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Valuing health in Canada

Who, how, and how much?

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Foreword

This is the second analytical commentary that Canada 2020 has produced in the health area. The two papers share much in common. Both draw on the experience of the UK – a country that wrestles with many of the same healthcare concerns as Canada does – and both seek to inject new vigour into the debate about the future of our health system.

The issue that this paper addresses – namely which treatments and services are and should be publicly funded in Canada – is of enormous importance, both to patients themselves and also to the sustainability of the system. The discrepancies in coverage that exist within Canada are, rightly, considered by many Canadians to be unjustifiable. This paper gets to the heart of the rationale for making coverage decisions, emphasizing, in particular the importance of considering cost effectiveness – in an absolute not a relative sense – and of explicitly including public input into the decision-making process.

The author explains the concept of Quality Adjusted Life Years (QALYs) and how these can be used to compare different spending options in a meaningful way. So often the choices policy makers are asked to take appear intractable. Options appear incommensurable: it is like comparing apples to oranges. The QALY measure attempts to make sense of this challenge in a dispassionate and transparent way.

But even with this tool in one's pocket, the process of determining coverage will be fraught with difficulty. Monetizing health, effectively asking people to accept a financial valuation of their quality of life, raises ethical and practical issues. It inevitably pits patient groups against each other. Governments understandably do not relish this. But, ultimately, it makes more sense to lay out and refine a process over time, so that it becomes widely defensible, than it does to hide one's head in the sand and rely on precedent, spiked with media-fed lobbying, as a guide.

We hope that this paper will contribute to the ongoing debate in Canada about how best to provide public healthcare in a financially constrained environment, in which the population is also rapidly aging. It is intended, as most Canada 2020 papers are, to act as a starting point for discussion. We hope that you will join that discussion: as always, we look forward to hearing your views.

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1. Introduction

Canadians have long considered health to be a national priority. Reflecting this, between 1997 and 2010 health spending rose from 7.9% to nearly 12% of GDP (about \$200 billion).¹ But provincial budget constraints and the capping of the growth of federal health transfers, are forcing Canadians to grapple with how to value health.² In a publicly funded system with a finite budget, what should be funded, and what should not?

Recent controversies have brought increased public scrutiny to drug and health technology coverage decision-making.³ When coverage for particular drugs has been rejected, activist groups or individual patients have taken to the media, focusing public attention on patients' personal circumstances and, sometimes, succeeding in pressuring governments to change course.

Take, for example, the case of an Ontario woman who was denied coverage for a \$40,000 drug for breast cancer treatment that would likely have been provided in other provinces. After mounting a strong media campaign, which garnered national attention, her case was debated at Queen's Park, forcing the Minister of Health and Long-Term Care to state that the province "cannot have a health system where the stories that land on the front page of the paper determine our health-care policy".⁴

In another case a man was denied drug coverage for prostate cancer treatment on the grounds of low cost-effectiveness, despite lobbying by his oncologist and patient rights groups. The patient made a statement to the Minister of Health, asking: "What's my life worth to you?"⁵ Similarly, a Vancouver man was initially denied treatment for a potentially life-saving treatment that would cost \$500,000 annually (and that was covered at the time in the province of Quebec).⁶ He took his case to the media. Soon after, at a meeting of Canada's premiers, it was announced that a pan-Canadian agreement had been reached to fund the treatment for all who needed it.⁷

It is not surprising, then, that online discussions are replete with Canadians debating what should or should not be covered, with much concern being expressed about how unfair or arbitrary decisions seem, especially when they vary by province.

This perception derives partly from the opaque way in which health authorities in Canada typically decide which drugs and technologies should be publicly covered. Bureaucrats appear to lead the process allowing little room for public input.

Recently, however, initiatives such as the public posting of reviews by the Common Drug Review⁸ have attempted to make the process more explicit and transparent, and there are new efforts to involve the public. But what level of transparency and public involvement is feasible, or even desirable in this area?

There is a growing literature on the use of cost-effectiveness analysis in Canadian rationing decisions⁹, but there remains a paucity of analysis on how transparent and inclusive the process is, can be, and potentially should be. This paper begins to address such questions.

First, the theory and literature on health coverage decision-making, and cost-effectiveness analysis in particular, is explored. This is followed by a review of the current coverage decision-making landscape in Canada, including measures of the use of cost-effectiveness analysis, public involvement and transparency. Finally, lessons are drawn from the United Kingdom, where there is a plethora of experience and much innovation taking place around attempts to understand value in healthcare and include the public in the decision-making processes.

