How cancer drug funding decisions are made
Acknowledgements

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Comments and questions

If you have any comments or questions about the tutorial, please contact pCODR at info@pcodr.ca or the Partnership at info@cancerview.ca.
This tutorial explains the process that decision makers in Canada follow to decide whether to publicly fund new cancer drugs. You’ll learn who is involved in this process, and how health benefits, costs and values play into the decision. At the end of the tutorial, you should be able to answer the following questions:

- Which groups make decisions in Canada about publicly funded cancer drugs and how are those decisions made?
- How do we know if drugs work and are better than current treatment?
- How do costs and benefits fit into the decision making process?
- What is a fair decision?
- How are decision makers held accountable to the public?
- How can you get involved in cancer drug funding decision making panels?

The principles described in this tutorial also apply to decisions about other non-cancer drugs and new health care technologies.

Who should read this tutorial?

This tutorial is for you if you are someone who is concerned or curious about how decisions are made to fund which new cancer drugs with public funds. This tutorial describes drug funding decision making in Canada as it is currently best practiced. The tutorial describes decision making at the societal level and will not help you decide which drugs to use for treatment.

Who developed this tutorial and how?

The Canadian Partnership Against Cancer and the pan-Canadian Oncology Drug Review developed this tutorial, with input from patient representatives, patient advocates, clinicians and decision makers. These key stakeholders provided important insights on the type of information that should be included.

Would you like to learn more?

You can do a free tutorial called PrePARE – Preparing Participants for Allocating Resources Equitably – to learn more about how health care funding decisions are made in general. You’ll have the opportunity to do interactive exercises and achieve a certificate of completion at the end. Here’s the tutorial: www.cancerview.ca/prepare.
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In Canada, our provincial and territorial governments manage health care so each jurisdiction identifies their local health priorities that will result in the best outcomes for their patients. This includes determining funding priorities for hospitals, medical services and drugs, as well as how much of their overall budget goes to health care versus other publicly funded services like education. Governments determine priorities by looking at the potential benefits, harms and costs of funding or not funding a service, and considering the values of the public. Although most of the funds for health care come from provincial taxes, the federal government also provides a significant amount.

In 2012, the total health care spending in Canada was expected to reach $207 billion. Drug spending was the second-largest component of health care spending after hospital spending. The ongoing introduction of new drugs, including for cancer, leads to rising costs that are likely to continue.

**Cancer drug funding decisions are tougher than ever**

The process of distributing funds and other resources to meet different needs is called resource allocation. Since resources are limited, it is necessary to set priorities by deciding which services among different options are more important than others. This involves assessing opportunity cost; the opportunity we lose when we fund certain services because the funds are no longer available for other services. Setting priorities in a deliberate way (priority setting) is important because it allows us to continue to fund priority services into the future.

In the health care system, resource allocation means deciding which health care services to fund before others. This includes drugs. The processes that are used to decide what is most important to fund is the focus of this tutorial.

Cancer drug funding decisions are tougher than ever because of trends like the increasing use of cancer therapies and the rapid introduction of new high-cost cancer drugs that may not have the same benefits as currently used treatments. Therefore, decision makers must assess which drugs work well enough or better than others and which ones are affordable and fit with what society values most.

In this module you will learn which organizations and groups are involved in drug funding decisions and how decision makers decide which new drugs to fund. As you will learn, decision makers follow a structured process with input from different organizations and groups of people to help with making tough decisions.
The decision making process includes a wide range of information, including what people value, health benefits, costs, and ‘value for money’. Decision makers base decisions on advice—in the form of recommendations—from various stakeholders. Stakeholders are the people who the decisions affect. In health care, stakeholders include patients, health care professionals, the pharmaceutical manufacturers, and other experts. The public is always an important stakeholder because tax payers pay for health care in Canada. Most important, feedback from patients is valued in the decision making process.

Before funding a drug, each drug goes through several approval stages with stakeholder input—including feedback from patients.
**Stage 1: Authorize for sale – Health Canada review**

- First, a pharmaceutical manufacturer seeking to sell a new drug in Canada submits an application to Health Canada for review.
- Health Canada assesses the information gathered from research (scientific evidence) about the drug’s safety, clinical effectiveness, and the quality of its manufacturing process. Clinical effectiveness is how well the drug works to prevent or control disease and improve health.
- Health Canada’s approval of a drug for sale in Canada does not necessarily mean that our provincial and territorial governments will fund it.

**Stage 2: Recommend to fund or not – Canadian Drug Review (CDR) for non-cancer drugs or the pan-Canadian Oncology Drug Review (pCODR) for cancer drugs**

- Next, based on input from expert committees, CDR or pCODR reviews the scientific evidence and costs to determine if the drug works better than the usual treatment and if the cost is reasonable. They can then recommend to the provinces and territories whether or not the drug should be publicly funded (except Québec, which has an organization called Institut national d’excellence en santé et en services sociaux (INESS), which conducts a similar process).
- For cancer drugs, the pharmaceutical manufacturer or a group of cancer experts, called a tumour group, starts the review process by requesting a review and giving information to pCODR about how well the drug works and its costs. In addition, an essential part of the pCODR review process is input from patients and clinicians. Clinicians include health care professionals who directly care for patients. pCODR’s review focuses on four main factors: clinical effectiveness, cost of the drugs, patient values, and how easy it is to add to the health care system. Learn more here: [http://www.pcodr.ca/idc/groups/pcodr/documents/pcodrdocument/pcodr_perc_deliberative_frame.pdf](http://www.pcodr.ca/idc/groups/pcodr/documents/pcodrdocument/pcodr_perc_deliberative_frame.pdf)
- Based on all of the input above, pCODR can make one of three types of recommendations: ‘Recommend’, ‘Consider with conditions’ or ‘Do not recommend.’

**Stage 3: Decide to fund – Provincial and territorial ministries of health and cancer agencies**

- Finally, provincial and territorial ministries of health and cancer agencies use the recommendations to make their own decisions—in combination with input from their own expert committees and based on other considerations like the effect on health services and the overall budget.
MODULE 1: What is the decision making process?

