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CIHR IRSC

Research Spotlight

Institute of Health Services and Policy Research

Pharmaceutical Research and Policy

Dr Steve Morgan

In sheer financial terms, pharmaceuticals are a serious issue, at least for those who end up paying for them. Canada will spend roughly $27 billion on pharmaceuticals in 2006. That represents over half what we will spend on hospitals ($45 billion) and 50 per cent more than we will spend on physicians ($19 billion) in 2006—and nearly three times what we spent on drugs in 1996 ($10 billion). While the majority of drug spending is for common, relatively cheap treatments for cholesterol, hypertension, heartburn & ulcers, and depression, several new, high-profile drugs are being priced at hundreds of thousands of dollars per patient, per year.

The individual costs of medicines are important because many Canadians lack adequate coverage for drug expenses. Aggregate drug costs are important because of the pressures they place on the rest of the health system. If the trends of the past decade continue, drug costs will surpass hospital expenditures by 2017. At that point, $85 billion (or one out of every four dollars spent on health care) would go to drugs.

In health-related terms, advances in pharmaceutical technology over the past 60 years have been nothing short of miraculous. Medicines can now help to cure, prevent or alleviate suffering from many illnesses. Not surprisingly then, nearly two out of every three Canadians will fill at least one prescription this year. Most will feel better and/or live longer as a result.

However, not all new medicines are breakthroughs. Recent CIHR-funded analyses show that about 80% of expenditure growth in the past decade has been driven not by breakthrough drugs, but by new "me-too" drugs that offer little or no advantage over lower-cost, time-tested alternatives.

Whether a breakthrough or otherwise, the use of any medicine involves a spectrum of health effects (positive and negative) that must be carefully measured and monitored. High-profile drug withdrawals, such as Vioxx, illustrate the worst-case scenarios. And, as important as safety and effectiveness are, there is also ample evidence that many Canadians suffer from avoidable problems of overuse, underuse and misuse of medicines. Improving the quality of medicine use—ensuring that the right patients get the right drugs, in the right doses, at the right time, and that they use them in the right way—would result in better outcomes from our $27 billion investment.

There is no doubt that Canadian patients would be better served, both health-wise and financially, through the more prudent and careful use of prescription drugs. However, past attempts at reform in the pharmaceutical sector have failed to achieve significant progress. Integrating pharmacare and medicare has been recommended since the 1960s, but always deferred until a "plateau" in drug expenditures would give policy makers the opportunity to implement policy change. This plateau has never occurred, and there is no evidence of its imminent arrival. Meanwhile, the use of drugs has steadily risen in our health care system without either universal access or systematic public oversight and management.

Canada's recently initiated National Pharmaceuticals Strategy (NPS) is a promising policy initiative. Established at the September 2004 First Ministers' meeting, the NPS involves federal, provincial and territorial decision

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makers working on nine policy domains, including gradual expansion of public pharmacare coverage, monitoring drug safety in the real world and promoting quality use of medicines.

The NPS appears to recognize that there are no "magic bullets" in pharmaceutical policy. Addressing policy challenges requires a coordinated approach involving a variety of interrelated policy levers. For example, promoting quality use of medicines requires that comparative safety and effectiveness be evaluated rigorously and objectively; that objective information be available to providers and the public; that the financial incentives facing providers encourage best practices in the use of medicines; and that information systems are used to reduce errors and provide the data necessary to continuously evaluate a drug's use and its impact on health and the health care system.

Timely, credible and relevant evidence are required to make a success of the NPS. CIHR and our health services and policy research community are playing an integral role on both of these fronts, as the diversity of policy-relevant research profiled in this *Research Spotlight* shows. We have an opportunity to help develop best practices in a sound and accountable national pharmaceuticals policy. The work has only just begun.

Steve Morgan
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Safe prescribing made simple

Principal investigator: *Robyn Tamblyn, McGill University*

Drugs are supposed to heal, not harm. But between 5% and 23% of hospital admissions, and an increasing number of deaths, are due to drug-related illnesses. The reasons for adverse drug events are numerous—the use of inappropriate drugs, dangerous combinations of drugs, allergies and excess dosages of drugs—but are also often avoidable.

Computerized systems have enormous potential for detecting and preventing errors in prescribing and dispensing drugs. Dr Robyn Tamblyn, a CIHR-funded researcher and member of IHSPR's Advisory Board, has pioneered an electronic prescribing and drug management system that gives Quebec doctors instant, computer-based access to a patient's drug, disease and allergy history, and alerts doctors to potential prescribing problems. Called MOXXI (Medical Office of the 21st Century), the program is designed to reduce the potential for human error. Doctors select prescription drugs from an automated list and indicate the medical problem the drug is supposed to treat, allowing inappropriate prescribing to be detected. The program automatically scans for known drug-disease, drug-age, drug-allergy and drug-drug contraindications, and notifies the doctor if a problem is detected.

