Fair Pharmacare: The myth

Many BC physicians have lost confidence in the province's drug review process through the Therapeutics Initiative. Here are some solutions.

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There is a growing concern in Canada and particularly in British Columbia that the public is not being well served by government policies for coverage of licensed medicines. This concern in British Columbia has led to the formation of a Pharmacare Coalition, made up of a large number of nonprofit organizations to pressure government to supply, under the Pharmacare plan, medications for patients with chronic diseases.

Recently the coalition met with the premier, minister of health, and senior ministry staff. The presentations made to the government were factual and relayed a recurrent theme among all disease groups—the prolonged delay or denial of Pharmacare coverage for new medications is unacceptable.

It is important to understand that medications undergo rigorous scrutiny before they are licensed for sale in Canada. In this country, drug licensing is the responsibility of the Health Protection Branch (HPB). This federal agency is charged with reviewing medications for safety and efficacy before they are licensed for sale in Canada. Like its counterpart in the US, the FDA, it must review all relevant trials to deem the medication eligible for sale. When the agency is satisfied, the drug manufacturer is provided with a notice of compliance. This is a formal document that agrees that the manufacturer has satisfied all licensing concerns. The manufacturer then must submit to the Patented Medicines Price Review Board (PMPRB). This body decides if the medication is indeed novel and sets a price accordingly. In simplistic terms, if the drug is yet another blood pressure pill of a recognized class, its price will be set with all the others. If it is a new formula working in a previously undiscovered mechanism, it may be granted a higher price, taking into account the cost of developing novel compounds. Thus, before a medication can be sold in Canada, it undergoes rigorous review and prices are closely scrutinized. We can be proud in Canada that the federal program is for the most part effective. But the process can be protracted, from a few months up to 7 years!

Thus, once a drug is licensed for sale in British Columbia, it has already been tested for safety and efficacy by a federal agency and its price scrutinized by a separate body. The process of evaluation, however, continues in British Columbia. Pharmacare relies on the so-called advice of the Therapeutics Initiative (TI). This body is funded by the government and screens new proposals. It has consistently claimed independence although its funding is essentially from one source, the government. The terms of reference for the body are laudable. It is there to advise Pharmacare on new medications. Let's examine a few examples from my perspective as an endocrinologist. I recognize similar frustrations exist in all chronic diseases.

Diabetes is an important disease. There have been spectacular improvements in care and outcome. Many of these improvements are based on increased knowledge of the disease and how aggressive multifactorial risk modification makes a huge difference. Let's look at some recent drugs in the treatment of the disease.

The Humalog story

For the first time in history, insulin became available that was modified to allow quick onset to more closely mimic the body's natural secretion of insulin. This insulin was licensed in Canada in 1996. It was shown to significantly reduce hypoglycemia. It had inconsistent effects on lowering A1C (the average level of blood glucose) but did reduce the frequency of low blood sugars, which can be troublesome, and at the extreme life threatening. The utility of this insulin in an insulin pump was well documented.

It took two further years until 1998 for Pharmacare to recognize this drug. Unfortunately, it is not fully funded. The patient must pay approximately

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$8 per vial. This is not a problem for many patients, but problematic for those on fixed incomes, social assistance, or young people working for minimum wage. It should be noted that five provinces cover it fully, the others on special authority.

The TZD story

For years this class of drugs (thiazolidinedione) has been licensed in Canada. These medications work differently from conventional medications to lower glucose. They work especially well in combination with other established therapies, such as metformin. Their effectiveness is not in dispute. The government has received advice from the TI, and the decision not to fund them under Pharmacare is beyond conventional logic. One excuse is that TZDs do not change mortality, i.e., the death rate from diabetes hasn't been shown to be different. Another excuse is that diabetes is a chronic disease and can take 25 years to develop complications. To obtain the data the TI wants will take a 20-year study. In the meantime, we know that this drug lowers A1C; we know that A1C lowering protects the body from toxic effects of glucose. Remember, this drug has been approved by the HPB and the PRB and is available in every other Pharmacare program. The drug is costly. Can that be a legitimate reason to totally disenfranchise Pharmacare users? When government is confronted with this issue it raises its hands. In a manner reminiscent of Pontius Pilate it blames the TI for the advice it has been given. When you try to talk to the TI, they tell you they don't tell the government what to do; they are just advisors.

Some modest proposals

How can we make the drug review process, which was founded on good intentions, workable again? The following are a few changes to improve the process.

Introduce transparency. Have a more transparent process for drug reviews with easy public access to the recommendations under the auspices of a freestanding independent body.

Establish limited terms. Implement a limited term for reviewers (e.g., no reviewer can stay for more than 2 years) so that a wide range of input is allowed.

Include clinicians involved with the actual treatment of disease in the review process.

Look at costs globally. Include all costs involved with a new medication; the silo approach currently taken is detrimental to overall cost savings.

Hold public meetings about new medications to allow for consumer input into these very important decisions.

Make quicker decisions. Commit to a timeline of 6 months or less to decide on new medications (remember, these medications are already licensed).

Monitor outcomes. Establish a jointly funded (government, industry) clinical research program to monitor the outcomes in newly funded medications. What may happen in a closely supervised clinical study doesn't necessarily translate into similar benefits when the therapy is made more generally available.

British Columbians deserve access to new and effective medications. Unfortunately the current system of review on Pharmacare approval is not providing this access in a timely or fair manner.

The BCMA comments

Dr Tildesley pleads for more rapid approval by Pharmacare for coverage of novel drugs used for the treatment of chronic diseases. He states that it can take up to 7 years for medications to be approved, despite their safety and efficacy having already been established by the Health Protection Branch. He has concerns about the advice given to Pharmacare by the Therapeutics Initiative and feels that their approval process is not transparent, and does not consider input from those clinicians who are actively involved in the treatments of these diseases on a day-to-day basis.

I have certainly heard concerns expressed by many of my colleagues that the TI seems to out of touch with the real world of day-to-day medicine. Examples include the initial difficulty getting atypical antipsychotics and some of the newer, more powerful antibiotics covered under Pharmacare, despite the fact that experience shows that using these admittedly significantly more expensive medications can save the system money by preventing hospitalizations and decreasing morbidity. I am sure that most of us physicians, for example, would personally choose to use a protein pump inhibitor to treat our acid reflux disease, rather than a histamine antagonist, because we know from clinical experience that they are more efficacious. However, Pharmacare makes us—and more particularly our patients—jump through hoops before they will grant coverage for these medications.

The cost of drugs is skyrocketing, and now consumes more of our health care dollars than do physicians. However, the overall cost to our system of denying novel pharmaceuticals to our patients is probably greater than the expense of providing them where appropriate. And most clinicians would argue that the benefits in terms of morbidity (although those may be long-term) are undeniable.

Dr Tildesley's suggestions for improving the approval process are worthy of consideration by government. I trust they will be prepared to re-examine the way new drugs are approved for coverage.

—Michael Golbey, MD, BCMA President