2. Making trade-offs: Cost-effectiveness analysis in health coverage decision-making

Canada's ageing population, together with new high-tech (usually high-cost) drugs and technologies, mean that healthcare costs seem to rise inexorably. Each year provincial health authorities attempt to match their annual budgets with the healthcare needs of their populations. The Canada Health Act requires only that provinces provide medically necessary hospital and physician services. Beyond these services, decisions must be made about whether the publicly funded health system should pay for the latest cancer drug, spend more on home-care, or invest in public health activities, for example.

When a decision is made to fund a particular treatment or drug, that money can no longer be spent on another treatment or drug, meaning that some potential health gain may be forgone. How governments go about making these funding decisions has long been debated and studied. A wide range of criteria can be used as part of 'health technology assessments'.¹⁰ The following are some of the most common considerations:

- disease severity: how life-threatening or quality-of-life reducing is the disease?
- size of population affected: is the disease common?
- limitations of comparator interventions: are similarly purposed drugs meeting all patient needs?
- efficacy of the drug or treatment: is the drug more efficacious or effective at reducing illness than comparator drugs?
- improvement of safety and tolerability: is the drug safer or easier to take than comparator drugs?
- public health interest: is there a broader public health benefit? (such as reduced transmission risk to others?)
- completeness and consistency of evidence: are there gaps or large variation in the evidence base?
- relevance and validity of evidence of effect: is the evidence related to the population of interest and in the same treatment context?
- budget impact on health plan: are there savings or additional costs on overall public budgets?; and
- cost-effectiveness: does it cost above or below some dollar level per unit health gain.¹¹

This last criterion, cost-effectiveness, has been especially contentious because in some ways it can be viewed as monetizing health – that is putting a dollar value on how much we value our health.

Cost-effectiveness analysis (CEA) allows, at least in theory, for the comparison of the relative cost (in dollars) and benefits (in health) of two different treatments or drugs. It can help us to measure the net health benefits in different scenarios by asking the question: is the health gain from one treatment or drug greater than the loss in health associated with the displacement of payment and provision of an alternate treatment?

In order to compare health outcomes across diverse people and illnesses, a standardized measure of health, called the QALY, is often used. The QALY, or quality-adjusted life year, is a composite measure of health combining both length of life, and quality of life. Each year in perfect health is given a value of 1.0 QALY. Being dead nets 0.0 QALY, while the range between 0–1 denotes years of life below ‘full’ quality. The gain in QALY from a treatment, and the cost spent on that gain, can thus be compared across treatments using a dollars per QALY measure, also known as the incremental cost-effectiveness ratio, or ICER.

As an example, one study explored the cost-effectiveness of renal dialysis.¹² The study attempted to model the probability of different outcomes (such as transplant rates, hospitalization, well-being when on dialysis, mortality) with or without treatment as well as how much people valued the different health states (the utility they derived), and the financial cost of the dialysis and necessary treatments, such as hospitalization. It was found that, on average, each QALY gained from dialysis cost \$129,090 USD.

Another study on the cost-effectiveness of a particular chemoprevention drug for prostate cancer found each QALY gained cost \$21,781 USD.¹³ Comparing these two figures it would appear that the latter drug provides more health benefits per dollar (as measured by QALYs) and is thus more cost-effective than the former.

2.1 Threshold values

The use of CEA in coverage decisions raises the question: how much should we pay for health? Clearly the prostate cancer prevention drug is relatively cost-effective compared to the dialysis. But deciding whether each drug is cost-effective in the context of the overall health system, rather than just compared to another drug, is an entirely different question. Perhaps both – or indeed neither – are truly cost-effective.

The challenge is to identify the optimal threshold cost per QALY for a given society. Purchasing a treatment that costs more than this threshold cost is inefficient because a cheaper treatment would provide more health per dollar spent. Failing to purchase a treatment that costs less than the threshold is similarly undesirable.

Identifying this threshold level is an extremely difficult task. There are many possible approaches. If a society were first to determine its total healthcare budget (for example what percentage of government expenditure should be devoted to healthcare), we could imagine lining up all new and old treatments in order of cost-effectiveness, and then allocating those treatments in order to those who need them until the budget was exhausted. This would give us the threshold level.¹⁴ At present, this appears to be an unrealistic approach: we simply do not have sufficient information.

Another option would be for a given health system to estimate its existing average cost per QALY, and use that as a threshold level. This approach also requires a great deal of information, but it is being developed as a viable option in the United Kingdom.¹⁵ The threshold approach is already in use to some extent in the UK but it is seen, at present, as somewhat arbitrary and not empirically-based. Efforts are therefore being made to determine a more meaningful threshold level.