The system also allows better communication between physicians and community-based pharmacists. This is increasingly important, as many patients now use more than one pharmacy, and have multiple prescribing doctors. In the MOXXI system, pharmacists use a unique number to access a patient's prescription information electronically. Physicians can transmit new information to stop or change medications in real time, ensuring that any pharmacist dispensing a prescription has access to the most up-to-date information.

While MOXXI clearly has the capacity to improve drug safety, it can also have benefits for both the quality and cost-effectiveness of drug prescribing. In terms of quality, both overuse and underuse of prescription drugs for certain conditions (e.g. minimizing antibiotic use for common viral infections, and making sure sufferers of heart attacks are using beta blockers) can be addressed through the use of reminders and alerts for physicians. For cost-effectiveness, a system like MOXXI can provide physicians with information about the real costs of medications at the time of prescribing and include recommendations for less expensive equivalents.

MOXXI has been running as a pilot program for ten years, and now involves over 200 physicians, nearly 80 pharmacies and almost 56,000 patients in Quebec. Follow-up studies by Dr Tamblyn clearly show that MOXXI can reduce the number of inappropriate prescriptions, and indicate that physicians believe such a system could improve continuity of care. Indeed, physicians were shown to selectively use the system for their more vulnerable patients: those with a greater number of medications, multiple doctors and more emergency department visits.

However, Dr Tamblyn knows better than most that there is no silver bullet for fixing the drug prescribing system. "It is the details that matter," she said. "With the MOXXI pilot, we found that it is still quicker for doctors to handwrite prescriptions, which means that it was not used consistently. If we want to see broad-scale adoption of electronic prescribing, we will need to make sure that, for doctors, the benefits of using the system clearly offset the costs."

FEATURE INTERVIEW:

Krista Connell *talks to* Ingrid Sketris *about how partnerships in health services research are making a difference to pharmaceutical management in Nova Scotia.*

Krista Connell is the first Chief Executive Officer of the Nova Scotia Health Research Foundation. As well as providing leadership and professional guidance to the NSHRF, she is responsible for outreach to the research community. Krista is co-chair of NAPHRO (National Alliance of Provincial Health Research Organizations) and serves as a member of the advisory board to the CHSRF/CIHR-funded Atlantic Regional Training Centre. She is also a member of IHSPR's Advisory Board working group on partnerships, and the CIHR-sponsored working group on the development of a National Strategy for Cognitive Impairment. Krista is a graduate of Dalhousie University's School of Physiotherapy, where she currently serves as an adjunct professor. She received her Masters of Health Services Administration from the University of Alberta and completed a post-graduate fellowship with the Nova Scotia Department of Health.

Photo courtesy of Dalhousie University

Dr Ingrid Sketris is a professor at Dalhousie University in the College of Pharmacy and the schools of nursing, health services administration, community health and epidemiology and computer science. She and her colleagues at IMPART (Initiative for Medication Management, Policy Analysis, Research and Training, http://www.impart.pharmacy.dal.ca) conduct research related to medication management. In June 2000, Ingrid received a CHSRF/CIHR Chair, co-sponsored by the Nova Scotia Health Research Foundation, in pharmaceutical policy and utilization management. She is a fellow of the Canadian Society of Hospital Pharmacists and the Canadian Academy of Health Sciences, and is currently on the editorial boards of the *Canadian Journal of Clinical Pharmacology* and *Clinical Therapeutics*. Ingrid has been a member of the IHSPR's Advisory Board since 2004. In 2006, Ingrid received the Anne and Neil McArthur Research Award, which is presented annually by the Father Sean O'Sullivan Research Centre, affiliated with McMaster University, to an outstanding researcher in the health sciences.

KC: Pharmaceuticals are the fastest-growing component of health care expenditures. For governments faced with increasing budget pressures, what role can health services research play in helping manage their drug benefit program costs?

Spending on pharmaceuticals was over $24 billion in Canada in 2005 and increased by 11% between 2004 and 2005. The GDP for the same year only increased by 2.9%. Concern around access to and the rising costs of pharmaceuticals has resulted in the federal-provincial-territorial governments' collaborative initiative, the National Pharmaceuticals Strategy, which has a number of different elements. The two in which I am most interested are trying to strengthen the evaluation of real-world drug safety and effectiveness, and increasing the use of health informatics to improve prescribing.

