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Re-thinking cost per QALYs in drug reimbursement decision making

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Forward thinking

"If we are ever going to get the 'optimum' results from our national expenditure on the NHS we must finally be able to express the results in the form of the benefit and the cost to the population of a particular type of activity, and the increased benefit that would be obtained if more money were made available."

Cochrane AL. Effectiveness and Efficiency: random reflections on health services. Nuffield Provincial Hospitals Trust, London, 1972.

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Definition of value

- Michael Porter, NEJM 2010
  - "Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent."

- It would seem that Cochrane and Porter agree despite a 40 year span!

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My starting point

- Benefit should be a construct of all relevant outcomes, even if they are hard to measure

- A *values* framework should underpin all decisions about the *value* of drugs

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Summary of points

- Decision makers have many criteria or factors that influence decision making, only two of which are captured in the QALY measure, so why would we want to base allocation decisions on such a limited construct?

- ICERs – and in this case cost per QALYs - necessarily lead to an increase in resources, yet decision makers often will view a low cost per QALY as 'cost-effective' and thus make reimbursement decisions without fully considering the opportunity cost of the budget impact

What are QALYs?

- Measurement of benefit that combines quality of life and quantity of life in a single index

What factors are important?

- Disease related factors
  - Prevalence, severity, who will benefit, alternatives
- Treatment related factors
  - Effectiveness, magnitude, safety, innovation
- Population related factors
  - Societal impact, distribution of health, SES policy

Paulden, Stafinski, Menon, **McCabe** 2014

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What factors are important?

- Comparative effectiveness
- Adoption feasibility
- Risk of adverse events
- Patient autonomy
- Societal benefit
- Equity
- Strength of evidence
- Incidence/ prevalence
- Innovation
- Disease prevention/ health promotion

Dionne, **Mitton**, Gibson, Lynd 2015

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Report from Ontario

- Report of the Ontario Citizens' Council: QALYs and Drug Funding Decisions in Ontario (2013)

<u>Recommendation #1</u>

- "QALYs should continue to feature prominently in making decisions for drugs to be put on the formulary. However they should not be the only consideration or even the primary consideration."

Non-drug priority setting

- Recent survey found that across all health authorities in Canada, only 7% of decision makers considered QALYs relevant when setting priorities and allocating resources