As you can see, Health Canada and pCODR have different responsibilities and assess different aspects of new cancer drugs.

- Health Canada assesses whether a new drug is safe and that it does what it is claimed to do. If Health Canada approves the drug, then the pharmaceutical manufacturer can sell it in Canada. Health Canada does not compare a new drug with other available options.

- pCODR assesses a new cancer drug’s clinical effectiveness and value for money (cost-effectiveness) to make recommendations to the provinces and territories. pCODR compares the new cancer drug with other available treatment options because the provinces and territories look at the value of new drugs in relation to other treatment options that they also fund and deliver (preventative, surgical, radiation, palliative).

Recap

Now you have a better understanding of the three stages a drug goes through, the organizations and stakeholders involved in the process, and the information they consider to make a drug funding decision. Module 2 explains in more detail how researchers evaluate whether a drug is safe, works as it should, and is more effective than other drugs.

pCODR reduces duplication

Before establishing pCODR, each province and territory did its own evaluation in different ways with different timelines. pCODR not only reduces duplication, the provinces and territories also benefit from timely assessments by leading Canadian experts with input from clinicians (individuals who directly care for patients living with cancer) and the pharmaceutical manufacturers. And especially relevant, they benefit from input from patients.
Each new drug undergoes what you could think of as an evaluation path. Before decision makers approve a new drug, they must be sure that it is safe and effective. Researchers evaluate new drugs in labs including how they affect animals before evaluating their safety and effectiveness in people—in studies called clinical trials. Decision makers use the results from clinical trials in two ways:

- **At the federal government level:** to help decide whether to allow the sale of a new drug in Canada. This is based on research about a new drug’s safety and effectiveness.

- **At the provincial and territorial government level:** to help decide whether to fund a new drug that the federal government approved for sale in Canada. Although the federal government is responsible for approving the sale of a new drug, the provinces and territories are responsible for deciding whether it is effective enough to fund especially if there are other affordable options.

Before a clinical trial can happen, an ethics committee—called a Research Ethics Board or an Institutional Review Board—must approve it. The ethics committee assesses:

- **Rationale:** there is a solid reason for conducting the trial.
- **Safety:** the trial is safe.
- **Informed Consent:** researchers tell participants before they agree to take part in the trial, what the trial is testing and how it may affect them.
- **Clinical Equipoise:** researchers are not sure whether the new drug is better than an existing approved options; this uncertainty is called clinical equipoise. If researchers are sure, then the trial wouldn’t be necessary.
MODULE 2: How are new drugs evaluated?

How do clinical trials work?

Researchers do clinical trials in cancer treatment centres where they can carefully check the procedures for taking the drug and the effect on the trial participants. Clinical trials evaluate a new drug’s safety and effectiveness:

- **Evaluating safety**: All phases of clinical trials evaluate different aspects of safety. For example, clinical trials check for any possible damage or harm to participants through blood tests and X-rays and by checking organs like the kidneys, heart and lungs. They also check how often what are called serious adverse events happen like death, hospitalization, and disability.

- **Evaluating effectiveness**: All phases of clinical trials look for signs of effectiveness by measuring outcomes:
  - **Overall Survival**: time from when a participant starts on a trial to death
  - **Progression-free Survival**: time from when a participant starts a trial to when the disease worsens
  - **Recurrence-free Survival**: time from when all signs and symptoms of the treated disease are gone to when the disease returns
  - **Tumour Response**: change in the size or extent of the tumour being treated
  - **Quality of Life**: changes in physical, psychological, social, and emotional well-being

Researchers report outcome events, such as death or disease recurrence, by when they happen. They measure time either from when the participant receives the drug treatment, or when the participant officially enrols in the trial until when the event happens. This approach evaluates effectiveness by determining how much longer a participant receiving the drug could live or live without disease progression or disease recurrence, as compared to no treatment or an alternative treatment. For example, a drug that delays recurrence for an average of 18 months is considered more effective than a drug that delays recurrence for an average of 6 months.

Researchers evaluate quality of life through a questionnaire that asks participants about changes in their health.

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**Generation of new knowledge that will ultimately improve the health of individuals and populations**
MODULE 2: How are new drugs evaluated?

What are the clinical trial phases?

In most cases, a drug must go through at least three phases of clinical trials before Health Canada approves it for sale:

**Phase 1 Clinical Trials**

Evaluate the drug’s safety and decide a safe dose for future studies by determining the drug’s maximum tolerated dose (MTD), which is the highest dose with acceptable side effects. Side effects are problems that can result from treatment such as pain and hair loss. If the drug is considered safe, it can then move on to a Phase 2 Clinical Trial.

**Phase 2 Clinical Trials**

Evaluate the drug’s promise for effectiveness in treating the disease typically using a dose slightly lower than the MTD. This phase also collects more information about safety and side effects. For example, the trial could measure a cancer drug’s ability to shrink or slow down tumours. However, although the drug helps control a disease, this does not necessarily mean that patients will live longer or have a better quality of life than without the drug, or when compared with other options. If the drug shows promise in Phase 2, for example, stopping or slowing down tumour growth, it goes on to a Phase 3 Trial for further evaluation.

**Phase 3 Clinical Trials**

Evaluate the drug’s effectiveness by comparing it with the best approved treatment option to determine if it performs at least as well as—or better than—the existing option because it is more effective, or safer, or both. A new drug could perform almost as well as an already approved option but have other benefits like being less expensive or easier for the patient to take.

To ensure that any differences in each drug’s results are related to the drug—and not characteristics of the trial’s participants or differences in procedures—researchers use a process to randomly give each participant a drug to take.

This process is called *randomization*; it’s like flipping a coin to decide who receives what. In some cases, to further reduce the risk of other influences on results, some participants take the real new drug while others take what is called a placebo, which looks just like the real drug and is safe but has no known effect.

When the participant doesn’t know if she is taking the drug or the placebo this is called *blinding*. When the participant and even the researcher don’t know who is taking the real new drug versus the placebo, it is called *double-blinding*.

