



UBC CENTRE FOR  
HEALTH SERVICES AND  
POLICY RESEARCH

# Sticker Shock

Finding value in an era of high-cost drugs

**Conference Summary**

October 2015

**CHSPR 2015** HEALTH POLICY  
CONFERENCE

Heather Worthington MSc  
Michael Law PhD



a place of mind

*Sticker Shock: Finding value in an era of high-cost drugs: Conference Summary*  
was produced by:

Centre for Health Services and Policy Research  
University of British Columbia  
201–2206 East Mall  
Vancouver, BC V6T 1Z3  
Phone: 604-822-4969  
Email: [enquire@chspr.ubc.ca](mailto:enquire@chspr.ubc.ca)

You can download this publication from [www.chspr.ubc.ca](http://www.chspr.ubc.ca)



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## About CHSPR

The Centre for Health Services and Policy Research (CHSPR) is an independent research centre based in the School of Population and Public Health of the University of British Columbia. Our mission is to stimulate scientific enquiry into health system performance, equity and sustainability.

Our faculty are among Canada's leading experts in primary health care, health care funding, variations in health services utilization, health human resources, and pharmaceutical policy. We promote interdisciplinarity in our research, training, and knowledge translation activities because contemporary problems in health care systems transcend traditional academic boundaries.

We are active participants in various policy-making forums and are regularly called upon to provide policy advice in British Columbia, Canada, and abroad.

We receive core funding from University of British Columbia. Our research is primarily funded through competitive, peer-reviewed grants obtained from Canadian and international funding agencies.

For more information about CHSPR, please visit [www.chspr.ubc.ca](http://www.chspr.ubc.ca).

## CHSPR's Health Policy Conferences

CHSPR's annual policy conference is an opportunity to present lessons learned and emerging research on a relevant issue in health services and health policy. The conference draws leaders and researchers from universities, governments, industry, health authorities, and health and patient organizations from British Columbia (BC) and the rest of Canada. In March 2015, the conference focused on finding value in an era of high-priced drugs. This document presents highlights and lessons learned from the 2015 conference. To view the conference program, speaker biographies, and selected slide presentations, please visit [www.chspr.ubc.ca/conference](http://www.chspr.ubc.ca/conference).



# About the Conference

## How can we find value in an era of high-cost drugs?

The pricing of new drugs has always been a controversial subject. While expensive used to mean hundreds of dollars annually per patient, it can now mean hundreds of thousands of dollars. Over the past year, drug prices have been a regular feature in the media, which has seized on the “sticker shock” that accompanies many new medicines. Amidst this hype, a fierce international debate has ensued between pharmaceutical companies, governments, insurers, and civil society on what is appropriate when it comes to setting drug prices.

With prices changing so rapidly and new products being introduced so frequently, how can we make evidence-informed decisions about what to cover, ensure we are getting good value for money, and still make treatments accessible to patients?

On March 3, 2015 health care decision-makers, researchers, industry leaders, and patients convened in Vancouver to engage in a dialogue about how we find value in an era of high-priced drugs. Sessions included discussions on how drug prices are determined, the impact of skyrocketing drug prices on different sectors, what the meaning of value is in pharmaceuticals, the role of evidence in drug coverage decisions, and what the impact of value-based insurance design for prescription drugs could be in the future.

## Key messages

**The landscape is changing.** The “inhuman” cost of a drug in 1989 was \$8,000 per year, now there are drugs on the market costing \$700,000 per year.

**New challenges are emerging.** There will soon be a shift of many costs onto public drug insurance programs.

**Always consider the opportunity cost.** When we pay for expensive drugs, what aren't we paying for?

**We know less than we think we know.** Systematic reviews intended to inform payers, guideline developers, and patient education material routinely conclude that the evidence is inadequate or of poor quality.

**We need to engage decision-makers.** Evidence gaps result from inadequate involvement of decision makers in all phases of the clinical research enterprise. There is also a need to engage decision-makers in price setting.

**Health technology assessment is not a simple task.** Simply using a cost per QALY (Quality Adjusted Life Year) threshold to make drug coverage decisions is not sufficient. There are many other factors that need to be considered.

**The system will need to adapt to be sustainable.** The concept of value based insurance design will become increasingly important.

...how can we make evidence-informed decisions about what to cover, ensure we are getting good value for money, and still make treatments accessible to patients?