Health services research is essential for examining the impact of various government policy levers. Governments can make changes to legislation related to pharmaceuticals, or to the design of pharmacare benefit programs, and they can also fund educational programs. Research can determine both the intended and unintended effects of those programs and can help provide guidance to government around the impact of the policies they are employing.

KC: You are the holder of a prestigious, ten-year CHSRF/CIHR Chair Award, which NSHRF is proud to co-sponsor. Your Chair focuses on developing and applying drug use management strategies and policies for Nova Scotia's provincial drug programs, in partnership with researchers, health care professionals, consumers and government. What are some of the activities you are involved in and how has the Chair Award facilitated the evolution and development of these partnerships?

In Nova Scotia we've been working with the Drug Evaluation Alliance of Nova Scotia (DEANS),* which was established by the Nova Scotia Department of Health to encourage appropriate drug use. Our team at Dalhousie University has been helping them evaluate the impact of their sponsored interventions to improve drug use. For example, DEANS led an intervention to promote the switch from respiratory medications delivered by mask to puffers (portable inhalers). The puffers are just as effective, less cumbersome and less costly. We were able to show that this intervention led patients to switch from masks to puffers with no adverse health effects, no increases in physician visits and no increases in hospitalizations. This switch also resulted in an estimated cost saving of $1 million per year.

We have strong leadership at the Pharmaceutical Services Division in the Nova Scotia Department of Health. They have a vision of using evidence and involving academia. Sometimes it frustrates me because I'll go to other provinces and they'll say, "Nova Scotia is little and so you can implement change. This can't be done in our province because it's too big." And I say, "Well, Australia's developed a quality use of medicines arm of their National Medicines Policy, in a country of 20 million." My

* More information on the DEANS initiative is available in the first IHSPR Knowledge Translation casebook, *Evidence in Action, Acting on Evidence: A casebook of health services and policy research knowledge translation stories.* Available at http://www.cihr-irsc.gc.ca/e/29484.html.

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sense is Nova Scotia has been able to implement change partly because of the strong leaders who said this is important, we're going to do it, we're going to make it happen.

Before I was awarded the Chair I worked primarily in pharmacy. After I received the Chair I became involved with graduate students from many disciplines, including medicine, nursing, occupational therapy, journalism, business, law, economics, health informatics and psychology. I've also had the opportunity to work with more universities, both within Atlantic Canada, and worldwide.

In terms of developing new partnerships outside the academic sector, one of the things that has been particularly beneficial for me is my advisory committee. We meet two to three times a year and my committee members provide expertise and stakeholder advice on the Chair's programs. My committee includes Carl Breckenridge, the vice-president of research at Dalhousie University, who now knows about my research and can pass on relevant opportunities. Nova Scotia's associate deputy minister of health has also been on my committee, and that's been extremely helpful. For example, Jim Millar, chief of program delivery, met with my students at the beginning of their residency to introduce them to the Department of Health and to discuss their projects. What is really good is that the residency is a two-way exchange, because the students also bring with them a wealth of knowledge.

KC: One of your core Chair activities has been the development of a 17-week residency program for students to promote the use of research in decision making. What have been some of the key successes and challenges of this program, for the students and the decision makers?

Since 2001, we've had 27 residents in the program. Residents are partnered with a decision maker to conduct a research or policy project. What the students say most often is that it gives them the opportunity and the ability to apply both theory and analytical methods to a real-world problem, and also that it helps them prepare for the job market by getting some really practical skills and begin to make some connections.

Students also learn to communicate with decision makers. During the residency they will do one-on-one briefings with key decision makers and write briefing notes. They also get media training and plain language writing training.

There are a number of challenges. One is that it takes time to build trust and understanding between the decision-making organization and academia. Another is the often different timelines within which academia and decision makers work. If a project is associated with a short, inflexible deadline, it may not be appropriate for a student.

Decision makers may also have different levels of exposure to research. Those who are graduate-trained already know what to expect from the students and what they can do. For others who have never had any exposure to research, more communication about what the student is going to do and how it might benefit them may be necessary. In some cases, the resident brings far more knowledge and skills than the department has internally. So the decision makers quickly come to understand what the resident can bring and the ways in which the residency can help them.

Another challenge is that for many decision makers, working with a student is an "off-the-desk" activity and as a result may not be particularly valued in their environment. They have their regular workload, and there can be many demands on their time. Even if the student produces something useful, it may not be of immediate benefit if the issue is not on the agenda. Decision makers also say that it takes time to orient some of the students to the environment. Then once you have them up and running, they're gone because it is only a four-month placement. Unless of course they hire them: we like that!

