



VALUE-BASED PRICING OF PHARMACEUTICALS IN CANADA: OPPORTUNITIES TO EXPAND THE ROLE OF HEALTH TECHNOLOGY ASSESSMENT?

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KEY MESSAGES

- ▼ The rate of spending on health in Canada is rising faster than the rate of economic growth, creating concerns about the sustainability of Canada's publicly funded healthcare systems. Expenditures on drugs is one of the fastest-growing areas.
- ▼ Canada's public drug plans currently use a formulary system informed by health technology assessment (HTA) to manage drug expenditures. There are concerns that the current formulary system limits consumer choice, provider autonomy, producer innovation and patient access. For example, if a drug is perceived as having low or uncertain value for money by a payer, it might not be listed on a public plan formulary, challenging prescriber autonomy and leading to out-of-pocket expenses for patients.
- ▼ In addition, current pricing and reimbursement policies and practices in some provinces undermine the efforts of others to negotiate lower prices, resulting in higher prices for everyone (e.g. best price policies and confidential rebates). Further, this type of price discrimination based on provinces' buyer market power is inequitable and can reduce access to drugs for certain individuals.
- ▼ To maintain private sector innovation, patient access, health system fiscal responsibility and sustainability, some jurisdictions internationally have turned to value-based price negotiation mechanisms. Value-based pricing consists of negotiating prices for new pharmaceuticals based on the value the new drug offers society, as assessed through HTA.
- ▼ Domestic and International evidence suggest that an effective and accepted mechanism of determining reimbursement price can result in reductions in net pharmaceutical expenditures.
- ▼ Canadians would benefit from a pricing system with two distinct features: 1) pan-Canadian coordination, to reduce the potential for whipsawing; and 2) real-time evaluation of the drug value and feedback, to create more opportunities for negotiation. The single price negotiation would (i) determine which drugs would require price negotiation, (ii) clearly communicate to stakeholders what constitutes good "value" and how this will be translated into a price, and (iii) have the legislative authority to negotiate price on behalf of other provincial (and federal) jurisdictions and to keep negotiated prices confidential.
- ▼ A single, coordinated price negotiation body would help reduce inequity across jurisdictions by leveraging the buying power and macroeconomic factors of provinces with larger drug budgets to those provinces with much smaller budgets and smaller industrial incentives. It would promote a standard regarding which interventions are legitimately valuable to society and which are not.
- ▼ A price negotiation mechanism tied to real-world assessment would allow for even more options for price negotiation. Real-world assessment of drugs would increase the capacity to conduct discipline-specific research, monitor health products throughout their lifecycle and strengthen Canada's knowledge economy.

EXECUTIVE SUMMARY

The rate of spending on health in Canada is rising faster than the rate of economic growth, creating concerns about the sustainability of Canada's publicly funded healthcare systems. Expenditures on drugs is one of the fastest-growing areas, representing an average of 6.3% compounded annual growth of real per capita healthcare expenditures in the last decade. Reimbursement for drugs has risen steadily over the past 10 years—in 2010, for example, spending on drugs reached \$31.1 billion, amounting to 16.3% of total healthcare spending.

In Canada and worldwide, one response to concerns about rising drug costs has been to implement public drug formularies—lists of pharmaceutical drugs covered by a prescription drug plan—that are informed by health technology assessment (HTA). HTA is a multi-disciplinary process of policy analysis that aims to bridge the world of research with the world of decision-making. It examines the medical, economic, social and ethical implications of the use of a medical technology, including pharmaceuticals, in healthcare, and uses the evidence to inform decision-making. In this context, the results of HTA are applied to pharmaceuticals to define, capture, and reward value creation, with the goal of making decisions that are fiscally responsible without sacrificing patient health.

There are concerns that the current formulary system limits consumer choice, producer innovation, provider autonomy, and patient access. If a drug is perceived as having low or uncertain value for money by a payer, it may not be listed on a public plan formulary; this challenges prescriber autonomy and leads to high out-of-pocket expenses for patients who would like the medication. Current pricing and reimbursement policies and practices in some provinces undermine the efforts of others to negotiate lower prices, resulting in higher prices for everyone (e.g. best price policies and confidential rebates). This results in differences in access to drugs across provinces, along with political pressure that can lead to health system inefficiency. Furthermore, manufacturers are tasked with predicting new drug uptake across jurisdictions and must expend time and resources to negotiate individually with provinces.

To maintain private sector innovation, patient access, and health system fiscal responsibility and sustainability, some jurisdictions internationally have turned to using HTA as a basis for making decisions on drug prices. Value-based pricing consists of a negotiated price on new pharmaceuticals based on the value the new drug offers to the jurisdiction, as assessed through HTA.

While international models have demonstrated that this approach is an effective and accepted mechanism of determining reimbursement price and that it can result in reductions in net pharmaceutical expenditure, there is little known about how value-based pricing might work across Canada. This report examines the successes and challenges of incorporating HTA for drug price negotiations of pharmaceuticals in the Canadian context, including what roles the governments and various HTA agencies at the federal, provincial and local levels could or should play. It synthesizes information from two key sources: 1) a comprehensive literature search for national and international evidence on the effectiveness and cost-effectiveness of value-based pricing of pharmaceuticals; and 2) semi-structured interviews with key informants—experts in health economic evaluation and drug policy, industry experts, and public and private drug insurance leaders.

Our findings suggest that currently many provincial drug programs lack resources, capability, legislative authority and price negotiation levers, in terms of volume of drug utilization, to be able to negotiate with drug manufacturers. Even among those provinces that do negotiate price, better prices might be realized for the provinces that are first to negotiate or those that have different industrial sectors. This decentralized process provides opportunities for “whipsawing”; that is, lack of substantial coordination of price negotiation means some jurisdictions, particularly smaller jurisdictions with less buying power, may be pressured to pay the list price of a drug by manufacturers seeking to maximize revenue.

One proposed option is to adopt a pricing system that harbors two distinct features: 1) pan-Canadian coordination, to reduce the potential for whipsawing; and 2) real-world evaluation of the drug value and feedback, to create more opportunities for negotiation. The single price negotiation body, governed or endorsed by Canadian public drug plan managers, could have the following functions: (i) a process for determining which drugs would require price negotiation; (ii) criteria communicated to manufacturers regarding what constitutes good “value” and how this will be translated into a price negotiation; and (iii) legislative authority to negotiate price on behalf of other provincial (and federal) jurisdictions and to keep negotiated prices confidential.

Although some may perceive this as an expanded role for the Patented Medicine Prices Review Board (PMPRB), this may not be a realistic option, given its federally legislated remit and considering that reimbursement is a provincial responsibility. The price negotiation mechanism would be linked to a separate research entity that provides information on real-world drug effectiveness and utilization. The research entity would be analogous to province-based research groups and linked to existing institutions that focus on collecting and analyzing drug effectiveness and utilization, such as the Institute for Clinical and Evaluative Sciences and the Canadian Institute for Health Information.

The development of a single, coordinated price negotiation body would help reduce inequity across jurisdictions by leveraging the buying power and macroeconomic factors of provinces with the largest drug budgets to those provinces with smaller budgets. It would promote a standard and coordinated approach to the evaluation of price and provide a strong signal to drug manufacturers regarding which interventions are legitimately valuable to society and which are not. Coordination should lead to improved methods for evaluating health system performance. A price negotiation mechanism tied to real-world assessment would allow for even more options for price negotiation and managed entry agreements, such as linking the price of a drug to its future outcomes and/or future volumes. Real-world assessment of drugs would facilitate strengthening the capacity to conduct discipline-specific research and the structures required to support it.

While there are advantages to having a central body negotiating prices based on drug value, this more coordinated process would require an explicit recognition of the amount of value society is willing to give up, as additional resources that could be used for other government programs, including healthcare, must be used to accommodate costs of health purchasing decisions. This includes the share of value society is willing to give up to support an adequate future global supply of pharmaceuticals. Without an explicit recognition of opportunity cost, either through empirical study or through clear communication from policy-makers as to what factors constitute good value, manufacturers lack clear incentives for innovation and may shift resources away from research and development to lobbying efforts.

HTA as currently practiced (i.e. using quality-adjusted life years or other health measures) may not accurately reflect the full value of health technology. Furthermore, determining what constitutes good value and the cost-effectiveness threshold (i.e., the amount society is willing to pay) poses a difficult

social challenge, as it may not adequately reflect important population heterogeneity and may need frequent updating with shifting politics or demographics. Health systems across Canada differ in design, delivery and related costs. Practice patterns differ, too. This means that provinces and territories could have different cost-effectiveness thresholds reflecting their different willingness to pay for a drug based on their needs and realities in their own health systems. In theory, value-based pricing could involve multiple prices for a single drug where this product is used to treat multiple indications, presumably with a different benefits and subsequent value in each.

Given that the assessment and appraisal of drugs in Canada have enjoyed cross-provincial coordination and the emergence of price-negotiation in some provinces, there is a potential for value-based price negotiation of pharmaceuticals to become more widespread in Canada. While some provinces (British Columbia, Ontario, Alberta and Manitoba) currently have systems in place to negotiate the price of drugs, Canada would greatly benefit from a coordinated system of price negotiation based on HTA. As well, there is an interest from public sector payers and private sector innovators for a system that links price to real-world assessment and managed entry of new pharmaceuticals. Managed entry refers to the process of payers working with industry to manage the way that new drugs are brought into the market. The terms and conditions of prices can be linked to future outcomes, future volumes, or both, to give payers and producers some assurance of potential value. The price and the conditions of listing are then drawn up into a product listing agreement. These processes are also called risk-sharing agreements, coverage with evidence development, pay-for-outcomes, and performance-based pricing.

This report was written together with a second report, *“The Use of Health Technology Assessment to Inform the Value of Provider Fees: Current Challenges and Future Opportunities.”*

1 CONTEXT

1.1 RISING HEALTHCARE COSTS AND KEY COST DRIVERS IN CANADA

The rate of spending on health in Canada is rising faster than the rate of economic growth. This raises concerns about the sustainability of Canada's publicly funded healthcare systems.¹ Reimbursement for drugs continues to be one of the fastest growing areas of spending, representing an average of 6.3% compounded annual growth of real per capita healthcare expenditures in the last 10 years, second to capital expenditures (e.g. construction, machinery, equipment, software for healthcare facilities).¹

In 2010, spending on drugs increased 4.8% from the previous year, reaching \$31.1 billion and amounting to 16.3% of total healthcare spending. Alberta, Ontario, Manitoba, Nova Scotia and British Columbia currently allocate more than 40% of their provincial budgets to healthcare, a figure that is expected to increase in years to come.¹

In Canada and worldwide, one response to concerns about rising drug costs has been to implement public drug formularies informed by health technology assessment processes, to help set priorities for funding drugs and ensure sustainability without sacrificing patient health.^{2,3} The primary role of HTA in the realm of drug policy, then, has been to support formulary development and policy decisions regarding listing drugs covered by the prescription drug plan and to a much smaller extent, to support implementation and provider-focused programs, like academic detailing.¹

Additional attempts to constrain growth in drug expenditures have led to other policies that may have undesirable or unintended consequences.⁴ Policies that require drug manufacturers to offer the lowest price in the country undermine the efforts of other provinces to negotiate lower prices, resulting in higher prices for everyone. To work around these policies, some public drug plans (in Ontario, for example) are negotiating confidential rebates on price, which can contribute to a high nominal price. This high nominal price becomes the price paid by other buyers with less bargaining power.⁴

For payers and patients, not reimbursing a product or service in public formulary may be perceived to conflict with liberal democratic concepts of consumer choice, provider autonomy and patient access. For producers of technology, all-or-nothing decisions about public coverage make predicting future revenues from investments in research more difficult; more capital must be shifted, potentially from research and development programs, to support market access processes or government lobbying efforts which, in turn, may stifle the ability of private and public sector actors to cooperate in a constructive and meaningful fashion.

