

Assessment of New Healthcare Technologies In Canada

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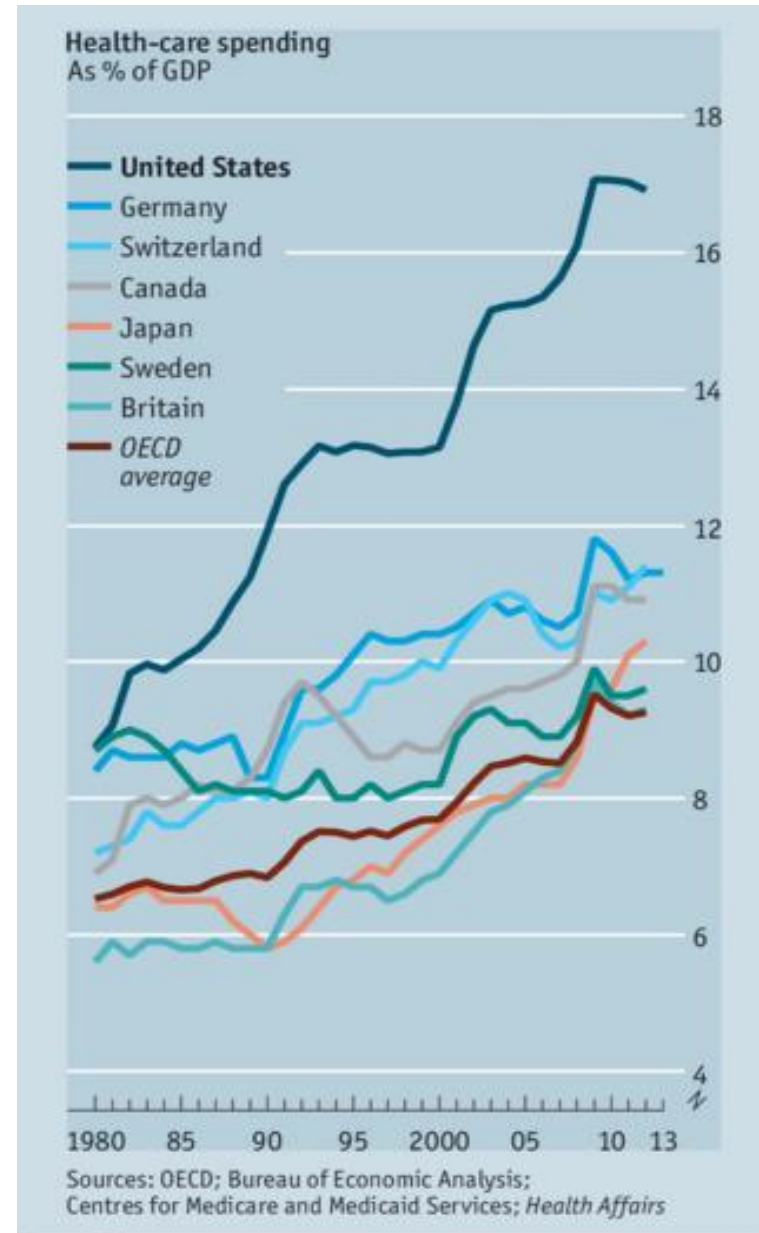
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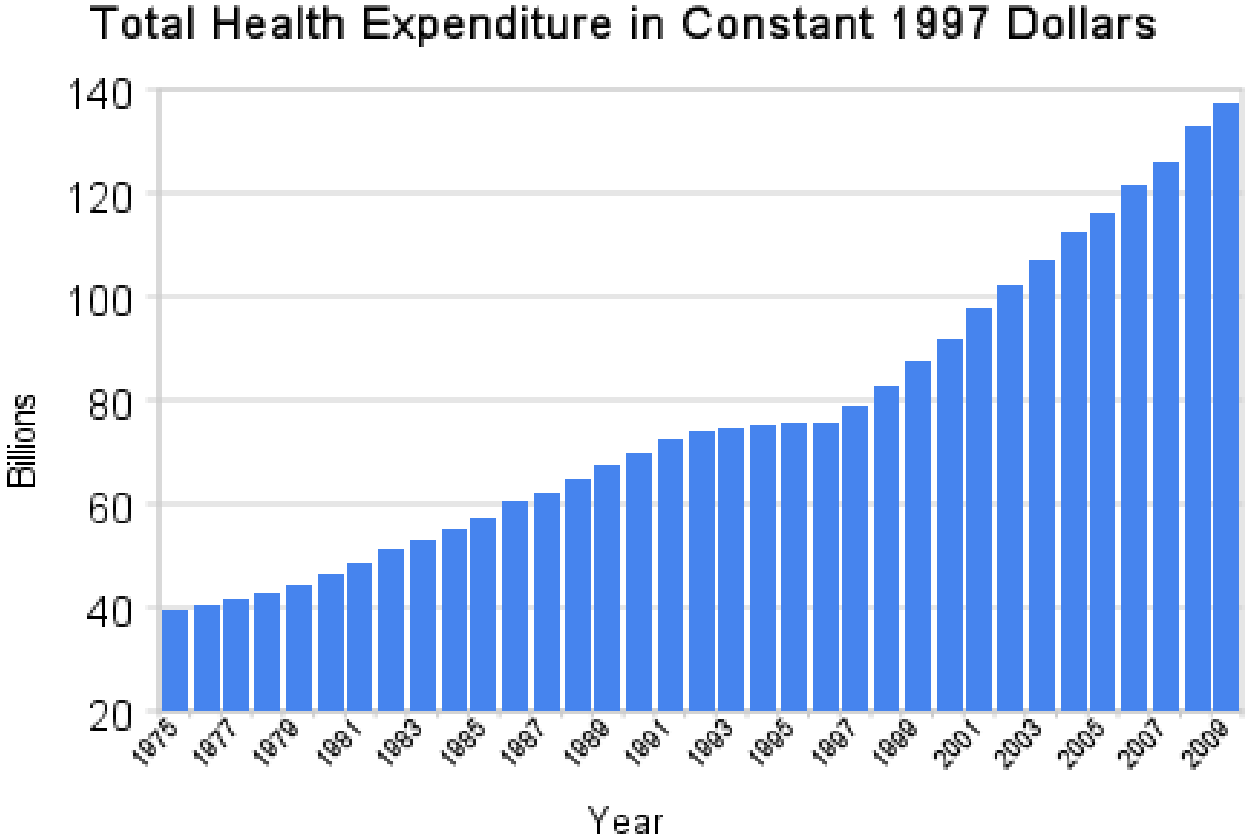
Disclosures:

Ad Boards and consulting contracts

Astellas, Astra Zeneca, Boehringer-Ingelheim, Becton Dickinson, BMS, Celgene, Gilead, Lilly, Roche, Takeda Canada

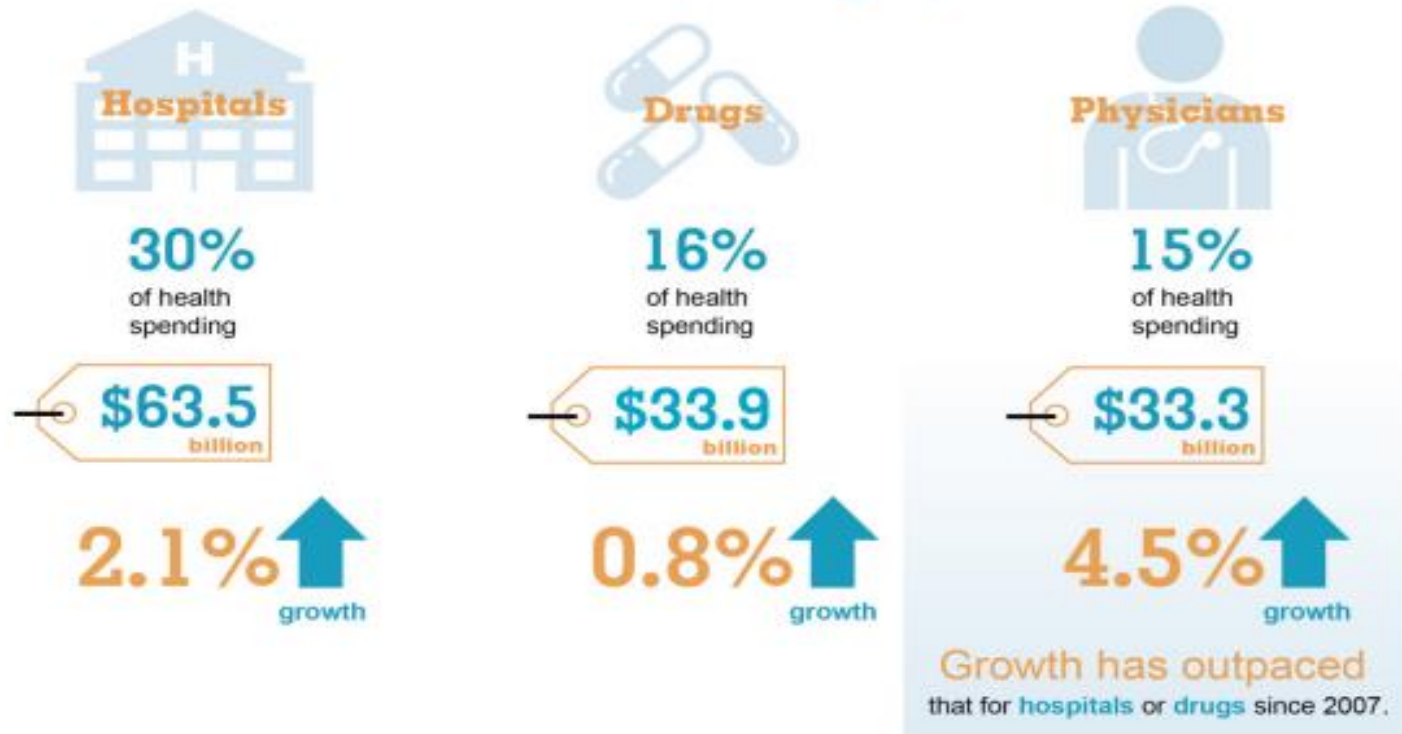


Growth in Healthcare Spending in Canada



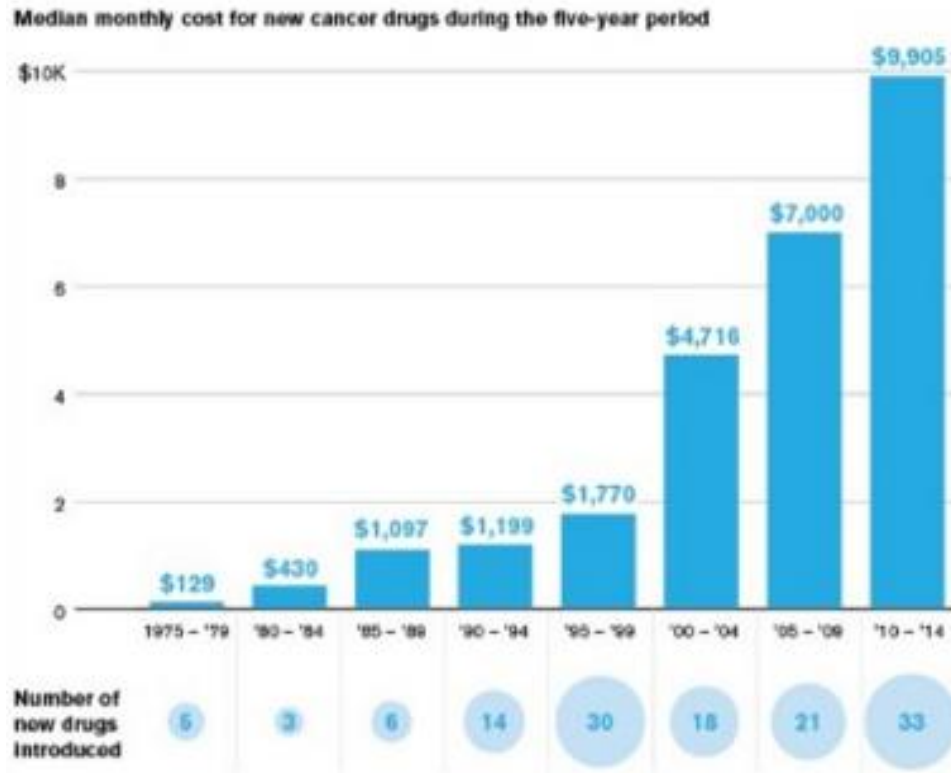
Major Categories of Healthcare Expenditure in Canada

Where is most of the money being spent?