We could also attempt to find out what citizens themselves think about how much should be paid for an additional QALY. This 'willingness-to-pay' (WTP) approach may have less relevance in a system such as Canada where health authorities work within a fixed budget. However, it could help shape future budget allocations to health as opposed to other sectors. An international survey found that the average willingness to pay for an additional QALY varied significantly from country to country, from \$36,000 in the UK to \$62,000 in the USA and \$77,000 in Taiwan (USD adjusted for purchasing power parity).¹⁶

Factors that might affect individuals' willingness to pay include cultural beliefs about health, the structure of the health system (who pays), past experience and expectations about which services should be covered as well as expectations about health and longevity.

A fourth approach to identifying the threshold value is for health professionals to come together and reach consensus about how to get the best from a given healthcare budget. This last approach may be the least technical, but is likely closest to the real world experience of many countries. In practice, many threshold values have been proposed, with a range between \$50,000-\$100,000 USD per QALY often being cited in the literature, though these figures seem to have emerged with little purposeful analysis or discussion.¹⁷

In the UK, £20,000-30,000 has been proposed as the approximate cost-effectiveness threshold range for coverage decisions, though again with limited rationale being provided for selection of these numbers.¹⁸ Using such a range, a treatment that costs £80,000 and increases healthy lifespan by 2 years (£40,000/QALY) might not be recommended for coverage. On the other hand, a treatment costing £100,000 which improves an individual's quality of life from ½ of perfect health to perfect health for their remaining 10 years of expected life (0.5 QALYs gained per year for 10 years gives 5 QALYS gained, or £20,000/QALY), would be recommended.

2.2 Concerns about cost-effectiveness analysis

The literature on cost-effectiveness analysis has been growing and details of implementation are being refined. Nevertheless, a number of concerns remain. One relates to the methodological challenges of measuring cost-effectiveness. A great deal of data is typically required. If this is not available, assumptions are made instead. This is a particular problem for rare diseases as data is typically scarce. Other issues include what goes into the cost-effectiveness calculation. Which costs and benefits should be counted? Should costs to society (in lost productivity, for example) be included? How about financial costs of future diseases? Do we include benefits to caregivers? These are important questions that greatly affect the calculations.¹⁹

Moreover, because the costs and benefits of treatments vary by patient, by province, and over time, challenges of using ‘averages’ remain, especially when, for example, the cost-effectiveness of a treatment varies a good deal depending on a person’s age.

Ethical concerns are also important. Some believe that allowing costs to inform treatment decisions is inherently unethical, though it is easy to argue the counterpoint: that it is unethical to ignore costs when different treatments are available and the budget is fixed.²⁰ Other ethical concerns may be more serious: equity and efficiency may be pitted against each other meaning that value judgments must be made.²¹ Another ethical dilemma relates to age: a treatment that saves the life a child will generally be more cost-effective than one that saves the life of a senior (since more years of healthy life will be added). Is this a fair valuation? Should we adjust for societal preferences?²²

A detailed discussion of the many nuances and challenges of cost-effectiveness is beyond the scope of this paper. However, when using cost-effectiveness analysis to allocate health resources, it is vital that these limitations and normative judgments be made explicitly and transparently.

2.3 Explicit, transparent and involved

Decision makers clearly have a tough task in deciding how to allocate limited healthcare resources within a publicly funded system. Coverage decisions have serious public implications. The public therefore has a legitimate right to worry about transparency, accountability and involvement in the decision-making process.

In the past, much health coverage decision-making has been implicit.²³ This is now changing. In Canada the call for greater public involvement and transparency and more explicit decision-making (based on publicly-stated criteria and established processes) derives at least in part from: eroding confidence in the health system and its leaders²⁴; the increased use of process guided decision-making²⁵; and concerns about the large variation in drug coverage between provinces.²⁶ Ultimately, if the public were more involved in and aware of how coverage decisions are made, the process might be perceived as more legitimate.

