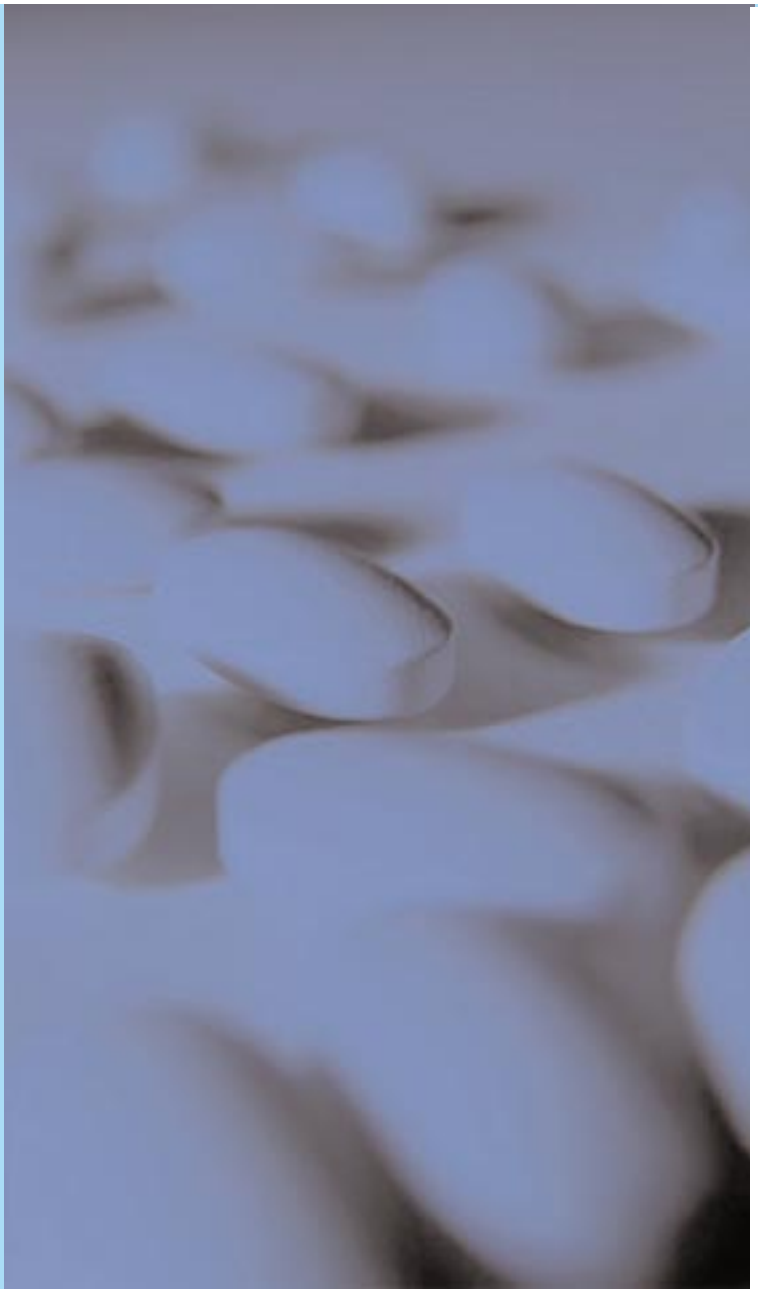
A MERCK FROSST POLICY CONFERENCE **Held in conjunction with the Canadian Association of Population Therapeutics annual meeting**



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ASSESSING THE IMPACT OF PHARMACEUTICAL INNOVATION

March 29 2003, Quebec City

MERCK FROSST
Discovering today for a better tomorrow.

Introduction

MONIQUE RICHER

This third annual policy symposium, organized and sponsored by Merck Frosst Canada Ltd., was held in conjunction with the Canadian Association of Population Therapeutics annual meeting. The symposium series attempts to encourage pharmaceutical policy that is built on evidence by bringing together policy-makers, health-care providers, patients, academics and industry to highlight best practices, showcase important research and stimulate open and constructive debate.

At the 2003 symposium in Quebec City, faculty discussed how we can benefit most from innovation in terms of health outcomes, cost and economic development. Three keynote addresses looked at the information we now use to judge pharmaceutical policy, the system impacts of pharmaceutical use on health outcomes and the potential effects of pharmaceutical policy on Canada's economic development. A first panel then described preliminary results of some new models of disease management across the country. The closing panel discussed strategies that could permit an exploration of the value of innovative therapies while safeguarding the fiscal viability of the health system.

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ABOUT THE SPEAKERS

RICHARD C. ALVAREZ
As President and Chief Executive Officer of the Canadian Institute for Health Information (CIHI), Mr. Alvarez is responsible for providing overall direction and leadership for the Institute's activities. He has articulated a broad national vision for health information, and clearly defined the role of CIHI in achieving this. He has led the evolution of CIHI from an organization focused on warehousing data to one that disseminates relevant policy material and has links with the research community.

DR. NEIL BELL
Dr. Bell is a Professor in the Department of Public Health Sciences and the Department of Family Medicine at the University of Alberta. He received his MD at the University of Alberta and his M.Sc. in Epidemiology at the Harvard University School of Public Health. Dr. Bell is in family practice at the Misericordia Hospital Family Medicine Centre in Edmonton. Dr. Bell is a Fellow of the Institute of Health Economics. He is currently one of the coprincipal investigators for the Alberta Improvement for Musculoskeletal Disorders Study, and has an interest in research in the areas of primary care, healthcare utilization and lung disease.

MARCEL CÔTÉ
Mr. Côté is Senior Partner of SECOR, a Montreal-based consulting firm. He is an economist, holding a M.Sc. from the Graduate School of Industrial Administration of Carnegie Mellon University in Pittsburg, Pennsylvania. He is also a Fellow of the Center for International Affairs at Harvard University. Mr. Côté taught at the Université de Sherbrooke and the Université du Québec à Montréal before founding SECOR in 1975. Mr. Côté is best known as a strategic advisor for senior management and an advisor to both provincial and federal government. Mr. Côté is director of Sobeys, ING Canada, Nurun and Positron. He is also President of the Board of the Montreal YMCA Foundation and director of the Montreal Symphony Orchestra.

ELEANOR HUBBARD, PHC
Ms. Hubbard is Director of Pharmaceutical Services with the Nova Scotia Department of Health. She has 20 years experience in health care, having worked in retail pharmacy, private insurance and as a consultant before moving to the public sector. Responsibilities as the Director of Pharmaceutical Services include policy and program development, standards development, implementation, administration and evaluation of the Nova Scotia Seniors' Pharmacare

Program, Department of Community Services Pharmacare Program, Special Disease Programs, Hospital and High Cost Drug Programs. She also serves on the Advisory Committee on Information and Emerging Technologies, and as Chair of the Canadian Coordinating Office for Health Technology Assessment.

DR ALAN KATZ

Dr. Katz is an Associate Professor in the Departments of Family Medicine and Community Health Sciences at the University of Manitoba. He is also the founding Director of the Primary Health Care Research Unit at the St. Boniface Research Centre. His major research interests are in measuring and influencing the quality of care provided by family physicians. He is one of the principle investigators in the Manitoba Appropriate Anti-inflammatory Utilization Project.

DR. JACQUES LE LORIER

Dr. Le Lorier is a Professor in the Department of Medicine and Pharmacology and in the Faculty of Medicine at the Université de Montréal. He is Adjunct Professor of Epidemiology and Biostatistics in the Faculty of Medicine at McGill University, and Head of the Pharmaco-epidemiology and pharmacoeconomy research unit at the Centre hospitalier de l'Université de Montréal. In January 1993, he became head of the Pharmaco-epidemiology and pharmacoeconomy Research Unit at the Research centre of the Hôtel-Dieu de Montréal Hospital. In 1998 he became director, and for the year 2001-202 President, of the International Society of Pharmacoepidemiology.

JEAN LÉGARÉ

Born in Quebec in 1946, Mr. Légaré is married to Lise Paquin, is father of three and proud grandfather of four (soon to be five) grandchildren. He worked for over 30 years in telecommunications engineering in Quebec and abroad. In 1997 he took advantage of an early retirement package offered by his employer and has since become involved in a number of organizations that defend the rights of people suffering from chronic diseases. Mr. Légaré was diagnosed with rheumatoid arthritis in 1985 at age 38.

