

First Do No Harm: Restoring Health to Pharmaceutical Use

Contents:

1. The pharmaceutical component of health care costs
2. How did we get here?
3. Reality check
4. Don't medicines make us better?
5. How can balance be restored?
6. Recommendations
7. References

Summary

Current patterns of pharmaceutical use threaten our health care system financially and qualitatively. To restore balance, we need improved health information technology to monitor health outcomes, and we need an informed population constrained by financial realities to choose more appropriate use of medications.

The pharmaceutical component of health care costs

The health of our health care system has become a foremost issue in the minds of medical professionals and all citizens in Canada. Recent reports have tried to convince us that our present system is simply not sustainable in its current form. A host of radical changes have been proposed, and indeed, are already being applied, in an effort to restore balance and prevent serious loss of universal and accessible health care.

We must have been doing some things correctly in health care in this country. A robust and unequivocal indicator of health quality is life expectancy, measuring as it does the accumulated wellbeing of a nation's citizens over a generation. Life expectancy in Canada is the second highest in the world, and it has shown dramatic increases even as we watch.

For improved health, we need to remember that the quality and distribution of health care services are NOT the principal indicators of good health. It has been repeatedly demonstrated that socio-economic factors are much more definitive of population health than doctors, hospitals or drugs.

Still, health care services are vitally important. And public confidence that they will be accessible when needed has been seriously eroded in recent years. While political battles are being fought over the costs of doctors, nurses and hospitals, the amount of public money spent to support these components of health care has not increased as a percentage of income per capita. Overall, our spending on health services has declined from 10.2% of GDP (Gross Domestic Product) a decade ago, to 9.5% today.

Drugs costs are the one component of health services that has been rising spectacularly, and almost uncontrollably. In BC, publicly funded Pharmacare has risen at an average rate of 15% per annum over the last decade. Canadians now spend more on drugs than they do on physicians' salaries. How has this situation arisen and gone virtually unchecked?

How did we get here?

When the cost of something rises at a rate of growth much higher than all related indicators, it usually implies the market forces that constrain that growth have been removed or weakened. Indeed, that is what happened to drugs prices in Canada since legislated changes in 1987 and 1993.

During the 1960s, drugs prices in Canada were among the highest in the world. This situation changed dramatically following federal legislation in 1969 that introduced compulsory licensing to import and/or manufacture generic versions of patented medicines. Compulsory licensing brought with it competition as companies had to compete for market share.

During the 1970s provincial drug plans began to proliferate, which reduced the burden of drug costs to individuals, especially the elderly and low-income populations.

Compulsory licensing of pharmaceuticals was severely restricted in 1987 (Bill C-22), and was abolished altogether in 1993 (Bill C-91). It was and is very apparent that the Canadian government was under intense pressure to conform our patent protection on drugs to American standards as a condition of free trade. With competition gone, seniors groups and consumer advocates predicted that the cost of drugs would spiral out of control, and threaten the ability of provincial drug plans to pay for them. This is in fact just what has happened.

The Patented Medicines Review Board, created in Bill C-22, attempts to contain drug prices now that market forces no longer apply to them. While this Board can claim some success, is simply no match for the power of the giant multinationals that dominate the drug industry today.

Reality Check

We have created a system wherein a drug company can produce a new drug or formulation at a price largely of their choosing (weakly influenced by the Patented Medicines Review Board), and the public is committed to buying that drug at public expense, whenever medically indicated. Is this reasonable?

Imagine an analogous scenario, for example in the electronics industry, in order to compare with what we have created in the pharmaceutical supply system. Let's say Sony introduces a new colour television with a bigger screen and novel features. If you can demonstrate a need for it (and everyone needs to be better informed and entertained), your insurance will pay for it – at little or no cost to you. Obviously this is a

ludicrous and unsustainable scenario. We don't have "better television provider insurance". We seem to have "better medicine insurance" since no one wants to use less than the best where health is concerned, even though many new drugs are not demonstrably better than their low-cost predecessors. This service is provided for much of the population almost free, with no discipline of competition or of cost-benefit applied.

To accept our current concept of the pharmaceutical supply system as valid, all of the following conditions would have to be true. For contrast, I have followed each point with a "reality check":

Concept: Drugs reduce medical system costs by reducing demand on hospitals and doctors.

Reality: Pharmaceutical companies have been extraordinarily successful at promoting this concept. The statement would be true if all medicines were good, properly prescribed and monitored, and had minimal side effects. While this is often the case, there are costly exceptions.

Concept: Drug manufacturers are motivated primarily by the desire to produce better medicines.

Reality: Drug manufacturers are motivated primarily by the desire to produce profits. The pharmaceutical industry has outperformed all other sectors of the U.S. economy in profit ratios for the past 20 years [reference 1].

Concept: Drug profits are used to research and develop new drugs.