Not knowing whether a participant is taking the actual new drug or the placebo helps avoid what is called *bias*, which means bringing other influences into play that could affect the trial’s outcomes. To ensure safety, there are emergency procedures for researchers to check who is taking what.
MODULE 2: How are new drugs evaluated?

Although not as common, there are also Phase 0 and Phase 4 Clinical Trials:

- **Phase 0 Clinical Trials** are very small trials that help researchers decide if it is worth the effort to evaluate a new drug in a Phase 1 Clinical Trial.
- **Phase 4 Clinical Trials** further assess drugs that are already on the market by evaluating their long-term safety and effectiveness.

Clinical trials do not delay getting new drugs. Trials are critical to ensure that Canadians get safe and effective drugs that work better than existing options. This is essential to ensure the long-term ability to provide safe and effective drugs for all Canadians; it ensures that decision makers fund the right drugs for the right patients at the right time.

Time-to-event analysis: using outcome events in practice

Researchers use time-related outcomes of clinical trials in what is called ‘time-to-event’ analysis.

**Example 1: Time-to-event analysis in Phase 2 Clinical Trials**

Phase 2 Clinical Trials generally involve one group of participants, and in most cases do not compare different treatments. In Phase 2 Clinical Trials, time-to-event analysis commonly uses time-related outcomes like ‘time-to-progression’ or ‘time-to-death’ for a group of patients. Let’s go through an example of time-to-event analysis that uses the time-related outcome measure of ‘progression-free survival time’—in other words, the time it takes for a disease to become worse.

For each individual participant, a clinical trial measures the progression-free survival time; the time it takes for the disease to get worse.

Researchers then combine all of the individual participant’s measurements by calculating the percentage of participants with no disease progression at various points in time.

The vertical axis (left vertical line) shows the percentage of participants who have had no progression. The horizontal axis (bottom line) shows the time in months.
What does this mean? At the beginning (0 months), no one has progressed, however, by 18 months half (50%) of the participants have had disease progression. The time at which half the participants have progression is called the **median progression-free survival time**. In this example the median progression-free survival time is 18 months.

**Example 2: Time-to-event analysis in Phase 3 Clinical Trials**

In Phase 3 Clinical Trials—which compare different drugs—time-to-event analysis calculates the time-related outcomes for each drug treatment group. In other words, it compares whether one drug is better than the other. Let’s go through an example that measures the percentage of progression-free survival at specific points of time to show which drug is better at delaying disease progression.

Comparing participants treated with Drug A and those with Drug B, the space between the curves in the graph shows that the percentage of participants without progression is higher for Drug B than for Drug A at each time point.

- What does this mean? Drug B is better at delaying disease progression than Drug A. In other words, it is more effective. The median progression-free survival time for Drug A is 18 months and 24 months for Drug B. This also shows that Drug B is more effective than Drug A.
Are all clinical trial results of the same quality?

Not all clinical trials are equally good at testing a drug’s effectiveness because they are not all done in the same way, so their quality varies. As a result, we should have more confidence in the findings of some clinical trials than others; in other words, we should trust the results of certain trials more than others. Researchers consider several factors to evaluate the quality of a clinical trial and to determine the confidence we should have in the results of that trial. Factors such as randomization, blinding and clinical trial size affect the quality of a trial and our confidence in clinical trial results.

Example: Clinical trial size

One factor that can affect our confidence in a trial’s results is the size of the trial—meaning its number of participants. For example, let’s say the clinical outcome is whether the participants’ tumours shrink. Which of the following trial results would you have more confidence in?

- 40% of participants’ tumours shrink in a trial of 5 participants, so 2 of the 5 participants’ tumours shrink.
- OR –
- 40% of participants’ tumours shrink in a trial of 50 participants, so 20 of the 50 participants’ tumours shrink.

Your confidence should be higher for the trial with 50 participants. The larger the clinical trial—meaning more participants—the more confidence decision makers have in the trial’s results.

How do decision makers use clinical trial results?

Often researchers do many clinical trials to evaluate the same new drug. Decision makers must consider all of the results from all of the trials combined with other information. Decision makers use clinical trial results in three ways that help them make decisions:

- Systematic reviews
- Clinical practice guidelines
- Health technology assessments
MODULE 2: How are new drugs evaluated?

Systematic reviews – using evidence in a comprehensive way

Clinical trials evaluating the same new drug can sometimes have different results—and sometimes the results do not agree. This is because of differences in variables like study methods, participant characteristics, number of participants, type of disease, trial quality as already discussed and so on. To ensure that decision makers consider all of the results from all of the clinical trials, decision makers use what is called a systematic review.

Based on rules for gathering clinical trial results, a systematic review combines the results from all of the clinical trials that evaluate the same new drug in similar groups of people if possible. A systematic review is essential to avoid bias, which means favouring or giving more weight to certain results. Decision makers check the characteristics of the different trials and decide which ones are most relevant for the decision they need to make, such as trials that use a certain age group of participants or disease type.

Clinical practice guidelines – using evidence to guide decisions about care options

Clinical practice guidelines (CPGs) are typically for health care professionals and their patients to help them make decisions about care options. Decision makers also use CPGs to help them make choices about drug funding.

- Evidence-based CPGs: explain the results from a systematic review to make recommendations about how health care professionals and patients should use a new drug.
- Consensus-based CPGs: are not based on a systematic review, but instead are based on expert opinions, usually when there are not enough research results. Decision makers generally prefer to base their decisions on evidence-based CPGs.

A panel usually develops CPGs that typically includes:

- A range of health care professionals who understand the disease and treatment options
- Scientists who help gather and interpret the research
- Patients or their representatives who share their experiences and values

Find CPGs

For cancer-related CPGs, visit the SAGE Directory under ‘Treatment & Support’ at: www.cancerview.ca

An example of a CPG recommendation is: Concurrent chemotherapy with Cisplatin (drug name) usually requires a 1- to 2-hour delay between giving the drug and delivering the radiation.
Health technology assessments – using evidence in policy decision making

Health technology assessments (HTAs) help decision makers decide whether to fund a new health care technology by evaluating all information available about health benefits, costs, resources needed to use the technology, and the effects that the technology may have on society. HTAs are typically based on: systematic reviews (if available), clinical practice guidelines, and economic evaluations, as well as the values of society, patients, and caregivers. HTAs help ensure that decision makers fund technologies that are:

- Safe (based on scientific evidence),
- Effective (based on scientific evidence and patient-relevant outcomes),
- Efficient and affordable (based on costs and budget, which are described in Module 3), and
- Acceptable to the public.

pCODR and CADTH do HTAs to provide information for their drug reviews. In addition, many other organizations do HTAs—usually at a provincial or local level because these groups are responsible for making funding and service delivery decisions (health region, health district or hospital). Examples of other groups that do HTAs include the Institute of Health Economics in Alberta, Health Quality Ontario and Institut national d’excellence en santé et en services sociaux, INESS (Québec).