Since 1993, Mr. Légaré has been a member of the Board of the Association des arthritiques de Québec and in 1994 began as a volunteer with the Arthritis Society. His activities intensified in 2000 when he started working with the Arthritis Society to get biologic therapies covered by Quebec's drug plan. In 2001 he joined the Canadian Arthritis Patient Alliance, and is also part of the Best Medicines Coalition.

DR. STUART M. MACLEOD

Dr. MacLeod is currently the Executive Director, British Columbia Research Institute for Children's and Women's Health, Vice President (Academic Development), BC Provincial Health Services Authority, and Assistant Dean (Research) and Professor of Pediatrics, Faculty of Medicine, University of British Columbia. Dr. MacLeod spent 14 years at the University of Toronto (pharmacology, clinical biochemistry, pharmacy, medicine and pediatrics), and has held hospital appointments at the Toronto Hospital, the Hospital for Sick Children, the Addiction Research Foundation and two general hospitals in Hamilton. He completed a five-year term as Dean of the Faculty of Health Sciences at McMaster University in 1992 and was the founding director of the Father Sean O'Sullivan Research Centre at St. Joseph's Healthcare, Hamilton until June 2002.

DR. TERRENCE MONTAGUE

A cardiologist and health researcher, Dr. Montague is a member of the Executive Operating Committee and leader of the Department of Patient Health at Merck Frosst Canada Ltd. The Patient Health team at Merck Frosst has expertise in health economics and health management. Patient Health supports the principles of evidence-based medicine, with a particular focus on broad-based partnerships with a strong community face, and a primary goal of closing the gap between usual care and best care. This partnership/measurement paradigm of disease and health management fosters innovation and sustainability of our health system through collaboration and knowledge creation and propagation.

Previously, Dr. Montague occupied a number of academic positions at the University of Alberta and Dalhousie University. He is an author of more than 300 academic papers and has served on the editorial board of several health journals. He is a retired lieutenant-colonel, Canadian Army.

DR. MONIQUE RICHER

Dr. Richer is Dean of Pharmacy at the Université Laval. Dr. Richer received her Bachelor of Pharmacy degree from the Université de Montréal and her Doctor of Pharmacy degree from the University of Texas at Austin. She completed a residency in hospital pharmacy at the Ottawa General Hospital as well as post-graduate residency in pediatrics from the University of Texas Health Science Center at San Antonio. She received a Medical Research Council/ Health Research Foundation post-doctoral award to complete her studies at the Université Laval. She holds a Masters in Health Sciences Education and is a law student at the Université Laval.

DR. ROLF J. SEBALDT

Dr. Sebaldt is an Associate Professor of Medicine and Associate Member of the Clinical Epidemiology & Biostatistics Department at McMaster University. He is also Director of Clinforma Data Systems & Management at the Centre for Evaluation of Medicines, and President of Fig.P Software Incorporated, a company based in Hamilton, Ontario.

Managing Medication: A growing imperative

DR. STUART MACLEOD,
BRITISH COLUMBIA RESEARCH INSTITUTE FOR CHILDREN'S AND WOMEN'S HEALTH

The term "medication use management" can mean many different things, from the study of variations in therapeutic approaches, to studies of pharmaceutical outcomes, to the analysis of gaps in treatment. At the hospital level, there is much talk about "continuous quality improvement" and "total quality management" in the drug arena. There is also strong interest in improving therapeutic decisions at the point of care, much of which centres on the use of electronic medical records.

There is not, however, much interest in U.S.-style managed care, where insurance companies and state governments are very directive about drug therapy. This approach has prompted negative responses from both patients and health professionals. However, there are many other ways to manage medication use.

The fundamental debate in medication use management is whether to rely on supply-side controls or demand-side management. Most of what has been tried in Canada to date has been supply-side control. As a clinical pharmacologist who has spent the last 30 years teaching health-care professionals how to make better therapeutic decisions, I believe it is high time that rigorous scientific studies were conducted on what can be achieved with demand-side management.

There has been a general unwillingness to use education to address concerns about prescribing practices such as the over-prescription of antibiotics, which can potentially lead to the emergence of antibiotic-resistant organisms. To deal with this problem, the government of Ontario imposed supply-side controls dictating restrictions on the prescription of certain antibiotics. There is as yet little evidence that this approach will reduce resistance and it may, in fact, have some adverse consequences. A better approach would be to study the effect of a major educational assault on physician antibiotic prescribing. There have been small educational experiments in Calgary and in Port Perry Ontario, but the Ontario Ministry has been unwilling to support a comprehensive study comparing the results of education to those of supply-side restrictions. This type of research is expensive, time consuming and will probably have to be funded through industry-government partnerships.

THE VOCABULARY OF RISK

Another central issue is our understanding of risk. Risk has many dimensions, none of which have been particularly well studied in therapeutic research. How is risk perception measured? How is risk analyzed? How can risk be reduced? And how do we communicate better approaches to those who are prescribing, dispensing or taking medications?

A British study of risk perception, conducted 12 years ago, showed that the vocabulary of risk has different meanings for different groups. In a pediatric clinic in Liverpool, researchers asked medical students and mothers what words such as "likely" and "rare" meant to them. Mothers thought that "likely" meant somewhere between 50 and 85

percent, medical students thought that it meant somewhere between 70 and 85 percent, while most physicians and scientists understand "likely" to mean virtually 100 percent certainty.

The other end of the risk spectrum was even more confused. The mothers felt that if the doctor said "there is a rare adverse reaction associated with this drug," that reaction was between 10 and 35 percent likely to occur. The World Health Organization and others, including the Canadian government, define "rare" as being a maximum of one event in 1000 exposures. Even the medical students considered a "rare" event as one that occurred five to 10 percent of the time. These differences in perception make it very difficult to talk about risk and drug safety.

THE PRICE OF SUCCESS

Success in innovation is exerting pressure on the drug prescribing system. This success has come as countries, especially the U.S., dramatically increase expenditures on life sciences research. Canada has reorganized the research enterprise, creating centres of excellence and networks of excellence. The Canadian Foundation for Innovation, alongside provincial governments, has channelled a great deal of money into university centres that are key to the shift to a knowledge-based economy. Most centres are now achieving a better balance between theoretical and applied research interests and are beginning to work on rapid knowledge transfer. Success is tied to the future of public/private partnerships, which forces us to look at what incentives there are for innovation and what kind of intellectual property rights we can provide, particularly at a university level.

IT IS HIGH TIME THAT RIGOROUS SCIENTIFIC STUDIES WERE CONDUCTED ON WHAT CAN BE ACHIEVED WITH DEMAND-SIDE MANAGEMENT

The past few years have seen a host of provincial and federal reports on health care, as well as a report on patient safety issued by the National Steering Committee on Drug Safety. While these reports recognize that science is important and that decisions ought to be based on research, only a few strong advocates for evidence-based decision-making have emerged, notably Don Mazankowski, Senator Kirby and John Wade on the drug safety issue. It is therefore difficult to see much progress resulting from these reports in the area of optimal drug therapy. What is desperately needed is an appropriate evaluation of some demand-side management strategies that might be used to improve therapeutics and therapeutic outcomes.

Forty percent of the world pharmaceutical market is in North America today, and while Mexico and Canada form some part of that, the activity is predominantly in the U.S. In the last decade of the twentieth century, 50 percent of new chemical entities originated in the U.S. and 70 percent of the sales of new chemical entities were in the U.S. American pharmaceutical and biotech firms are the major beneficiaries of this market growth and there is some relationship here to the fact that the U.S. is almost alone in providing relatively open access to innovative therapies.

To some degree the European countries, Canada and other developed countries have backed away from innovation, watching pharmaceutical companies relocate the drug discovery enterprise elsewhere. Canada is also making sacrifices on the clinical side and accepting delays in the introduction of new therapies. But these are just delays: eventually, these new chemical entities are embraced all over the world.

Innovative therapies are likely to cost more, so embracing them means accepting additional treatment costs. The benefits include, one hopes, better health outcomes, but also the drive to constantly improve biomedical knowledge. It is important not to lose sight of the fact that the whole process of therapeutic innovation is of overall benefit to a province and a country. It is quite possible that the indirect economic benefits of embracing innovation may be even more important than the economic benefits that accompany improved health outcomes.