One of the strongest intuitive arguments in favour of making the system more explicit is that citizens should have clear information about policies that significantly affect their lives. The public

can only accurately judge the fairness of healthcare allocation decisions if these are taken in an open manner. More open systems are also better able to change over time to ensure that coverage decisions reflect public priorities and preferences and that the government can be held to account for such decisions.²⁷ Moral issues or boundaries around allocating scarce health resources are less likely to be violated if the public is more informed about the process and can help identify the limits.²⁸

However, there are also criticisms of explicit decision-making. One of the most common arguments against it is that it is impractical or unfeasible. Some hold that it is impossible to obtain consensus on which principles should guide allocation decisions or that data limitations make deciding difficult.²⁹ The counter argument to this is that, though we are not perfect in this regard, we do have a large amount of information and can make more informed decisions than in the absence of explicit processes.³⁰ Instead of giving up, we should focus on the need to improve our methods while recognizing that policy-makers will always have to make decisions in conditions of incomplete or imperfect information. So governments in Denmark, Norway, and the UK have all chosen to focus on strengthening the decision-making process and including the public more clearly in order to maintain legitimacy in the face of technical limitations.³¹

A second area of concern is that an explicit process may not be publicly stable: strong individual preferences that differ from those prioritized by the explicit process may engender dissent from affected individuals, weakening the resolve of health authorities and ultimately resulting in a return to more flexible, implicit approaches to rationing.³² Public outcry is, though, often a response to 'mistakes' in the process that can be corrected, if acknowledged.³³ Indeed, well-publicized 'tragic' cases in implicit decision-making certainly help increase the attention and scrutiny placed on how decisions are made.³⁴

A third issue with explicit rationing is that it may introduce more 'disutility,' or unhappiness, than the potential gain in wellbeing from a more efficient and explicit allocation of resources. Essentially the argument is that patients will find it less distressing if they are not told the real reasons they are being denied treatment (or not having it offered or recommended) by their physician. This argument flies in the face of any preference citizens have to be informed and empowered. The existence of 'tragic cases', growing concern about wait lists, and awareness of new treatments all mean that patients will continue to push for information and involvement: keeping patients in the dark is unrealistic (and undesirable). In the UK, for example, where a threshold value is used, patients groups such as the MS Society, have stated that they believe the government has a responsibility to explicitly to justify the threshold level.³⁵

In efforts to understand how decision-making can become more explicit, several frameworks for involving the public have been proposed.³⁶ One of the most widely studied and cited frameworks, the 'Accountability for Reasonableness' (A4R) framework, suggests four conditions that should be met to ensure explicit rationing: publicity, relevance, appeals and enforcement.³⁷

1. **Publicity** is achieved when decisions and their underlying rationale are transparent, and publicly accessible.

2. Decisions meet the **relevance** condition when they are made on the basis of reasons that “fair-minded” people can agree upon.
3. The **appeals** condition requires that there be opportunities to revise, and even challenge, decisions.
4. The **enforcement** condition is satisfied when regulations are in place to ensure the other three conditions are met.

Other frameworks have focused on how to involve the public. Abelson and colleagues break down public involvement into two types: direct representation through membership/voting power on decision-making committees, or the incorporation (through formal or informal means) of public input into the assessment of different treatments.³⁸

In the next section these criteria and frameworks are used to develop a simple rubric to assess how Canadian authorities responsible for coverage decisions are faring when it comes to transparency and accountability, public involvement, and the use of cost-effectiveness analysis.

3. Healthcare coverage decision-making in Canada

Provincial and territorial health authorities have responsibility for meeting the basic health service requirements of the Canada Health Act (CHA), with the federal government providing services only to veterans and First Nations populations. Outside the basic “medically necessary” health services required by the CHA, provinces have the power to decide what package of drugs and other services they will provide. This provincial independence has resulted in a large variation in drug coverage between provinces.³⁹ There are differences in the range of treatments covered, in age eligibility (seniors vs. non-seniors) and by income-group of patients. This can have a major impact upon people’s liability for out-of-pocket drug expenses.⁴⁰ One study analyzed 796 drugs and found that provincial coverage varied between 55% and 73% with particular discrepancies for anti-dementia drugs, anti-migraine drugs, and sedatives.⁴¹

The use of formal reviews, known as health technology assessments (HTA), to inform drug coverage began in Canada over 20 years ago with the creation of the Conseil d’évaluation des technologies de la santé (now called the Agence des technologies et des modes intervention en santé, or AETMIS). While Quebec led the way at a provincial level, a federal body was formed soon after: the Canadian Coordinating Office of Health Technology Assessment, which in 2006 was renamed the Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH is a national not-for-profit agency funded by federal, provincial, and territorial governments. It is responsible for providing evidence-based information to health coverage decision-makers.