In response to the need to maintain private sector innovation and freedom to choose while still maintaining health systems fiscal responsibility and sustainability, some jurisdictions internationally have turned to value-based price negotiation mechanisms and to managed entry agreements to improve access to new drugs. Value-based pricing consists of a negotiated price on new pharmaceuticals based on the value the new drug offers to the jurisdiction, as assessed through HTA. Managed entry refers to the process of payers working with industry to manage the way that new drugs are brought into the market. Condition of listing and prices can be linked to future outcomes, future volumes, or both, based on real-world assessment, to give payers and producers some assurance of potential economic value. Given the emerging duplication and potential for inefficiency from drug price negotiation happening in some provinces (e.g., Ontario, British Columbia, and Alberta) and given that the assessment and appraisal of drugs in Canada

i Academic detailing is one-on-one non-commercial based educational outreach to prescribers provided by trained healthcare professionals. In Canada, these groups belong to the Canadian Academic Detailing Collaboration (CADC) which provides evidence-based information or educational outreach to physicians and other healthcare providers in Canada.

have enjoyed cross-provincial coordination, there is a potential for value-based price negotiation of pharmaceuticals to become more widespread in Canada. In fact, the desire for coordination through a “bulk purchasing alliance” has recently been announced by provincial ministers.⁵

There is a need to examine the evidence of effectiveness and cost-effectiveness of these approaches along with the opportunities and barriers that exist within the Canadian health system. This in turn will help Canadian policy-makers decide whether such systems should be adopted in Canada and how these might best operate.

1.2 PURPOSE OF THIS STUDY

This study began in February 2010 as part of a comprehensive program of work in the areas of healthcare financing, innovation and transformation sponsored by the Canadian Health Services Research Foundation. The intent of this reportⁱⁱ is to provide information to support dialogue among key stakeholders, with a goal of identifying, refining, and implementing feasible options that use health technology assessment to improve the sustainability of the health system.

The objectives of this paper are to:

- (i) synthesize relevant international and domestic evidence on the successes and challenges of incorporating HTA in price negotiations of pharmaceuticals;
- (ii) understand the types of institutional structures needed to support this activity;
- (iii) explore the potential for implementation in Canada;
- (iv) make recommendations as to whether this approach should be adopted more widely in Canada, and if so, suggest possible ways forward

The structure of the report is as follows: First, a conceptual overview of what health technology assessment is, how drug policy in Canada is informed by HTA, what HTA attempts to do, and evidence of its effectiveness and cost-effectiveness is presented. Then, a discussion of how HTA could support value-based pricing in theory is presented. Finally, some of the potential challenges of this approach are discussed, feasible policy options for Canada are presented and a recommendation is made.

1.3 METHODS

The information presented in this study is a narrative synthesis based on two key sources of information: 1) a comprehensive literature search for national and international evidence on the effectiveness and cost-effectiveness of value-based pricing of pharmaceuticals; and 2) semi-structured interviews with key informants—experts in health economic evaluation and drug policy, industry experts, and public and private drug insurance leaders. The informants are listed in Appendix A and the questions asked in Appendix B. This information was then used to create feasible options for Canada and final recommendations.

ii This report was originally written together with a second report, “The Use of Health Technology Assessment to Inform the Value of Provider Fees: Current Challenges and Future Opportunities”, so some of the core conceptual material presented in this report also appears in the second report.

2 HEALTH TECHNOLOGY ASSESSMENT (HTA), VALUE AND PRICE

2.1 WHAT IS HEALTH TECHNOLOGY ASSESSMENT?

Health technology assessment (HTA) is a multi-disciplinary process of policy analysis that examines the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in healthcare.^{6, 7} It is intended to bridge the world of research with the world of decision-making.⁸ It is a growing field internationally, fostered by the need to support management, clinical, and policy decisions, and fueled by advances in methods of evaluation in the applied and social sciences, including clinical epidemiology and health economics. HTA is becoming an increasingly important policy tool to help policy-makers define and measure (i.e., capture) value from the use of health technology.⁹

Health technology assessment of pharmaceuticals is well-established; some who engage in the discipline may not necessarily see it as an extension of HTA, as its academic origins extend from the specific disciplines of hospital pharmacy: clinical pharmacology, therapeutics, managed care, drug information and formulary review. Nonetheless, drug formulary review is based on the same principles of assessment, often focusing on clinical, economic and budgetary dimensions of impact.

2.2 HTA PROCESSES FOR DRUG EVALUATION IN CANADA

HTA is widely practiced in Canada and organizations can be found at hospital, regional, provincial, and national levels.^{2, 10} The number of organizations conducting both drug and non-drug HTA in Canada has grown in recent years. Some of the organizations are academic coalitions, funded through health research bodies or with matched government funding and with informal linkages to policy-makers. Others are entirely funded by health systems or ministries. All provinces currently have some capacity to conduct drug assessments through health ministry programs, through shared resources or through commissioned third-parties or academic groups. Two pan-Canadian programs of health technology assessment for new drugs currently exist: 1) the Common Drug Review, and 2) the pan-Canadian Oncology Drug Review. These are jointly funded by all provincial—and federally-funded drug programs (except Quebec).

2.3 HOW DOES HTA BRIDGE SCIENCE AND POLICY?

HTA attempts to project and estimate relevant outcomes associated with policy choices surrounding health technology to inform healthcare decisions. The majority of HTA-based formulary processes in Canada and Internationally focus on clinical and economic outcomes.^{11, 12}

To better illustrate the fundamental components of any HTA process, Schwarzer and Siebert have recently characterized HTA as having three distinct components or phases (see Figure 1).¹³ The first component is a “science” phase, where research and analyses are carried out. Technologies are assessed using discipline-specific appropriate scientific methods and judgments. For example, an assessment of the health consequences of using a technology would typically use current scientific methods and judgments from the fields of epidemiology and pharmacology.

In the “science” phase, economic evaluations typically use a utilitarian frameworkⁱⁱⁱ—i.e., estimating the time enjoyed in preferred states of health. This approach allows a decision-maker to understand which strategy leads to the highest payoff, or health gain achieved, and allows for a comparison of health with the associated cost of resources incurred by a health system or society. A popular unit of health gain, or effectiveness, is the quality-adjusted life-year, or QALY, which measures preferences for length and health-related quality of life. Cost-effectiveness studies—namely, studies that compare costs with effectiveness measures—that use utilitarian measures like QALYs are called cost-utility analyses. The advantage of using QALYs in cost-effectiveness analyses is that it allows decision-makers to compare resource use across competing health programs. For example, a health system administrator can compare health gains from technologies intended to treat cardiovascular conditions versus health gains from technologies intended to treat urological conditions. The QALY provides a common currency to assess the extent of the benefits gained from a variety of interventions. Despite these advantages, this single unit of benefit harbors some significant shortcomings as well: issues of equity, social justice, patient autonomy and fairness are not incorporated into QALYs. (This is discussed in a later section.)

A second distinct phase in HTA is a “policy” phase, where societal values and judgments are brought to bear on scientific evidence to arrive at a policy decision. Rather than relying on policy-makers to passively use the results of technology assessment to create policy changes, many organizations conducting HTA today use formal expert committees that include healthcare providers, researchers, and members of the public to examine and deliberate on the scientific evidence available from assessments, with the goal of creating recommendations for policy-makers. These “deliberative” approaches, particularly when they bring together decision-makers and researchers, are a much more effective approach to ensuring knowledge from HTA (evidence) is correctly interpreted and applied, compared to simply producing scientific reports in hopes this will be translated to policy by others.^{14, 15}

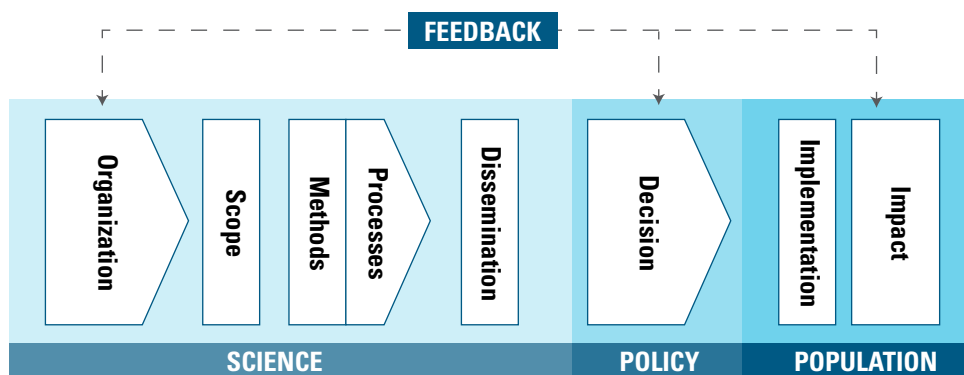
Deliberative approaches and processes within HTA organizations have evolved to become more transparent and have borrowed from political and ethical approaches to public policy development.¹⁶ In particular, it has been suggested that the use of evidence to inform deliberation and healthcare decisions should, in theory, facilitate deliberation and agreement by stakeholders, and that any legitimate and fair assessment of healthcare resource allocation decisions should be transparent, rest on reasons that stakeholders agree are relevant, be revisable in light of new arguments, and have assurances that these conditions can be met.^{17-19, 16}

A third phase in HTA has been labeled a “population” phase, where evidence-informed recommendations are implemented and an evaluation of decisions from these recommendations can occur. This phase might involve re-assessing the decision and the impact of the decision. It may also involve supporting policy-makers or providers in their attempts to use HTA recommendations, or promoting the use of HTA-driven policies through the use of tools or other interventions. Good evaluations in this phase can feed back to future assessments of technology, which in turn can feed back to policy changes.

The process of drug assessment and recommendation for formulary reimbursement can be described using this framework.²⁰⁻²² In Canada, HTA organizations are generally governmental or quasi-governmental, focus on various types of drugs, use a rigid framework of analysis (e.g., strictly health, cost, and fiscal impact) with a predictable time course, and do some (although very limited) evaluation and assessment after decisions are undertaken.

iii Utilitarianism is an ethical theory that suggests that the “good” from any individual action is determined by its consequences in terms of total good on society. The best actions result in the greatest overall “good.” Utility is a measure of the “good” to be maximized and generally relates to measures of satisfaction or happiness. This can be contrasted with other moral theories, such as egoism, where the consequences for the individual taking action are the only thing considered.

FIGURE 1: DISTINCT PHASES OF HTA PROCESSES (ADAPTED FROM SCHWARZER¹³)



2.4 CAN HTA-BASED PRICE NEGOTIATION LEAD TO OPTIMAL USE OF HEALTHCARE RESOURCES?

Hospitals that purchase pharmaceuticals in Canada often negotiate with manufacturers and suppliers. As these price agreements are held in confidence, there is currently little information regarding whether these mechanisms have effectively reduced growth in spending on pharmaceuticals. In New Zealand, the impact of three years of price management of pharmaceuticals using a national coordinated approach across 29 major hospitals was assessed. Savings of between NZ\$8 million to NZ\$13 million annually were achieved, with some reduction in growth in pharmaceutical expenditures for inpatients.²³

Provincial formularies similarly hold agreements on drug prices in confidence with manufacturers, although there is some evidence that these agreements have led to reductions in growth. In 2009, the Ministry of Health and Long-Term Care in Ontario suggested product listing agreements led to a 5% lower growth rate in spending on drugs, improved access via faster funding decisions and agreement negotiations, and two-year savings of more than \$600 million.²⁴ It is believed most provincial product listing agreements in Canada go beyond simply receiving a rebate per reimbursed product, but instead may have tiered rebates related to the volume reimbursed or other risk-sharing or managed entry measures.^{23, 25-27} Price reductions through mass rebates are believed to be between 3–16% percent of the retail price of the drug.²⁸

2.5 PRICE AND VALUE

Value is technically defined as what consumers would be willing to pay or to give up for a good or service. In markets where many producers seek to sell goods to many consumers, the balance between consumer demand and producer supply determines the price of a good. Healthcare is a unique and imperfect market for several reasons, including: 1) consumers do not actually pay directly for the goods that they receive; 2) consumers have little choice in what health product they receive; 3) inconsistent alignment of incentives for cost control between physicians and the hospitals in which they practice.^{iv, 29, 30}; and 4) drug manufacturers are provided a temporary monopoly on a particular good and need not be concerned about loss of revenue to other manufacturers. As such, health technology assessment that looks at economic impact facilitates a broader understanding of what a healthcare purchaser (society) might be willing to pay for a health technology or service by making tradeoffs for health and resources more explicit.

iv Providers may choose medical technologies or services without concerns about overall expenditures, often because they are paid directly by a health insurer while hospitals must pay all non-physician expenses, including technology funded through a global budget.