Source
Canadian Institute for Health Information, *National Health Expenditure Trends, 1975 to 2014*.

Soaring Cost of Oncology Drug Prices, a Major Concern

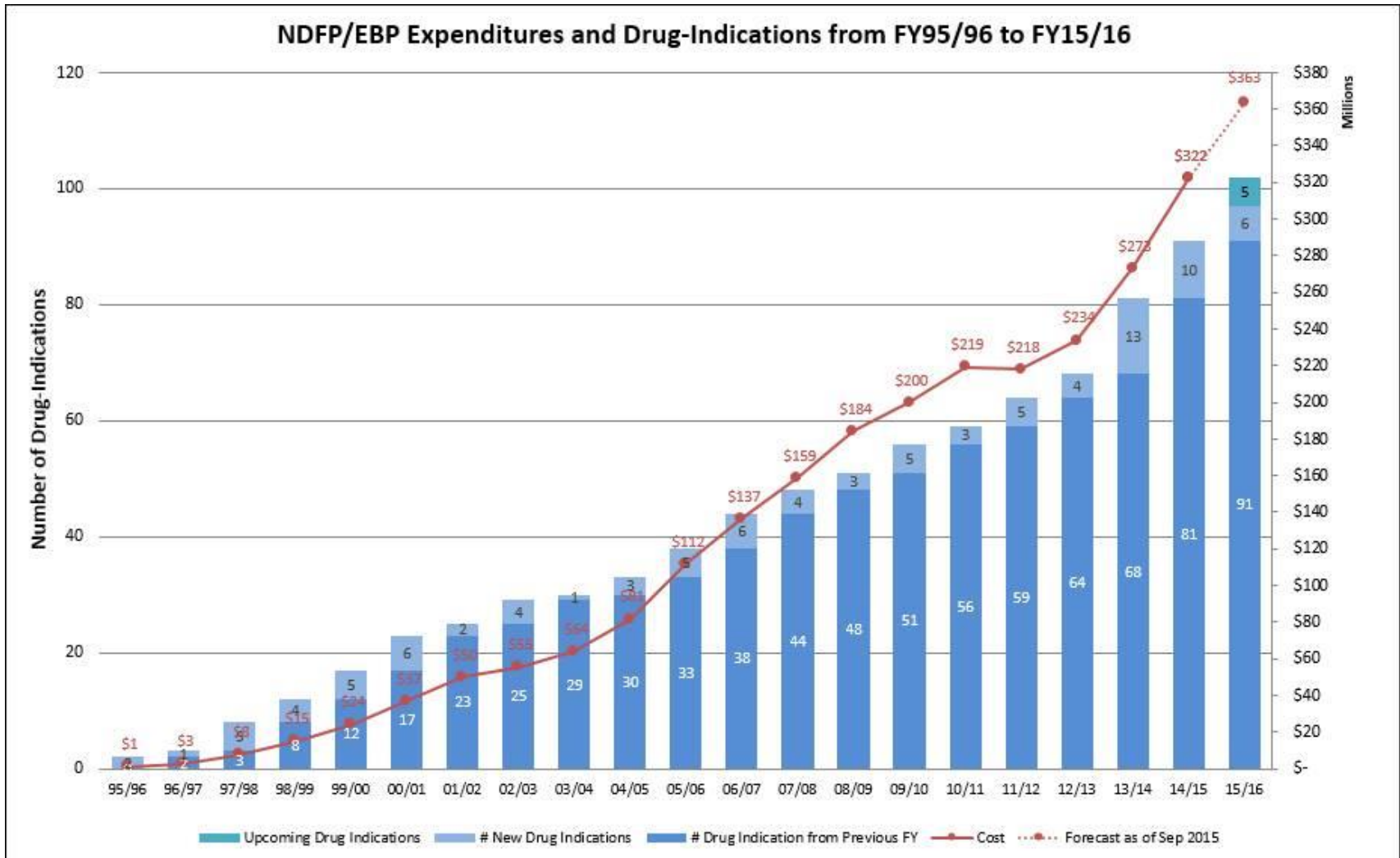


Note: Costs are monthly Medicare prices for each drug the year it was introduced, adjusted for inflation.