Both decision makers and the university encounter challenges. The university is geared towards teaching and research while the government is geared towards policy development and program delivery. It is essential to find the common fits. We're getting much better at figuring out the size and scope of projects that fit, what we need to do for orientation, how to recognize the problems we've had before and how to work them out. With the Chair award, I have started to understand some of the issues for the decision makers and I can now refer new decision-maker partners to people who have experienced the same challenges.

KC: One of the objectives of the Chair award is to support the uptake of research by health system decision makers. At NSHRF, one of our indicators of success for knowledge transfer is informed decision making. What have been some of your experiences in this area?

One of the things that students learn is that research results are just one piece of the information matrix that informs a decision. Other factors influencing decision making include habits, the way things have been done before, values, professional experiences, other competing objectives and so on. Students also learn that once the research and knowledge is developed, it's available for anybody at any time. If the political climate changes, the research is still there; if the context in Nova Scotia does not facilitate uptake of that research, it can be taken up elsewhere.

I think that DEANS is an interesting structure for informed decision making. DEANS allows evidence from many perspectives to come into play. For example, the students and other researchers bring in literature syntheses and database analyses. But DEANS also uses practitioners, general practitioners in the community and people working in a variety of health sectors to bring in other kinds of evidence that can be helpful.

KC: Your Chair Award recently passed its first review with flying colours. Congratulations. What are some of your goals for the next six years and beyond? What are some the emerging priorities you see for knowledge translation, and training and mentoring in this area?

One of the areas I would like to look at is the impact of the residency on

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the career development of participants. For example, how does exposure to the decision-making environment early in the career of the trainees affect the way they think in the longer term? We know that it sometimes takes a long time for research to be taken up, and also that the strongest forms of evidence emerge from multiple studies over longer periods of time. It may take several years, or longer, for the necessary evidence to emerge, or it may require the turnover of government, until decision makers are actually able to use a particular body of evidence to bring about a change. Additional time will allow us to follow the results of some of the research we've conducted so far over the longer term.

For some students, their four-month residency acts as a springboard for a PhD thesis topic. One of the students in the second cohort did a four-month residency, went on to work in the same area in his PhD, which he finished this year, and has now written a book chapter on the topic. That's one of the nice things about having the Chair—you can see the career progression from the residency to the PhD, as well as the generation of new knowledge.

KC: Do you see untapped opportunities for provincial health research funding agencies such as NSHRF to partner with CIHR or other agencies in ways that will increase the extent and effectiveness of knowledge translation at the provincial or regional level?

Provincial granting agencies have good connections with the ministries or departments, health agencies, the voluntary health sector and professional groups. They really understand the context of the environment: who the key government players are, who the key stakeholders in the health care field are, who the key opinion leaders are and what some of the barriers or facilitators to the uptake of research might be. They can be very helpful in a provincial context.

Granting agencies could continue to sponsor workshops to bring some of the players together in specific areas, particularly those of interest across the country, such as wait lists, pharmaceuticals or health human resources planning.

I also work with other groups here, including the Atlantic Regional Training Centre, and the CIHR training programs in health law and policy, ethics of health research and policy, and health informatics. So even though my team is quite small, we get cross-fertilization between other CIHR- and NHSRF-funded initiatives and we are able to work together and share infrastructure.