In economics, the value of a good or service is defined not only by the price paid and quantity of goods sold, but also by what price consumers are willing to pay and what price producers are willing to supply at. This combined economic value is referred to as the total or “social surplus” (See Figure 2a). Because prices in Canadian public drug plans are driven by an imperfect balance between consumer demand and producer supply, prices are usually regulated when decisions about purchasing or policies to support purchasing are developed by single (i.e., monopsonist) payers and single (i.e., monopolist) producers using trading rules that both are comfortable with.^{31, 32}

FIGURE 2A: SOCIAL SURPLUS AT MARKET EQUILIBRIUM

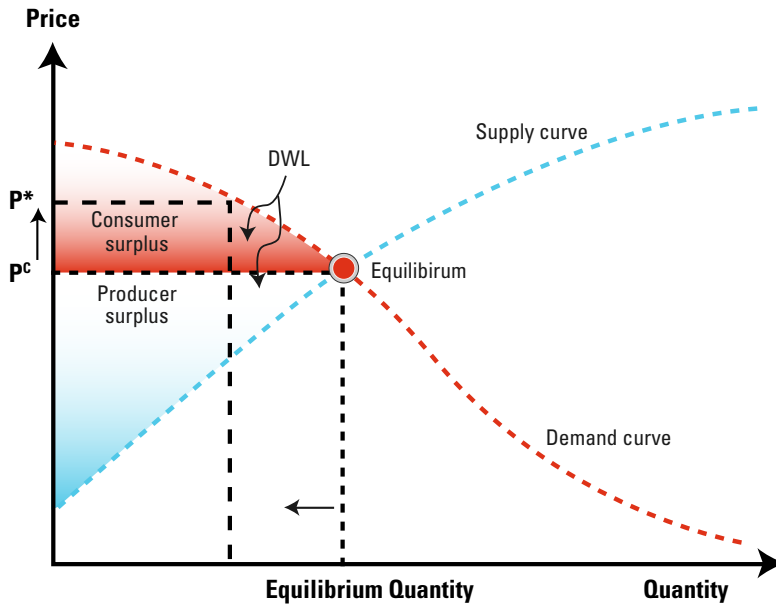


Figure 2A – The red and blue areas represent the consumer and the producer surplus in a competitive market (at P_c). The social surplus is the sum of both areas. In a monopolistic market, the monopoly price (P^*) is above P_c and the quantity produced is reduced. The consumer surplus is reduced to the area under the demand curve and bounded by the price line (P^*). The producer surplus is the area below the price line (P^*) and above the supply curve. Because a monopoly does not produce at the competitive level, the social surplus is not maximized. This lost social surplus is the deadweight loss (DWL) that results from the monopoly.

The current use of economic evaluations in HTA to inform public policy is intended to bring societal preferences for tradeoffs between health and dollars into discussions about the need for the good or service. Ultimately, the price for goods and services paid by public and private insurance plans for new technologies will affect the balance of economic value that is realized by consumers and manufacturers. This represents a distribution which is termed the balance of the social surplus. If no price regulation exists, the price of newly patented technologies would reflect the maximum that society is willing to give up; typically, this means, on average, consumers do not receive surplus value from paying for goods (and non-discriminating producers with a temporary monopoly capture most or all of the social surplus)—that is, until less expensive versions of the technology (for drugs, generics) become available. Once patents expire, lower-priced generics become available and the health system has the potential to ultimately benefit.^v

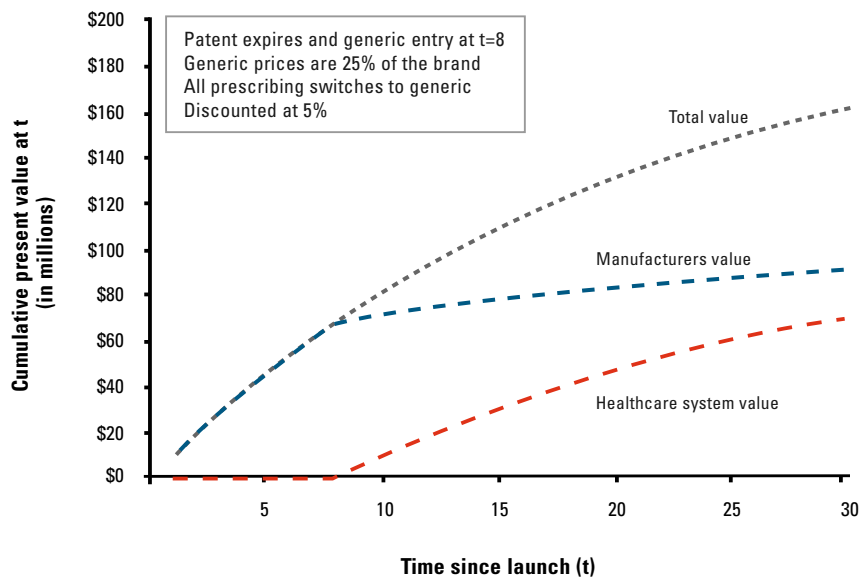
Using an analysis by Claxton and colleagues adapted for the Canadian context³³, Figure 2b illustrates the cumulating value of an innovation over time (discounted at a rate of 5%) and how this total value is shared between the manufacturer and the Canadian healthcare system. Initially, during patent protection price all value is appropriated by the manufacturer (i.e., assuming a net health benefit of zero). At 8 years, the patent expires and assuming that competitive generics enter then market prices fall. In this example, manufacturers

^v Consumers benefit through the introduction of generic medicines can only occur if certain conditions are met: i) the generic market remains competitive; ii) that the prices of future newly patented drugs reflect their value when compared to the cheaper generic versions of the previous innovation, and; iii) if they do not, then all prescribing switches to the generic version of the old brand. If these conditions are not met, consumers may never benefit from innovation and the low or negative net benefits observed in the short term will be realized in the longer run as well. When these conditions are met the private sector will retain a significant proportion of value in the long run.³²

will appropriate 57% of the value after 30 years and retain 49% of the share with an unbounded time horizon (i.e., under a scenario where the innovation is forever relevant)^{vi}. This example assumes that: i) competitive generic entry occurs, reducing prices to 25% of the brand; and either ii) all prescribing is switched to generics; or iii) any new patented drugs are priced relative to the generic version of the old. If the three assumptions do not hold and none can be taken for granted, then the manufacturers share would be higher.

There is no clear answer or rule of thumb as to what the appropriate balance is in rewarding manufacturers with some share of the social surplus to incentivize innovation in the long term. But by deciding what price to pay, policy-makers are directly deciding how value should be shared between Canadian citizens and manufacturers in the short term and how Canadians will contribute to the future global supply of pharmaceuticals. An important question is how the manufacturers' share will influence their willingness to invest in new research and development. This is a question of "dynamic efficiency," which is about good value for money in the long-term as opposed to "static efficiency," which is about good value for money in the short-term, i.e., at the current price.³⁴ A concern is that overt focus on short-run health measures to represent value will ignore other long-run metrics of social value (outside of health) realized from research and development efforts.

FIGURE 2B: SHARE OF VALUE FROM HEALTH TECHNOLOGY BETWEEN THE MANUFACTURER AND THE CANADIAN HEALTHCARE SYSTEM, ADAPTED FROM CLAXTON³³



vi The share at time t is obtained by dividing the manufacturer's value by the total value. In this example, the manufacturer's value is about \$ 90,000,000 at year 30 divided by approximately a total value of \$157,000,000.

3 CURRENT AND FUTURE ROLE OF HTA IN PHARMACEUTICAL PRICE NEGOTIATION

3.1 CURRENT REIMBURSEMENT PRICE PROCESS FOR DRUGS IN CANADA

The price of patented pharmaceuticals in Canada is regulated and monitored by the Patented Medicine Prices Review Board (PMPRB), an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act*. The PMPRB acts in a regulatory capacity “... to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive.”³⁵ Non-patented drugs, including generic drugs and brand pharmaceuticals without Canadian patents, are not regulated by the PMPRB. Patentees are required to file price and sales information twice a year for each strength of dosage form of each patented medicine sold in Canada, to comply with the Patent Act. The PMPRB will review prices that are perceived as excessive and may order patentees to reduce their prices and take measures to offset any excess revenues patentees may have received. For example, in 2009, Eli Lilly Canada Inc. voluntarily reduced drug prices and made two payments to the government of Canada that totaled in excess of \$15 million due to selling a treatment at prices judged to be excessive for children diagnosed with Attention Deficit Hyperactivity Disorder.³⁶

Activities by the PMPRB led to the establishment of a publicly available price that is available to the provinces and other international markets. Since the prices apply only to prices charged by a manufacturer, many provinces have taken additional steps to restrict payments to pharmacies and wholesalers in order to further regulate prices. These prices are determined by assessing the claimed benefits of the new drug compared to other similar drugs, and by comparing the price with other markets internationally. Manufacturers are allowed a price premium based on perceived therapeutic benefits versus current alternatives, but this does not consider whether the benefits are worth the additional cost.

The reimbursed price of brand and generic hospital drugs may vary considerably from hospital to hospital, as confidential price arrangements between hospitals or regional health authorities and drug manufacturers are commonplace. Manufacturers may offer loss-leading prices to hospitals to promote other products or the use of a drug outside of hospitals. These arrangements may involve bundling, rebates or future purchasing commitments. Decisions regarding the adoption of drugs in hospital are usually managed through hospital- or region-based pharmacy and therapeutic committees, which recommend coverage based on clinical, cost, and hospital budget impact. Consistent with the Canada Health Act, patients are provided medically necessary in-hospital drugs on a prepaid basis.

The reimbursement price of out-of-hospital (or outpatient) drugs is determined by a variety of factors. Some provinces have no ability to negotiate price and will manage costs through restricting access to drugs on formularies, or simply not reimbursing. Some provinces, such as Quebec, have a policy that demands the best price offered across Canadian public jurisdictions. Decisions to list new brand drugs will almost always consider information provided by health technology assessments similar to hospitals (i.e., clinical, cost and fiscal impact). A unique feature of provincial drug programs is additional consideration of public or patient values in listing decisions. The use of HTA information in listing decisions is facilitated by the national Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR), which provide a review of the clinical, economic, and patient impact of drug listing decisions for provincial and federal drug plans. Each province also has a provincial or inter-provincial mechanism for conducting further assessments. Quebec does not participate in either CDR or pCODR processes, but has its own internal review and recommendation processes for supporting listing decisions. It is important to note that these coordinated

national processes facilitate listing decisions but are not a substitute for decision-making. In some cases, provinces may choose to make listing decisions that do not follow recommendations because of concerns specific to their jurisdiction. In some cases, a “no” based on a manufacturer’s list price might lead to a “yes” if an individual jurisdiction can negotiate price further. Similarly, a “yes” does not immediately translate into a decision to list and the timing of this decision will vary by jurisdiction.