## Establishing and Assessing Prescription Drug Prices

Speaking at the conference, Neil Palmer, President and Principal Consultant of PDCI Market Access Inc. outlined how pharmaceutical prices are determined. He relayed a range of factors that are considered when drug manufacturers set prices: return on investment, competition, price regulation and reimbursement policies, as well as consideration of the international/global context. Underpinning all of this is the concept of “willingness to pay”. For example, a manufacturer who enters into a niche market will set a high price because of the increased risk to get a return on their investment. Drug pricing and reimbursement planning begins early in the clinical development of a drug and continues through the launch of the drug. There is no one “optimal price” for a drug. However, there may be an optimal price range that allows markets to move as close as possible to optimal pricing while at the same time limiting the potential for parallel trade. These are known as “international pricing corridors”.

Some pharmaceutical manufacturers have established tiered or differential pricing to maximize social welfare. This involves setting lower prices for low-income markets with high demand elasticity and higher prices for high-income markets with lower demand elasticity to recover research and development costs. In this way pricing is often tied to standard of living.

Many countries, including Canada, France, and Germany, have price-assessing authorities that operate similarly. These authorities generally accept a greater price premium for drugs that provide a greater amount of therapeutic improvement. In Canada, the Patented Medicine Prices Review Board (PMPRB)’s mandate is to ensure that the prices of patented medicines are not excessive. This is measured by the degree of therapeutic improvement offered by the new drug and cannot exceed the International Maximum Price.

International Health Technology Assessment (HTA) agencies consider medical importance, comparative effectiveness, cost effectiveness, and the quality of evidence to inform decision-making on new drugs. However it is important to keep in mind that health economics cannot save poor or irrelevant clinical data, it has to build on good clinical evidence. Neil suggested that health economic considerations be built into phase III clinical trials and seek early engagement with HTA agencies.

In the future, Neil believes that there will be more patient involvement in price setting. This is already beginning in some countries. For example, in the United Kingdom multiple sclerosis drugs were funded due to political pressure.

# Payers Perspective

## Public drug plans

Barbara Walman, assistant deputy minister, medical beneficiary and pharmaceutical services division, BC Ministry of Health, discussed how high drug prices affect public drug plan decision-making.

Barbara began by outlining the context of the BC public drug plan. The provincial PharmaCare budget is 1.079 billion dollars this fiscal year, which is a reduction of \$100 million from last year. Claims are increasing, and, despite attempts at cost control through generic pricing regulations, Canadian generic drugs are still much more expensive than other comparable countries.

The drug review process to get on the provincial formulary involves four stages:

1. Health Canada
2. Common Drug Review (CDR) by the Canadian Agency for Drugs and Technologies in Health (CADTH)
3. Pan-Canadian Pharmaceutical Alliance (pCPA)
4. BC Ministry of Health

This process is evidence-informed and aims to select the best drugs for the best value. With the increasing prices of patented drugs, attempts have been made to manage drug price and cost pressures at these stages. A rigorous drug selection process, price negotiations, and attempts to optimize prescribing are included in these management strategies.

Despite these cost-control strategies, many ongoing challenges face the public drug plan. Expensive drugs for rare diseases are one such concern. How do you decide what to fund and what not to fund? There are always competing opportunity costs in governments. Health Canada will soon release Canada's Orphan Drug Regulatory Framework, which is intended to improve patient access and manufacturer accountability of drugs developed for rare diseases. Yet this framework will allow approval of even higher priced drugs with less evidence, and it is difficult to stop coverage if drugs are later found to not be beneficial. Patient and prescriber expectations and demand are a major challenge the system must face.

Moving forward, Barbara described the need to consider fair pricing approaches. Though it is unclear exactly how to proceed, and there is a need to explore alternative pricing models such as price setting based on willingness to pay, profit-based tiered pricing, or pricing based on effectiveness.





## Health care environment

Arden Krystal, Executive Vice President and COO, BC Provincial Health Services Authority, discussed managing pharmaceuticals in the health care environment and the challenges they are faced with. As an example, she provided details of the BC Cancer Agency (BCCA).

The drug spend for BCCA is \$230 million annually. The incidence and prevalence of cancer is increasing by approximately 3% annually and this increased clinical demand in combination with new drugs always coming down the pipe is a challenging situation with limited funding.

The BCCA has developed a rigorous decision making process to combat challenges and ensure approved drugs are effective and to balance that with cost control. They aimed to develop “a process you can stand behind”, with the key components of transparency, appeal, and consistency. The Priorities Evaluation Committee (PEC), a clinical committee with input from health economists, carries out priority setting for new drugs through the clinical evaluation, administrative evaluation, and policy setting phases.

The challenge is that the public expects that they should have access to any available treatment that could “help”. So it is extremely important to be consistent when applying criteria for decision making when faced with a coverage concern.