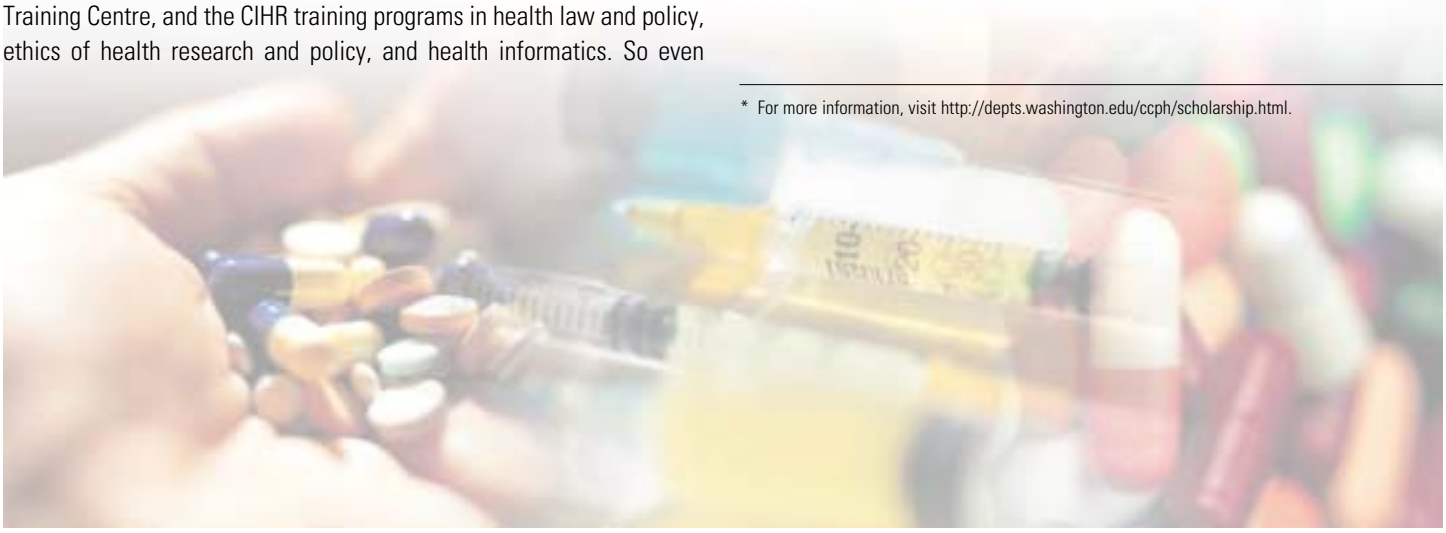
KC: Research foundations struggle with how to get more recognition in university promotion and tenure criteria and processes, for the labour-intensive types of linkage and exchange activities expected of a CHSRF/CIHR Chair. What has your personal experience been on this front and do you see positive changes at Dalhousie or other universities in Canada?

An interesting approach is being promoted by the Community-Campus Partnerships for Health.* They talk about community-engaged scholarship, which involves a professor working in a mutually beneficial partnership with the community. The organization provides information to people participating in this kind of research on how they can assemble evidence that illustrates the depth of expertise in their discipline, and how they are putting it to work to move the discipline forward. Universities look for this kind of information.

If you're going to be spending time in community-engaged scholarship, you need to think about how to document it appropriately for tenure and promotion purposes down the road. For example, I've been suggesting to trainees that they document specifically the types of expertise sought from them by decision makers.

I have personally found that structures or processes that facilitate interdisciplinary research can be very helpful. Dalhousie, like many other universities, has an interdisciplinary PhD program which allows faculty members who didn't know each other beforehand to get together, and lets students gain from the breadth of expertise within the university. For example, one PhD student with a background in business was looking at models of adoption of new drugs and the effect of factors such as pharmaceutical marketing and physician characteristics on physician prescribing of drugs. While his PhD supervisor had marketing expertise, his committee included those with expertise in pharmacy, public policy and computer science. Areas of interdisciplinary study are complex and often require multiple perspectives or multiple sorts of expertise to solve the problems. It would be very helpful if universities continued to develop structures and processes that help facilitate interdisciplinary research.

* For more information, visit http://depts.washington.edu/ccph/scholarship.html.



Improving pharmaceutical care for older adults

Co-principal investigators: *Paula Rochon, Baycrest and the Institute for Clinical Evaluative Science; Geoffrey M. Anderson, University of Toronto and the Institute for Clinical Evaluative Sciences*

Many older adults have one or more chronic diseases, such as diabetes, kidney disease or heart disease. Although appropriate use of pharmaceuticals is an integral part of high quality care for these older adults, they are at high risk for adverse events and inappropriate care—either over-prescribing (i.e. excessive or unnecessary drug use) or under-prescribing (i.e. failure to get beneficial therapies).

CIHR is supporting a multidisciplinary, international team of researchers to study the real-world impact of drug therapies in older adults with chronic disease through a New Emerging Team (NET) grant. The NET is based at the Institute for Clinical Evaluative Sciences and jointly sponsored by CIHR and the Canadian Diabetes Association, the Kidney Foundation of Canada and the Heart and Stroke Foundation of Canada.

The NET brings together junior and senior clinician-researchers and methodologists based at the University of Toronto, Queens University, the University of British Columbia, Harvard University and the University of Massachusetts to refine and explore methods for studying the effects of drugs in real-world settings, and to apply these methods to examine the effects of drugs used to treat important medical problems in the elderly.