Some public insurance programs (including federal drug plans) now have the legislative authority to negotiate the price of drugs on behalf of the health minister or government. For example, the Ministry of Health Services in British Columbia (BC) established the Business Management and Supplier Relations Branch in 2007, which helps to negotiate the price of drugs newly approved as a benefit on their public drug plan formularies. Similar processes for price negotiation exist in Ontario, Alberta, and Manitoba. Similar to hospital price agreements, reimbursement prices for drugs on provincial formularies are usually subject to confidential listing agreements. In practice, this means the public insurance plan is being partially reimbursed on prescription sales, as prescription vendors and the public are not aware of the negotiated price. Price negotiation may also be linked to larger considerations and processes, including managed entry agreements or economic development opportunities. Public insurance plans may demand deductibles and co-payments can vary widely from province to province.

The reimbursement price of generic outpatient drugs has been, until recently, largely the result of legislation in Ontario. The Ontario Drug Benefit Plan allows for a reimbursement price of up to 75% of the brand price. In 2010, regulations under the Drug Interchangeability and Dispensing Fee Act³⁷ and the Ontario Drug Benefit Act³⁸ legislated that prices be reduced to a maximum of 35% of brand prices in the Ontario Drug Benefit Plan as of April 1, 2011, and to 25% on April 1, 2012. Quebec, Alberta and British Columbia have enacted similar legislation.

Private insurance plans will generally pay an ex-factory price for brand and generic drugs without price negotiation. Employers may demand a drug benefit formulary that mirrors a public benefits package, without receiving the same price as the provincial plan that they are being asked to emulate. Higher individual drug prices are embedded in the price and premiums of the overall insurance package. The Canadian Institute for Health Information estimates that 39% of the \$28 billion of prescribed drugs sold were reimbursed by public insurance plans in 2008, compared with 30% by private insurance plans.²

3.2 A GREATER USE OF HTA IN DRUG PRICE NEGOTIATION – A VALUE-BASED PRICING SYSTEM

HTA is linked to drug price negotiation in almost all major hospital or health region settings across Canada through pharmacy and therapeutics committee mechanisms. Price negotiation linked to out-of-hospital technology assessment currently exists in Alberta, British Columbia, Manitoba and Ontario: confidential agreements are created between manufacturers and provinces regarding the conditions required for products to be listed on provincial formularies and the rebate that will be returned to the province.²⁵

Formulary reference pricing, a system where a payer chooses to pay for a single “reference” price for a group of similar drugs, is another system of pricing that is linked to HTA. It has been successfully implemented in British Columbia, where patients can receive a drug priced at the reference price for free (or a nominal fee) but must pay a co-payment for similar drugs that are priced higher. The co-payment represents the difference in price between the price of a prescribed drug and the lower-priced reference drug. There is sufficient evidence suggesting this system has led to net expenditure reductions without adversely affecting health outcomes in B.C.³⁹⁻⁴¹ and internationally.⁴² For example, a net expenditure

reduction of \$6.7 million was seen in the use of antihypertensive drugs during the first 12 months of implementation of reference-based pricing in B.C.⁴¹ For the manufacturer, it has the advantage of allowing the freedom to charge a maximum-allowable price, but from society's perspective, it has the disadvantage of more narrowly focusing on relative clinical effectiveness, rather than relative value.⁴³ Because price is directly linked to the manufacturer's share of social surplus and future investment in research and development, it may also have the disadvantage of stifling innovation, if formulary reference prices are made public and influence other countries that may reference these prices.²⁷

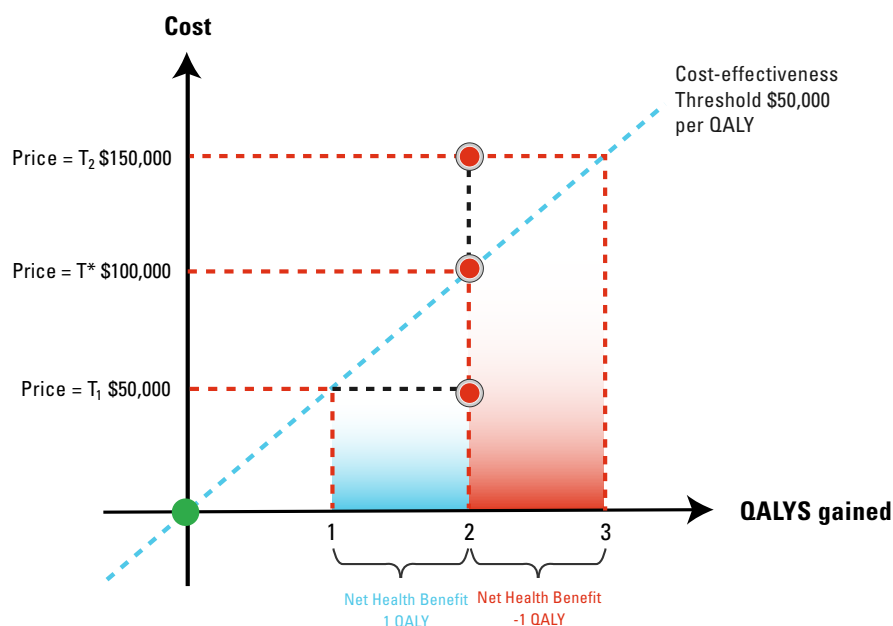
Australia and some Canadian jurisdictions (notably British Columbia, Alberta, and Ontario) have implemented price negotiation processes linked to HTA.⁴⁴ There are also many examples of HTA-based processes that lead to implicit price negotiation. For example, in Canada, the Common Drug Review will issue a recommendation by its expert committee to the manufacturer for an embargo period. During this time, the manufacturer is given the opportunity to resubmit its application based on a reduced price. The application will then be re-appraised by the expert committee and a new recommendation will be issued.

Similarly in Sweden, assessments occur prior to widespread distribution (*ex ante*) and continued assessments and reviews of price occur after launch (*ex post*). There have been some suggestions that this policy, along with other pharmaceutical policies, has led to lower than average expenditures.^{45, 46} Other countries, such as Germany, France and Spain, have mechanisms for product listing agreements for pharmaceuticals.²⁸ The terms and conditions of these listing agreements may extend to price or may involve conditional rebates or reimbursement based on drug volume or performance.⁴⁷

Much has been written about the U.K. announcement to adopt value-based pricing in 2014.⁴⁸ The details of this scheme have yet to be worked out, but it is believed that HTA, along with other inputs, will formally be used to establish the prices of drugs.³³ Value-based pricing consists of a negotiated price on new pharmaceuticals based on the value the new drug offers, as assessed through HTA. The concept of value-based pricing of health technology based on cost-effectiveness analysis is illustrated in Figure 3. At Price T*, the health technology offers a gain of two QALYs, at an additional cost to the Canadian healthcare system of \$100,000—i.e., an incremental cost-effectiveness ratio (ICER) of \$50,000 per QALY gained. One must therefore determine whether the investment in this particular health technology, resulting in an expected gain of two QALYs, is greater than the QALYs forgone elsewhere in the healthcare system due to other health technologies being displaced (i.e., the opportunity cost of adopting the technology).

This is represented by an incremental cost-effectiveness ratio (ICER) threshold set at \$50,000 per QALY. That is, price T* represents the value-based price of the technology. At prices below T* (i.e., T1 or \$50,000), the health technology is expected to offer overall health benefits because it improves health by two QALYs and displaces only one QALY elsewhere. This technology would be considered cost-effective because the ICER is less than the cost-effectiveness threshold. If the price of the health technology were set higher (i.e., T2 or \$150,000), then this would have a negative effect on health outcomes of Canadians. The health benefits forgone (three QALYs) are greater than the benefits conferred (two QALYs) by the technology, resulting in a negative QALY. This technology is not cost-effective—the ICER is above \$50,000 per QALY—and does more harm than good to the Canadian healthcare system. The calculations of health benefits that consider opportunity costs are called “net health benefits.”

FIGURE 3: VALUE, PRICE AND COST-EFFECTIVENESS (ADAPTED FROM CLAXTON ET AL. ³³)



One of the main advantages of value-based pricing over reference-based pricing or a standard formulary listing system is how much more options are available to payers and producers. Value-based pricing allows for the creation of a menu of prices to be set, both across technologies within a similar drug class or by patients who use a given technology (see Box 2). This differs from current pricing approaches in Canada, where list prices reflect reference prices based on international references and therapeutic equivalence set by the PMPRB.

Prices of new health technologies in Canada submitted for reimbursement will often reflect what the market, including public drug plans, is willing to pay. There is no explicit cost effectiveness threshold applied to reimbursement decisions of new drugs, although a recent analysis of listing recommendations based on cost-effectiveness revealed a majority of positive decisions were associated with ICERS below \$100K.⁴⁹ The Canadian healthcare system receives no immediate net health benefit if it chooses to pay for the drugs priced at or above the threshold because the costs to society to produce the benefits from the new drug requires resources that can produce a similar or greater amount of health elsewhere in the healthcare system. The payer can choose to not fund the drug, which is a standard approach in Canada's formulary-based system. This, in turn, causes political pressure from patients and providers to provide access.^{vii}

Instead of making these decisions based on average benefits to the whole population, a value-based pricing system allows different groups within the population to access the drug at different prices.^{viii} This approach allows different prices based on the value offered by a new drug in different applications. As a result, there would be more overall net health benefits to the Canadian health system, since technologies that offer poor value on average, but are cost-effective in smaller sub-groups would not be rejected.⁵⁰ This approach could

vii In other countries, such as the existing system in U.K., a standard cost effectiveness threshold is applied to all new products, with some flexibility to take account of additional relevant factors, including societal preferences. However, the mechanism for taking wider factors into account is not completely transparent, and may lead to perceptions that important factors are not adequately reflected in the assessment process. For this purpose, they are working on establishing a value-based pricing system for 2014.

viii HTA as currently practiced in Canada would need to be adapted for a value-based pricing system. As an example, weights could be applied to the benefits provided by new drugs, which would imply a range of price thresholds reflecting the maximum the payers are prepared to pay for drugs. These thresholds or maximum prices would be explicitly adjusted to reflect a broader range of relevant factors so they could be used to calculate the full value of a new product. This is further discussed in section 2.4.

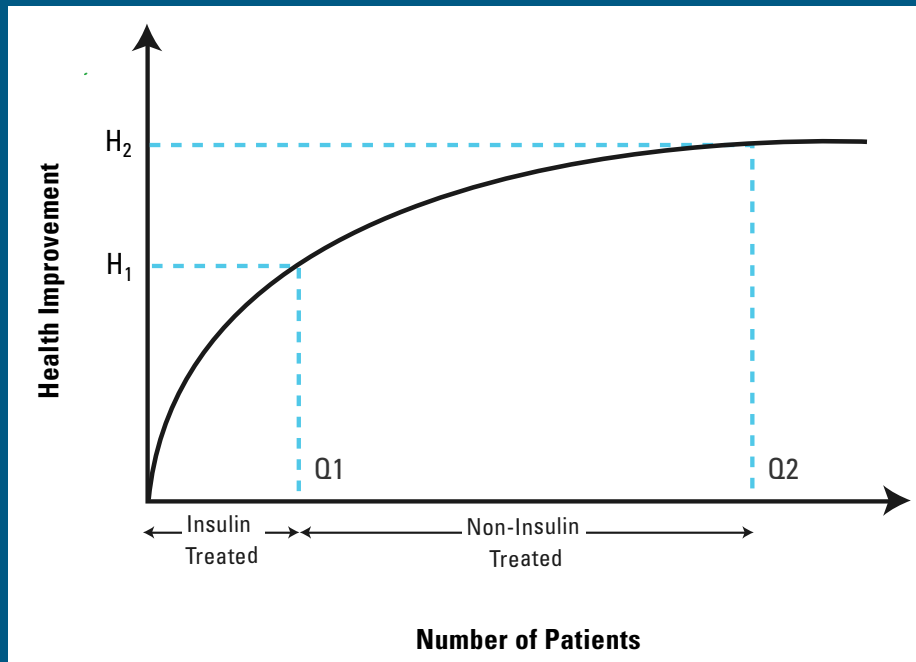
help to avoid other costs in the system for specific subpopulations. Box 1 demonstrates an example of this using the case of test strips for patients with type 2 diabetes.⁵¹ The resources saved by using test strips (which would not be cost-effective on average) for a particular subpopulation could then be reallocated to fund other health technologies and improve management of overall healthcare expenditures.