The Art of Pharmaceutical Policy-making: Data rich, information poor

BY RICHARD ALVAREZ

Policy making in pharmaceutical areas is less a science than an art. Part of the Canadian Institute for Health Information's (CIHI) mandate is to tip the balance a little more towards science by improving the availability of data and information. CIHI started out its work looking at priority needs for information in a variety of areas and developing a road map that could guide future work. CIHI's job is really to try and answer two questions: How healthy are Canadians and how healthy is the health-care system? Indicators for these two questions fall under four major domains: health status, non-medical determinants of health, health-system performance and community and health-systems characteristics (Figure 1).

In terms of health status, we are no longer just interested in whether Canadians are alive or dead, but whether they are living long and functioning well. The more we look at the non-medical determinants of health, the more we realize that the health system itself plays but a very small part in terms of overall health. Personal resources, health behaviours and environmental factors account for much of the variation.

The assessment of health-system performance is still focused on cost efficiency, while it should be equally concerned with the quality of care received. However, assessing the quality of care

Figure 1. Health Indicators Framework

requires measuring a variety of dimensions, from the acceptability of treatments and the state of the system, to accessibility, appropriateness and competence, continuity, effectiveness, efficiency and above all safety. Community and health-systems characteristics cannot tell us how well the system is performing but do tell what resources are available by counting utilization rates and the dollars in the system.

To answer complex policy questions, these four domains must be looked at together. Are differences in outcomes following a myocardial infarction or heart attack due to variations in treatment or secondary prevention measures such as aspirin and beta blockers, etc., or are they due to other factors? To answer questions of optimal drug spending within the continuum of care and determine which strategies are most effective at controlling costs while ensuring high-quality patient care, we need to look at the interaction between the different domains.

WHAT DO WE KNOW?

As CIHI set out to answer some basic questions and peel back the layers of the onion, it became obvious that in many cases the data did not exist. Huge data gaps appeared in areas such as health status, non-medical determinants of health, acceptability, accessibility, appropriateness, continuity and safety. There is some good data in parts of the country, but it is not standardized nor uniformly available, so cannot be put together to provide a national perspective. We need to pick up on the good work that is going on in certain parts of the country and create linkages with less advanced regions in order to start producing comparable information.

The are data available in community and health-system characteristics because the system has traditionally been funded according to data such as numbers of hospital beds, numbers of inpatient days, numbers of MRIs, numbers of visits to doctors, utilization rates and costs. If any information is, in fact, driving policy, it is the information in that box. However, it does not reveal anything about outcomes and system performance. Compounding these difficulties, to establish indicators we have to be sure we are comparing apples with apples. This requires linking information about morbidity, mortality, vital statistics, rehabilitation systems, etc.

DRUGS IN HEALTH SPENDING

We do know something about dollars. Canada spends about $112 billion on health care every year. The growth rates in drug expenditures have been consistently higher than the growth rates in total health expenditures, even as growth in health expenditure is now at its highest in history. In 2002 it was forecast that drugs would consume 16.2 percent of total health expenditures (over $18 billion). On a per capita basis, there is considerable variation in growth rates of drug expenditures between provinces, from $462 per capita in British Columbia in 2002 to $640 in Ontario (see Figure 2).

Prescription drugs accounted for 80.3 percent of total drug expenditures in 2002 and there is steady growth in that area; between 2001 and 2002, the growth rate was 8.8 percent. Non-prescription drugs maintained a more modest growth rate of about 3.6 percent in 2001 and 2002. While non-prescription drugs are typically financed from our own pockets, prescription drugs are financed by many different payers.

In 2002, 45 percent of prescription drug expenditures in Canada were financed

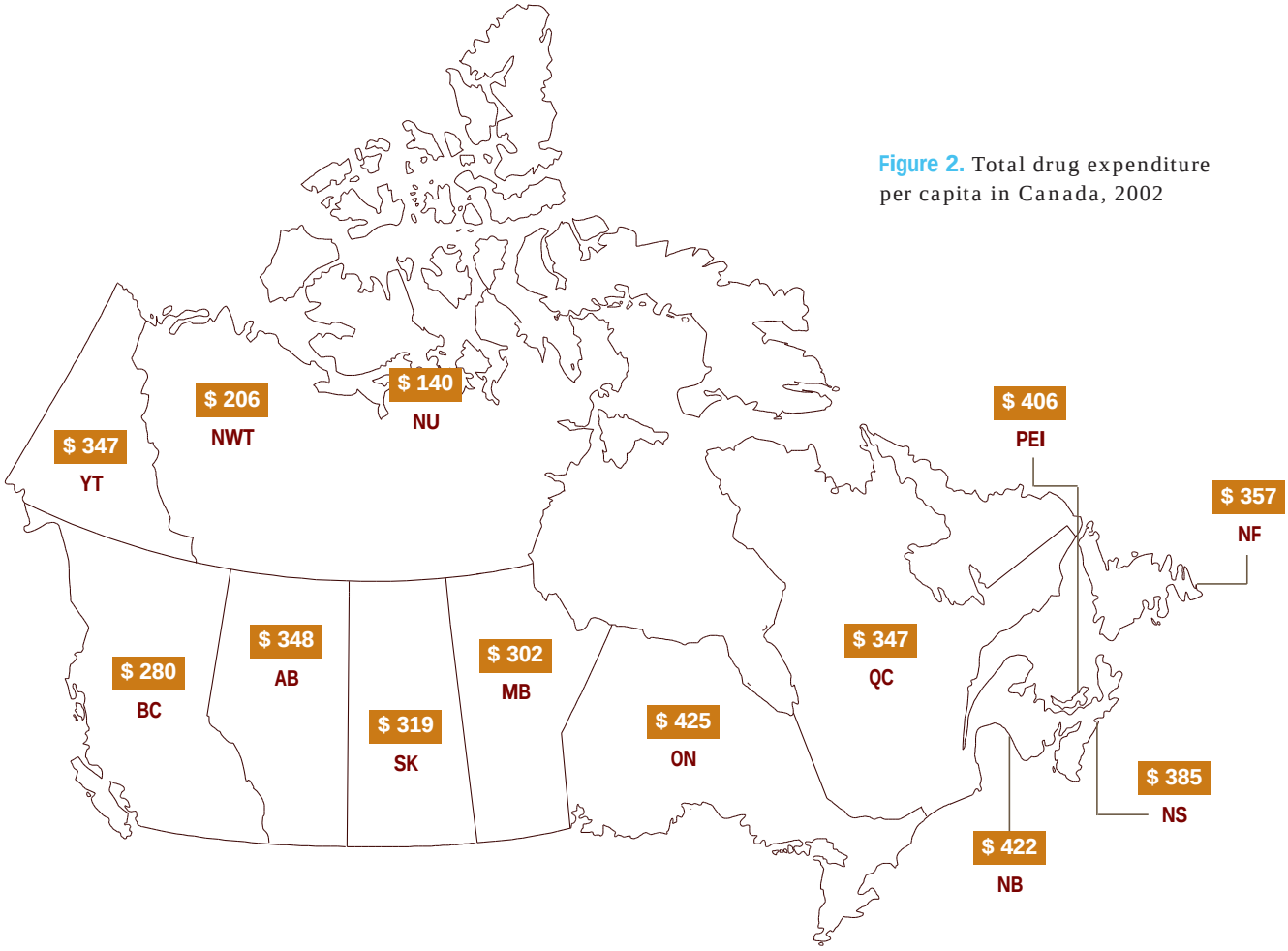


Figure 2. Total drug expenditure per capita in Canada, 2002

by the public sector and 55 percent by the private sector. Interestingly, and this is where health ministers grow quite concerned, the share of prescription drugs in public health spending has more than doubled since 1985, even as private health-care spending on prescription drugs has remained fairly stable, consuming about 30 percent of private spending each year from 1985 to 2002. The proportion of prescribed drugs financed by the public purse varies across the provinces, from a low of 34 percent in P.E.I. to a high of 52 percent in British Columbia (Figure 2).

The upward curve in drug expenditures has occurred in all G-7 countries with the possible exception of Japan. The U.S. leads the pack, while Canada is at about fourth place after the U.S., France and Italy. Many countries spend more public money on drugs than we do.

WHERE ARE DRUG DOLLARS GOING?