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## Private insurance

Mike Sullivan, President of Cubic Health Inc., discussed how high drug prices are soon to have a major impact on private drug plans.

Mike described how it is “the end of an era”. The past few years (2011-2014) were a great time for private plan sponsors in terms of passive cost containment within drug plan benefits due to generic pricing reforms and a wave of patent expirations that helped offset the impact of specialty therapies. The next few years will not be the same, and private plans are unprepared for what’s coming.

Plans covering Canada’s workforce now spend more on specialty drugs than on all generics combined. Mike said that “generics have blinded plans about what they’re about to face”. Appropriate plan designs for the changing private payer marketplace will have a profoundly negative impact on containing costs moving forward. The inflation of catastrophic claims insurance premiums is also an issue, as it will put more pressure on the affordability of existing plans. There is also pricing asymmetry on the private side, meaning that there is wide variation in what private plans pay for specialty drugs.

Chronic drug spending is going to drastically increase in the next few years. Just considering the annual cost increase due to chronic, recurring therapies most current plans are not affordable.

In the future, Mike believes that plan designs will need to change dramatically. Service providers and members will need to be held more accountable and there will be a need to consider appropriate cost offsets for plan sponsors through integration of drug and disability datasets in order for private plans to be sustainable.

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## What is a Fair and Reasonable Price?

As the keynote speaker of the conference, Sean Tunis of the Center for Medical Technology Policy presented his thoughts on what is a fair and reasonable price for highly effective drugs.

A drug should be considered priced at a fair and reasonable amount if the benefits justify the amount paid, there is good “value” for money, it is in line with alternative options, and it is affordable in light of opportunity costs. On the other hand, a drug must be priced high enough to interest investors to even be developed. There is some evidence of a relationship between life years gained and price; though having a high launch price is independent of more “value”. Profits have come from an increase in launch price. Due to specialty drugs, pipelines are back and a huge number of new drugs are entering the market.

Sean posed the very important question: what is value? We don’t always know what it is in every case and so we measure the most reasonable outcomes. Value in healthcare is generally defined as “health outcomes achieved per dollar spent”, yet health outcomes are inherently condition specific and multi-dimensional. All stakeholders seem to be in agreement that patient health is at the core of value, but the problem is that high care value isn’t necessarily high health system value so it becomes a balancing act.

There is also what Sean called the evidence problem: how much less we know than we think we know about the effectiveness of therapies. Despite tens of thousands of clinical studies published every year systematic reviews intended to inform payers, guideline developers, and patient education material routinely conclude that evidence is inadequate or poor quality. Sean proposed the reason for this ‘evidence paradox’ is that there is inadequate involvement of decision makers (payers, patients, and clinicians) in all phases of the clinical research enterprise.

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# How Should Evidence Be Used in Drug Coverage Decisions?

Chris McCabe, Capital Health Endowed Research Chair in Emergency Medicine Research at the University of Alberta and Craig Mitton, professor and senior scientist at the Centre for Clinical Epidemiology and Evaluation at UBC, began the afternoon session with a lively debate about whether the cost per QALY (Quality Adjusted Life Year) is useful for making drug coverage decisions. Larry Lynd, professor at the UBC Faculty of Pharmaceutical Sciences, moderated the debate. Though the debate presented a polarizing topic that instigated many entertaining moments between the two rivals (some of which had nothing to do with the topic), by the end of the hour the two had basically come to an agreement: though cost per QALY is a good place to start, there is so much more to consider when deciding whether or not to fund a drug.

A QALY is a measurement of benefit that combines quality of life and quantity of life into a single index. QALYs are used in combination with the Incremental Cost-Effectiveness Ratio (ICER). An ICER is a measure of how much more cost-effective a new program/drug/treatment is compared to what is currently available by dividing the incremental resources required by the intervention by the incremental health effects gained by using the intervention. A simple decision rule is used to determine whether a new drug is added to a formulary: if an ICER for a new drug is less than or equal to \$50,000/QALY, the drug is funded, if the ICER for a new drug is greater than \$50,000/QALY, the drug is not funded.

However, there are many other factors that are important in determining the value of a drug. There are disease related factors (prevalence, severity, who will benefit, alternative treatments), treatment related factors (effectiveness, magnitude, safety, innovation), and population related factors (societal impact, distribution of health, SES policy). Aside from these factors, the other vital thing that a QALY does not consider at all is opportunity cost. Trade-offs have to be made. The health system operates with limited resources, so in order for resources to be devoted to one service, resources are then not available for others.

