Personalized Medicine:

THE FUTURE OF BENEFITS PLANS?

Genetic testing can significantly improve treatment strategies, but it also raises issues for plan sponsors and members

By ***Anna Sharratt***

Genetic testing offers great potential from a drug plan management perspective, but it also raises lots of questions. How do you implement it effectively? What about privacy concerns? How does it integrate with more traditional strategies, such as prior authorization and step therapy? And who's going to pay for it?

In February, *Benefits Canada* held a roundtable with key industry stakeholders to discuss the promise and challenges of personalized medicine. Here's what we learned.

Roundtable Participants (in alpha order):

Dr. Elaine Chin,
chief medical officer,
Executive Health Centre

Luigi Formica,
private healthcare
manager, Roche

Wendy Jackson,
manager, Canadian benefit
programs, Magna International

Alan Kyte,
pharmacist and principal,
Mercer

Barb Martinez,
practice leader, benefit
solutions, Great-West Life

Dr. Michael Prouse,
director, operations,
Personalized Prescribing Inc.

When it comes to getting the right drug to the right patient for optimal results, pharmacogenetics—which studies how genetics influence how well a drug works—is a game changer.

"This allows patients to bypass drugs that wouldn't work," says Dr. Elaine Chin, chief medical officer at Executive Health Centre. "We can discover in advance whether a patient will respond to a medication or need more or less [of it] to prevent side effects."

It also has the potential to change the way benefits plans work. "In theory, this could reduce or eliminate the need for step therapy in many cases," says Barb Martinez, practice leader, benefit solutions, with Great-West Life.

How It Works

Pharmacogenetics involves laboratory testing of a person's DNA to determine gene variations that can predict how a person will respond to medications. For example, if a person is a fast metabolizer, he or she may need more of a given drug

PETER RYANN

WHAT'S IN YOUR DNA?

Controlled genetic testing to personalize treatment regimens is one thing; widespread personal genetic "profiling" to determine risk levels for disease is quite another. Mention 23andme, for example, and just about everyone in benefits plan management winces.

The widely available U.S. genetics test advertised on TV claims to be able to determine a person's individual risk levels for certain diseases. But in late 2014, the U.S. Food and Drug Administration (FDA) issued a warning letter expressing concerns over the product's accuracy and advising the company to cease marketing until it receives FDA approval as a medical device (a process that is currently under way).

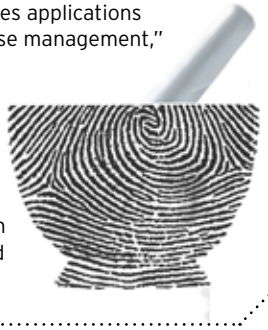
Health Canada has issued no such warning, and it's estimated that thousands of Canadians have purchased the product. Will consumer interest trickle over to employee benefits? "I've got to imagine there are going to be employees calling HR to say, 'This is a medical test–is it covered?'" says Barb Martinez, practice leader, benefit solutions, with Great-West Life.

Even if the testing is accurate, a family physician presented with heaps of information about a patient's genetic makeup may not know what to do with it and what actions to take. That information needs to be carefully synthesized, with established guidelines on how to proceed, says Dr. Elaine Chin, chief medical officer at Executive Health Centre.

To complicate matters even further, few physicians in Canada actually practice personalized healthcare (i.e., including genetic testing in a protocol to customize an individual's plan for both the treatment and prevention of illnesses). "I'm going to guess there's half a dozen of us," says Chin.

But that doesn't mean personalized healthcare won't have broader implications going forward. The future of genomics includes applications well beyond personalized medicine. "It goes beyond disease management," Chin explains.

Nutrigenomics and lifestyle genomics, for example, examine how individuals respond to various foods and the impact of exercise on their health. For example, while some people will respond well to exercise and lower their cholesterol, others will not and will require medications, says Chin. Such knowledge could reduce drug spending on statins as well as change how fitness-related products and services are covered under employee benefits plans.



or more frequent doses; if he or she is a slow metabolizer, lower doses of a drug may be necessary to avoid an overdose. Test results can also identify which medications will be effective, avoiding the use of medications that would have little or no effect, or many side effects.

This type of genetic testing should not be confused with personal genetic tests such as 23andme, which are direct-to-consumer products that partially sample DNA to assess a person's risk of developing certain genetic disorders and illnesses. Data may be offered to customers without any interpretation, and the accuracy of these tests is under scrutiny (see "What's In Your DNA?").

In pharmacogenetics, the testing process is fairly simple. A non-invasive cheek swab extracts cells containing DNA and is sent to a lab for analysis. Results go to the prescribing physician, usually in a week or two, who then decides the most appropriate medication and its dosage for that particular patient, says Dr. Michael Prouse, director of operations at Personalized Prescribing Inc. (a health benefits provider that offers employers pharmacogenetic testing as an employee benefit).

In many ways, it's a win-win: the patient regains health and can return to work, the employer doesn't pay for drugs that might not have worked and the physician takes evidence-based medicine to a much higher level, using the patient's own DNA. "Because it's so tailored to the individual, when you link something with a diagnostic test, it brings a level of certainty that the individual is going to maximize the benefit of the drug," adds Luigi Formica, private healthcare manager at Roche.

"He was a guinea pig for 18 months. Had they known that all beta blockers would not be very effective for him, his doctors may have decided to move forward with a surgical option sooner."

— Dr. Elaine Chin, Executive Health Centre

A Boon for Benefits Plans?