Our data on drug spending comes from the Patent and Medicine Price Review Board (PMPRB), which surveys drug purchases by hospitals and retail outlets (which include wholesale and other distribution mark-ups), IMS, which surveys drug purchases by hospitals and retail outlets (which include wholesale and other distribution mark-ups), and CIHI, which reports on final consumption of drugs purchased by consumers, generally from retail outlets (and including professional fees).

Before drugs can be purchased, they need to be approved by Health Canada. In 2001, Health Canada took a relatively

THE ASSESSMENT OF HEALTH-SYSTEM PERFORMANCE IS STILL FOCUSED ON COST EFFICIENCY, WHILE IT SHOULD BE EQUALLY CONCERNED WITH THE QUALITY OF CARE RECEIVED

aggressive stance for priority reviews of drugs that hold promise for life threatening or severe debilitating conditions for which there are very few effective therapies on the market. Their target turnaround for these is 180 days, while for all other drugs it is 300 days. Health Canada has not succeeded in conducting priority reviews within even a year, much less their own target of 180 days. The average is closer to 16 or 18 months.

PMPRB data on sales of patented and non-patented brand-name drugs and generic drugs shows that the value of sales in patented drugs has grown in recent years, to about 65 percent of total sales, while sales of non-patented generic drugs have stayed relatively stable. The top selling therapeutic groups of drugs are similar in Canada and other developed nations, with cardiovascular drugs typically leading the pack. Over 300 million prescriptions are filled every year in Canada. A Statistics Canada survey found that nearly 80 percent of all Canadians reported having used one or more prescribed drug or over-the-counter medication in the past month, and many reported using multiple drugs. Painkillers account for a great number of those medications.

A Commonwealth Fund study conducted by a group from Harvard University compared five countries, Australia, New Zealand, the U.K., the U.S. and Canada, in terms of access to prescription drugs. One of the questions they asked was "What is the percentage of adults in the past year who did not fill a prescription because of cost?" While the Canadian rate of 13 percent was almost half the rate in the U.S., it was also almost double that of the U.K., which spends more public money on drugs.

WHAT'S THE OUTCOME?

On a regional basis, there are variations in clinical outcomes in diseases such as asthma, hypertension and diabetes that require ambulatory care. But we cannot link that to the use of prescription drugs because we do not have national information on drug utilization. We can see variations in survival after myocardial infarction and stroke, but we cannot yet tie it to use of beta-blockers and aspirin. Work at a provincial level to collect and link this data remains to be done.

When trying to assess the value of a new medication, we still do not have good information about whether it reduces the need for other medications or services. Nor have we fully studied the impact of eligibility criteria or cost-sharing policies on the accessibility of therapies. Compliance is another complicating factor. Should our coverage policies take compliance into consideration for drugs such as lipid-lowering therapies where there is very poor compliance? Or do we invest more in education to improve compliance?

FILLING THE GAPS

There are major data gaps in so many areas that I believe pharmaceutical policy-making is still an art. However, a number of very interesting projects are attempting to produce evidence that can enhance our knowledge base. At a national level, CIHI is working with the Canadian Institutes Health Research

(CIHR) on information about adverse events in Canadian hospitals, and we can anticipate a new patient safety institute at a national level in the next few years. The Common Drug Review process decided by federal and provincial health ministers will see the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) performing single assessments of new drugs with much more expertise than each province could bring to the process singly. There is also cooperative work underway on electronic pharmaceutical claims for both the public and the private sectors. CIHI is also involved in a major national initiative to gather more information about prescription drugs that will permit research into exposure to new drugs, numbers of drugs per user, compliance, patterns of prescription refills and renewals, accessibility, appropriateness and safety.

For the moment, CIHI is still at the stage of developing drug utilization indicators. We must move fast from there to the pinnacle, which is information support and better health. We are beginning to move from a narrow focus on costs to a much more comprehensive view around aspects of substitutions and outcomes. Most importantly we are moving from technical reports to producing comprehensive reports that inform the public debate.

More than Just Health Care: The Impact of pharmaceutical innovation on the economy

BY MARCEL CÔTÉ

The pharmaceutical industry has traditionally positioned itself as a research-driven enterprise. Its R&D sector is the most intense in Canada, with $3.5 billion a year spent on biomedical and pharmaceutical research. But it is also the fastest-growing area of health expenditure, with drugs representing 1.5 percent of the gross domestic demand and 16 percent of health expenditures. The industry accounts for 0.2 percent of total employment in Canada, two-thirds of which is in the big 20 pharmaceutical companies There are 500 firms, mostly small biotech, about 20 large pharmaceutical companies and two large Canadian generic firms, as well as about 10 or 15 smaller ones.

The main issues concerning the pharmaceutical industry in Canada are intellectual property, access and formularies, approval delays, and the question of efficacy and the growing cost of drugs. But there are also international issues, evidenced by the fact that stock prices of the larger pharmaceutical companies have been declining since 1998. Reasons for this include the dearth of new blockbuster drugs, but more important are problems with intellectual property, grey markets, global pricing pressure from insurance companies and governments to reduce the cost of drugs, and competition from generic drug makers. Also problematic are the issues of access to new drugs in lower-income countries.

INNOVATION IS THE PRINCIPLE

Using a model developed with Roger Miller, we sought a new way of looking at the pharmaceutical industry. Until about 15 years ago, technological progress was considered an external factor in economics, which was primarily concerned with capital and labour. Now economists have developed the "new growth theory," which focuses on the innovation process as a main factor in

economic growth. In short, their theory stipulates that the application of knowledge to new uses explains growth in the economy. The interactions between the different aspects of the innovation system are described in Figure 3.

NOW, ECONOMISTS HAVE DEVELOPED THE "NEW GROWTH THEORY," WHICH FOCUSES ON THE INNOVATION PROCESS AS A MAIN FACTOR IN ECONOMIC GROWTH

Our work started with the principle of innovation that lies at the core of the new theory. Innovation is a two-tier process, conducted via public or basic research on basic mechanisms and on the effect of applying a particular molecule in a specific circumstance, and then, through product development research (R&D) accomplished by pharmaceutical firms. As such, innovation in the sector is also greatly shaped by regulations around safety, efficacy and cost.

The innovation process is very different from the equations economists have used in the past to explain economic growth, and it must be described in terms of interaction between the innovators who generate ideas and the decision-makers who shape and regulate products. At the top of the innovation pyramid in the biopharmaceutical industry is scientific advancement, where the basic ideas are in the public domain, do not belong to any particular party and are disseminated very rapidly. Advance in science is a public good and thus needs public investment. The move from ideas to product is the most challenging stage from an industrial point of view. The pharmaceutical industry works to select new products and successfully market them, thereby establishing a revenue stream with profits generated by new products.

The health-care industry can also be assessed through its players, as innovation in health care involves numerous players at various levels (Figure 4). The key suppliers of ideas are universities, teaching hospitals and research centres. Next, there are the granting agencies

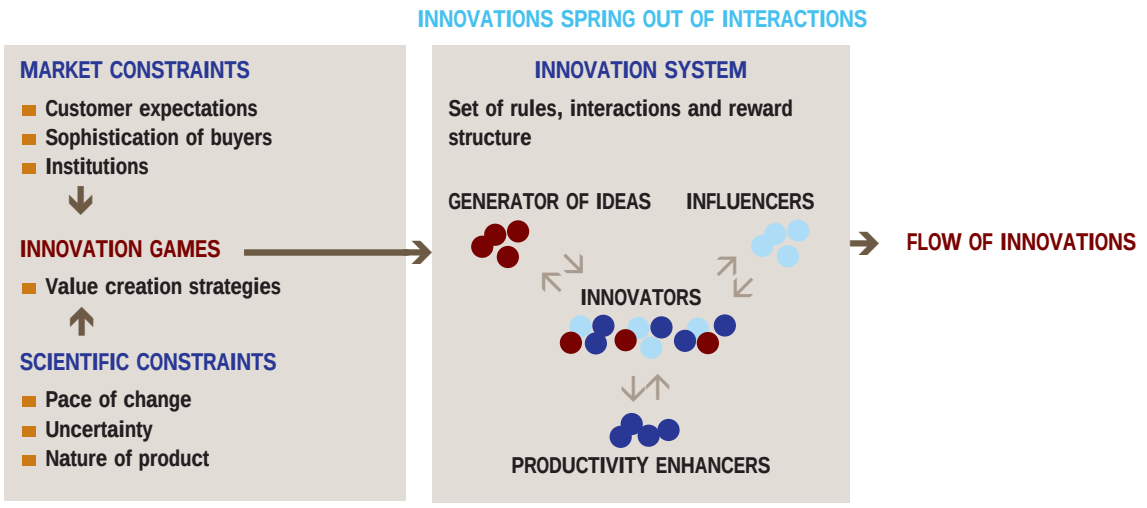


Figure 3. Understanding the innovation process. Players choreograh their interactions through innovation games, which are strategies designed to capture the economic benefits of an innovation in a specific context

and pharmaceutical companies that provide funding and direction. After that, product development is conducted by pharmaceutical and biotech companies, which must satisfy the regulatory bodies before the last stage of marketing can take place.