As part of the NET, Dr Paula Rochon has led a series of studies on the use and impact of antipsychotic drugs, which are used to manage behavioural problems associated with dementia. These therapies have the potential for serious adverse events, including drug-induced parkinsonism, falls, stroke and death. The research team found that almost one in four elderly Ontarian patients started treatment on antipsychotic therapy within a year of admission to a nursing home. At the same time, use of these drugs among the community-dwelling elderly was increasing, with growing use of newer, more costly antipsychotic agents, leading to a marked increase in the cost to Ontario's provincial drug plan.

"This widespread use was particularly worrying because we also found that the newer antipsychotic drugs appear to offer only modest improvements for dementia patients," said Dr Rochon. "We looked at the published studies and found that few randomized trials had actually evaluated them in the management of the symptoms of dementia that they were supposed to be treating, and that the studies often failed to include comprehensive information on serious adverse events."

In a series of studies on the real-world effects of anti-psychotic drugs, Dr Rochon and the team have found that, when used in high doses, the newer antipsychotics were no safer than conventional agents, and that caution should be used when prescribing these drugs.

Members of the NET team were recently awarded a CIHR Interdisciplinary Enhancement (ICE) grant, under the Reducing Health Disparities and Promoting Equity for Vulnerable Populations initiative, to examine issues related to the quality of care provided to vulnerable nursing home residents. "The new ICE grant is an extension of our work on appropriate drug use in the elderly, and will allow us to expand and focus our knowledge translation efforts to help nursing homes provide the best care they can," said Dr Rochon.

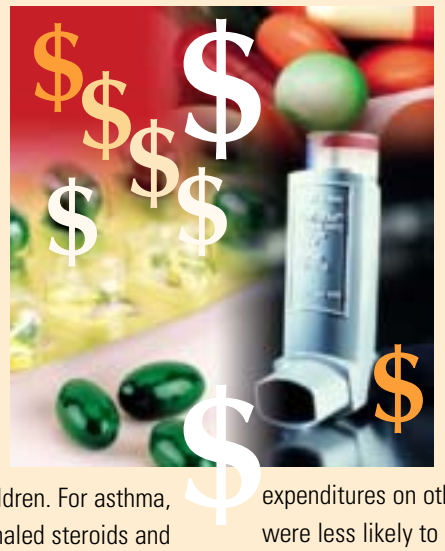
For more information on this NET grant, visit http://www.ices.on.ca/webpage.cfm?site_id=1&org_id=2&category_id=38

How cost-sharing affects drug use

Pharmaceutical cost-sharing and health outcomes in children with asthma
Principal investigator: *Dr Wendy Ungar, The Hospital for Sick Children*

The impacts of drug benefit co-payment on the use of antidepressants
Principal investigator: *Dr Carolyn Dewa, Centre for Addiction and Mental Health*

Asthma is the most common chronic disease in children. In Canada, one in ten children is now affected, and the rate continues to rise. Asthma is a significant health issue: it can be life-threatening, reduces a child's quality of life and places a heavy economic burden on families and the health care system.



Dr Wendy Ungar, a CIHR New Investigator and researcher at Toronto's Hospital for Sick Children, studies the effects of pharmaceutical policies on access to medications and asthma control among children. For asthma, the drugs most needed for daily control, inhaled steroids and combination agents, are among the most costly.

In a 2005 study published in *Healthcare Policy*, Dr Ungar demonstrated that Canada's provincial drug plans vary considerably in whom they cover, what drugs are covered and how much people must pay out of pocket. "The families of many Canadian children experience significant financial barriers to accessing needed medications," said Dr Ungar.

More importantly, differing levels of drug coverage affect how well a child's asthma is controlled, said Dr Ungar. Uninsured children visit a hospital emergency room more frequently, and have the lowest rate of use of recommended therapy with controllers (inhaled steroids). They also have the highest rate of use of relievers, drugs that are used to control acute symptoms, indicating that their asthma is not being well managed.

"By demonstrating the health and health care system impact of financial barriers to medication access, this research may help policy makers achieve better health outcomes and more appropriate delivery of services to the pediatric asthma population," said Dr Ungar. "The results will provide key evidence in informing the pharmacare debate."

At the Centre for Addiction and Mental Health in Toronto, Dr Carolyn Dewa is also looking at the impact of out-of-pocket costs on prescription drug use. In previous research, Dr Dewa had found that about 3% of employed workers collect short-term disability benefits for depression, totalling 140,000 lost work days. Depression is becoming a leading cause of disability worldwide and has significant costs in both lost productivity and the price of treatment. In many cases, early treatment can significantly facilitate an earlier return to work.