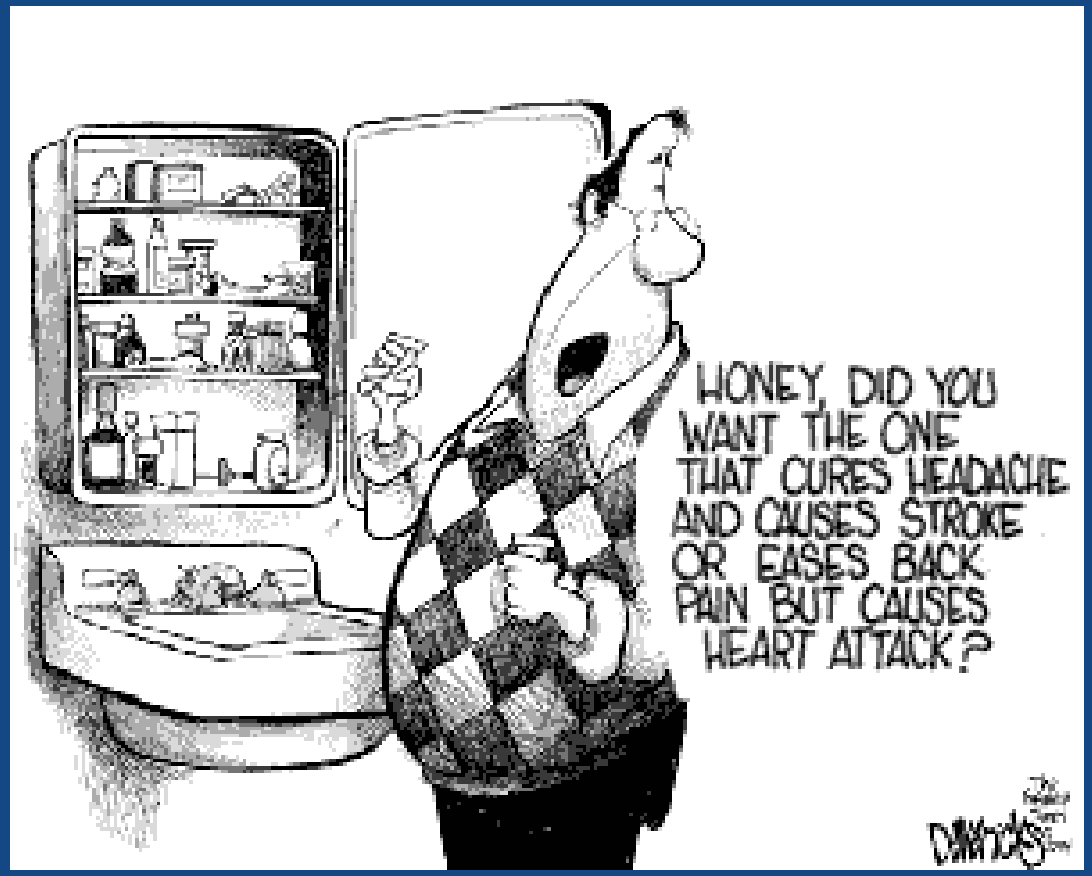
Smith et al. 2012

Summary #1

- QALYs are limited as they only capture two of potentially many factors relevant in drug reimbursement decision making

- (and if anyone is to blame, its those darn UK health economists who started the whole QALY business… but that was rather un-Canadian of me to say so I'm very sorry!!)

Explicit trade-offs required



Trade-offs have to be made, important to weigh out both costs and benefits and apply knowledge within broader framework

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Incremental Cost-Effectiveness Ratio

$$\frac{(\text{Cost}_{new} - \text{Cost}_{old})}{(\text{Effectiveness}_{new} - \text{Effectiveness}_{old})} = \textbf{ICER}$$