Source: Peter Bach and Geoffrey Schnorr at Memorial Sloan Kettering Cancer Center

Bloomberg Graphics

Rising Drug Costs plus Increasing Volumes Result in Large Budget Impact



Assessing New Cancer Drugs in Canada

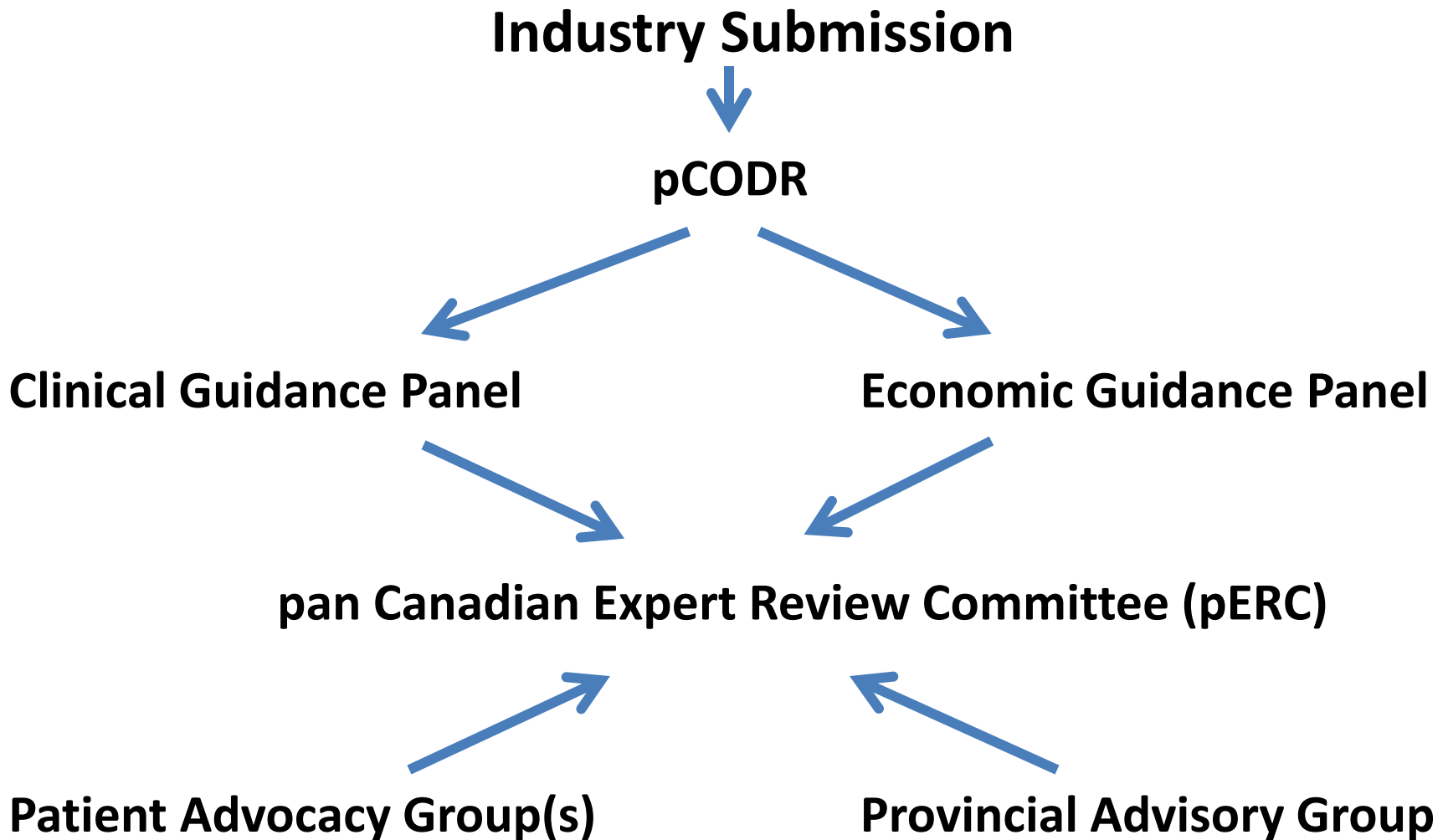
- **Health Canada**

- Evaluates quality of manufacturing, efficacy and safety
 - Enables manufacturer to market drug
- **NOC**