Reality: Pharmaceutical companies spend far more on aggressive marketing than they do on research.

Concept: Drugs are thoroughly tested prior to licensing.

Reality: Drug tests usually are conducted for a period of a few weeks or a few months. Long-term effects are not known when drugs are introduced to the market.

Concept: Federal drug licensing requires unbiased pharmaceutical evaluation.

Reality: Despite scientific pretences, drug companies have injected various forms of bias into virtually every aspect of the product evaluation process [reference 2].

Concept: Doctors acts as "gatekeepers" to prescription drugs, allowing only appropriate drug use.

Reality: Doctors are encouraged by our "fee-for-service" system to write a prescription and get the patient out the door as fast as possible. There is no financial incentive in our system for the doctor to monitor the appropriate use of drugs by the patient.

Don't medicines make us better?

On September 10, 2001 an astounding event in the history of scientific medicine occurred. Thirteen of the world's leading medical journals, including the New England Journal of Medicine, the Journal of the American Medical Association and The Lancet, launched an outspoken attack on the rich and powerful drug companies, accusing them of distorting the results of scientific research for the sake of profits. They

claimed the multinational drug giants use money and threats to tie up academic researchers with legal contracts so that they are unable to report freely and fairly on the results of drug trials [3].

In Canada, there have been at least four recent reports of medical researchers suffering threats, lawsuits and loss of jobs after making statements or reports unfavorable to drug companies [2,4]

The history of medicines is full of wonderful discoveries and some terrible errors. At the end of this paper I have named just a few books that detail some of the terrible errors society has made and is making in the use of medicines.

I suggest the following snippets are symptoms of deep problems within our approach to the use of prescription drugs in our society:

- Before the discovery of the first anti-depressant medicines half a century ago, clinical depression was considered a medical rarity. Today, we have all kinds of publicly funded agencies telling us that one person in three is depressed, and perhaps should be one medication (forever!). (Now that I think about it, it does make me rather depressed!)
- We are building a drug-dependent society. Many prescription drugs create dependence, which carries with it a horrendous toll on individuals, families, and society.
- Virtually every anti-anxiety drug and sleeping pill ever prescribed has proved to be a drug of dependence – yet we continue to authorize and subsidize such use as if this risk didn't exist.
- Use of benzodiazepine drugs (such as Valium and Mogadon) in Canada remains high, even though warnings about the dependences they create have been issued repeatedly. A decade ago Britain found they had created 300,000 benzo-dependent citizens from widespread use of sleeping pills. At that time, one in four seniors in British Columbia were receiving these drugs, free. A similar rate of usage is found even today in aboriginal communities. Status natives receive drugs free through a federal program [5].
- Some experts believe psychotropic medications put users at a high risk of suicide [4].
- Prescribing of central nervous system stimulant drugs (such as Ritalin) to young people has reached epidemic proportions in North America.

How can balance be restored?

Over the period 1989-1999 in British Columbia, prescription drug costs per capita for seniors rose by a factor of 2.5, even though the prescribing rate rose only 15% [6]. This illustrates the trend for physicians to prescribe newer, costlier drugs over older cheaper ones, even when the efficacy of both may be comparable.

In an effort to contain the cost of drugs of comparable benefit, British Columbia introduced Reference Drug Pricing to its Pharmacare coverage. This program has produced savings of about \$50 million per year, with no significant negative impact on health outcomes. It seems to be an effective way to rationalize spiraling drug costs. After all, if the patient really wants the more expensive drug, he can pay the difference in cost.

Recently, reference drug pricing has been attacked by advocates for the drug industry. In the February issue of the Fraser Forum magazine [7], it is claimed that price reductions ascribed to reference-based pricing can be attributed to other market forces. This is a rather startling claim, considering that we have built a pharmaceutical supply system that is almost totally shielded from the discipline of market forces!

Canadian law allows that pharmaceutical advertising be directed only to physicians, and drug companies spend an astounding \$20000 per doctor per year to promote their products! [1] At the present time, the federal government is under pressure to legalize direct advertising of pharmaceuticals to the general public. Only two countries in the industrialized world (the United States and New Zealand) allow this at present, and both the merits and dangers of this approach are compelling [8,9]. In effect, Canadians are already experiencing direct pharmaceutical advertising through our wide exposure to American print and electronic media.

Can we have a system that provides vital, life-saving drugs at prices that reflect a true competitive free market pricing, and yet ensure the patient can afford such drugs when they are needed? And sustain the incentives to pharmaceutical manufacturers to research and develop new drugs? And discourage the distribution of drugs with low cost-benefit value? Building a system that will resolve these conflicting criteria is no small challenge!

Any solution must provide some measure of financial protection for the health client, and must impose a stronger cost-containment mechanism than has been applied under the present system. Pragmatically, the only mechanism strong enough to do this is some form of free market competition in drug pricing.

