

Dealing with the Challenges of Health Innovation

Stirling Bryan, PhD

Centre for Clinical Epidemiology & Evaluation

Vancouver Coastal Health Research Institute
& University of British Columbia

Overview

What is 'innovation'?

When is health innovation a challenge (and when is it not a challenge)?

The NICE approach to this challenge

Views of two notable commentators:

- Tomas Philipson (Chicago)
- Jack Dowie (London)

Conclusions

What is 'innovation'?

Innovation is a new way of doing something

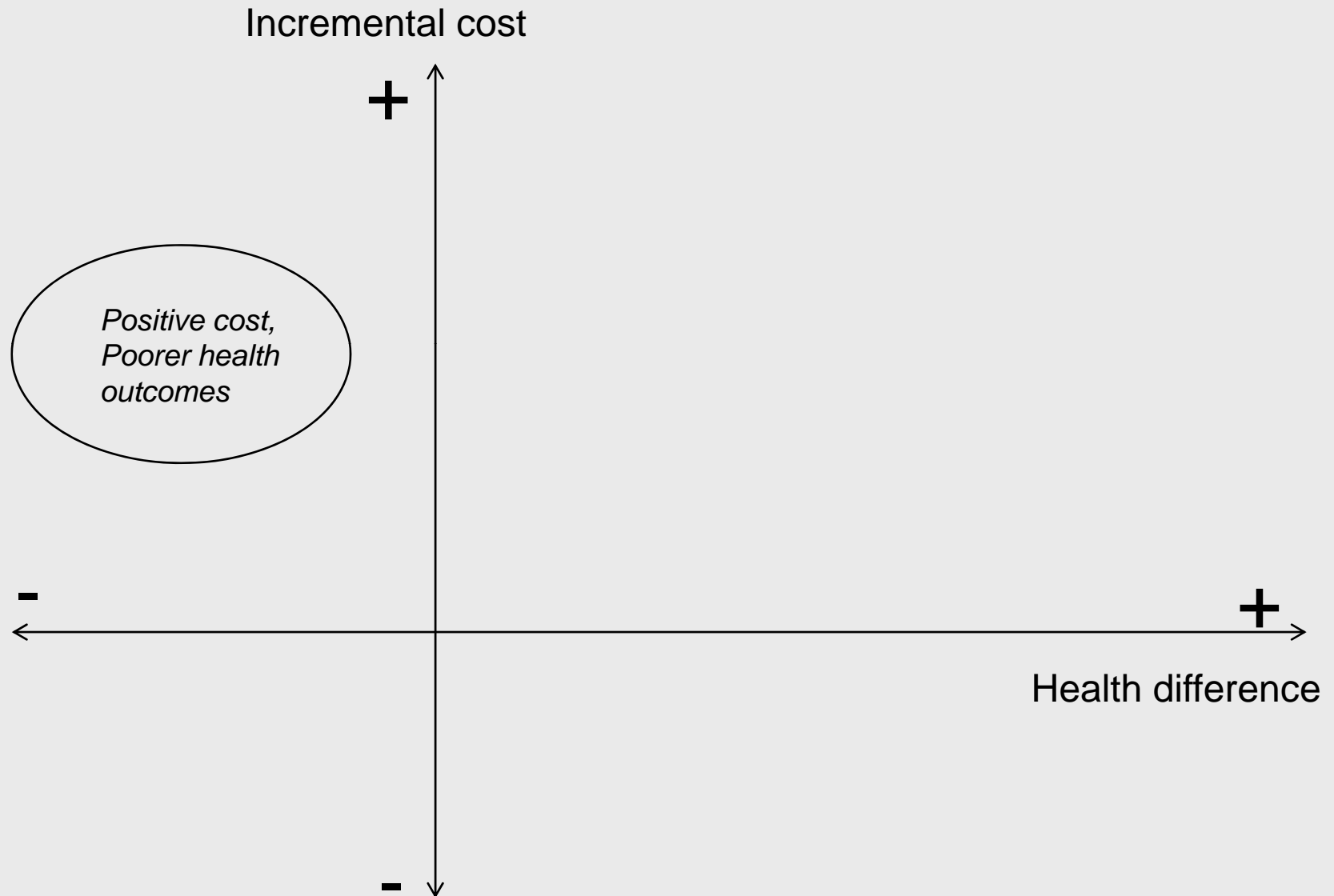
Mckeown (2008):