Recap

Now you have a better understanding of how decision makers use scientific evidence to evaluate new drugs. Module 3 explains how costs and benefits are used as part of the decision making process. Economic evaluation helps evaluate costs and benefits.
Economics is about the choices we make—and how we make them—because choices show us our preferences and values. For instance, what we spend money on—especially with a tight budget—is a choice that shows our preferences based on what we value. The amount we are willing to pay shows how much we value a certain product or service. Put another way, economics shows the price we are willing to pay for the benefits we receive.

Researchers can use information to understand our preferences including how much we are willing to spend for a specific product or service, and what trade-offs we are willing to make to afford specific products and services.

Improving overall health for society and considering those most at risk is a difficult balancing act. To do this, decision makers must consider efficiency, which means finding the best way to distribute resources for the greatest health for society as a whole. Economic evaluation helps decision makers evaluate the efficiency of various options.
Economic evaluation

An economic evaluation compares the costs and effectiveness of two or more new drugs. It helps decision makers decide whether they should fund a new drug compared with other funding options. Economic evaluation considers not just the price and associated costs of two or more new drugs but also their benefits in terms of safety and effectiveness.

Although an economic evaluation might show that, for example, a new drug is cost-effective, the drug may not be affordable. **Affordability** means whether there is enough money to fund the new drug. The opposite may also be the case where the new drug is affordable but not cost-effective.

Common types of economic evaluation

Decision makers most often use **cost-effectiveness analysis** and **cost-utility analysis** for economic evaluation.

Cost-effectiveness analysis

Cost-effectiveness analysis (CEA) evaluates costs in relation to the effectiveness of the new drug when compared with other options. The measure of effectiveness depends on the type of new drug. For example, effectiveness can be measured for a population in terms of number of life-years gained, number of deaths avoided and so on.

Cost-utility analysis

Cost-utility analysis (CUA) is a type of CEA that evaluates costs in relation to how a new drug performs to improve quality of life and number of years lived when compared with other options. The measure of effectiveness is Quality-Adjusted Life Years (QALYs).

Quality-Adjusted Life Years (QALY) measures both the quality and quantity (length) of a patient’s potential lifetime by using the drug. The QALY is the number of additional years of life expected due to treatment multiplied by the quality of life of the additional years.

Researchers measure quality of life in units called **utility**. A utility score shows a person’s preferences in terms of how they value different levels of health. Understanding patient preferences helps decision makers decide between different drug funding options.

However, because what people value is very personal, what someone values varies from person to person. As a result, utility scores are difficult to determine, especially an average utility score across many people. Utility scores are often based on estimates or assumptions rather than real data, so many researchers are skeptical of CUA; however, it is still often a part of economic evaluation.
Calculating QALYs from utility

A utility score shows a person’s preferences for different levels of health in a number from 0 to 1, where 0 represents what the person values least (the least utility like death) and where 1 represents what the person values most (the most utility like perfect health). For example, one year of additional life with perfect health equals 1 QALY:

\[ 1 \text{ additional year} \times 1 \text{ Utility} = 1 \text{ QALY} \]

As another example, one year of additional life with a low quality of life represented by a low utility of 0.5 equals 0.5 QALY:

\[ 1 \text{ additional year} \times 0.5 \text{ Utility} = 0.5 \text{ QALY} \]

When comparing drug funding options, let’s say that a study of patients with terminal cancer compares the utility of good quality end-of-life care with the utility of a drug that prolongs life for an additional two months. From a QALY perspective, one month with a utility score of 0.80 is better than two months with a utility score of 0.15.

Incremental Cost-Effectiveness Ratio (ICER)

Decision makers use the ICER to decide if the additional costs between two drug options are worth the additional benefit. Incremental is just another word for additional.

The results of a cost-effectiveness analysis (CEA) or cost-utility analysis (CUA) show the additional dollars necessary for each year of life gained or each quality year of life gained. The Incremental Cost-Effectiveness Ratio (ICER) shows this trade off. The ICER is the difference in the cost of two options divided by the difference in their effectiveness:

\[ \text{ICER} = \frac{\text{Difference in costs}}{\text{Difference in effectiveness}} \]
Example: Let’s say researchers are assessing a new drug (Drug A) with an existing drug (Drug B).

The cost comparison of Drug A and Drug B is:

| Drug A Lifetime Cost | = $ 87,075 |
| Drug B Lifetime Cost | = $ 83,159 |
| The difference in cost | = $ 3,916 |

What does this mean? It means that Drug A is more expensive than Drug B.

The effectiveness comparison for Drug A and Drug B is measured in terms of Quality-Adjusted Life Years (QALYs) is:

| Drug A QALYs | = 14.13 QALYs |
| Drug B QALYs | = 13.98 QALYs |
| The difference in effectiveness | = 0.15 QALYs |

What does this mean? It means that Drug A provides 0.15 Quality-Adjusted Life Years more than Drug B, so Drug A is more effective than Drug B.

The ICER is the difference in cost between Drug A and Drug B ($3,196) divided by the difference in effectiveness between Drug A and Drug B (0.15 QALYs). The ICER is $26,107 for each Quality-Adjusted Life Year gained. Here’s the math:

\[
\frac{\text{Difference in costs}}{\text{Difference in effectiveness}} = \frac{\$3,916}{0.15} = \$26,107 \text{ per QALY}
\]

What does this mean? It means that Drug A—which is more effective and more expensive than Drug B—costs $26,107 per Quality-Adjusted Life Year gained more than Drug B.
Using economic evaluation to guide drug funding decisions

Economic evaluation is just one factor that decision makers consider in drug funding decisions. They also consider other factors such as the availability of other treatment options, side effects, seriousness of the conditions, and social factors that are important to patients and the public.