BOX 1: VALUE-BASED PRICING (VBP CASE STUDY): SELF-MONITORING OF BLOOD GLUCOSE (SMBG)

Although not a pharmaceutical, reimbursement of test strips comes from the budget of public formularies in most provinces. Self-monitoring of blood glucose with test strips in patients with diabetes who use insulin may contribute to improved glycemic control and reduced hypoglycaemia by allowing for self-adjustments in insulin dose to be made based on readings. The utility of SMBG, however, is less clear for patients not using insulin. Hypoglycaemia is less frequent in patients not using insulin. Moreover, the degree to which patients can adjust the dose of oral antidiabetes drugs in response to readings is limited.

The diminishing marginal utility of SMBG by treatment modality is depicted in Figure 4. Patient sub-groups (e.g., insulin versus non-insulin treated) are presented on the horizontal axis and total health improvement on the vertical axis. Based on Figure 4, treating all of the patients with insulin-treated diabetes will produce a total improvement in health of H_1 and an average improvement of H_1/Q_1 for the patient. Expanding treatment to include patients who are not using insulin will produce a marginal health improvement equal to $H_2 - H_1$ and yield an average marginal improvement per patient that is smaller than the corresponding value for patients using insulin. Given that the cost of test strips does not vary by patient group in Canada, the cost-effectiveness of SMBG in patients not using insulin is likely to be less than in patients using insulin.

FIGURE 4: DIMINISHING MARGINAL UTILITY OF SMBG

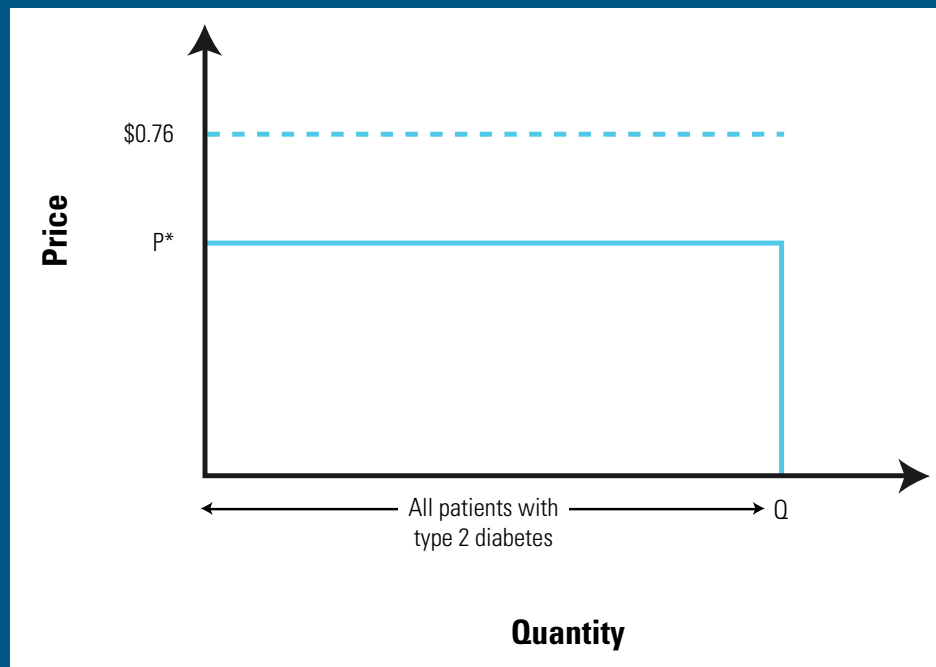


Based on the above, public payers in the Canadian healthcare system may wish to propose different prices and sales volumes for the specific patient populations (e.g., insulin versus non-insulin treated). However, this is currently not practiced in Canada. Rather, drug plans in Canada negotiate a common price of test strips for the entire diabetes population. In an efficient healthcare system, prices of technologies are set at P^* so that the ICER is just equal to the cost-effectiveness threshold.^{ix} However, for test strips, it appears that the price is set well above P^* ($P=\$0.76$)⁵¹

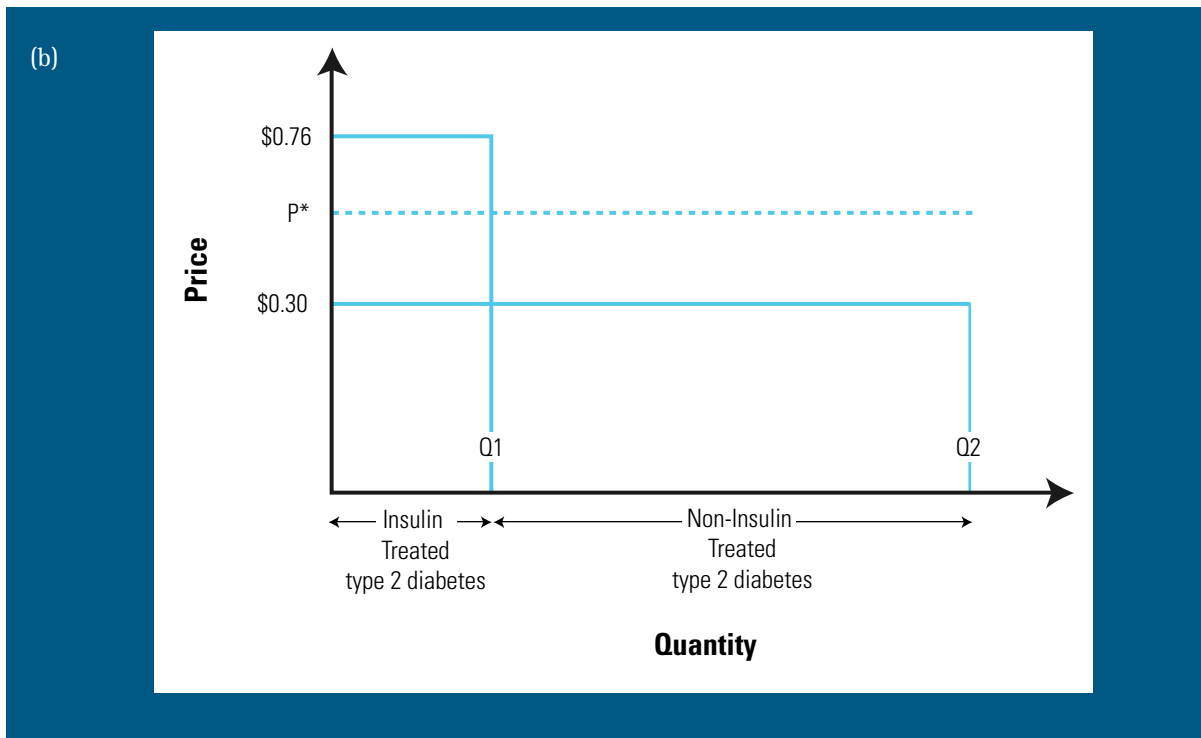
As discussed above, this excessive price would have a negative effect on the net health benefits of Canadians. The investment in SMBG in all patients with diabetes at current prices results in health benefits gained that are less than the health benefits foregone if the resources were invested elsewhere. Now consider a situation where prices are able to be negotiated for different identifiable subgroups of patients. For example, consider two subgroups (insulin versus non-insulin treated) within the original diabetes population in Figure 5(a), where the SMBG is most cost-effective for patients using insulin and less cost-effective for those not using insulin. This is illustrated in Figure 5(b). Now there are choices. You can choose \$0.76 but will only get coverage or approval for use in patients using insulin and will sell Q_1 , or they can choose \$0.30, and get wider coverage, including all patients with diabetes—insulin and non-insulin treated patients.

FIGURE 5: (A) CURRENT PRICING OF TEST STRIPS IN CANADA (DASHED LINE), (B) VBP OF TEST STRIPS AT COST-EFFECTIVENESS THRESHOLD OF MARGINAL SUB-GROUP (I.E., NON-INSULIN TREATED DIABETES)

(a)



ix The exact value for P^* is not calculated here. It is less than the list price.



Theoretically, the principles of value-based insurance design can also be used for drug coverage in Canada. Value-based insurance design creates demand-side incentives for providers and patients by allowing access to high-value drugs at little or no co-payment.⁵² Co-payments for drugs are allowed in most provinces, given drugs are not an insured service under the Canada Health Act.²² This principle is already being applied in Canada, where patients are being asked to pay co-payments for brand drugs when generic drugs are available. It exists in B.C., under a reference-based pricing scheme, where the use of reference drugs is promoted through lower co-payments. For many public drug plans, assigning different co-payments in relation to value would require changes in legislation or ministerial authority. Some other public drug plans do not have the remit to charge co-payments to their plan recipients. There is compelling evidence to suggest patient copayment interventions decrease non-preferred drug use, reduce overall insurer costs, and increase patient out-of-pocket expenses.⁵³

Without a formal linkage of prices of health technologies to the therapeutic value to patients and the broader Canadian healthcare system, investment incentives for manufacturers are distorted. There exists some evidence that strategies of developing second-in-class drugs have higher payoffs for manufacturers.⁵⁴ In theory, value-based pricing should incentivize the development of health technologies that are more likely to be of value to Canadians, particularly in areas of unmet patient need. Overall, this alignment of incentives with value should send stronger signals to manufacturers about which treatments are of value to Canadians and are likely to produce greater revenues, while at the same time improving long-term health outcomes and access to health technologies.

4 CHALLENGES OF IMPLEMENTING A VALUE-BASED PRICING SYSTEM

4.1 WHOSE VALUE?

Health systems that function within a liberal democracy have goals that will sometimes appear conflicting. As suggested by Hausman, the key responsibility of government is to “create an environment that secures fundamental interests, including the fundamental interest in being able to pursue one’s personal interests.”⁵⁵ This means government has an important responsibility to ensure people have the ability to achieve their health goals. An examination of similarities in health policy objectives in OECD countries reveals a similar pattern of common objectives that reflect concerns about justice: adequacy and equity in access; income protection; freedom of choice for consumers; and appropriate autonomy for providers.⁵⁶

Despite the need for providing opportunities and choice, public providers of healthcare must additionally concern themselves with ensuring value for healthcare money spent. Health technology assessment has supported value-for-money assessment by examining how technology can affect health outcomes and consumer satisfaction given budgetary constraints. Governments must equally consider questions of how money spent on health may affect opportunities for societal benefit from other government programs, like justice and education.^{56, 57} Importantly, these tradeoffs are not as simple as fewer resources for increased provider autonomy. Increasing choice in the healthcare sector may reduce choices in other sectors.

It has been suggested that HTA, as currently performed, may not reflect or measure other important sources of societal value. Some have suggested economic evaluations in HTA do not incorporate relevant societal or other impacts from health decisions—for example, the potential impact on private sector investment in research and development from decisions to fund.^{31, 58} Since higher prices and positive reimbursement decisions provide a larger share of the economic value (i.e., social surplus) for producers, some have suggested the effect of lowering price on stifling future technology innovation should be a consideration of policy-makers.^{34, 58-60} Others have suggested that producers have sufficient incentives under certain conditions to innovate⁶¹ and that paying premiums for new technologies based on anticipated (rather than current) benefits does not make good sense.²⁸ A recent report by CADTH suggested that paying premiums for a product that is “innovative” “... will not encourage Canadian innovation through research activities and will otherwise misalign incentives for efficient development; damaging not enhancing future innovation.”[*in press*, personal communication, Don Husereau]

Others have suggested issues of equity, social justice, patient autonomy and fairness are not incorporated into conventional HTA-based economic evaluations.⁶² For example, economic evaluations do not typically distinguish between additional health gained by the very old (for which there is precious little health remaining) or for the very sick (who may value small health gains to a greater extent). Other criticisms of HTA relate to the lack of consideration of the quality of life of caregivers and benefits achieved through enhancing patient compliance. While debate on the merits and failings of HTA centre around methods employed in the economic evaluation of new technologies (mostly drugs), many HTA organizations have adopted approaches that attempt to mitigate these criticisms. The use of patient input or citizens’ councils to capture value beyond clinical and cost-effectiveness has become widespread practice in the evaluation of pharmaceuticals in Canada. Several recommendatory committees also feature “public” members, so that public policy recommendations consider other social values.