Pharmacogenetic testing opens the door to simpler drug plan designs. "It cleans up prior authorization," which requires physicians to provide documented justification for a drug before insurers approve coverage, says Formica. "It's going to make prescribing easier."

Alan Kyte, a pharmacist and a principal at Mercer, feels personalized medicine may help alleviate the trial and error of current benefits plan designs that include step therapy, which requires members to first try—and prove the ineffectiveness of—lower-cost medications *before* physicians can prescribe higher-cost second- and third-line therapies.

For some patients, it can take weeks or even months to arrive at the most effective therapy. During that time, their condition can worsen. And the process can be arduous for patients suffering from conditions such as cancer, heart disease and mental illnesses—and costly for the plan sponsor. "If we were able to accurately pinpoint when specific drugs will be effective, we'd save money with less wastage resulting from trial and error," says Kyte. "Plan sponsors should be willing to pay for this."

Chin has seen first-hand the failings of current drug plan designs. She cites the case of a patient who had an irregular heartbeat that put him at risk of a stroke or heart attack. "They tried him on five or six beta blockers. He didn't respond," she says. "He was a guinea pig for 18 months. Had they known that all beta blockers would not be very effective for him, his doctors may have decided to move forward with a surgical option sooner."

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MORE THAN 2 MILLION NORTH AMERICANS **ARE HOSPITALIZED** EACH YEAR **DUE TO ADVERSE REACTIONS** TO PRESCRIPTION DRUGS

SOURCE: *THE ANNALS OF PHARMACOTHERAPY,* 2008

But do the cost savings from reduced drug wastage justify the extra costs for pharmacogenetic testing? A genetic test generally costs at least $1,000, says Prouse.

In her practice, Chin has had patients with breast cancer who have gone to the U.S. for more complex genetic testing (requiring the analysis of a breast tissue sample), which cost them approximately $2,500. "That allowed the patient to bypass the utilization of a drug that did not work on that tumour. Now who pays for the testing?" she asks.

Wendy Jackson, manager of Canadian benefit programs at Magna International, has seen the value of pharmacogenetic testing. "In our U.S. divisions, we *do* pay for the testing on some of the drugs that qualify. This is cost-effective for us in the long term."

Given that it's early days for genetic testing as an employee benefit, many plan sponsors are in the wait-and-see stage, weighing the pros and cons and wondering how they'll pay for it.

Insurers need to determine the appropriate evidence-based approach for coverage. For example, what are the criteria for plan members to undergo testing? "Our contracts don't have genetic tests built into them," says Martinez. "If it makes sense to add them contractually to plans, we would certainly examine this."

And for all types of genetic testing, there is also the issue of the accuracy of the test results. "Genetics testing is a probability, not a certainty," says Chin, adding she personally would not disclose a patient's genetic status if it was not required by an insurance company.

Confidentiality Concerns

Unlike the U.S., Canada does not yet have genetic privacy laws, meaning employers and insurers could be privy to potentially discriminating personal information. Bill S-201, the *Genetic Non-Discrimination Act,* has been before the Senate Committee since June 2014. The proposed legislation would amend the Labour Code to protect employees from being required to undergo or disclose the results of a genetic test, while providing them with other protections related to genetic testing and test results.

Meanwhile, in September 2014, the Canadian Life and Health Insurance Association released its "Industry Code: Genetic Testing Information for Insurance Underwriting," for adoption by its member life and health insurance companies. It states, in part: "Where an individual has voluntarily and independently undergone genetic testing, insurers may consider those results as part of their risk assessment."

And what if an employer has access to information indicating its employee may get very sick, requiring ongoing care and costly therapies? "Chances of discrimination can still occur," says Prouse. "However, this only pertains to genetic testing for *disease risk* and not to genetic testing for *therapeutic response,* as is the case with pharmacogenetic testing."

But questions remain. How much information should insurance companies be allowed to have? How can a plan member's privacy be ensured if genetic tests are covered? What will it cost the plan sponsor? How are results measured? And do the benefits outweigh the risks?

Working Out the Logistics

When looking at coverage for genetic testing, industry experts agree pharmacogenetics is a good place to start. For certain classes of drugs, plan members could be required to have a genetic test before receiving a prescription drug.

With that in mind, education upfront is important so members understand the value of that extra step in treatment, which can take up to two weeks to complete. "The claim comes in, at which point the insurer may request a genetic test. Now that person may not understand why there is a delay in getting treatment," explains Martinez.

"We would want to thoroughly communicate on this topic to ensure the employee understands why we would be moving in this direction," agrees Jackson, adding the likelihood of employee buy-in is high. "I believe, if given a choice, people do not want to continue taking drugs that are not working."

Coverage for the genetic test could be triggered by the need for a specific therapeutic class of drugs, or plan members could have the option of requesting a test and sharing the costs. "Plan members should have the option to participate in more comprehensive pharmacogenetic testing even though they may not already be on medication," adds Prouse. "These plan members should have the ability to requisition a test via co-pay."

And then there's another option: making genetic tests available under healthcare spending accounts. In that case, says Jackson, a test would have to be prescribed by a doctor and ordered from a reputable lab sanctioned by the insurer.

While there are still more questions than answers, many feel personalized medicine is an exciting field where the benefits will justify the costs. And it's an area insurers will need to address going forward.

Great-West Life, for one, is exploring how personalized medicine can help achieve the company's dual bottom line: helping members achieve optimum health outcomes while maintaining the cost-effectiveness of their group benefits plans. "From an insurer's perspective, this is an emerging area that holds a lot of promise," says Martinez.

Anna Sharratt is a freelance writer based in Toronto. asharrattcommunications@gmail.com

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