Economic evaluation gives decision makers information about efficiency, and ‘value for money’. The ICER is one way to measure ‘value for money’, which includes all of the benefits and all of the harms related to a drug’s performance, as well as all of the costs associated with that performance.

Although the ICER provides some guidance about whether a certain drug is worth funding, in addition, decision makers must consider the amount of money available for spending in the drug budget. With a specific budget, the ICER Ranking Method, the ICER Threshold Method, and the Budget Impact help guide drug funding decisions.

ICER Ranking Method: ranks new drugs by ICER from the most efficient use of dollars—meaning that it ranks the drugs from the least additional cost for the most additional benefit.

For example, let’s say researchers rank five drugs from the lowest to highest ICER, meaning from most cost-effective to least cost-effective. Decision makers could start by funding the drug with the best (lowest) ICER—the one that shows the most efficient use of dollars—to the one with the worst (highest) ICER by continuing down the list until the budget runs out.

<table>
<thead>
<tr>
<th>Drug</th>
<th>ICER</th>
<th>ICER Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>$15,000</td>
<td>1</td>
</tr>
<tr>
<td>Drug B</td>
<td>$25,000</td>
<td>2</td>
</tr>
<tr>
<td>Drug C</td>
<td>$60,000</td>
<td>3</td>
</tr>
<tr>
<td>Drug D</td>
<td>$85,000</td>
<td>4</td>
</tr>
<tr>
<td>Drug E</td>
<td>$175,000</td>
<td>5</td>
</tr>
</tbody>
</table>
**ICER Threshold Method:** sets an ICER threshold—meaning an upper limit—where all options below it may get funding, whereas all options above it would not.

For example, let’s say the ICER threshold is set at $80,000 per life-year gained. Decision makers have the option of funding Drug A, Drug B, and Drug C. However, they cannot fund Drug D and Drug E.

<table>
<thead>
<tr>
<th>Drug</th>
<th>ICER</th>
<th>Approve for funding or not</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>$15,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Drug B</td>
<td>$25,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Drug C</td>
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<td>Drug D</td>
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<td>No</td>
</tr>
<tr>
<td>Drug E</td>
<td>$175,000</td>
<td>No</td>
</tr>
</tbody>
</table>

**Budget Impact:** ranks new drugs by their potential budget impact—which means how much budget the new drug uses if funded.

The ICER Ranking Method and ICER Threshold Method show the best funding options based on efficiency—the most benefit with least cost. However, the options may not be affordable so decision makers must also determine the Budget Impact.

The Budget Impact is the drug price multiplied by the estimated number of patients who could possibly receive it over a specific period of time like one year.

For example, let’s say that a decision maker has a drug budget of $2 million so they could fund the most affordable drug options until reaching the $2 million budget limit. They would fund Drug A, Drug B, and Drug D, but not Drug C and Drug E.

<table>
<thead>
<tr>
<th>Drug</th>
<th>ICER Ranking</th>
<th>Budget Impact</th>
<th>Budget Impact Ranking</th>
<th>Approve for funding or not</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>1</td>
<td>$400,000</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>Drug B</td>
<td>2</td>
<td>$350,000</td>
<td>1</td>
<td>Yes</td>
</tr>
<tr>
<td>Drug C</td>
<td>3</td>
<td>$1,350,000</td>
<td>4</td>
<td>No</td>
</tr>
<tr>
<td>Drug D</td>
<td>4</td>
<td>$900,000</td>
<td>3</td>
<td>Yes</td>
</tr>
<tr>
<td>Drug E</td>
<td>5</td>
<td>$1,750,000</td>
<td>5</td>
<td>No</td>
</tr>
</tbody>
</table>
Recap

Now you have a better understanding of how decision makers use costs and benefits to assess and compare new drugs. Decision makers need to weigh costs and health benefits because they have a limited budget and because they have a responsibility to do the best for society as a whole. To do this they must ensure that they spend money efficiently. However, they must also consider other important factors in the decision making process like public and patient values. Each drug funding decision depends on the specific situation; decision makers do not make decisions based on just costs or economic efficiency. Next Module 4 explains the principles that guide fair health funding decisions.
Values are what is most important or what matters most to us. Our values affect what we think is fair or not. Decision makers must consider many different values when making health care funding decisions so some people may think that certain decisions are fair while other people may not. This is one of the biggest challenges decision makers face. For example, let’s say you were asked these questions, what would you answer?

- Should decision makers distribute limited resources to reach the best outcomes for society as a whole even if some individuals don’t receive the most effective treatment?
- When is it right to limit individual choices to reach overall gains for society or to help those most in need?

These kinds of questions show the importance of ensuring a fair way to make decisions when we have limited resources and different values. To understand how values affect the answers to these questions, we need to understand different types of values.
Values

The decision making process for funding new drugs considers different types of values. Values are what is most important or what matters most to us. There are many kinds of values including personal, ethical and social. Values are complex – they can overlap, affect each other and conflict with each other.

- **Personal values**: a person’s combined religious, cultural, ethical, and family values. In the decision making process, it is important that decision makers are aware of their own personal values.

- **Ethical or moral values**: beliefs about how people in a community or society should treat each other. Examples that might affect a funding decision about a new cancer drug include:
  - **Fairness/Equity**: ensuring fair process of funding and distributing new drugs and equal access to new drugs. Equity requires that people are treated fairly while considering differences in their situations like medical need or poverty.
  - **Utility**: maximizing benefits and minimizing harms like valuing the greatest good for the greatest number of patients. Here, the term ‘utility’ is used differently than in economic evaluation.
  - **Liberty**: ensuring the right of individuals to make their own choices.

- **Social values**: a community or society belief in how it should be set up and how it should work. For example, communist, socialist, and capitalist societies have different social values that affect how resources are distributed for new drugs.