The Common Drug Review (CDR) is a pan-Canadian process hosted by CADTH, initiated in 2003. Its specific task is to provide reviews of the clinical, cost-effectiveness and patient input for drugs (the lived experience of patients). It also provides listing recommendations for new drugs to Canada’s

publicly-funded drug plans (except for anti-cancer drugs, which are covered by the pan-Canadian Oncology Review).⁴²

The aim of the CDR is to ensure quality reviews, reduce duplication and increase consistency across the provinces and territories. While almost all provinces use the information and recommendations from CADTH and the CDR, they are not bound by its recommendations. In fact, some provinces have chosen to develop their own drug and treatment review organizations, which often conduct wholly independent reviews, and/or incorporate CDR and CADTH evidence when making health coverage decisions. The reason for this duplication is not entirely clear but it may relate to provinces' desire for independence or to their ability to adjust reviews to accommodate provincial needs or special interests.

It is notable that the smaller provinces, such as New Brunswick, do not typically have the resources or technical ability to maintain their own review organizations.⁴³ This may lead to them being more willing to accept CDR recommendations, though they may also be more inclined to reject drug coverage because of small budgets. Many of the larger provinces have maintained their own substantial, independent bodies. Almost all provinces accepted less than 60% of recent CDR recommendations, though Saskatchewan, New Brunswick, and Nova Scotia accepted around 70% of recommendations – some of this low acceptance could also be explained by provinces with independent bodies taking longer to accept CDR recommendations.⁴⁴

Researchers have attempted to measure the degree to which various provincial and federal assessment agencies involve and inform the public in decision-making, and also how and to what extent cost-effectiveness analysis affects the decision to recommend. In 2007 Abelson and colleagues reviewed public involvement processes in five bodies: the Canadian Coordinating Office for Health Technology Assessment (later CADTH), the Canadian Drug Expert Advisory Committee (CEDAC), Agence des technologies et des modes intervention en santé (AETMIS), the Ontario Health Technology Advisory Committee (OHTAC), and the Policy Advisory Committee of Cancer Care Ontario (PAC-CCO).⁴⁵ They found that none of the organizations involved the public in developing or applying decision criteria, and that only CEDAC, AETMIS and OHTAC provided rationales for their recommendations online. In terms of appeals, CEDAC was alone in providing appeal provisions, but for industry only.

Studies on the use of cost effectiveness analysis in drug coverage decision-making show mixed results. A 2009 review found that at the submission stage (the point at which manufacturers provide evidence about the drug), only 59.9% of submissions to the CDR included a cost per QALY calculation (with 35.3% of submissions submitting only cost-minimization data, comparing costs to existing drugs rather than providing full cost-effectiveness data).⁴⁶ By contrast, 93.4% of drug submissions in the UK included this information. The same study did, however, find evidence that cost-effectiveness was being used to inform some decisions, though there did not appear to be a firm threshold level above which drugs were rejected.

A more recent study of the CDR attempted to identify which factors between submission specifics, drug characteristics, clinical factors and economic factors were most predictive of whether a drug

would be recommended for listing. Confirming the findings of other studies, it found that less than 50% of recommendations mentioned cost-effectiveness.⁴⁷ It tested cost-effectiveness thresholds of \$20,000/QALY, \$50,000/QALY, and \$100,000/QALY and found that these were not predictive of whether a drug would be accepted or rejected. However, from a more qualitative standpoint, it was found that when the CDR stated that the cost-effectiveness was 'attractive', the drug was always listed. When it was described as 'not attractive', 75% of submissions were rejected.

Although there is evidence that price information is being used, the approach is quite simplistic, focusing on unit cost rather than cost effectiveness. So the odds of a drug being recommended increase nine fold if that drug is cheaper than a comparator drug, regardless of absolute cost-effectiveness.

Ultimately, though, the researchers found that economic factors were not nearly as predictive of recommendation as were clinical reasons and clinical certainty of effect. This is in contrast to the UK where studies found that cost-effectiveness alone explained about 85% of recommendation decisions produced by the National Institute for Health and Care Excellence (NICE).⁴⁸ Such a commitment to cost-effectiveness should arguably lead to more consistent and predictable decision-making and, if done well, to more efficient allocation of resources.

3.1 Transparency, accountability and public involvement

This section provides a descriptive review of transparency, public involvement and use of CEA in four HTA agencies in Canada as well as one in the UK, for the purposes of comparison (see Box 1).

Box 1: Bodies reviewed

Canadian Drug Review (CDR) and Canadian Drug Expert Committee (CDEC) – CDR refers to the overall pan-Canadian process for conducting reviews of drugs hosted at CADTH. CDEC is the advisory board to CADTH. It is composed of expert individuals and public members and is the body that oversees CDR reviews and makes listing recommendations to provincial and territorial drug plans.

Drug Benefit Council (DBC) – DBC is an independent advisory body that makes evidence-informed recommendations to the Ministry of Health about the listing of drugs on the British Columbia PharmaCare program formulary.