One criticism of using patient and public input is that it does not improve the reliability of listing decisions. This is a particular problem for manufacturers, who must reliably project the returns from their research and development decisions. Going from a list/no-list model to a value-based pricing model will not circumvent this problem. Manufacturers of pharmaceuticals still require a reasonable expectation of what price and population they can expect to sell their products to at market launch. One solution that has been suggested is for public payers to use a program budgeting marginal analysis (PBMA)^x approach when making budget allocation decisions. This has been used successfully in several Canadian jurisdictions for reducing net expenditures.⁶³ PBMA allows for a transparent and simultaneous consideration of diverse healthcare objectives: clinical effectiveness, efficiency, equity, and fairness. This approach would enable consideration of elements of value not captured by traditional economic evaluation, while at the same time incorporating opportunity cost considerations—value of benefits foregone as a result of making a decision. It does pose problems for public policy-makers, however; PBMA approaches require additional resources and might lead to a level of inflexibility that is politically undesirable. For example, the values reflected in PBMA may change with shifting political agendas or evolving population demographics, or may fail to capture value unique to particular medical technology products.

The formal use of HTA in price negotiation is attractive in principle, but it may be costly and difficult to implement. The resources may not be available in Canada to undertake detailed value-based pricing assessments of all health technologies. Moreover, there may be difficulties in conducting assessments of similar and sufficient quality. Therefore, it may make sense to prioritize value-based pricing assessments towards health technologies that have a significant budget impact and for which there is a large price differential over other available technologies. For example, an assessment of the value-based price of biologics for rheumatoid arthritis may be considered reasonable. Biologics are among the largest expenditure in public drug plans and the price of biologics greatly exceeds that of conventional therapies for rheumatoid arthritis. In contrast, it probably does not make sense to undertake a thorough assessment of health technologies that have a small budget impact and where the price is similar to other similar technologies offered currently.

4.2 IS PRICE ALWAYS RELEVANT?

Under certain conditions, the price of drugs may be less relevant, as the share of the value appropriated to consumers will never be realized or be extremely small. One condition is if the price of the technology being provided is never reduced, because the patent is extended indefinitely (and assuming the monopolist wants to maximize their surplus) or when the introduction of a similar technology at a greatly reduced price (like 25%) cannot be achieved. The latter is the case with subsequent entry biologics, also called “biosimilars,” for which regulatory processes in Canada and internationally are still provisional and evolving.

Another condition is if the net health benefits (health benefits after accounting for opportunity costs) are excessively low. In theory, value-based pricing allows payers the opportunity to bargain with producers so that net health benefits are zero or positive. However, if a monopolist is unwilling to change the price of the product, and a consumer elects to pay for it, the producer may recoup all of the value associated with the technology. There may be very good reasons not to lower a price, even if it represents poor value. Situations may arise where the producer of the technology is aware that the new drug may be used off label in an

x Program budgeting and marginal analysis (PBMA) is a process that helps decision-makers maximise the impact of healthcare resources on the health needs of a local population. It weights the costs, risks, and benefits of various resource allocation decisions for a given set of resources (i.e. fixed budget). The approach relies on two fundamental economic principles: opportunity cost, or the forgone benefits of the next best alternative use of a given set of resources, and marginal analysis, which examines the incremental costs and benefits of shifting resources from one area to another, to provide insight into whether changes should be made.

entirely different setting, producing a much higher net-benefit. However, if the payer is more narrowly focused on the licensed market indication, the producer potentially loses an unfair share of the surplus by selling a drug that leaks into other markets. Similarly, with the advent of parallel imports and cross-border vending of pharmaceuticals, producers may need to consider other losses in revenue from in-Canada prices.

4.3 COST-EFFECTIVENESS THRESHOLD

The cost-effectiveness threshold represents a point at which additional costs will require the health system to forego opportunities for health due to the additional costs required to fund the drug. As such, it is, i.e. it can be thought of as the maximum price that a decision maker should be willing to pay for a QALY.⁶⁴ The cost-effectiveness threshold plays a critical role in value-based pricing since funding drugs above the threshold will lead to net health losses. In Canada, a cost-effectiveness threshold for healthcare reimbursement decisions has never been formally evaluated. A threshold of \$20,000–\$100,000 per QALY has been suggested.⁶⁵ However, an analysis of listing recommendations between the years 2003–2008 revealed a majority of positive decisions based on cost-effectiveness were associated with ICERS below \$100K.⁴⁹ Use of cost-effectiveness thresholds in healthcare resource allocation decisions in Canada is controversial, as estimates are not based on empirical evidence and using them for decisions may not lead to optimal resource allocation decisions.⁶⁶ However, empirical evidence on cost-effectiveness thresholds is emerging from other countries. For example, studies have been undertaken to reveal decision-maker thresholds for cost-effectiveness in the U.K.^{67, 68} These have led to suggestions that previously stated thresholds of £30 000 per QALY may be too high.^{67, 68} Similar empirical research is needed in Canada for value-based pricing to emerge as a viable policy option.

4.4 QALYS

While the use of QALYs in resource allocation decisions does allow health system choices to be made explicit, it is far from a perfect outcome measure.⁶⁹ There are several limitations to the QALY that will have to be considered when using HTA to establish prices of medical technologies. Issues of equity, social justice, patient autonomy and fairness are not incorporated into QALYs. For example, each QALY gets equal weight and there is no distinction between QALY gains by age or disease severity. Issues related to unmet need are also not incorporated in QALYs—i.e., placing greater value on health technologies that treat diseases for which no therapy is previously available. As the U.K. moves forward with plans to implement value-based pricing, discussions regarding the role of QALY measures continue. In the last several years, the public body for assessing and appraising drugs in Germany (the Institute for Quality and Efficiency in Health Care, IQWiG) has adopted a system for estimating the value of new medicines that is less reliant on QALY measures.

If pharmaceuticals have a significant impact on elements not captured in the QALY, these benefits may have to be incorporated into the price negotiation either formally (e.g., alternative QALY weighting) or by other methods. In 2010, CADTH developed a patient input process into its CDR program. Similar mechanisms were introduced in Ontario and B.C., and are under development in the new pan-Canadian Oncology Drug Review process. The Ontario government has also developed a citizens' council, where Ontarians discuss and provide their opinions on the values that reflect the needs, culture and attitudes of Ontario citizens about government drug policy. Information from these processes could help inform price negotiations of medical technologies.

4.5 MANAGED ENTRY AGREEMENTS

Price negotiation as it is currently practiced is often linked to managed entry agreements. Managed entry refers to the process of payers working with industry to manage the way that new therapeutics are brought into the market. These are also called risk-sharing arrangements, value-based pricing, pay-for-outcomes, conditional coverage, coverage with evidence development, and performance-based pricing.⁷⁰ Prices can be linked to future outcomes, future volumes, or both, to give payers and producers some assurance of future economic value. The price and the conditions of listing are then drawn up into a product listing agreement.²⁷

There has been a great deal of interest in this approach because it satisfies producer and payer needs for revenue (and access) while reducing uncertainty of budget impact or value for money.²⁶ Producers are particularly interested in not having to lower a list price, which can then be referenced and have impacts on parallel trade and research and development. Managed entry agreements provide both parties with a larger menu of options than simply negotiating on price. Information on experiences in Canada and abroad was developed for a recent round table by the Institute of Health Economics (IHE).²⁶ The findings of this discussion suggest that both producers and payers recognize the necessity of these arrangements, and need to be prepared to strengthen the approaches to developing agreements in years to come.²⁶

4.6 HEALTH RESEARCH ENVIRONMENT AND INFRASTRUCTURE

HTA in price negotiation requires an environment that marries applied health research with policy-making. HTA-based price negotiation will require significant intellectual capital in the form of highly trained and experienced policy scientists with discipline-specific training in clinical epidemiology, health services research, information science, health informatics, political science, ethics and health economics, as well as structures required to support them. There are currently very few opportunities in Canada for HTA-specific learning. Few universities currently have graduate programs with HTA specialties. Additionally, if assessment of technologies occurs *ex post* (i.e., after the launch of a product or service), the use of real-world information to measure and evaluate services and products will be required. Although Canada has an “information-rich” environment,⁷¹ with registries, discharge abstracts, and administrative physician and drug utilization databases, coordination of these environments for the purpose of assessing value of fees and services will be required.

Efforts are underway to strengthen this research infrastructure in ways that would improve the information available for tracking value delivered. The Canadian Institutes of Health Research recently announced its Strategy for Patient-Oriented Research, which is intended to: improve the research environment and infrastructure; set up mechanisms to better train and mentor health professionals and non-clinicians; strengthen organizational, regulatory and financial support for multi-site studies; and support best practices in healthcare.⁷² Additionally, in 2007, the federal government announced \$32 million over five years and \$10 million per year ongoing to establish the Drug Safety and Effectiveness Network (DSEN). In February 2011, the DSEN announced the establishment of two collaborative centres for research: the first is focused on active surveillance and prospective studies and the second is focused on innovative methods for comparative analysis.⁷³

4.7 INTERNATIONAL REFERENCE PRICING

Companies operate within international pricing frameworks. Canada is one of many countries used in external referencing of prices, and the list price of a technology in Canada may impact the price of the identical technology when sold in other foreign countries. This means that lowering prices in Canada will have a multiplier effect on reductions in the producer surplus. This in turn could translate into less investment in research and development (globally, and in Canada). Consequently, companies may be unwilling to lower their list price in Canada to match the value-based price identified in the HTA.

In the short term, however, the Canadian healthcare system has a stake in negotiating lower prices of health technologies for Canadians—lower prices means more health technologies and services, increased access, and improved health outcomes. Based on this, individuals who are negotiating prices with companies may allow companies to retain their official list price (sometimes this may be higher) even though a lower price was negotiated.²⁵ If negotiations do not happen at a pan-Canadian level, this may result in price inequities across individual jurisdictions within Canada. In fact, this has been an issue for Product Listing Agreements (PLA)²⁵ in Ontario and provinces to investigate whether they have been treated unfairly as a result.²⁵ However, this issue could be alleviated if a pan-Canadian price negotiation mechanism is created. In 2010, at the Council of the Federation Meeting in Manitoba, Canada's Premiers announced that the provinces and territories were working to establish a pan-Canadian purchasing alliance for drugs and medical supplies.⁵ In the long run, the broader effects of pan-Canadian price negotiation on R&D and the Canadian economy will require careful consideration.