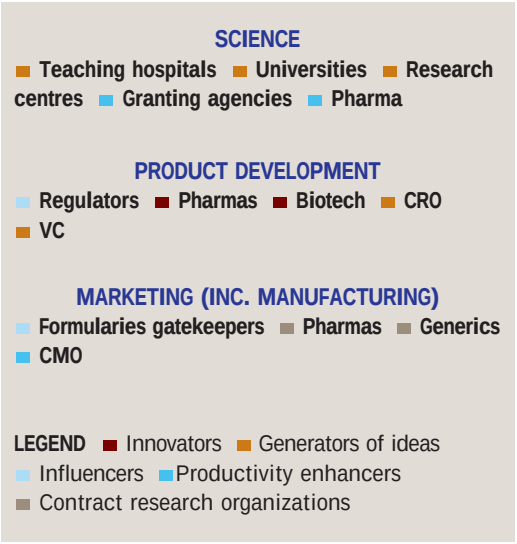


Figure 4. The Key players

THE ELEMENTS OF INNOVATION

New ideas in the biopharmaceutical sector originate mainly within the publicly-funded science sector. Although the forum of ideas is global, proximity to new ideas always enriches the chance of productive linkages.

There are essentially two paths of product development. First, there is the organized pharmaceutical avenue (or "big pharma"), systematically pursuing new products within a well-defined development strategy. Mastering this product development process is critical for big pharmaceutical companies. The second avenue is the entrepreneurial route of the biotech companies, which couples promising ideas with venture capital. Globally, the biotech dream has not yet produced the results we thought it might. As a process for product development, it remains greatly shaped by regulators and issues concerning intellectual property.

Marketing is largely dictated by two interrelated elements: novelty (the continual introduction of new products) and obsolescence (the reality of short product life in view of competition and innovation). This combination is the reason why drug prices are high (as a limited number of successful drugs finances a trial-and-error process) and why the marketing of pharmaceuticals is complex, expensive and very detailed in comparison to most other industries. The companies involved also operate in a marketplace dominated by government, which runs the drug formularies and thereby controls market access, but also funds the outcomes research increasingly used to independently assess drug efficacy. As well, it is government that weighs the views of the big pharmaceutical companies and the generic drug makers and then passes legislation governing the contentious issue of intellectual property rights.

A SYSTEMIC VIEW

There is no doubt that innovation in the pharmaceutical industry is good for the overall economy because it is intrinsically knowledge-based: it capitalizes on ideas rather than on large investments in labour and capital. Second, public research is essential for product development; the more public research we have, the healthier the industry will be. Product development is inevitably high risk, high reward. Not winner take all, but rather winner pay for all. The industry has to pay for all the losers because they are all on the same team. Whereas the large pharmaceutical companies are diversified enough to withstand risk, smaller biotech companies are rarely in that position because product develop-

ment is not the cornucopia people sometimes think it is.

There are currently eight significant issues facing the pharmaceutical sector in Canada:

1. FUNDING PUBLIC RESEARCH

Canada has supported a regular increase in public funding, now totalling around $1.7 billion a year. That works out to about $50 per capita as compared to $85 a head in the U.S. But despite that disparity, there is a more pressing question to ask: Is the quality of Canadian biomedical research growing or being maintained as we increase funding?

With respect to the long-term sustainability of funding levels, we need to multiply links and alliances between basic research facilities and the industry in a way that benefits both parties and the Canadian people. However, we have to be careful how this is done. For instance, we may have already gone too far in the recruitment of biotech entrepreneurs from academic settings. Every university now has structures which encourage professors to become entrepreneurs and commercialize their discoveries. I would argue that they should reverse the current trends and focus increasingly on basic research as the university's main role.

2. EXPANDING BRANDED PHARMA R&D

If we consider innovation to be the core of the pharmaceutical industry, we have to accept that we are not doing as well as most other countries. R&D expenditures in Canada represent 10.9 percent of the sales of the big pharmaceutical companies, compared to a global average of 19.5 percent. While some companies (such as Merck Frosst) do a lot of research in Canada, many others use Canada mostly as a marketing territory and do a negligible amount of R&D here.

What then are the determinants for expanding R&D in a given country? Market friendliness — the positive interrelation of regulation, cost and efficacy — plays a big role. In particular, it allows local managers in multinationals to make a case for increasing the budget allocation in their country. Other key elements are the efficiency of local R&D, the availability of researchers, the condition of the infrastructure and the availability of government collaboration and support.

3. THE FORMULARIES DILEMMA: COST VS ECONOMICS

In terms of pharmaceutical sales per capita, Canada is a middle-usage country, below Japan and France, and far below the U.S., but slightly higher than the European Union average. Our prices are also somewhere in the middle of the pack, with a price structure much lower than the U.S., Switzerland, Germany and the U.K., but higher than Sweden, France and Italy.

The dilemma of formularies in Canada illustrates the conflict of interest in which provincial authorities find themselves. They administer access and control the length of the approval process, and can even freeze prices. But they deal with a host of conflicting criteria. Should they just consider cost efficacy or also the general well being of the population? Should they view pharmaceutical treatments within the context of other medical treatments? And then there is the economic offset: Is it more advantageous for a province to be a "free rider" or pay its share of the cost of developing drugs? It is concerns like these that make establishing a national drug agency a good

idea. Along with the pooling of resources to share analysis, a common approach in preparing and administering formularies would be beneficial.

4. PROVINCIAL INDUSTRIAL POLICY

Canada's provinces have two levers at their disposal: They control the formularies and can amass financial support for developing industry. In Quebec, a province with a clearly articulated industrial policy, the intensity of R&D in the pharmaceutical sector is higher than in the rest of the country. In Quebec, 19 percent of sales are spent on R&D versus only 9 percent of sales elsewhere in Canada. Per capita research costs and drug costs are lower in Quebec than Ontario, for example, although so is the overall consumption of drugs. As well, R&D in Quebec is mainly expressed in grants to universities.

IN QUEBEC, A PROVINCE WITH A CLEARLY ARTICULATED INDUSTRIAL POLICY, THE INTENSITY OF R&D IN THE PHARMACEUTICAL SECTOR IS HIGHER THAN IN THE REST OF THE COUNTRY

Are such policies a zero sum gain? Our analysis suggests they are not. If other provinces were to follow Quebec's lead and institute similar policies, we feel that Canada as a whole would gain more attention (and thus, R&D budgets) from the pharmaceutical multinationals when it came time to dispersing their global budgets. Ontario and perhaps B.C. stand to gain the most as they already have a strong research base.

5. INTELLECTUAL PROPERTY

Intellectual property protection is a critical issue for all knowledge-based industries. In the pharmaceutical industry, the generic companies are aggressively nibbling around the edges of existing patent protection. To be the first on the market with a medicine that is off-patent gives a generic firm a tremendous marketing advantage.

The trend in the European Union and the U.S. is to move towards an effective 15-year patent protection plan. Canada is likely to follow suit, eventually. It is actually just a change in the patents as it applies to pharmaceuticals; instead of 20 or 17 years, it will be 15 years of effective life on the market. The vagaries of the development process will no longer dictate the length of protection.

The other major challenge to intellectual property is grey markets, where citizens of a country with higher drug prices can now purchase drugs at lower cost from outside their country, thanks largely to the Internet.