At this point in our collective experience, I believe two levels of discipline need to be applied to achieving a rationalization of cost-benefit in drug pricing: centralized intelligence and distributed intelligence.

Centralized intelligence comes with the health information health systems that our now just coming within our grasp. In British Columbia, we now track individual drug use, monitoring for duplicate prescriptions and other possible abuses. With individual electronic health records, we soon be able to track individual health outcomes. Statistically, if 2000 people suffer the same illness, and 1000 are treated with drug A and the other 1000 with drug B, we will soon be able to accurately compare overall health costs for both groups over any period of time. We can then place a relative value on the efficacy of both drugs. A program to measure cost-benefit monitoring of drugs after licensing has already been proposed by researchers at the Centre for the Evaluation of Medicines at McMaster University.

Distributed intelligence is that inherent in each individual. An individual can tell better than his physician or pharmacist if a medicine is improving or impairing his health. We have downplayed our ability to make this

judgment by placing too much confidence in health professionals. We have dulled this ability by the notion that medicine is free, and can't do any harm. Medicines are not free, and they can do great harm.

Another currently-discussed method of containing costs is to use medical savings accounts. These allow each person an amount to be spent on medical expenses each year, and the person is rewarded for not using the allotment by either a cash refund or a credit towards future health costs. This writer does not believe medical savings accounts are appropriate for most medical expenses. Physician and hospital expenses are usually unforeseen in occurrence, and there are direct and usually understandable consequences of each decision made in physician and hospital care. In contrast, major drug expenses are often foreseeable, but their nature and outcomes are far less clear for many individuals. To enforce the role of personal decision in personal wellbeing, I propose that drug savings accounts are a responsible approach to drug use.

Recommendations

This writer recommends three elements to the rationalization of the pharmaceutical aspect of health: wiser governance, wiser patients, and wiser drug insurance.

Wiser Governance:

Wiser governance means creating publicly-funded, publicly accountable bodies to monitor drug performance and place a "benefit" value on each specific medication. Specifically, we should:

- Rapidly develop our federal-provincial health information management capability to monitor drug use and health outcomes in all parts of the country.
- Replace the Patented Medicines Review Board with a network of university-based research institutes that would compile the data on drug efficacy. They would assign an economic "benefit" value for each drug. These national centres for medicine would also monitor reports of adverse drug reactions.
- Allow the rapid licensing of new drugs that pass basic safety and efficacy testing. Health Canada appears to have already accepted this reduced role in drug licensing.
- Allow drug companies to charge whatever market price they please for newly-licensed medicines.
- Prohibit public insurance coverage for newly-licensed drugs until either:
 - 1) a set period of time (such as five years) has elapsed, or
 - 2) the drug has demonstrated clear cost/benefit advantage within defined criteria.

Wiser Patients:

Wiser patients results from citizens becoming better informed of their drug choices, and placing the burden of drug choices on both doctors, pharmacists AND patients. Specifically, we should:

- Permit public advertising for prescription drugs, within carefully defined protocols. The information offered would have to be based on demonstrable fact. Drug advertising should be confined to

printed textual information; images should not be allowed. Lifestyle messages and subliminal content must be totally avoided.

- Allow direct reporting by doctors (and patients in consultation with their doctors) of adverse drug reaction incidents to the national centres for medicine.
- Provide searchable online databases on medicines for the general public. This database would contain information on individual drugs supplied by the manufacturer, and reports from the national centres for medicine on drug efficacy, both rendered in as non-technical language as possible.

Wiser Insurance:

Wiser Insurance allows access to essential medications without cost-barriers when needed, but provides incentives for choosing the most reasonably priced medicine. It rewards the patient for not needing any medications at all, and for choosing a healthy lifestyle. Such a system could be configured in many different ways. The following is proposed as a model for discussion:

- Give every person a “drug insurance” account of \$150-600 per year, depending on age. Higher amounts could be allowed for persons with permanent disabilities
- Charge patients only the pharmacist’s dispensing fee for each prescription filled, with the actual drug cost being paid from their personal “drug insurance” account.
- Unused balances in an individual’s “drug insurance” account would carry over from year-to-year, providing cumulative protection against future major illness.
- When a person’s “drug insurance” balance was exhausted, they would pay remaining drug costs “up front”, with compensation later for a fraction of the cost of the expenditure. One way this could be handled is as follows: At the end of the year, their provincial drug plan would issue a receipt for their total personal expenses. A fraction (50%?) of their personally paid drug expenses could be used as a credit on that person’s income tax account (not on taxable income, but on tax payable).

Closing Comment: (from Michele Brill-Edwards, [reference 10])

“The current system is not working, patients are suffering unnecessary harm as a result, money is being wasted, and we are allowing the perpetration of deception on a massive scale. It is time to commit to building a new system that is open and accountable; a system that serves the public good and puts safety above profits, as the law requires.”

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