Studies show that Canadians want an **equitable health care system** in which each Canadian has the same health care options based on what Canadian society can afford. This is unlike a **value health care system** in which each member of society has the best health care that they can personally afford.

Canadians want an equitable health care system because it does the greatest good for the greatest number of Canadians while taking into consideration the needs of the most vulnerable Canadians.
The role of values in decision making: An exercise

Here is an interesting exercise that provides insight into how our values influence our choices. Although not related to health care, it shows how making the best choices for a group as a whole can put certain individuals in the group at risk. (This exercise is based on the ‘Black Hole of Calcutta’ exercise developed by Stuart Peacock in 1998.)

- Imagine you are part of a rescue team in Vancouver, Canada, when an emergency call comes in. You must lead your team to rescue a group of eight Canadian tourists trapped in a cave that is gradually flooding.

- Your team is the trapped tourists’ only hope of rescue. However, if you try to take the entire group of eight out all at once, everyone will drown. You must take out one group of four and then go back for the remaining four.

- You will be able to save everyone in the first group of four, but there is a 50% chance that the remaining four will drown before you return.

- You have to tell the rescue team which four tourists to take out first.

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Occupation</th>
<th>Family Responsibilities</th>
<th>Immediate Condition</th>
<th>General Health</th>
<th>Other Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tony</td>
<td>17</td>
<td>student</td>
<td>single</td>
<td>cold and numb</td>
<td>good</td>
<td>steals and does drugs (for many years)</td>
</tr>
<tr>
<td>Eric</td>
<td>43</td>
<td>car mechanic</td>
<td>divorced, no children</td>
<td>good</td>
<td>mild heart attack two years ago</td>
<td>smokes, drinks quite heavily and doesn’t exercise</td>
</tr>
<tr>
<td>Brenda</td>
<td>37</td>
<td>mother</td>
<td>married, 2 children</td>
<td>good</td>
<td>depression</td>
<td>left the workforce to have children, hasn’t been able to re-enter it</td>
</tr>
<tr>
<td>Mary</td>
<td>55</td>
<td>musician</td>
<td>widowed, no children</td>
<td>badly sprained ankle</td>
<td>mild osteoporosis</td>
<td>plays first violin for the Vancouver Symphony Orchestra</td>
</tr>
<tr>
<td>Charlie</td>
<td>27</td>
<td>unemployed</td>
<td>married, 1 child</td>
<td>good</td>
<td>Insulin-dependent diabetic, history of renal failure in the family</td>
<td>lives in northern Canada</td>
</tr>
<tr>
<td>Sylvia</td>
<td>63</td>
<td>doctor</td>
<td>married, 3 children, 1 grandchild</td>
<td>good</td>
<td>good</td>
<td>finding a cure for hepatitis C (it’s imminent and would not happen without her)</td>
</tr>
<tr>
<td>Jack</td>
<td>71</td>
<td>retired academic</td>
<td>single</td>
<td>good</td>
<td>good</td>
<td>enjoys fishing having retired from an internationally distinguished career</td>
</tr>
<tr>
<td>Bridgette</td>
<td>23</td>
<td>factory worker</td>
<td>single, 1 child</td>
<td>good</td>
<td>good</td>
<td>enjoys spending time with her family</td>
</tr>
</tbody>
</table>
MODULE 4: What principles guide fair health care funding decisions?

Who did others choose?

Here is the percentage of times readers picked each person for the first group of four:

- Bridgette 25.1%
- Brenda 24.9%
- Sylvia 21.5%
- Charlie 20.1%
- Mary 12.7%
- Tony 12.7%
- Jack 6.3%
- Eric 3.9%

Readers were students, health care professionals, researchers, health policy makers, and members of the general public who were part of the original Black Hole of Calcutta exercise.

The factors that most influenced decision making included: family obligation, age, acute health needs, contribution to society, and general health.

Reflecting on fair decision making

In this exercise you had to make tough choices, just like a health care decision maker. Not all health care decisions are like an emergency rescue; however, they all involve considering the positives and negatives about who to help. Although health care decision makers care about individuals, they have a responsibility to do the most good for the most number of people.

Making the decision making process explicit means to openly share which values guide distributing resources. This is often challenging and even uncomfortable for decision makers because it may seem as if their decisions favour some people over others. However, decision makers must be explicit about values because this improves understanding among stakeholders and helps identify and resolve any disagreements. Differing values and personal priorities mean that not everyone considers every decision fair. However, everyone must feel confident that the decision making process is fair. To ensure a fair decision, the decision making process must include:

- Representation
- Transparency
- Accountability
MODULE 4: What principles guide fair health care funding decisions?

**Representation**

Representation means that all stakeholders have an opportunity for input so that decision makers consider the values and perspectives in the decision making process. For example, patient representation ensures that decision makers consider patient values. This is especially important because patients have first-hand experience with the health condition and the effects of treatment.

**Transparency**

Transparency means that there is no secrecy about how decision makers decide to fund drugs. Transparency allows everyone to understand fully how decision makers make each decision including who is involved and what information and perspectives the decision makers consider.

**Accountability**

Accountability means that the decision makers are responsible to the public for the funding decisions. The decision making process is set up so that accountability requirements are part of it at all levels: policy level, legislative level, professional level, and individual level.

**Recap**

Now you have a better understanding of how different values can influence decisions and why it is important to have a fair process. Module 5 explains how representation, transparency, and accountability come together in the decision making process.

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**Including patient perspectives**

The voice of the patient is a critical part of health care decision making because funding decisions directly affect their well-being.

The patient perspective comes from patients themselves or from family members or close friends, often referred to as patient representatives.

Patients or their representatives get involved in the decision making process through funding committees, advisory committees and special meetings, or they may share their experiences, opinions, and advice in writing.
Health care funding decisions affect everyone in different ways and they can have long-term effects. We must feel confidence in the decision making process and in decisions that come out of the process if we are to accept them. Canada’s health care system has several levels of accountability so there are numerous checks in place to encourage that decision makers make responsible decisions. For example:

- **Policy level accountability**: must follow the Canada Health Act, which describes the principles that all provincial and territorial health systems must follow to qualify for federal health care funds.