Committee to Evaluate Drugs (CED) – CED is an independent expert advisory committee that provides recommendations about drug listing and use to the Executive Officer of Ontario Public Drug Programs.

Expert Committee on Drug Evaluation and Therapeutics (ECDET) – ECDET is responsible for reviewing all drugs not eligible for review by the CDR. It provides recommendations to the Minister of Health on listing in the Alberta Drug Benefit List.

National Institute for Health and Care Excellence (NICE) – Established in 1999, NICE decides which drugs are available through the publicly-funded National Health Service in England and Wales. Unlike many of the Canadian HTA bodies, NICE provides recommendation decisions and guidance not only for drugs, but also for

procedures, devices, clinical guidelines and public health guidance. The Technology Appraisal Committee (TAC) is the independent committee that makes final decisions on technologies such as drugs, devices and surgical procedures. The NHS is legally obliged to fund and resource medicines

Table 1 summarizes transparency, accountability and public involvement in Canadian health technology coverage bodies.

Table 1: Transparency, Accountability, and Public Involvement in Coverage Decisions

	CDR/CDEC (Canada)	Drug Benefit Council (BC)	CED (Ontario)	ECDET (Alberta)	NICE/TAC (UK)
Decision criteria listed?	Yes	Yes	Yes	Yes	Yes
Decision process described?	CDEC panel uses a simple majority vote to recommend drugs using the evidence and review provided by the CDR.	DBC uses a simple majority vote to recommend drugs using the evidence and review provided by CDR, and BC's own Pharmacare Drug Review. The Ministry of Health uses the DBC recommendation in making a final coverage decision.	CED reviews drug recommendations made by CEDAC or cancer drug recommendations made by a joint Cancer Care Ontario-CED committee, and makes a recommendation to the Executive Officer, who makes the final decision.	ECDET reviews drugs not reviewed by CDR, and makes recommendations to the Minister of Health. The Minister makes final decisions about coverage based on CDR and ECDET review and advice.	The TAC uses a simple majority vote to recommend technologies.
Rationale for decisions made public?	Yes – database available online with separate coverage decision reports for 247 drugs. Also provide status updates for drugs in review.	Only available for some (23) decisions, though “new decision summaries are added regularly”. Unclear how decisions that will be explained are chosen.	Yes – database available online with separate coverage decision reports for 123 drugs. Also provide status updates for drugs in review.	Summary reports (with multiple drugs included in single summary document) produced every few months, with varying degree of explanation for drug decisions.	Extensive reviews of drugs and technologies (277) available online. Also provide status updates for drugs in review, and list upcoming appraisals.

Public input in health technology assessment?	Patient groups or organizations (not individuals) are invited to submit information about expected patient and caregiver impact of the new drug.	Registered patient groups, and individuals who have the disease of interest or are caregivers can give input.	Patient evidence submission allowed through registered advocacy groups. Citizen's council may provide advice to Executive Officer.	Not mentioned. May consider "patient care concerns related to factors external to the Drug Product", but no formal mechanism described.	'Citizen's Council' (30 member panel) provides public perspective especially on ethical issues. Invited patient groups and health care professional groups can contribute to and comment on draft technology appraisals.
Public involvement in decision-making?	2 out of 14 members of the decision making panel are members and designated representatives of the public.	3 out of 12 members of the decision making panel are members and designated representatives of the public.	2 out of 16 members of the decision making panel are lay representatives.	No lay/public representatives involved.	Decision making committees include at least 2 lay members. Members of the public are allowed to observe TAC meetings.
Appeals mechanism?	Only manufacturers can ask for reconsideration.	No online mention of appeals or reconsideration mechanisms.	Only manufacturers can ask for reconsideration.	Manufacturers and the Minister can ask for reconsideration or resubmission through 'the product listing agreement'.	'Consultees' (groups that were invited to contribute to appraisals, such as patient groups, or manufacturers) can make appeals.

Every organization listed provides some justification for its decisions, though there is little consistency in what this entails. Ontario's CED and CDR lead the way with extensive publishing of reasons for coverage decisions, while BC is beginning to move in this direction (though little information has been released to date and it is not clear how/why some decisions are explained, but not others). Alberta is also inconsistent in the level of explanation it provides for decisions, often simply referring to the CDR recommendation for rationale when available.