- **Pan-Canadian Oncology Drug Review (pCODR)**

- Established in 2007
- Evaluates clinical benefit and cost-effectiveness
- Takes account of patient values
- Considers feasibility of implementation
- Integrated with CADTH

Pan-Canadian Oncology Drug Review (pCODR)



pCODR's Deliberative Framework

Clinical Benefit

- Net clinical benefit
- Disease specific context
- Magnitude and type of benefit
- Level of uncertainty

Patient Values

- Increased survival
- Improved quality of life
- Better disease control
- Less treatment related toxicity
- More choice

Cost-effectiveness

- Incremental cost-effectiveness
- Appropriate comparator
- Economic model used
- Projection of survival benefit
- Time horizon

Feasibility

- Practical issues: chair time
- Specific patient criteria
- Drug wastage
- Line of therapy
- Scope creep

Pan-Canadian Oncology Drug Review

- Makes an initial recommendation,
 - publically posted for feedback.
 - If no negative feedback from stakeholders, rapid conversion
- Final Recommendation may be to fund, to not fund or fund with conditions; commonly “fund conditional on improved cost-effectiveness”;
- A clear rationale is provided for all decisions

Strengths of the pCODR Process

Broad stakeholder engagement

- Manufacturers
- Patients – registered patient advocacy groups
- Clinical experts – 11 disease site Clinical Guidance Panels; 12 of 16 members of expert review committee (pERC) are oncologists
- Health economics experts - Economics Guidance Panel and 2 members of pERC

Strengths of the pCODR Processes

Multiple Opportunities for Stakeholder Input:

- Manufacturer has opportunity to engage before submission through pre-submission meetings; approach to economic evaluation discussed
- Manufacturers can review the clinical and economic guidance reports to identify factual errors
- All stakeholders can comment on the initial pERC recommendation
- pERC recommendation includes advice on implementation issues raised by provincial advisory

Strengths of the pCODR Processes

High Level of Transparency

- Recommendations are written in a standardized fashion
- Both initial and final recommendations are posted along with feedback from all parties
- With the exception of confidential prices, all information contributing to the funding recommendation must be disclosed in the posted recommendation

Mapping the ASCO and ESMO Frameworks to Canadian Deliberative Framework

Clinical Benefit			Patient-Based Values			Economic Evaluation			Adoption Feasibility		
	ASCO	ESMO		ASCO	ESMO		ASCO	ESMO		ASCO	ESMO
Effect*	✓	✓	Experience with disease	✗	✗	Cost effectiveness	✗	✗	Budget Impact	✗	✗
Safety	✓	✓	Experience with drug	✗	✗	Drug Cost	✓	✗	Implementation	✗	✗
Burden of Illness	✗	✗									
Need	✗	✗									

* Please note: Effect includes quality of life data

Defining Cost-effectiveness

The cost-effectiveness ratio (*CE*) is the *incremental* cost of an intervention divided by its *incremental* benefits, as given by the formula:

Cost-Effectiveness =

$$\frac{\text{Cost}^1 - \text{Cost}^2 (\Delta C)}{\text{Effectiveness}^1 - \text{Effectiveness}^2 (\Delta E)}$$

Effectiveness usually measured as survival gain in years

Defining Cost-effectiveness

- $ICER = \frac{\Delta C}{\Delta E}$
- To be cost-effective: $ICER < \text{Willingness to Pay (WTP)}$
- WTP varies by jurisdiction
- WHO “reasonable” upper threshold may be up to 3X the GDP per capita per unit of valuation
- NICE (UK) £ 20-30,000/QALY
- CADTH/pCODR (Canada) \approx \$100,000 CDN/QALY
- US not used