- **Legislative level accountability**: must follow legislation such as the Canadian Charter of Rights and Freedoms, which protects against discrimination. Provincial and territorial governments must also obey the legal rules that describe how they must manage health care.

- **Professional level accountability**: must follow standards for medical or legal practice, which professional groups like the College of Physicians and Surgeons oversee.

- **Individual level accountability**: must follow processes like considering recommendations from stakeholders and ensuring the public’s right for information and the right to appeal decisions.
MODULE 5: How are decision makers held accountable?

**Accountability in action**

To ensure that pCODR follows a fair process, it follows the Accountability for Reasonableness (A4R) framework for fairness:

<table>
<thead>
<tr>
<th>A4R Principle</th>
<th>In Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transparency: the decision making process is well known, easy to understand and publicly available.</td>
<td>pCODR makes available all information about a drug review, including who was involved, on their website at <a href="http://www.pcodr.ca">www.pcodr.ca</a> under the section ‘Find a Review’.</td>
</tr>
<tr>
<td>Representation: the decision making process gives those who are affected by the decision a voice.</td>
<td>pCODR Expert Review Committee develops drug review recommendations with significant input from patient groups and clinicians.</td>
</tr>
<tr>
<td>Reasons and Relevance: the decision making process uses clear and explicit decision making criteria.</td>
<td>pCODR considers scientific evidence, economic evidence, and patient input as part of its process. It provides the evidence and reasoning behind recommendations as part of its drug review reports, which are online at <a href="http://www.pcodr.ca">www.pcodr.ca</a>, ‘Find a Review’.</td>
</tr>
<tr>
<td>Appeals: the decision making process allows stakeholders to question recommendations and get a response.</td>
<td>pCODR encourages feedback on all aspects of its recommendations so that stakeholders can question the content and the decision making process, as well as provide new information for review.</td>
</tr>
</tbody>
</table>
| Enforcement: the decision making process has checks to make sure that it meets all conditions for fairness. | pCODR posts stakeholder feedback on its recommendations as part of a fair process.  
  pCODR encourages participants to submit a request for procedural review if they do not feel the process was fairly applied.  
  pCODR checks how well it follows its own codes of conduct, codes of communication, and guidelines for conflict of interest to ensure the process is respected and credibility is maintained. |

*pCODR’s accountability framework is based on the following article: Daniels N, Sabin JE. Setting limits fairly: Can we learn to share medical resources? Oxford: Oxford University Press, 2002.*

**Recap**

Now you have a better understanding of the different levels of accountability in Canada’s health care system and how pCODR uses principles of accountability in its process.

Now that you have finished this tutorial, which provides an overview of how decision makers make cancer drug funding decisions, you can also find out how to get involved and see answers to frequently asked questions about pCODR.
**MODULE 5: How are decision makers held accountable?**

**Learn more?**

To gain a more in-depth understanding of issues involved in health care funding decisions you can do a free tutorial called PrePARE – Preparing Participants for Allocating Resources Equitably: [www.cancerview.ca/prepare](http://www.cancerview.ca/prepare). It has interactive exercises and you receive a certificate of completion.

**Questions or comments?**

Please contact pCODR at [info@pcodr.ca](mailto:info@pcodr.ca) or the Canadian Partnership Against Cancer at [info@cancerview.ca](mailto:info@cancerview.ca).

*Thank you for reading this tutorial.*

We hope you enjoyed learning about the principles, processes, and stakeholders involved in funding new cancer drugs.
Get involved in pCODR’s Drug Review Process

At the beginning of a drug review process, patient advocacy groups provide input on issues about a specific drug or type of cancer. This helps pCODR understand how people value and prioritize different aspects of cancer treatments and outcomes so that pCODR more fully considers both the positive and negative effects that a drug may have on all those affected by a drug funding decision.

As part of a patient advocacy group, you can also comment on the pCODR Expert Review Committee (pERC) recommendations to further ensure that the Committee considers your perspective. You can also apply to join a specific committee—patients, doctors, pharmacists, economists, are all part of the process.

Get involved in other ways

Get involved by checking out these other organizations. If you are part of a patient advocacy group, register with the most appropriate organization so that the review considers your input.


For a list of patient advocacy groups, visit: [http://www.pcodr.ca/idc/groups/pcodr/documents/pcodrdocument/pcodr-registered-patientadgrps.pdf](http://www.pcodr.ca/idc/groups/pcodr/documents/pcodrdocument/pcodr-registered-patientadgrps.pdf)

For a list of pCODR committees, visit pCODR and select ‘Opportunities’ at the end of the homepage: [www.pcodr.ca](http://www.pcodr.ca)

Frequently asked questions about pCODR

Why was pCODR created?

pCODR was created to provide a clear, pan-Canadian drug review process for cancer drugs. pCODR makes sure that every province, territory, and cancer agency has access to the same expert recommendations and evidence to guide their funding decisions. A consistent and clear process saves time and improves the quality of the new cancer drug review process.

What kinds of recommendations does pCODR make?

Based on all of the input, the pCODR recommendation states one of three types of recommendations:

- ‘Recommend’: a drug with a clear clinical benefit and economic benefit
- ‘Consider with conditions’: a drug that a province or territory could consider funding if it is able to meet certain conditions that affect the drug’s clinical effectiveness or cost-effectiveness
- ‘Do not recommend’: a drug does not have a clear clinical benefit and economic benefit

What is the role of the pharmaceutical manufacturer in the pCODR’s drug review process?

Pharmaceutical manufacturers need a recommendation from pCODR before the provinces and territories can consider their drug for funding. A pharmaceutical manufacturer or tumour group starts the pCODR review process by giving pCODR clinical evidence and economic evidence. Throughout the review process, pCODR consults the pharmaceutical manufacturer to clarify and get additional information as needed.