$$\textbf{ICER} = \Delta C / \Delta E$$

Incremental resources required by the intervention

Incremental health effects gained by using the intervention

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A simple decision rule

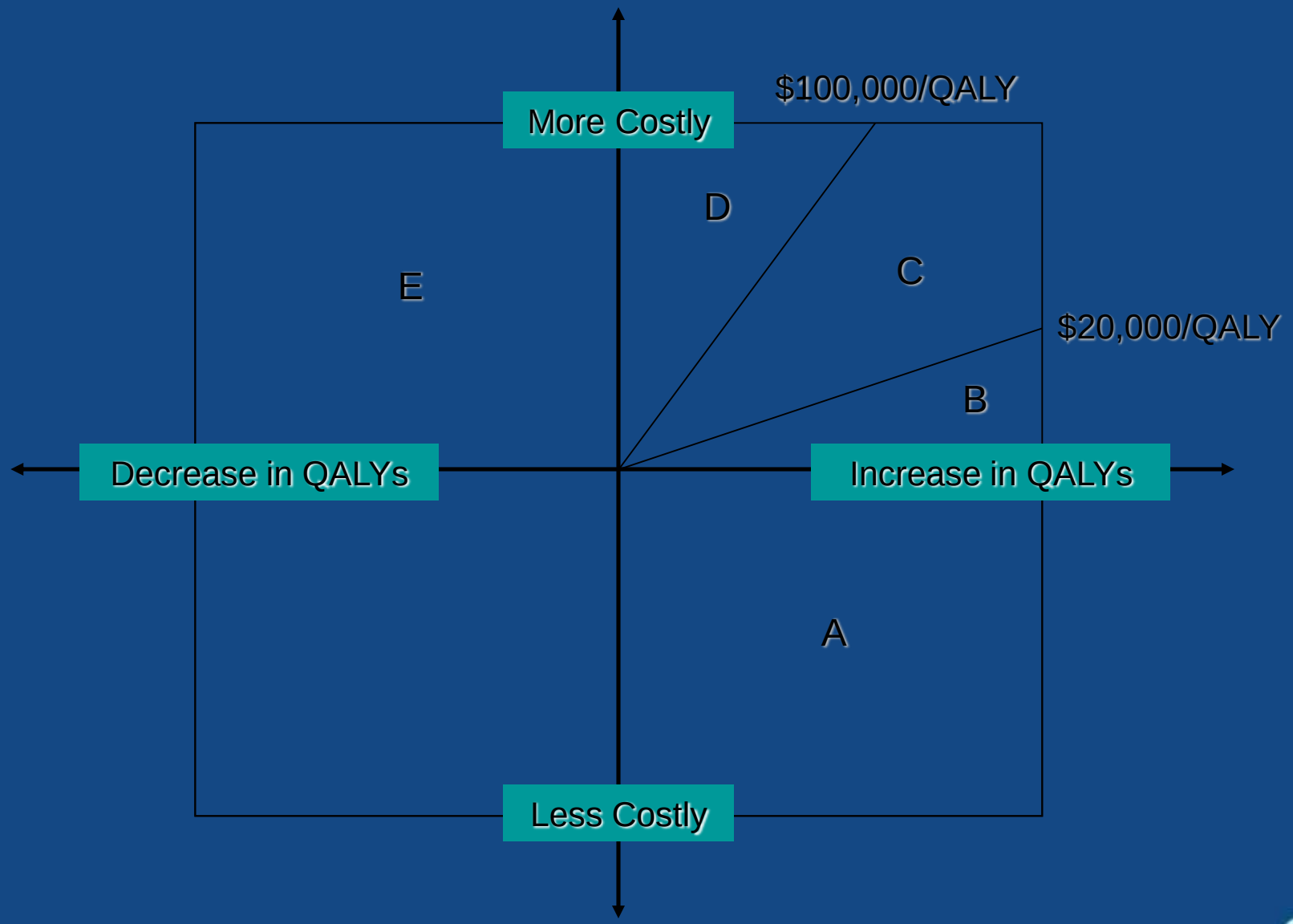
ICER for new program ≤ $50,000/QALY

Decision: adopt new program

ICER for new program> $50,000/QALY

Decision: do not adopt new program

Grades of recommendation



The Cost-Effectiveness Acceptability Plane

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So what's the real issue?

"Resources devoted to one service provided by a hospital or doctor are of necessity not available for other services." **[Donaldson et al. 2002]**

AKA its all about opportunity cost!!!

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Budget impact the key

- BIA is key as it's the overall budget impact that provides an indication of the cost-effectiveness
- Drug X might have a low ICER compared to Y and will cost the Province $10M over 3 years
- Its that $10M that needs to be considered in terms of the opportunity cost
- Currently our structures don't enable explicit comparison but they absolutely could

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Navigating forward

- Economic evaluation methods are well developed; many studies now include an economic component
- Simple decision rule does not recognize concept of local opportunity cost as even a 'favourable' ICER will require an increase in budget to achieve some additional gain
- Need a priority setting approach that can be informed by economic evaluation and other forms of evidence

Economics and ethics

- Literature on priority setting has economics and ethics contributions
- Useful to see these disciplines as complementary
  - Value for money
  - Fair process --- *values based*
- Develop and implement an approach to priority setting which incorporates both perspectives

[Gibson et al. 2006]

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What might this framework look like?

- Identify stakeholder values
- Use this to construct decision criteria
- Determine costs and 'benefits' of options
- Explicitly assess trade-offs
- Validate and communicate
- Accept winners and losers