All organizations, except Alberta's ECDET, have set up a formal process for public input into the health technology review process. Since 2009, Ontario has made use of a Citizen's Council approach, especially for "values based" questions (building on the experience of the UK Citizen's Council which was established in 2002).⁴⁹ So far there has been no systematic analysis of the success of Ontario's Citizen's Council: some reports applaud the Council's output and engagement, though concerns remain about its mandate being poorly defined.⁵⁰

Public involvement extends beyond the technology assessment itself to the process of decision-making. CDEC, DBC and CED all involve at least two public representatives (elected/nominated

non-experts with a mandate to represent public views) in their decision panels while ECDET does not include any formal public involvement at this stage. In addition to including lay members, NICE also allows members of the public to observe decision-making meetings – something that no Canadian body reviewed here has yet done.

NICE also stands out from the Canadian bodies when it comes to its appeals mechanisms. Some Canadian HTA bodies allow manufacturers to make appeals and in Alberta the Minister of Health can ask for a reconsideration of decisions. No Canadian organization in the review allows for any other sort of public appeal. It is not everyone in the UK that can ask for a reconsideration, but groups representing patients or healthcare professionals that were involved in contributing to the technology review are allowed to submit their concerns which are then considered by an appeals panel.

Finally, all three provincial bodies reviewed ultimately make recommendations to the Minister of Health or Executive Officer, who makes the final decision about coverage taking the review into account (though not bound by the recommendation). It remains unclear how closely recommendations are followed. In contrast, the National Health Service in the UK is legally bound to cover drugs and technologies recommended by NICE. This disconnect between the final decision maker and the panel recommendation is completely opaque and suggests that all of the efforts and transparency at the panel level might be for naught.

3.2 Cost-effectiveness

One reason to have such strong measures in place to ensure transparency and enable public involvement is so that the criteria used to decide coverage decisions are considered fair and appropriate by the population – this is especially true when it comes to the use of cost-effectiveness analysis and thresholds (Table 2).

In addition to clinical and therapeutic benefits, all bodies reviewed mentioned cost-effectiveness or value as one of the criteria used to make coverage decisions. However, the Canadian bodies emphasized relative value – often saying cost-effectiveness should be compared to the current accepted therapy, rather than saying cost-effectiveness should be evaluated in its own right. Applying cost evidence in this way does not necessarily mean technologies are being decided on their own value, but simply according to historical precedent set by drugs already covered. This could mean that a drug that actually offers little in the way of additional QALYs for each dollar spent might be approved because it is cheaper than an existing drug, while other drugs that are very cost-effective might be rejected.

If cost-effectiveness and efficiency are true objectives in the health system, the cost-effectiveness of already approved drugs must be retrospectively examined so that each drug is judged in its own right. An incremental system is less efficiently and arguably less fairly distributed than a full review system: treatment of certain illnesses, for example, may be favoured over others simply because of precedent.

In the UK, NICE originally focused exclusively on new technologies, but this led to inflationary pressures on the health system.⁵¹ It now takes a retrospective approach as well. This can be politically challenging as it may result in drugs that have already been approved being rejected, which is a particular problem since evidence suggests that people place greater value on services they already receive relative to new ones.⁵²

For new classes of drugs or those with unique benefits (and no comparator drug already covered), Canadian HTA bodies have little guidance as to how to use CEA or what ICER would represent good value. Indeed, there is no mention of threshold values in the terms of reference of these bodies. In contrast, NICE states that it employs a cost-effectiveness threshold range of £20,000-30,000 (\$32,000 to \$48,000) per QALY, though evidence suggests that in practice the threshold is closer to £40,000 (\$64,000).⁵³ While no threshold is mentioned in Canada, investigation into the use of CEA at CDR suggests that there may be a general acceptability threshold of about \$50,000/QALY, with a grey zone extending up to \$80,000/QALY. Other analysis finds no evidence of a consistent threshold range and large variation in use of ICERs.^{54,55}

Table 2: Decision criteria and use of cost-effectiveness analysis

	CDR/CDEC (Canada)	Drug Benefit Council (BC)	CED (Ontario)	ECDET (Alberta)	NICE/TAC (UK)
Listed decision criteria	<ul style="list-style-type: none"> • safety • efficacy & effectiveness, • therapeutic advantage • cost-effectiveness (‘relative to current accepted therapy) • patient and public impact 	<ul style="list-style-type: none"> • clinical effect • good value for people of BC • comparison to existing drugs • clinical practice and ethical considerations • sponsors (manufacturers) written comments • budget considerations (Ministry level) 	<ul style="list-style-type: none"> • therapeutic value • cost-effectiveness • patient and societal impact • budget considerations • advice from groups such as Citizen’s Council 	<ul style="list-style-type: none"> • safety • efficacy • “must have” therapeutic advantage OR greater cost-effectiveness than current therapy 	<ul style="list-style-type: none"> • clinical effectiveness • cost-effectiveness
Implicit of explicit use of criteria?	Implicit – no mention of how each criterion should be weighted or considered.	Implicit – no mention of how each criterion should be weighted or considered.	Implicit – no mention of how each criterion should be weighted or considered.	Implicit – no mention of how each criterion should be weighted or considered.	Implicit – no mention of how each criterion should be weighted or considered, except rough CE threshold.
Cost-effectiveness threshold	No mention.	No mention.	No mention.	No mention.	“Generally” £20,000-30,000 per QALY