6. REGULATORY APPROVAL

We can learn much from the integration of the European system of regulatory approval that now means a drug can be approved in Madrid or London and that ruling is valid for the whole European Union. If we could encourage the industry to stop playing games globally, by going into one country where access or price control is more liberalized, it would speed up the process of approval. Everybody gains from a greater exchange of information and more acceptance of approvals by other countries.

7. STRENGTHENING BIOTECH

In some sectors, we observe a “scientific

effervescence" that leads to a lot of business creation in an initial burst, which then subsides as interest declines. The key elements to sustaining these companies are financing and alliances, and Canada is weak on the alliance side. When biotech companies get to the phases of product development and marketing, they have to get into some kind of alliance or buy-out with a big pharmaceutical company with clout and a marketing organization. Often the company is based on a single product, so they need to reach an accord with the company that has the ability to sell their product.

8. THE POLICY FRAMEWORK

Will we ever have a clear public policy framework in Canada? As an optimist, I would say yes. But Canada's 13 provinces and territories will also always be in the public policy equation. Moreover, different departments within the federal government have differing agendas and clashing policies. Nevertheless, when taking everything into account, Canada's public policies supporting the scientific realm work relatively well. But policies on the product development and marketing side lack coherence, and reforms are required to allow industry to perform better.

Lessons From the Ground: Achieving outcomes in disease management

INTRODUCTION

DR. TERRENCE MONTAGUE

What is disease management? Broadly speaking, it is a focused application of available resources to drive improved health outcomes (1). Key features of modern disease management programs are: patient centrality in optimizing diagnosis, prescription, compliance and access in health care; a shift from isolated inputs and controls to a system view featuring collaboration of providers; and the creation and sharing of new knowledge, particularly as it relates to the measurement and feedback of practices — all leading to improved health of whole populations. The primary premise of all players is that care and outcomes can be better.

Because it focuses on defining and closing gaps between usual and best evidence-based care and outcomes, the partnership/measurement model of disease management goes a long way to answering the question: Are we getting the best return on the health dollars we spend?

Currently, Merck Frosst Canada Ltd. is partnering with researchers across the country on several innovative programs in musculoskeletal health. These projects have distilled some key learning points relevant to outcomes-oriented projects, particularly around defining the appropriateness of care. A summary of the early results follows.

ASSESSING THE BURDEN OF ILLNESS

DR. NEIL BELL, UNIVERSITY OF ALBERTA

The first step in many disease management projects is to accurately determine the burden of illness from the target disease in the relevant population at risk. The Alberta Improvement for Musculoskeletal Disorders Study (AIMS) sought to determine the disease patterns of all major musculoskeletal disorders

for the entire province of Alberta, with a subsidiary goal of comparing disease burden in urban and rural areas.

Using the administrative databases of the Department of Health and Wellness, the clinical and demographic scope of patients seeing health-care providers in Alberta for musculoskeletal problems was assessed. Musculoskeletal disorders embrace numerous clinical diagnoses, varying from rheumatoid arthritis, osteoarthritis, unspecified arthritis, back pain, back strain and back sprain, to fibromyalgia. Patients with one or more of these diagnoses made up about 40 percent of the total patient population of Alberta between 1998 and 2001, and represented the primary reason for about 20 percent of all patient visits. Most of these patients were in the working-age population between 20 and 65 years, with a slight preponderance of males in patients under 50 years and a female dominance among older patients. Patients with rheumatoid arthritis accounted for one percent of this patient population; osteoarthritis, for six percent; and, back-related diagnoses, for 24 percent.

The lack of specificity in the patient diagnostic categories makes it challenging to evaluate diagnoses against the level of utilization of services, particularly in terms of estimating severity of diagnosis-related disability versus likelihood of appropriateness of treatment. Nonetheless, some preliminary observations are very interesting. For example, chiropractors provide more than 50 percent of the care, by visit, for patients under 60 years of age, compared to about 30 percent for patients over 70 years; in these older patients the primary provider becomes the community-based family physican (Figure 5). Medical specialists and other non-physician providers account for less than 20 percent of patient visits at any age.

In summary, the early findings of AIMS include: the universe of patients with musculoskeletal problems is large and represents a significant proportion of total demand for health-care services in Alberta; a large number of the assigned diagnoses appear symptom-based, relatively non-specific and back-related in terms of anatomy; and the type of care provider varies markedly with patient age.

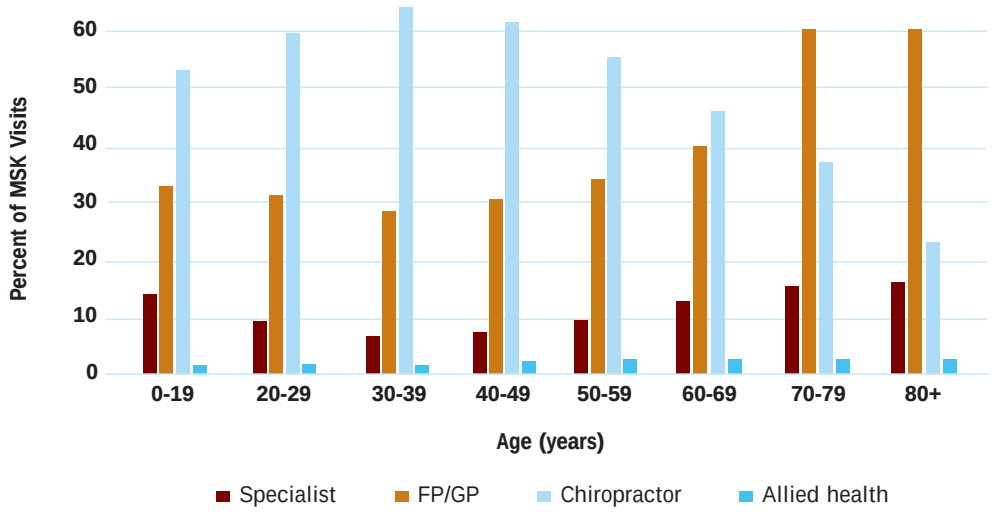


Figure 5. Figure 5. Distribution of visits, by age of patient and type of provider, for patients with musculoskeletal disorder diagnoses, Alberta, 2001.

Ongoing AIMS studies include verification of ICD diagnostic codes against chart diagnoses, as well as assessment of potential care gaps and determination of solutions to improve patient outcomes in the specific diagnostic groups.

APPROPRIATE PRESCRIBING

DR. ALAN KATZ,
UNIVERSITY OF MANITOBA

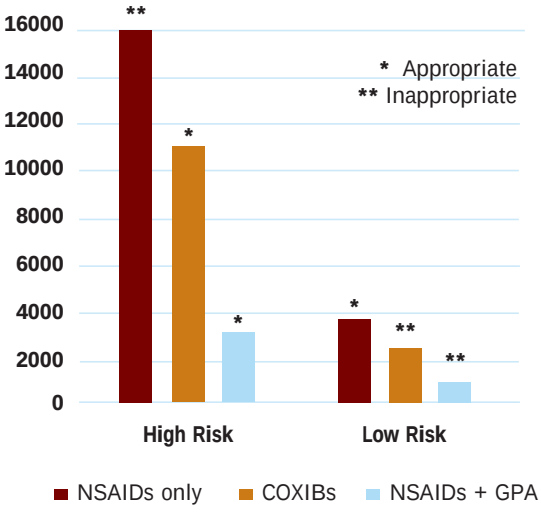
Following burden of illness assessment, a logical next step in disease management is measurement of the contemporary patterns of practice around the treatment of the disease. When these usual care patterns are compared to evidence-based best practices, any deficiencies are considered a care gap and a target for improvement. The Manitoba Anti-inflammatory Appropriate Utilization Initiative (MAAUI) was designed with a first phase to determine the prescribing patterns for chronic anti-inflammatory drug use and, in anticipation of finding care gaps, subsequent intervention phases to close the gaps.

In the MAAUI study, patients prescribed anti-inflammatory medications on a chronic basis and who were either over 65 years of age or had a previous history of peptic ulcer or bleeding disorder, or required anticoagulants or steroids, or had other serious co-morbidity were considered high-risk patients. Patients on chronic anti-inflammatory drugs in the absence of these risk factors were considered low-risk.