With funding from a CIHR Operating Grant, Dr Dewa looked at antidepressant use among a population of workers collecting short-term disability benefits. She found that workers with higher out-of-pocket costs for antidepressants before an episode leading to the short-term disability claim were more likely to use antidepressants during the illness. However, workers with high out-of-pocket expenditures on other prescriptions (not antidepressants) were less likely to use antidepressants during the period when they were recommended.

"What this means," said Dr Dewa, "is that the picture is more complex than we might have thought initially. The cost of existing treatments, for chronic physical conditions for example, clearly makes a difference to whether someone uses antidepressants during a short-term episode of illness. Yet the strategies for drug benefit plan cost-containment, such as cost-sharing, that can lead to high out-of-pocket costs, are very blunt instruments that don't necessarily account for this complexity."

Dr Dewa's current work is examining the relationship between private prescription drug expenditures and barriers to the use of antidepressants among workers disabled by depression.

Direct-to-consumer advertising: CanWest's Charter Challenge

Colleen Flood *and* ***Michelle Zimmerman****, Faculty of Law, University of Toronto*

All but two industrialized countries (the US and New Zealand) ban advertising of prescription drugs to the public (direct-to-consumer advertising – DTCA). But in late 2005, CanWest Mediaworks, a conglomerate with interests in television, newspapers and the Internet, launched a challenge to Canada's *Food & Drugs Act*, claiming that limits on DTCA infringe their rights to freedom of expression as guaranteed under the *Canadian Charter of Rights and Freedoms*. Why is CanWest bringing this claim? The drug industry spent US$4.8 billion on DTCA in the US last year. If even one-tenth as much was spent in Canada, this would result in over $500 million of revenue for broadcasting interests.

Pharmaceutical companies do already advertise in Canada. While a strict reading of the *Food and Drugs Act* might seem to preclude any advertising of prescription drugs, since 2000, Health Canada has allowed two types of advertisements. The first are reminder ads, which promote the brand of drug but do not make any direct health claims. The second are disease-oriented ads, which do not mention a brand but can highlight certain illnesses or symptoms and counsel viewers "to ask their doctor" about treatment.

CanWest's challenge rests on two arguments. First, they claim it is arbitrary to limit DTCA of prescription drugs whilst allowing advertising of non-prescription drugs, given that there are also safety concerns with the latter. Second, they claim that DTCA of prescription drugs is permitted in the US and, although prohibited by Canadian broadcasters, Canadians are exposed to these advertisements through US media sources.

The first argument glosses over the fact that prescription-only drugs are generally more hazardous than non-prescription drugs like cough and cold remedies—that is, after all, why they are "prescription-only." The second argument suggests that the federal government needs to be more consistent and vigilant in enforcement of existing laws to alleviate any concerns about unfairness in treatment of US broadcasters relative to Canadian broadcasters.

From both health and health policy perspectives, the consequences of a successful challenge are very serious. Pharmaceutical companies use advertising for one purpose: to increase sales. Market research on the effects of DTCA in the US suggests that DTCA in Canada could lead to at least $1.1 billion in extra sales of prescription-only products in the first year.

In terms of safety, there have been a number of recent high-profile cases associated with the adverse effects of drug consumption. For example, Dr Barbara Mintzes, a CIHR-funded researcher with the Therapeutics Initiative at the University of British Columbia, notes that from 1999 to 2004, Merck spent US$550 million advertising the arthritis drug Vioxx (rofecoxib) to the US public. Around one quarter of Vioxx sales were likely stimulated by direct-to-consumer advertising, based on sales data and returns on advertising investments. According to a Lancet study by a senior US FDA official, it is estimated that 35,000 to 45,000 Americans died from heart attacks due to Vioxx use. Without the extra sales stimulated by DTCA, around 10,000 of these deaths might have been avoided.

Photo courtesy of Actonel Good Housekeeping July 2006

In terms of cost and sustainability concerns, it is well known that drug costs are the fastest-growing component of health care spending. An extra $1.1 billion of drug costs would place further pressure on provincial plans already straining under the weight of maintaining their drug insurance programs. It would also create additional burdens for private employment plans that cover drug costs for employees, and likely result in reduced coverage, increased deductibles and co-payments, or both.

The health services research evidence suggests that there is no benefit to DTCA. According to Dr Mintzes, it has not been shown to improve patient-doctor relationships, or the quality of prescription drug use. It is also not associated with reduced hospitalization costs or other health care savings.