Why wouldn’t pCODR recommend a drug?

pCODR bases its drug recommendations on a framework that it uses for all cancer drugs and all situations including rare cancers or end of life care. The framework tells pCODR all of the factors it must consider like information on clinical benefit, cost of the drugs, fit with patient values, and how it can become part of the health care system. The individual drug, disease, and situation determine whether pCODR recommends a drug or not. Visit the pCODR website at www.pcodr.ca and select ‘Our Review Process’ to learn more.
Frequently asked questions about pCODR

Why would a province or territory reject pCODR recommendations?
In addition to pCODR recommendations, each province’s and territory’s cancer agency or ministry of health considers a variety of local factors. These factors like the potential effect of any funding decision on their residents, patients, health services, and overall budget, may result in a different decision than the pCODR recommendation.

Which provinces have accepted pCODR’s recommendations?
To find out, please look at the Provincial Funding Summary that tells each province’s and territory’s funding decisions for each drug that went through the pCODR review process. Visit the pCODR website and the ‘Find the Review’ section.

Where can the public get pCODR’s drug review recommendations?
Each pCODR drug recommendation and a detailed discussion about the recommendation process—including clinical and economic reports and stakeholder comments—is on the pCODR website at www.pcodr.ca in the ‘Find a Review’ section.

Want to learn more about pCODR?
Visit the pCODR website at www.pcodr.ca and click on ‘FAQs’ at the bottom of the home page.
<table>
<thead>
<tr>
<th>Word</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bias</td>
<td>Bias means bringing other influences into play that could affect a clinical trial’s outcomes. For example, a researcher who wants to believe that a drug works may subconsciously give the drug to patients who he/she thinks are more likely than others to get better.</td>
</tr>
<tr>
<td>Blinding</td>
<td>Some research studies may be ‘single-blinded’ and others may be ‘double-blinded’. Single-blinded means that the participants don’t know who is talking the real new drug or a fake drug (called a placebo). Double-blinded means that the participants and the researchers don’t know who is taking the real drug versus the placebo.</td>
</tr>
<tr>
<td>Clinical effectiveness</td>
<td>Clinical effectiveness means how much the new drug delays negative events like the disease coming back, the disease getting worse, or death.</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>Clinical trials are research studies that researchers do to evaluate a drug’s safety and effectiveness in people.</td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td>Cost-effectiveness means a drug’s ‘value for money’; it is cost-effective if it leads to better health than if the cost of it was put towards other options.</td>
</tr>
<tr>
<td>Cost-effectiveness analysis</td>
<td>Cost-effectiveness analysis evaluates costs in relation to the effectiveness of the new drug when compared with other options.</td>
</tr>
<tr>
<td>Cost-utility analysis</td>
<td>Cost-utility analysis it is a type of evaluation that considers costs in relation to how a new drug performs to improve quality of life and/or number of years lived when compared with other options.</td>
</tr>
<tr>
<td>Disease progression</td>
<td>Disease progression means that the disease gets worse.</td>
</tr>
<tr>
<td>Disease recurrence</td>
<td>Disease recurrence means that the disease comes back.</td>
</tr>
<tr>
<td>Economic evaluation</td>
<td>An economic evaluation is an analysis that compares the costs and effectiveness of two or more new drugs.</td>
</tr>
<tr>
<td>Efficiency</td>
<td>Efficiency means the most benefit with the least cost.</td>
</tr>
<tr>
<td>Equity</td>
<td>Equity means that everyone is treated fairly while considering differences in their situations like medical need or poverty.</td>
</tr>
<tr>
<td>Health care technology</td>
<td>‘Health care technology’ refers to drugs, devices, procedures, diagnostics (e.g., imaging or laboratory tests) and other interventions involved in promoting health or in the prevention, monitoring or treatment of, or recovery from, specific medical conditions.</td>
</tr>
<tr>
<td>Word</td>
<td>Definition</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Health technology assessment</td>
<td>Health technology assessment is an evaluation that helps decision makers decide whether to fund a new health care technology by evaluating all information available about health benefits, costs, resources needed to use the technology, and the effects that the technology may have on society.</td>
</tr>
<tr>
<td>Incremental Cost-Effectiveness Ratio</td>
<td>Incremental Cost-Effectiveness Ratio is a measure that helps decision makers decide if the additional costs between two drug options are worth the additional benefit. Incremental means additional.</td>
</tr>
<tr>
<td>Opportunity cost</td>
<td>Opportunity cost is the opportunity we lose when we fund certain services because the funds are no longer available for other services.</td>
</tr>
<tr>
<td>Placebo</td>
<td>A placebo looks like a real drug but it has no known effect and it is safe to take.</td>
</tr>
<tr>
<td>Progression-free survival</td>
<td>Progression-free survival is the length of time from when a participant starts a trial to when the disease gets worse.</td>
</tr>
<tr>
<td>Priority setting</td>
<td>Priority setting is deciding which options are more important than others.</td>
</tr>
<tr>
<td>Quality-Adjusted Life Year</td>
<td>Quality-Adjusted Life Year is a measure of the quality and quantity (length) of a patient’s potential lifetime as a result of using the drug.</td>
</tr>
<tr>
<td>Quality of life</td>
<td>Quality of life means someone’s physical, psychological, social, and emotional well-being.</td>
</tr>
<tr>
<td>Resource allocation</td>
<td>Resource allocation is distributing funds and other resources to meet different needs. For example, in the health care system, resource allocation is deciding which health care services to fund before others.</td>
</tr>
<tr>
<td>Scientific evidence</td>
<td>Scientific evidence is information gathered from scientific research that is published in scientific journals.</td>
</tr>
<tr>
<td>Side effect</td>
<td>A side effect is a health problem that is the result of a treatment. For example, common side effects of a cancer drug are pain and hair loss.</td>
</tr>
<tr>
<td>Systematic review</td>
<td>A systematic review is research that combines the results from all of the clinical trials that evaluate the same new drug in similar groups of people.</td>
</tr>
<tr>
<td>Utility – related to economic evaluation</td>
<td>Researchers measure quality of life in units called utility. A utility score shows a person’s preferences in terms of how they value different levels of health.</td>
</tr>
<tr>
<td>Utility – related to values and ethics</td>
<td>Utility is maximizing benefits and minimizing harms like valuing the greatest good for the greatest number of patients.</td>
</tr>
</tbody>
</table>