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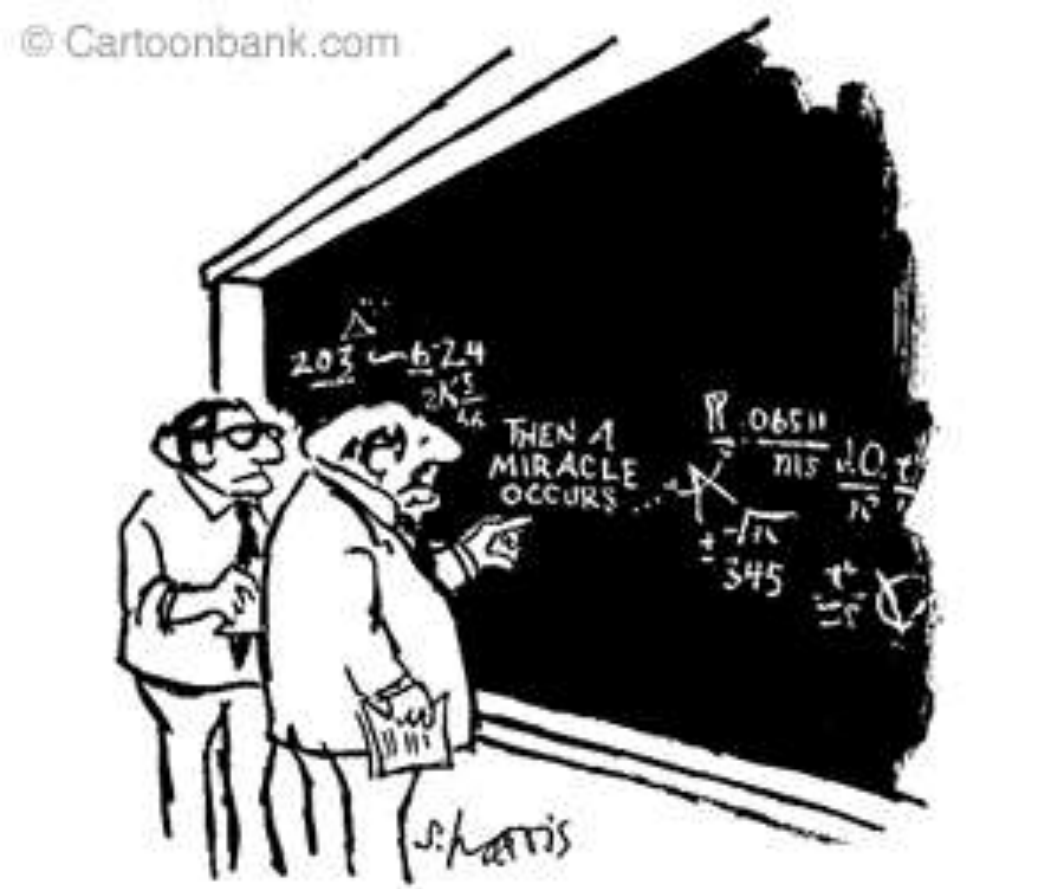
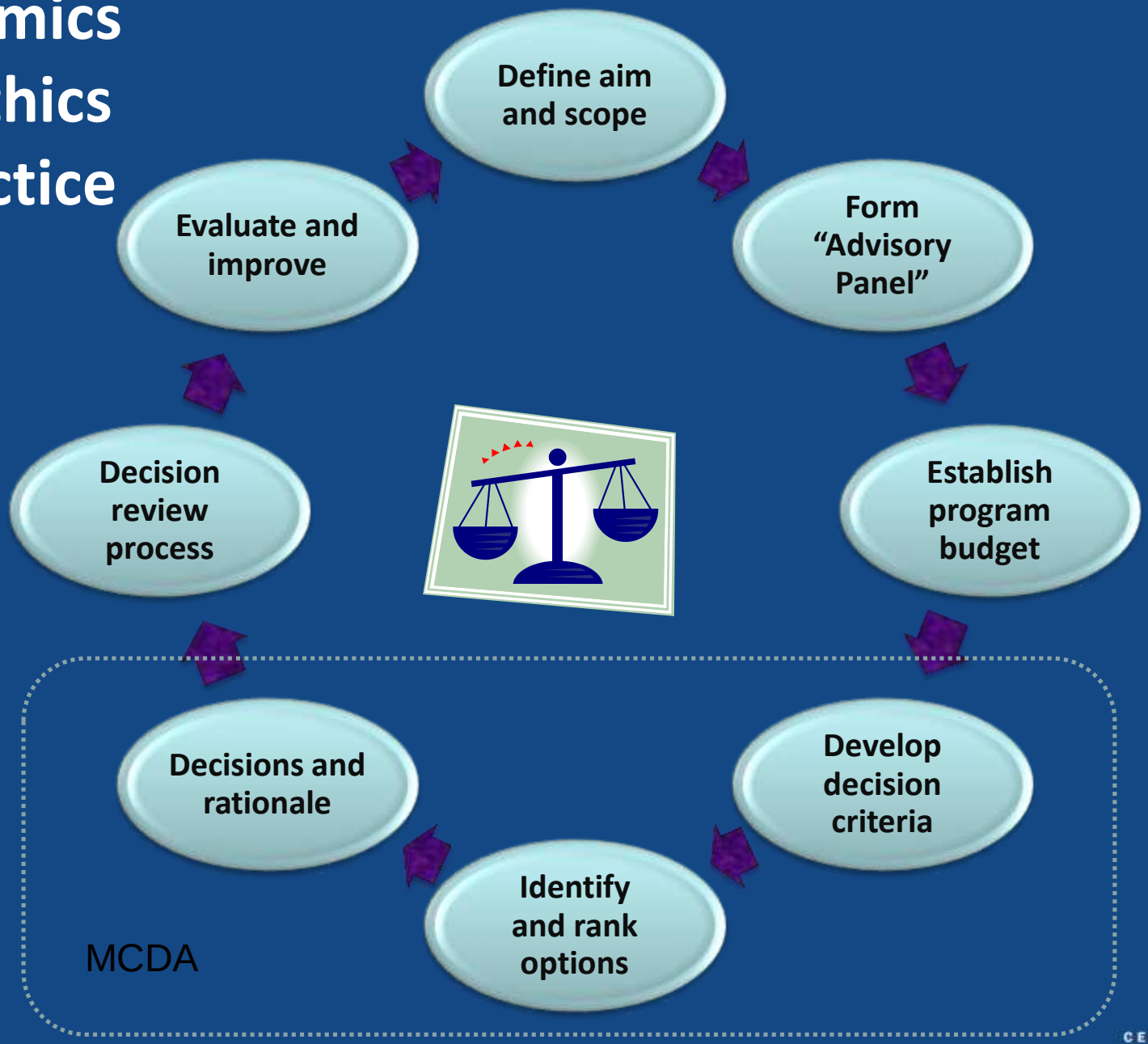


"I think you should be more explicit here in step two."

Economics and ethics in practice



[Peacock et al. 2006]

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Summary #2

- Methods are available to assist decision makers in making difficult choices
- Has to be based on *public values* which then inform the criteria that decisions will be based on
- Big stakes both in terms of $$$ and equity so not clear why greater sophistication isn't being sought

Where to from here?

- Critical need for a broader values based framework for decision making that moves away from simplistic cost per QALY assessment of one off decisions

- Application of a multi-criteria approach set within a values framework will ensure full range of benefit is being considered in drug decision making whilst achieving greater gains in terms of value overall