- 'Invention', an idea made manifest
- 'Innovation', an idea applied successfully

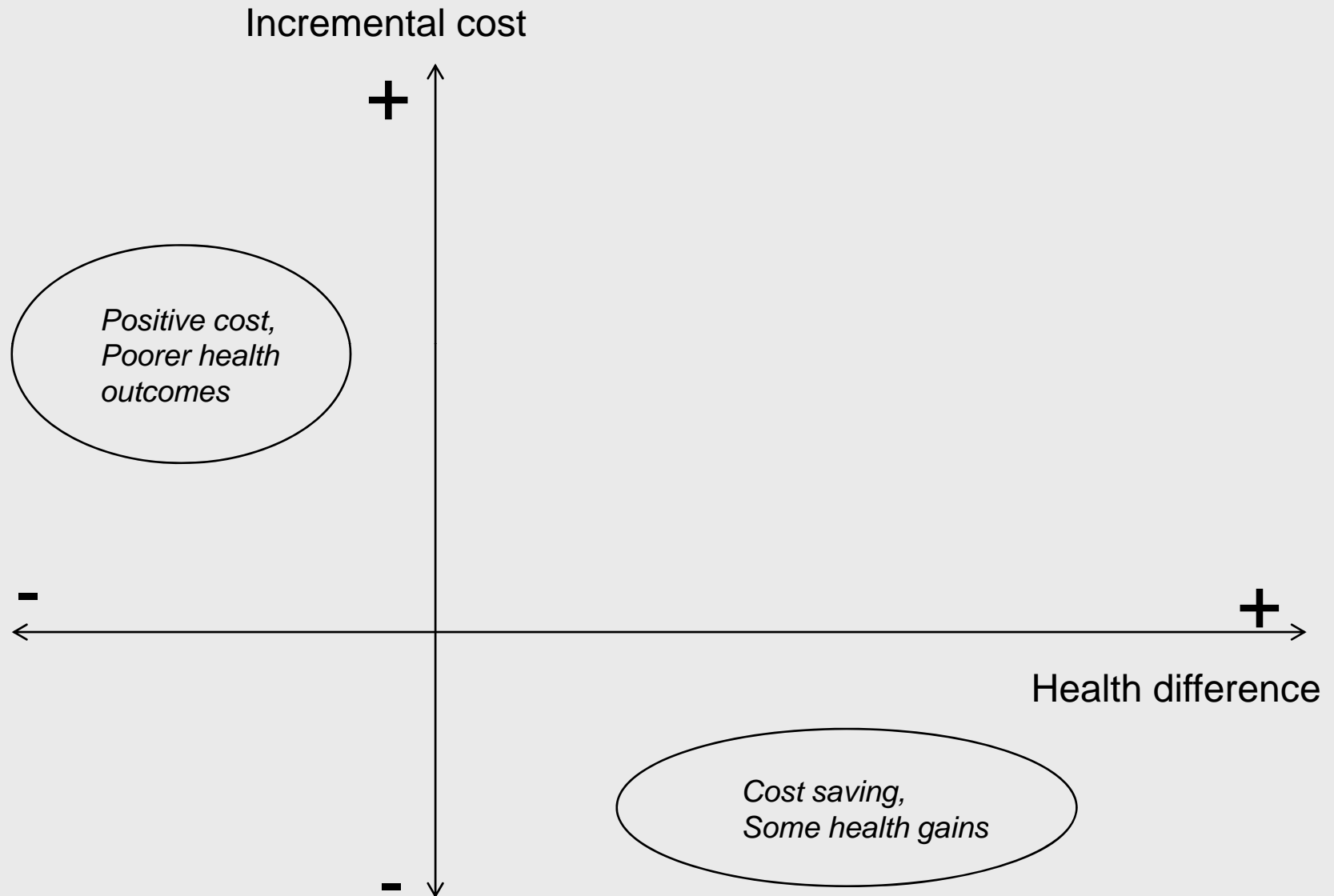
Something new must be substantially different to be innovative, not an insignificant change