In the future there is a need for a priority setting approach that can be informed by economic evaluation and other forms of evidence. This will require contributions from both economics (value for money) and ethics (values based).

Themes that arose during the debate included: why are there only two criteria? When we talk about the budget impact, why do we never talk about opportunity cost (there will always be winners and losers in resource allocation)? And finally, if a \$50,000 per QALY threshold continues to be used, effort needs to be made to help decision makers truly understand what the criteria mean.



# Value-Based Insurance Design

## Background and evidence

Teresa Gibson, Senior Research Scientist, Arbor Research Collaborative for Health Lecturer, Health Care Policy, Harvard Medical School, introduced Value-Based Insurance Design to conference attendees.

The premise of Value-Based Insurance Design (VBID) is to align patients' out-of-pocket costs, such as co-payments and deductibles, with the value of health services. Value-Based Insurance Design increases adherence for the same cost and uses financial incentives in a meaningful way. The first evidence for VBID came out of the RAND Health Insurance Experiment, where a sample of representative cities in the US assigned patients to different fee-for-service plans ranging from free to 95% coinsurance. The study strongly supported that the use of medical services responds to changes in the amount paid out of pocket.

Since the RAND Health Insurance Experiment, numerous other studies have found evidence in support of VBID. A 2013 systematic review by Lee et al. found that across 13 studies that examined VBID, there was an average increase in adherence to 3.0 percent in a year, there was lower out-of-pocket spending for patients, and no changes in overall spending. Studies of VBID have also been conducted within specific chronic condition patient groups. Studies evaluating VBID in patients with diabetes have found dramatic increases in adherence (maximum 15% in the first year), and were cost neutral to the health plan. A trial in post myocardial infarction patients found that those randomized to a plan with a \$0 co-payment for statins, beta-blockers and ACEI/ARB had higher adherence for all medication classes and lower rates of major vascular events than patients in the usual coverage group.

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## Future

Michael Chernew, Professor, Harvard Medical School, discussed the role VBID may play in the future.

Mike outlined how the status quo is not sustainable and that payers have limited control over the current system. Cost sharing is extensively used to lower premiums and improve incentives (to reduce excess use and encourage price shopping). Yet, It has been shown that consumers make suboptimal decisions: co-payments reduce the use of preventative services and as well as the use of 'high-value' pharmaceuticals.

In theory, VBID provides an insurance strategy that solves these issues by balancing incentives with risk aversion, having low coinsurance in a situation with unresponsive demand, and has efficient resource allocation. However, there are many challenges in deciding the best way to implement VBID.

The first challenge is that there are several possible variations of VBID. Do you keep it simple and just target one service, such as providing blood pressure medication for everyone, or do you make things more complicated by targeting services only for specific patient groups, such as providing blood pressure medication to patients with diabetes. Do you just lower co-payments across the board or do you target increases to align with value?

The second challenge is how to finance VBID. Value Based Insurance Design may lead to lower costs due to fewer adverse events, so these offsets may contribute to funding. With healthier people comes more productivity, so these gains may also help to offset the cost of implementing VBID. Another consideration is to potentially increase costs for "low value" services to finance VBID. The goal of VBID must be to eliminate waste by not spending more than we already are while increasing the value of the system.

Moving forward, it will be important to expand the diseases with VBID designs beyond diabetes and heart disease, as well as to expand VBID to health services other than prescription drugs. Value Based Insurance Design implementation strategies will need to be developed while considering the complexity of the system and synergized with other cost containment initiatives.



## Summary

Helen Stevenson, Founder, President, and CEO, Reformulary Group Inc. concluded the thought-provoking day by summarizing the themes that emerged. Affordability and sustainability are major concerns with high drug prices, and the system will need to adapt to be sustainable moving forward in this era of high prices. The decision-making process needs to be taken into consideration, and decision makers need to be more involved in all aspects of drug development and price setting. Willingness to pay is an issue; the public feels entitled to anything that “helps”. However the system must strive for consistency in drug coverage decisions. Resource allocation and priority setting cannot be forgotten even when under excessive pressure from the public to fund high cost drugs. The greatest theme of the day was about opportunity costs: when we decide to fund an expensive drug there are other things that will no longer be funded, and this should always be taken into consideration when making coverage decisions.

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The University of British Columbia

201-2206 East Mall

Vancouver, B.C. Canada V6T 1Z3

Tel: 604.822.4969

Fax: 604.822.5690

Email: [enquire@chspr.ubc.ca](mailto:enquire@chspr.ubc.ca)

[www.chspr.ubc.ca](http://www.chspr.ubc.ca)