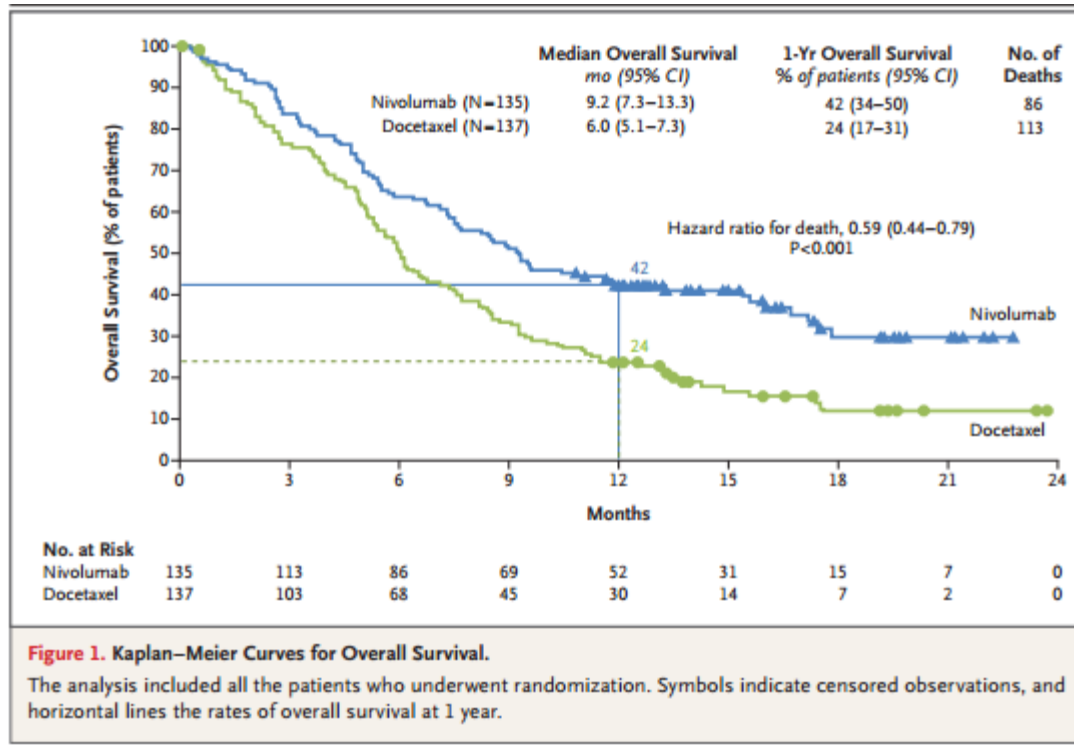
Approval Conditional on an Acceptable ICER?

- To improve ICER
 - ΔC : ↓ cost
 - ΔE : ↑ outcome (not possible)
- Increase WTP: ↑ budget (limited capacity, but possible for rare tumours, tumours with few treatment options)
- Negotiation of price: Pan-Canadian Pricing Alliance (PCPA)

The Challenge Ahead for HTA: Immuno-oncology Drugs

- Patient values
 - Survival – tail on the survival curve
 - Urgency to gain access to new promising therapy
 - Choice versus risk
- Determining Cost-effectiveness
 - Estimating the area under the curve (uncertainty)
 - What time horizon to use?

Nivolumab versus Docetaxel in Advanced Squamous NSCLC



10 drugs appear to deliver more clinical benefit... but also much more cost

- Nivolumab \$28.78/mg
 - 3 mg/kg Q2 weeks = \$12,068/ month
\$145,050 / year
- Pembrolizumab \$51.79/mg
 - 2mg/kg q2weeks \$16,700/month
\$200,400 / year
 - 10 mg/kg q2 weeks \$83,500/month
\$1,002,000/ year

Evaluating the Cost-effectiveness of IO Drugs

A Hypothetical Example

	Drug A (IO Agent)	Drug B
Name	Long Tail	No Tail
Effect (survival)		
• At 2-year	10%	0%
• From 2-4 years	10%	0%
Cost (per year)		
• Cost per patient	\$500,000	\$100,000
N	1,000	1,000
Average cost per patient		
• At 2-year	\$592,500	\$95,000
• At 4-year	\$692,500	\$95,000
Incremental cost		
• At 2-year	\$15,800 per life-year gained	
• At 4-year	\$12,043 per life-year gained	

In the Immediate Future

- Cost-effectiveness may be insufficient to make funding decisions, certainly at provincial level (the payer)
- Greater need to consider the budget impact

Conclusions

- Healthcare resources are finite
- The growth in healthcare expenditures is consuming a large percentage of resource in publicly funded systems and is becoming unsustainable
- New health technologies in Canada must have a clinically meaningful benefit, be valued by patients and providers and demonstrate cost-effectiveness to be publicly funded

Thank you

Questions?