In economics the change must increase value - consumer value, producer value, or both

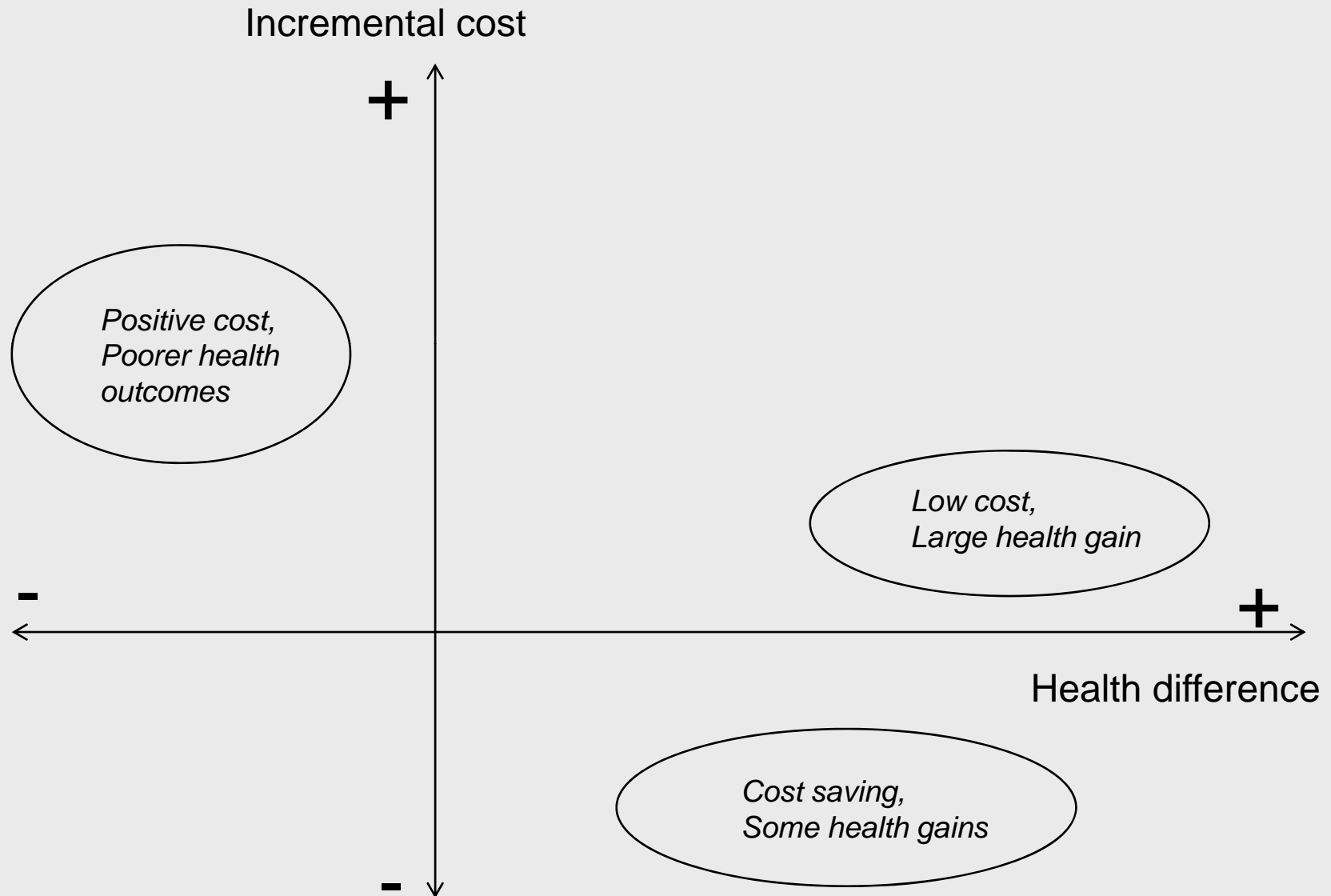
When is health innovation not a challenge?