4.8 GENERICS

Concerns have been expressed regarding the comparison of on-patent brand name medicines with generics when conducting HTAs because this may disincentivize manufacturers for developing technologies.²⁸ Ignoring relevant generic comparators, however, would have a negative effect on the health of Canadians. It would have the same effect as paying higher prices, shifting the share of the value of innovation (i.e., the social surplus) away from consumers (i.e., funders of public pharmacare) toward producers. The use of HTA in price negotiation has the potential to provide incentives for innovation and improve health³², by freeing available resources (see Box 2) which can then be used to fund additional healthcare technologies, and by encouraging innovators to target areas of unmet patient need.^{28, 74}

A brand premium has been recommended by the Office of Fair Trading in the United Kingdom, even if there are no differences in clinical benefits between brand and generic comparators. This recommendation was motivated by two considerations: recognizing benefits that have not been demonstrated formally in randomized control trials for pragmatic reasons (e.g., large sample size requirements) but are plausible; and to ensure the stability of the generics market. For example, if brand name drugs are priced at parity with generics, physicians may always prescribe the brand name product, which in turn may destabilize the generic drug industry. A vibrant and stable generic drug industry is vital to ensuring healthcare system sustainability. Consequently, Canada may wish to offer a brand premium similar to those imposed in other countries. The Swedish pricing authority LFN, for example, offers a premium of 25%, even if products are clinically equivalent.⁴⁵ The United Kingdom has recommended a premium of 50%, although this has yet to be introduced.²⁸

BOX 2: IMPACT OF GENERIC DRUGS ON VALUE-BASED PRICES OF BRAND NAME MEDICINES

There have been recent changes to generic reimbursement rates across various public drug plans in Canada. Ontario has reduced the generic reimbursement price to 25%. B.C. has dropped its rate to 35% and Alberta has dropped its rate to 45%.^{75, 76}

Under a value-based pricing scheme, changes to the prices of generic medicines could also affect the prices of on-patent medicines. Essentially, the prices of all on-patent products—where generic comparators are available (e.g., statins)—could, in theory, be affected. For example, if an on-patent HMG CoA reductase inhibitor (statin) was required to demonstrate its therapeutic value in relation to generic statins (at new generic prices rather than old prices), the cost per QALY estimates for this on-patent statin would be much higher.

To improve cost-effectiveness estimates (i.e., bring down cost per QALY values to within cost-effectiveness threshold), the price of the on-patent statin would have to be reduced. In some cases, the prices would have to be reduced substantially to demonstrate value. In light of the significant expenditure on on-patent statins in public drug plans in Canada, the cost savings realized through this value-based pricing process would be substantial, even if a “brand premium” of 25% to 50% were applied over the generic comparators.

4.9 RARE CONDITIONS

Frameworks for evaluating treatments for rare diseases have been debated nationally and internationally.^{77, 78} Some argue that different policy frameworks are needed for rare diseases.⁷⁷ Others argue that treatments for rare diseases should be treated the same way as other technologies.⁷⁸ The justification for a special framework has been prompted by concerns that: 1) drugs for rare conditions demonstrate consistently low value-for-money compared to other new drugs based on traditional economic evaluation methods; 2) clinical data are often too sparse to allow for estimates of cost-effectiveness; and 3) QALYs do not sufficiently capture disease severity or unmet need. The challenges are considered unique to these drugs and have been attributed to the high costs of developing a drug for a rare disease because of the small market sizes and high production costs.

However, some of these issues are also relevant to more common diseases. As such, some argue against having a separate framework for rare diseases because it would be inequitable and unjust. It is beyond the remit of this paper to establish whether an alternative pricing framework is warranted for rare diseases in Canada. However, it seems apparent that using HTA in price negotiation of medical technologies for rare diseases will pose some interesting challenges. Nevertheless, payers will have to pay very close attention to agreed-upon prices for these technologies. Given the small market size, generic entry may be limited and public payers may end up paying high prices for these products indefinitely.

4.10 EX-ANTE AND EX-POST ASSESSMENT

Although consistent attempts are made to predict the value of a new good or service prior to its launch (i.e., *ex-ante*), many jurisdictions internationally have developed methods to re-assess the value post-launch (i.e., *ex-post*). This is because predicting the value of a good or service in the real world is difficult: the evidence-base may be lacking or difficult to generalize to a Canadian population or unpredictable effects of technology adoption may occur. Performance-based agreements linked to pricing are attractive to manufacturers, as they do not delay revenue generation, and attractive to policy-makers, as patients are given immediate access to licensed medicines. Ontario has recently announced “conditional” access to certain cancer drugs, where access will be granted to medicines conditional to the performance of a drug in the real world.⁷⁹

The uncertainty about performance at the time of adoption reduces the value proposition of any new drug and can be factored into the price of adoption. (See Claxton³³ and Box 3, below.) *Ex-post* assessment provides opportunities for decision-makers to evaluate previous decisions, particularly when there is considerable decision uncertainty. Canada has shown leadership internationally by providing access to health technologies as real-world evidence is still being captured (also known as conditional access with evidence development).⁸⁰ This is notable in Ontario, through the Medical Advisory Secretariat Field Evaluation Program, where the value of reducing uncertainty through ex-post assessment not only provides additional information for future re-assessment, but enjoys widespread policy uptake when providers are intimately involved with the design and implementation of research.

Additionally, ex-post assessment allows technologies that were never previously evaluated to be assessed (when comparing new service A to existing services B and C), as they may be of particularly low value and lead to health system inefficiency.^{81, 82}

BOX 3: VALUE OF INFORMATION (FROM CLAXTON, 2011³³)

The value of access to a new technology with uncertain benefits and the value of additional evidence about the technology are illustrated in the table below.

FIGURE 6: THE VALUE OF EARLY ACCESS AND THE VALUE OF EVIDENCE. TWO TREATMENTS ARE COMPARED: DRUG A (CURRENT TREATMENT) AND DRUG B (NEW TREATMENT).

	NHB, QALYS (DRUG A)	NHB, QALYS (DRUG B)	MAXIMUM NHB, QALYS
1	4	1	4
2	10	10	10
3	16	22	22
AVERAGE	10	11	12

Value of Access Value of Evidence

NHB=Net Health Benefit
QALYs=Quality-adjusted life-years

In this example, on average, the net health benefit of the new technology (NHB(B)=11) is expected to be greater than current treatment (NHB(A)=10), so at current prices, early access to the new technology is expected to offer one additional QALY per patient. However, this assessment is uncertain (represented by the three possible resolutions of NHB) and there is a chance that the new treatment may not be cost-effective, i.e., a probability of 1/3.

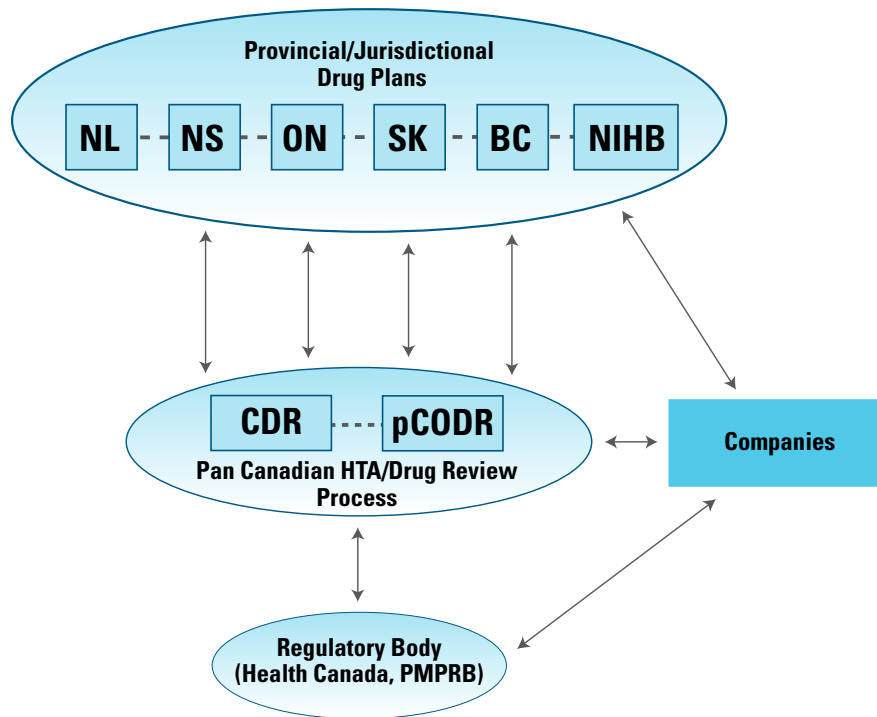
If more evidence could be acquired to resolve this uncertainty then better decisions could be made, improving net health benefit (Max NHB=12, as shown in the final column). The upper bound on the value of additional evidence is the difference between the best that can be done if the uncertainty could be resolved and the best that can be done if decisions are based on existing information, i.e., also one QALY per patient.

Therefore, evidence about the performance of a new and effective technology is valuable for the same reasons as access to it: both improve health outcomes and the value of evidence may be as great, or greater, than the value of the technology itself.

5 MOVING FORWARD WITH HTA-BASED PRICE NEGOTIATION IN CANADA

All of Canada's public drug plans currently use a formulary system informed by HTA to manage drug expenditures. Some jurisdictions have the capacity to conduct HTA while others can access HTA information and advice from coordinated HTA processes (e.g., Common Drug Review (CDR), The pan-Canadian Oncology Drug Review (pCODR)). Value-based price negotiation, informed by HTA, is already occurring in some individual provinces and other provinces are expanding their capacities in this area. The manufacturer list price, which is influenced by PMPRB guidelines, is usually a starting point for price negotiation. In some cases, a confidential price is submitted to pan-Canadian drug review processes to influence listing recommendations. Currently, drug manufacturers work with regulators, HTA bodies and individual provinces for market access and reimbursement (Figure 7).

FIGURE 7: CURRENT USE OF HTA IN PRICE NEGOTIATION OF PHARMACEUTICALS



5.1 MAIN CONCERN/PROBLEM

Formulary systems informed by considerations of cost-effectiveness measures are a common and effective policy tool to manage growth in drug expenditures.^{53, 83} However, if a drug is perceived as having low or uncertain value for money by a payer, it may not be listed on a public plan formulary; this leads to reduced access and high out-of-pocket expenses for patients who would like the medication and challenges prescriber autonomy. This may in turn lead to political pressure to reimburse drugs that are not cost-effective.⁸⁴ Value-based price negotiation can be used as an alternative or complementary approach to existing formulary management policies. It provides more flexibility than formulary systems for payers to provide access to patients and providers and has demonstrated the potential to further reduce growth in expenditures in a Canadian setting.²⁶ Because the value of a new drug is also linked the uncertainty surrounding its actual cost-effectiveness, price negotiation linked to real-world assessment systems provide additional options for payers and drug manufacturers to where reimbursement can be linked to real-world drug performance or impact on health outcomes.

Currently, many provinces lack resources, capability, legislative authority and price negotiation levers, in terms of volume of drug utilization, to be able to negotiate prices with drug manufacturers. Even among those provinces that negotiate prices, better prices might be realized in provinces who are first to negotiate or who have different industrial sectors. This decentralized process provides opportunities for “whipsawing.” That is, lack of substantial coordination of price negotiation means smaller jurisdictions may be pressured to pay the list price of a drug and this price may be overvalued by manufacturers that are seeking to maximize revenue. The process is not symmetrical, in that jurisdictions will never be challenged to lower the price of a good or service when a comparison reveals they have overvalued the price of a good or service. Overall, this lack of coordination can lead to overpricing and unnecessary expenditure on pharmaceuticals, especially in drug plans which have limited purchasing power.

There are also challenges to the current approach for the manufacturer. Manufacturers who currently wish to negotiate prices must do so individually with each jurisdiction that has the capacity to do so. This process is timely and requires resources. Moreover, a lack of a systematic, coordinated approach leads to difficulties in predicting the successful uptake of a new drug between drug plans, and does not provide clear, uniform, pan-Canadian signals to manufacturers regarding what the health system is willing to reimburse.

5.2 PROPOSED OPTION

One proposed option is to adopt a system that harbors two distinct features: 1) pan-Canadian coordination, to reduce the potential for whipsawing; and 2) real-time evaluation of the drug value and feedback, to create more opportunities for negotiation. To effectively coordinate price negotiation, a new body, governed or endorsed by Canadian public drug plan managers is required to conduct these negotiations on behalf of the provinces. Although some may perceive this as an expanded role for the PMPRB, this may not be a realistic option given its federally legislated remit and that reimbursement is a provincial responsibility. The Common Drug Review and the pan-Canadian Oncology Drug Review and their associated interim bodies are good examples of how provincial/territorial processes can be built (relatively) quickly and efficiently on existing provincial/territorial processes without the need to reinvent or create a separate federal/provincial/territorial entity. A joint process could theoretically be hosted within a province where price negotiation already exists, such as Alberta, British Columbia, Manitoba, or Ontario. However, legislative changes, which take some time to occur, might be necessary to allow a single body to conduct price negotiation on their behalf (see Figure 8).