Based on the available evidence regarding reducing risk of gastrointestinal complications, consensus guidelines for chronic anti-inflammatory drug use most often suggest that best practice for high-risk patients is prescription of either a COXII inhibitor (COXIB) or a combination of a traditional non-steroidal anti-inflammatory drug (NSAID) with a gastro-protective agent (GPA). For study purposes, prescription of either of these therapies in high-risk patients was considered appropriate therapy. In low risk patients, prescription of traditional NSAIDs was considered appropriate drug treatment.

Using existing databases, medication use and other clinical and demographic data were analyzed for 36,593 patients chronically prescribed anti-inflammatory drugs in Manitoba from August 1 1999 to September 30 2000. The findings are summarized in Figure 6.

Overall, 29,871 (82 percent) patients were considered high risk, with age over 65 years and serious co-morbidity being the most common factors. Thirty percent of the patients had two or more risk criteria. Among this high-risk group, only 47 percent were prescribed COXIBs or a combination of traditional NSAIDs and



High-risk patients, n=29871
Appropriate Rx, n=14,047 (47%)
Under Rx, n=15,824 (53%)

Low-risk patients, n=6722
Appropriate Rx, n=3767 (56%)
Over Rx, n=2955 (44%)

Figure 6. Comparison of appropriate and inappropriate prescribing patterns for anti-inflammatory medications among high and low risk patients in Manitoba, 1999-2000.

UNDER TREATMENT OF HIGH-RISK PATIENTS (N=15,824) WAS A MUCH GREATER PROBLEM THAN OVER TREATMENT OF LOW-RISK PATIENTS (N=2955)

GPAs; 53 percent were prescribed NSAIDs only. Of the 6722 (18 percent) patients in the low-risk group, 56 percent were treated with NSAIDs alone and 44 percent received either COXIBs or combination treatment. Subgroup analyses revealed a higher use of inappropriate NSAID-only therapy in low income and rural patients.

In terms of therapeutic appropriateness, there were two care gaps. In high-risk patients, 53 percent were inappropriately treated with NSAIDs only, not receiving either COXIBs or combination therapy. On the other hand, among low-risk patients, 44 percent were treated with COXIBs or combination therapy, which could be considered unnecessary over-treatment. In terms of absolute patient numbers, under treatment of high-risk patients (n=15,824) was a much greater problem than over treatment of low-risk patients (n=2955). In cost effectiveness terms, this is probably also the case, given the likelihood of continued high-risk status for patients in this category and their associated high likelihood of manifesting medical complications.

These Manitoba findings are very compatible with those from a large data base analysis of a Nova Scotia seniors' population, using very similar definitions of patient risk and prescription appropriateness for chronic anti-inflammatory drug use (2).

In summary, MAAUI, and similar robust database analyses elsewhere, provide a population-based approach to assess appropriateness of prescribing and utilization patterns among patients with chronic disease. They also allow serial comparison of practice patterns, including those before and after interventions designed to improve practices.

ASSESSING PRESCRIBING BY LAYERED-IN DATA COLLECTION

DR. ROLF SEBALDT,
MCMASTER UNIVERSITY

The Canadian Osteoarthritis Treatment Program (CANOAR) began in 2001 with a goal of determining contemporary prescribing practices of a selected cohort of Ontario primary-care physicians, and the potential influence of availability and type of drug reimbursement coverage on patients with a clinical diagnosis of osteoarthritis. Measurements of clinical and demographic data were directly entered at point of care in community physicians' offices at the time of individual patient visits.

Throughout its course the study stressed the development of methods that busy physicians with a high prevalence of osteoarthritis patients in their practice would find valuable in helping them in the routine care of these patients. The study repeatedly highlighted the concept of partnership, particularly the value of community physicians' input into decisions about study design and implementation. This partnership was instrumental to making diagnostic criteria, data forms, patient enrollment and communications processes as simple and layered into physicians' daily routines as possible. Guided by a prelaunch focus

group and pilot test, the data form was developed to feature pragmatic inclusion criteria, particularly physicians' clinical diagnosis of osteoarthritis and other practical clinical information relevant to and focused on the care of an osteoarthritis patient. This process enabled the substitution of the completed data form for the clinical chart note, if so desired. Anonymous patient data was submitted by toll-free fax to the project data centre, where automated translation into electronic form, cleaning, encoding, aggregation, progress monitoring, monthly feedback reporting and analysis was performed.

Recruitment invitations resulted in 130 community-based Ontario doctors agreeing to participate, of whom 119 submitted data over the course of 14 months on 5947 patients during 8846 consecutive patient visits. Of the patients enrolled, 60 percent were women and 47 percent were over 65 years of age. Co-morbidity was common, including hypertension (36 percent), coronary artery disease (12 percent) and previous clinically significant gastrointestinal event (8 percent). Anti-hypertensive therapy was prescribed in 34 percent of patients; 20 percent were on gastro-protective agents; and 17 percent were taking an anti-platelet medication. In terms of anti-inflammatory prescribing practices, 56 percent of patients were prescribed COXIBs and 44 percent traditional NSAIDs. Among patients with a history of a clinically significant gastrointestinal event, COXIB use was 66 percent overall and 85 percent if the event was within two months. Thus, although prescribing patterns appeared appropriate in the majority of these high-risk patients, there was still a significant minority being inappropriately under-treated in terms of reduction of risk for further gastric events.

Subgroup analyses revealed 39 percent of the study cohort had private-plan insurance coverage for their medications. The 61 percent of patients without private coverage were older by an average of nine years, more likely to be women and to have a higher prevalence of co-morbidity, including twice the number of risk factors for gastrointestinal events. Despite their overall greater risk, these latter patients were more likely to receive traditional NSAIDs only (24 percent) than were patients with private-plan coverage (19 percent), who had a lower average risk. Similarly, they were less likely to receive COXIBs (48 percent) than patients with private-plan coverage (67 percent). Physicians indicated that availability of private insurance would have altered their prescribing decisions for anti-inflammatory drugs as follows: 31 percent would have switched from a traditional NSAID to a COXIB; 15 percent would have switched from a COXIB to a traditional NSAID.

In summary, CANOAR demonstrated the feasibility of rapid, facile and prospective data collection at point of care in the data-rich environment of real-world, community-based care. CANOAR data confirmed care gaps are present in the management of osteoarthritis patients who receive anti-inflammatory drugs and suggest that they may be related, at least in part, to the type of patient insurance coverage for drug reimbursement.

EDUCATING FOR IMPACT ON PHYSICIAN PRACTICES IN OSTEOARTHRITIS

DR. JACQUES LE LORIER, UNIVERSITÉ DE MONTRÉAL

The end game in modern disease management is to close care gaps between

usual and best care and gain the associated improved patient outcomes. The three most commonly used interventions to improve provider prescribing practices, and patient compliance, are: education; measurement and feedback; the use of reminders; or some combination of these (3). Comparative evaluation of specific intervention tools, in specific disease settings, is still uncommon.

The *Concertation pour une Utilization Raisonée des Anti-inflammatoires dans le Traitement de l'Arthrose* (CURATA) project evaluated the impact of two educational interventions on the appropriate use of anti-inflammatory agents in patients with osteoarthritis. One intervention was a convenient evidence-based treatment algorithm, printed on plasticized paper and distributed to physicians caring for patients with osteoarthritis. The other intervention was an interactive workshop, conducted by a group of rheumatology specialists and family physicians, focusing on representative case studies of osteoarthritis patients.

Two evaluation tools were used: a pre- and post-test of physicians' knowledge of the evidence-based treatment of osteoarthritis and comparison of physician prescribing patterns, determined from the comprehensive government (RAMQ) database, for patients with osteoarthritis over 65 years of age, before and after the educational interventions. The interventions were conducted in eight randomly selected geographic areas of Quebec. Two sites received both the algorithm and workshop, two received the workshop alone, two received the algorithm alone and two were control sites, receiving no educational intervention.

Practice patterns of community general practitioners prescribing at least one anti-inflammatory drug in the period of July 2000 to June 2001 were monitored for four months in the pre-intervention control period and for six months following the interventions. Physicians' anonymity was maintained throughout the trial and only collated data were reported. All study interventions were associated with improvement in practice patterns. The algorithm had the least beneficial effect, the workshop more and the combination the greatest. In terms of appropriateness, the interventions had a greater impact on improving the use of risk-reducing therapies for high-risk patients, compared to decreasing the use of these more expensive therapies in low-risk patients.