4. Discussion

The system through which healthcare coverage decisions are made in Canada is likely to become ever more contentious as governments struggle to rein in growth in public healthcare expenditure. In reviewing the current state of health coverage decision-making in Canada, it is clear that there is much to be done to ensure that the process is considered legitimate by the Canadian public. While efforts are in place to ensure transparency and public involvement, there remains significant variation across Canada, as evidenced by the four bodies reviewed here.

The comparison with the UK national body, NICE, is instructive as it suggests a number of options for improvement, including: allowing public observation of decision-making meetings; allowing appeals by the public and not just manufacturers; and expanding the use of citizens' councils to increase public discussion about values and ethics related aspects of health coverage decision-making.

Explicit cost criteria, including a threshold value, are part of NICE's protocol. By contrast, these are only implicitly mentioned as one of many important criteria in Canada, with the emphasis being on cost-minimization rather than cost-effectiveness. In none of the jurisdictions reviewed is there an explicit process for the inclusion of non-cost criteria. This is something that has been noted in the past. The development of a specific weighting formula that incorporates different types of criteria has been called for by both experts and laypersons in Canada.⁵⁶

NICE was launched in the UK against a backdrop of significant socioeconomic and geographic variation in treatment and a very public debate over drug coverage. A decision to restrict coverage was challenged by Pfizer in court and the court ruled in favor of Pfizer, on the grounds that the process for determining coverage was inadequate. NICE was launched soon after. Since that time, the organization has stood out for its efforts continually to enhance processes for assessing the evidence behind NHS treatments and for including and informing the public. In 2009 an NHS constitution was passed in parliament, formalizing what care citizens could expect from the NHS, nationwide, and making clear that the treatments that NICE recommends represent patients' rights⁵⁷ – this is quite distinct from the broad and loose expectations for care set out in the Canada Health Act.

Certainly NICE has faced challenges: criticisms about particular decisions remain and can sometimes result in legal battles and intense public debate. However, public awareness of NICE and its functions has increased steadily and over 70% of those familiar with it are neutral or positive about NICE.⁵⁸

Ensuring the legitimacy of health coverage decision-making in Canada should be a greater priority. CADTH and the provinces must demonstrate leadership in further refining the process of allocating scarce healthcare resources and we should look to other countries for guidance and best practice. Provinces must cooperate to ensure consistency and national efficiency, but they could also be more deliberate in using their independence to engage in constructive experimentation and learning.



Progressive policy for a modern Canada

It remains to be seen if similar public pressure in Canada will precipitate change, but if anything is likely to increase that pressure, it is the slowing growth in provincial healthcare budgets. As the process for determining coverage becomes more advanced and more critical, transparency will allow the public to scrutinize decisions and ensure they are defensible. Ultimately, more public involvement will require serious discussion about how Canadians value health and how their values should be translated into health coverage.

Appendix

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Glossary

A list of organizations, acronyms and other short-forms that appear in the paper:

AETMIS – Agence des technologies et des modes intervention en santé (Quebec)

CADTH – Canadian Agency for Drugs and Technologies in Health (Canada)

CCOHTA – Canadian Coordinating Office of Health Technology Assessment (Canada)

CDEC – Canadian Drug Expert Committee (Canada)

CDR – Common Drug Review (Canada)

CEA – Cost effectiveness analysis

CED – Committee to Evaluate Drugs (Ontario)

CEDAC – Canadian Drug Expert Advisory Committee (Canada)

CHA – Canada Health Act

DBC – Drug Benefit Council (British Columbia)

ECDET – Expert Committee on Drug Evaluation and Therapeutics (Alberta)

HTA – Health technology assessments

ICER – Incremental cost-effectiveness ratio

NICE – National Institute for Health and Care Excellence (UK)

OHTAC – Ontario Health Technology Advisory Committee (Ontario)

PAC-CCO – Policy Advisory Committee of Cancer Care Ontario

QALYs – Quality adjusted life years

TAC – Technology Appraisal Committee (UK)

WTP – Willingness to pay

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