But the courts do not necessarily approach evidence in the same way that researchers do. Although from a health policy perspective there is no evidence that would warrant a change to the status quo, the court will start from a different place. For the courts, the key issue on which they will be asked to sit in judgement will be rights—in this case, the right to freedom of expression—and their task is to ensure that such legally-enshrined rights are protected. In order for the current

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legislation to be upheld, courts will need to be persuaded that nothing short of the existing limits on DTCA would allow the federal government to achieve its other pressing societal concerns, such as protecting patient safety. This will be a difficult task. The Supreme Court, only one year ago in *Chaoulli*, which dealt with Quebec's legislation banning private insurance, sent a powerful message that widely-accepted justifications for a given policy will not suffice to defend a violation of a charter right in the absence of robust empirical evidence.

In order to meet the evidentiary challenge, the federal government will need the best national and international evidence. Provincial governments should also seek to be part of this challenge, given their interest in protecting the safety of their residents and the cost consequences, which will fall directly on provincial drug plans, of shedding federal limits on DTCA. If the federal government is serious about defending this challenge, the health services research community and CIHR-funded researchers—like Barbara Mintzes and Steve Morgan (a leading health economist with expertise in pharmaceuticals)—will have an important role to play.

Health services researchers must provide the best possible evidence on the costs, benefits and burdens of DTCA. The health services research community would be well-advised to keep in mind the stiff test that the federal government faces—not merely to demonstrate that there is no evidence to justify changing the status quo, but that there is sufficiently compelling evidence of the negative consequences of DTCA to justify the present restrictions.

Further reading

Canada's *Food and Drugs Act* and Regulations R.S., 1985, c. F-27. Available at: http://lois.justice.gc.ca/en/F-27/text.html.

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Student Feature: Pharmaceutical policy in the field

The Western Regional Training Centre (WRTC) is one of several regional training initiatives funded by CIHR and CHSRF. The Alberta Heritage Foundation for Medical Research also provides funding to the WRTC through the CADRE program. Based at the universities of British Columbia and Manitoba, it is designed to equip applied health services researchers with the tools to meet the research needs of a wide range of health care policy makers.

The applied training elements of the WRTC include field placements with decision-maker agencies, providing students with an opportunity to understand the issues facing health care organizations in the evaluation of their programs, policy development and why they make the decisions they make.

As a WRTC student, Megan Coombes spent her field placement working with the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia, and decision makers involved in the introduction of a new income-based pharmacare program, Fair PharmaCare, in BC. Megan conducted interviews with decision makers—ranging from the Health Minister to program personnel—to investigate the rationale and objectives of the program, as well as their perceptions of "fairness" in drug coverage.

Megan's field placement led to a second study to compare the private financial burdens that Canadians would face if each of the provincial pharmacare models were adopted as the national standard. One of the key elements of the National Pharmaceuticals Strategy is to develop options for catastrophic pharmaceutical coverage for all Canadians, in direct recognition of the fact that public prescription drug plans vary markedly across the country.

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Through simulation modelling of a variety of household types in each provincial drug plan, Megan and colleagues at CHSPR demonstrated that comprehensive, tax-financed pharmacare models that limit out-of-pocket expenditures, such as those found in British Columbia, Saskatchewan, Manitoba and Ontario, provide the greatest protection against catastrophic drug costs. The study was published in late 2004, gaining some timely media attention immediately prior to a First Ministers' meeting where national pharmacare was on the agenda.

"What we were investigating—how a new pharmacare program was chosen in BC, and how pharmacare programs across the country compare—are clearly important areas to understand in the context of a National Pharmaceuticals Strategy," said Megan. "The insights gained through these experiences as a WRTC student were invaluable and have shown me how well knowledge gained through research and studying policy issues can inform each other."

Since graduating, Megan has consulted for many clients, including British Columbia's Provincial Health Services Authority, BC's Ministry of Health, the Heart and Stroke Foundation - BC & Yukon branch, and the Canadian Council for Donation and Transplantation. She has recently relocated to her home province of Ontario where she is leading a research project with investigators at the Juravinski Cancer Centre and the Centre for Evaluation of Medicines in Hamilton, Ontario. The project aims to understand the issues facing clinicians when attributing causality to adverse events that occur during clinical trials of investigational new drugs, and to improve the consistency of causality assessments.

For more information about the Western Regional Training Centre, visit http://www.wrtc-hsr.ca.

Contact

As of 1 September 2006, the new home of the Institute of Health Services and Policy Research will be at the University of Toronto, led by Scientific Director, Dr Colleen Flood.

IHSPR MANDATE

The CIHR Institute of Health Services and Policy Research is dedicated to supporting outstanding research, capacity-building and knowledge translation initiatives designed to improve the way health care services are organized, regulated, managed, & financed, paid for & used and delivered, in the interest of improving the health and quality of life of all Canadians.