The price negotiation mechanism would be linked to a separate research entity that provides information on drug performance. The research body would be analogous to province-based research groups and linked to existing institutions that focus on collecting and analyzing drug performance information, such as the Institute for Clinical and Evaluative Sciences. This system could build on current initiatives, including possible regulatory reform to monitor health products throughout their “lifecycle” and Canadian Institutes for Health Research (CIHR) initiatives to promote applied health research capacity and its environment, including a soon-to-be-announced collaborative centre for monitoring drug safety and effectiveness. It can also build on and provide direction to the collection and analysis of health information at the Canadian Institute for Health Information (see Figure 8).

5.3 BENEFITS

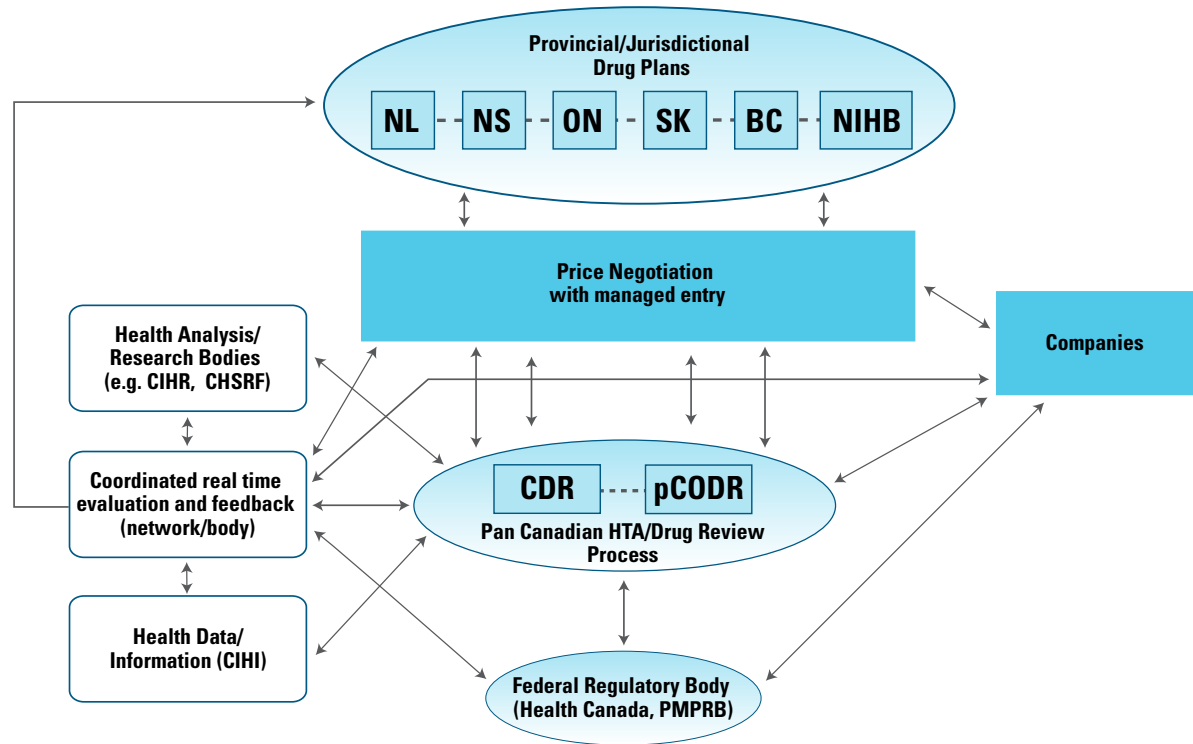
The development of a single, coordinated price negotiation body would help reduce inequity across jurisdictions by leveraging buying power and macroeconomic factors of provinces with larger drug budgets (e.g., Ontario) to those provinces with much smaller budgets and smaller industrial incentives (e.g., New Brunswick). It would also promote a standard and coordinated approach to the evaluation of price which would provide a strong signal to drug manufacturers regarding which interventions are legitimately valuable to society and which are not (Figure 8). The single price negotiation body could also serve the following functions: (i) Process for determining which drugs would require price negotiation, (ii) Development of criteria for what constitutes good “value” and how this will be translated into a price negotiation and convey this information to manufacturers, and (iii) have legislative authority to negotiate price on behalf of other provincial (and federal) jurisdictions and to keep negotiated prices confidential.

Given the current uncertainty regarding the real-world effectiveness of pharmaceuticals, and the desire by regulators and payers to provide access and “conditional” access as early as possible, a price negotiation mechanism tied to real-world assessment will enable more options for price negotiation. Real-world assessment of drugs will facilitate strengthening capacity to conduct discipline-specific research and the structures required to support it. Coordination should lead to improved methods for evaluating health system performance. An improved research environment will also provide incentives for private sector innovators to invest in Canada and economic incentives for Canada’s “Knowledge Economy.”

5.4 EXPERIENCE/SUCCESS

Value-based pricing linked to HTA is already occurring across Canada with several provinces working on systematic approaches to innovative agreements. HTA appears to be the most appropriate and available policy tool for measuring and rewarding value and informing policy decision-making, although there is room for improvement. There is existing HTA capacity currently available through province-specific and coordinated bodies, although increased capacity and training in HTA will be necessary. There is also growing experience with managed entry linked to price negotiation, where drug performance is assessed in a real-world setting based on existing health information systems.²⁶ More complex real-world assessments require significant capacity in applied health research, of which Canada has considerable capability, and this is likely to improve with the current and future direction of the Canadian Institutes for Health Research. There exists significant health information that is collected and analyzed across Canada that could be further used to quickly and thoroughly re-assess outcomes associated with the value of drugs.⁷¹

FIGURE 8: COORDINATED PRICE NEGOTIATION WITH MANAGED ENTRY



5.5 CHALLENGES/LIMITATIONS

While there are advantages to having a central body negotiating prices and managed entry agreements, this more coordinated process will require an explicit recognition of the amount of value society is willing to give up, as additional resources that could be used for other government programs including healthcare (and even, investments in business development) must be used to accommodate costs of health purchasing decisions. Price is also linked to the future economic value of technology, and societies must decide what share of value they are willing to give up to support an adequate future global supply of pharmaceuticals. Without an explicit recognition of opportunity cost, either through empirical study or through clear communication from policy-makers as to what factors constitute good value, manufacturers lack clear incentives for innovation and may shift resources to lobbying efforts.

The downside of declaring social value is that it is imperfect, may not adequately reflect important population heterogeneity, and may need frequent updating with shifting politics or demographics. Moreover, a single price across Canada implies common Canadian values. However “value” captured through HTA may encompass demographic and political concerns that change by province and over time, making common price negotiation difficult. Health systems across Canada differ in design, delivery and related costs. Practice patterns differ, too. This means that different decisions (with respect to

price) may be appropriate or consistent with regional realities in their own health systems. A national negotiation process would need to consider this. Similarly, it has also been suggested there must be a trusted relationship between researchers and policy-makers.⁸⁰ This means that although a research entity could exist entirely within a single province, drug performance information gathered from across a representative sample of jurisdictions will have more credibility.

6 CONCLUSIONS AND RECOMMENDATIONS

The development of a single, coordinated price negotiation body would help reduce inequity across jurisdictions by leveraging the buying power and macroeconomic factors of provinces with larger drug budgets to those provinces with much smaller budgets and smaller industrial incentives. It would promote a standard and coordinated approach to the evaluation of price and provide a strong signal to drug manufacturers regarding which interventions are legitimately valuable to society and which are not. A price negotiation mechanism tied to real-world assessment would allow for even more options for price negotiation. Real-world assessment of drugs would increase the capacity to conduct discipline-specific research and strengthen Canada's knowledge economy.

The proposed option is to adopt a pricing system with two distinct features: 1) pan-Canadian coordination, to reduce the potential for whipsawing; and 2) real-time evaluation of the drug value and feedback, to create more opportunities for negotiation. The single price negotiation body should also have the following functions: (i) a process for determining which drugs would require price negotiation, (ii) criteria communicated to manufacturers regarding what constitutes good "value" and how this will be translated into a price negotiation, and (iii) legislative authority to negotiate price on behalf of other provincial (and federal) jurisdictions and to keep negotiated prices confidential.

The formal use of HTA in price negotiation is attractive in principle. There is good evidence from Canada and abroad that HTA-based price negotiation is an effective and accepted mechanism for determining reimbursement prices. A coordinated system of price negotiation and managed entry in Canada is feasible. It could be built on existing provincial processes, applied health research and HTA capacity. This would require the creation of a new pan-Canadian body governed by and with the full participation of Canada's public drug plans. The negotiation body must be linked to or embody a research entity that is able to collect information regarding drug performance from across each of Canada's health systems. Value-based pricing linked to HTA is already occurring across Canada. Several provinces are individually working on systematic approaches to price-negotiation mechanisms. Sufficient HTA capacity is currently available through province specific and coordinated bodies. There is also sufficient capacity to conduct real-world assessment, and that capacity is on the rise through province-specific and national initiatives, such as those from the Canadian Institutes for Health Research (CIHR), including a soon-to-be-announced collaborative centre for monitoring drug safety and effectiveness, resulting in reductions in net expenditures.

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APPENDIX A: LIST OF PARTICIPANTS IN SEMI-STRUCTURED INTERVIEWS

LAST NAME	FIRST NAME	AFFILIATION	
Bryan	Stirling	Director	Centre for Clinical Epidemiology & Evaluation, Vancouver Coastal
Ferdinand	Mark	VP, Policy Research and Analysis	Rx&D
Frank	Stephen	Director of Policy Development and Analysis	CLHIA
Fraser	Brent	Provincial Drug Plan Manager	Ontario
Hoch	Jeffrey	Health Economist	Ontario/CCO
Lun	Eric	Provincial Drug Plan Manager	British Columbia
Palmer	Rocky	Drug Plan Manager	Federal Drug Plans

APPENDIX B: SEMI-STRUCTURED INTERVIEW GUIDE

The interview begins with the interviewer stating the purpose of the interview, the topics that he wants to explore and the depth of response expected.⁸⁵ Identification of literature and interviews were conducted by a single individual.

PURPOSE

Interviewer: The purpose of today's interview is twofold:

1. It will help to create an understanding of current and past activities undertaken in your jurisdiction in regards to the use of HTA in price decisions including the successes and challenges of these activities that you are aware of
2. To explore future needs of the use of HTA in pricing decisions

As you might already know, CHSRF is an independent, not-for-profit organization with a mandate to promote the use of evidence to strengthen the delivery of health services in Canada.

The current initiative which has been undertaken as HTA was identified as a potential solution to curb healthcare expenditure and value-based pricing is a way in which HTA has been used successfully. The discussion paper will be used as the basis of future discussion among key stakeholders with the view of using evidence to create change in the health system.

Interviewer: I would like to cover a few topics today that will help answer the question concerning how HTA is currently used to inform pricing decisions and how it could be better used in the future.

In each case, I will try to describe how much feedback is needed. However, I want to encourage you to speak freely in response to each question, even if you feel it doesn't directly address the question. We will have 30 minutes for discussion.

QUESTIONS

Value-based pricing has several definitions but for the purposes of our discussion it is an attempt to have the price of a good or services reflect the value of the good or service.

1. Do you personally think the use of HTA to inform price is important? (Touring question)
2. Can you tell me what is currently happening in your jurisdiction in regards to Value-Based Pricing? (Touring Question)
3. In an ideal world what kinds of things could be in place in the future to facilitate the use of HTA in setting prices?
4. Permission to Use Name, Interviewee demographics