While focused on educational intervention only, and measuring impact for a short time, the results of this study support previous data that education is efficacious in improving practices and that multiple interventions are better than single initiatives. In this project, there were risk-specific differences with respect to the impact of the interventions, with improvement in under-use of proven therapies in high-risk patients being more readily accomplished than decreasing over-use of the same therapies in low-risk patients.

CONCLUSION

DR. TERRENCE MONTAGUE

The results of these contemporary applications of disease management processes in real-world practice are complementary and consistent. There is a large burden of illness from musculoskeletal disease, but markedly different patterns of care provision dependent on patient age. Among patients receiving chronic anti-inflammatory drugs, high-risk patients outnumber low-risk patients

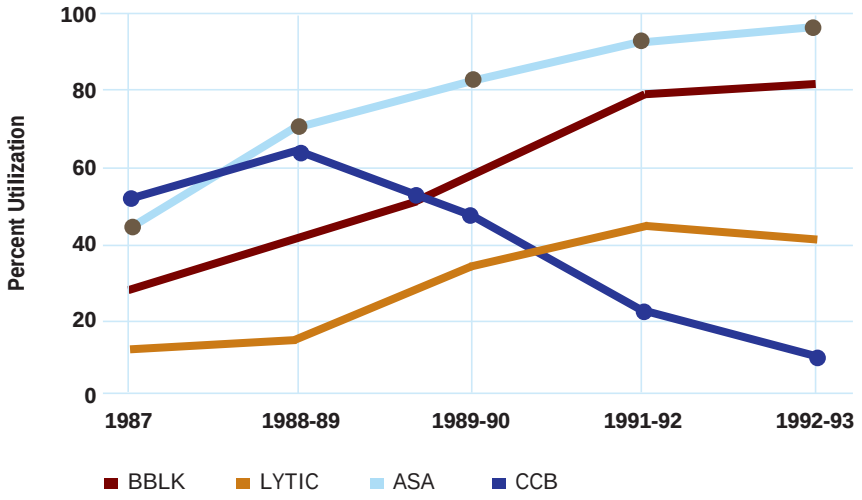


Figure 7. Temporal changes in prescribing patterns for proven and unproven therapies for consecutive patient cohorts with acute myocardial infarction at the University of Alberta Hospitals 1987-1993, where the principal intervention was repeated measurement and feedback of practice patterns to care providers Reproduced, with permission, from Montague et al, *Can J Cardiol* 1995;11:487-92 (2). ASA=acetylsalicylic acid; BBLK= beta blockers; CCB=calcium channel blockers; LYTIC=thrombolysis.

by a ratio of about 4:1. For high-risk patients, the dominant care gap is under-use of risk-reducing strategies; in low-risk patients, there is over-use of these same medications in a minority of patients. Educational interventions improve appropriateness of prescribing patterns, although further improvement is needed.

The addition of repeated measurement and feedback of practice patterns to education interventions offers one promising approach to improve appropriateness of both under-use and over-use of medications (Figure 7).

While the initial phases of the projects outlined above were not designed to show improvements in outcomes for patients taking chronic anti-inflammatory therapy, future studies will undoubtedly be constructed with this end-point. It is certainly a realistic expectation that, with improved practices, improved outcomes will follow; collaborative partnerships, measurement and feedback loops and education are effective (1).

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Creating Practical, Predictable Arrangements to Benefit from Innovation: HIGHLIGHTS FROM A PANEL DISCUSSION

Dr. Stuart MacLeod
Richard Alvarez
Marcel Côté
Dr. Terrence Montague
Eleanor Hubbard
Jean Légaré

THE CONDITIONAL APPROVAL OF NEW DRUGS

Dr. Jacques Le Lorier felt that the impetus should be to get the drug to the public as soon as possible while still ensuring reasonable safety. Canada today tends to wait until the drug has been in use elsewhere for awhile. He felt Canada's reporting system for adverse events was inadequate. A system of conditional approval, coupled with registering patients and tracking adverse events would both allow drugs to be approved sooner and provide better information about safety. It would also provide information about how a drug would be used, an opportunity to define proper use, and would allow the conditions of proper use to be defined and monitored as funding would be contingent on these factors.

Jean Légaré added that, according to the Therapeutic Products Directorate at Health Canada, an average 9000 adverse reactions are reported each year in Canada, while the U.S. has 40 times that number. This may suggest that Canadians are not reporting adverse reactions. Balancing safety and timeliness objectives is something the Canadian Arthritis Patient Alliance is working on with Health Canada, and part of the solution may be to have an effective post-market surveillance system.

Richard Alvarez suggested that the impetus for outcomes research may in fact come from concerns with safety and from the quality councils being set up in several provinces and at the national level. "These may provide an important incentive to move the agenda along in this area," he said.

COOPERATION ON IMPROVING OUTCOMES

If Jean Légaré had not been introduced as a person having rheumatoid arthritis, we probably would not be able to tell. "This is mainly due to the effectiveness of the new drugs that have come on the market these last years," he said. "If I were not taking these new breakthrough drugs, I would probably not be able to walk, I would certainly not be able to play golf, ride a bicycle, go fishing and enjoy life as I now do."

Marcel Côté thought that if we put 10 percent of the concern we have for regulation and control into making sure that the products are well used, we would see a tremendous difference in care. Outcomes research should be undertaken by the pharmaceutical industry and by government and if physicians cannot be relied upon to collect this data on drug utilization, pharmacists should be recruited into the process.

Eleanor Hubbard noted progress in the national effort around the electronic health record and provincial work on decision-support tools for physicians and patients. She expected the Common Drug Review to free up some provincial resources to work on those areas.

Dr. Terrence Montague thought that one area where industry, clinicians and government might come together is in the under-use resulting from poor patient compliance, especially in long-term conditions like heart disease or osteoporosis. "At six months," he said, "half the people who are at risk and could benefit are no longer taking the medications that they were correctly and appropriately prescribed."

THE COMMON DRUG REVIEW SYSTEM MUST SHORTEN LISTING TIMES AND NOT ADD YET ANOTHER LAYER TO AN ALREADY LENGTHY PROCESS

Dr. Le Lorier felt that other conditions, such as infectious disease, were much more plagued by over-use than under-use.

Patient safety and drug interactions may well provide the launching platform for an electronic health record, thought Richard Alvarez, though the resulting data would have many other benefits as well. Of course, there will be many other benefits in terms of access to huge data banks, the immediacy of the data and the ability to look at outcomes.

A COMMON DRUG REVIEW PROCESS

Eleanor Hubbard felt that the national common drug review would improve the listing time (or at least not make it any worse), provide better quality information on which to make decisions and make that information more consistent across the country. She believed it could replace provincial drug reviews for formulary listings. However, she also stated that as long as drugs remain a provincial jurisdiction, provinces would not give control of the formulary over to a national drug agency. "Certainly in Nova Scotia we have strict control over our formulary, conduct rigorous reviews and have all kinds of cost control and management strategies around our drug plans. We are trying to move away from cost control to education and information and technology tools, but we still have to be concerned about cost."

Dr. Le Lorier also thought it would be "totally schizophrenic" to have drugs managed by one agent that is federal and the rest of the health-care system managed by a province. "They are competing for the same budget," he says, "and should be handled together." Likewise, Mr. Côté expressed doubts about the likelihood of a national agency deciding which drugs the provinces cover on their formularies. "As long as the province pays for drugs, the drug formulary will be controlled by the province," said Mr. Côté. "Provinces each have different criteria and interests. Quebec and Ontario will always be more sensitive to the industry concerns, whereas Newfoundland can be a free-rider without too much concern." The more constructive path, in his estimation, would be more cooperation and better information flow through a central clearing house such as an agency like CCOHTA.

Jean Légaré expressed the concern that the common drug review system must shorten listing times and not add yet another bureaucratic layer to an already lengthy process. Millions of Canadian patients put their hopes in accessing the best medicines available to them in a timely manner. "There are delays in the federal approval system, delays in getting new drugs on provincial formulary, all of which causes people unnecessary suffering, compromises their quality of life and may decrease their chances of recovery." He described access as an ongoing concern in Canada.

Canadian patients, concluded Légaré, want:

- safe and effective drugs, based on the most up-to-date clinical data from high-quality trials;
- universal access to the best medicines in a timely manner; and
- drug review systems, whether they are provincial, federal or common, that are open and accountable. ■