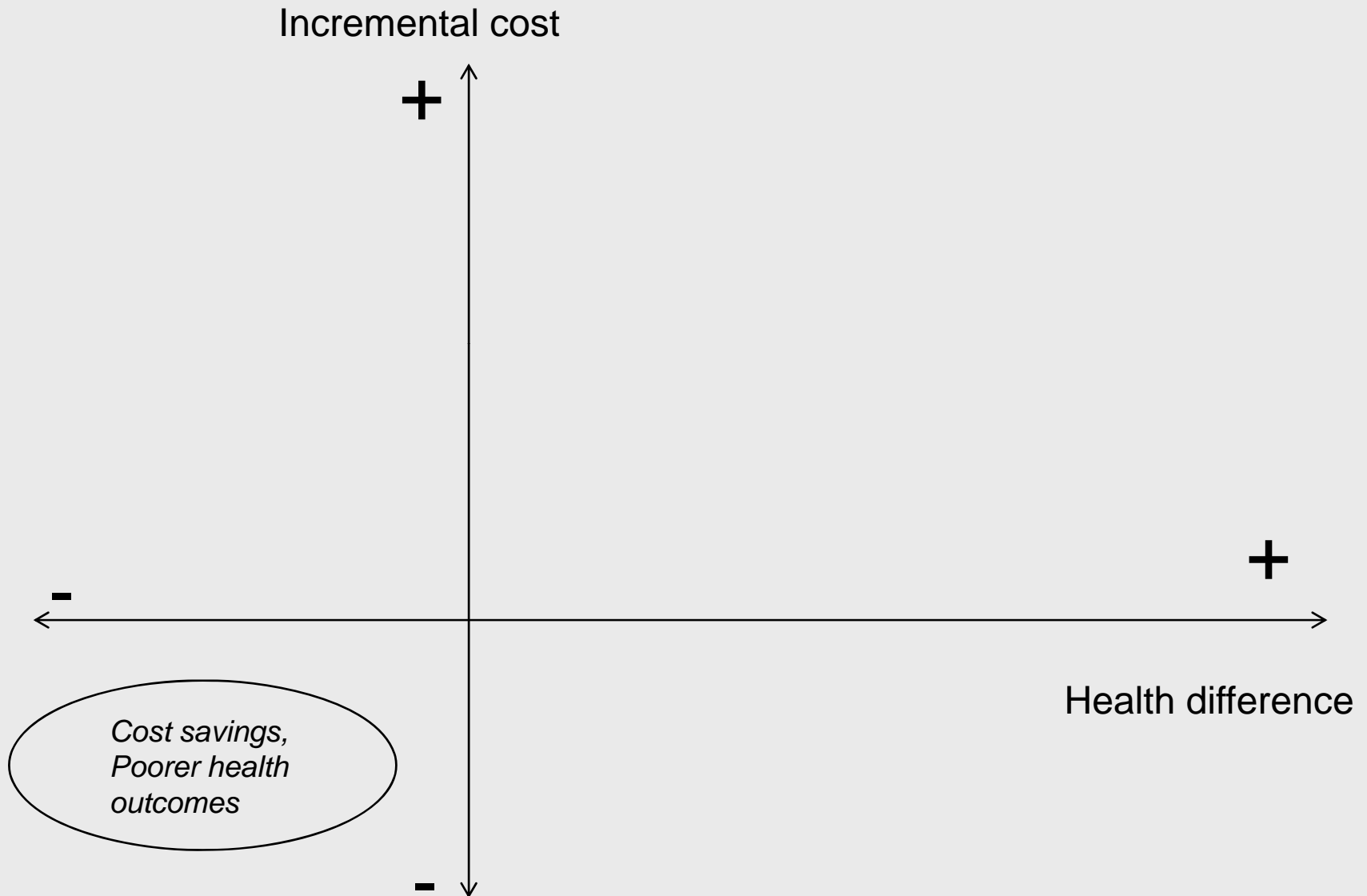
When is health innovation not a challenge?



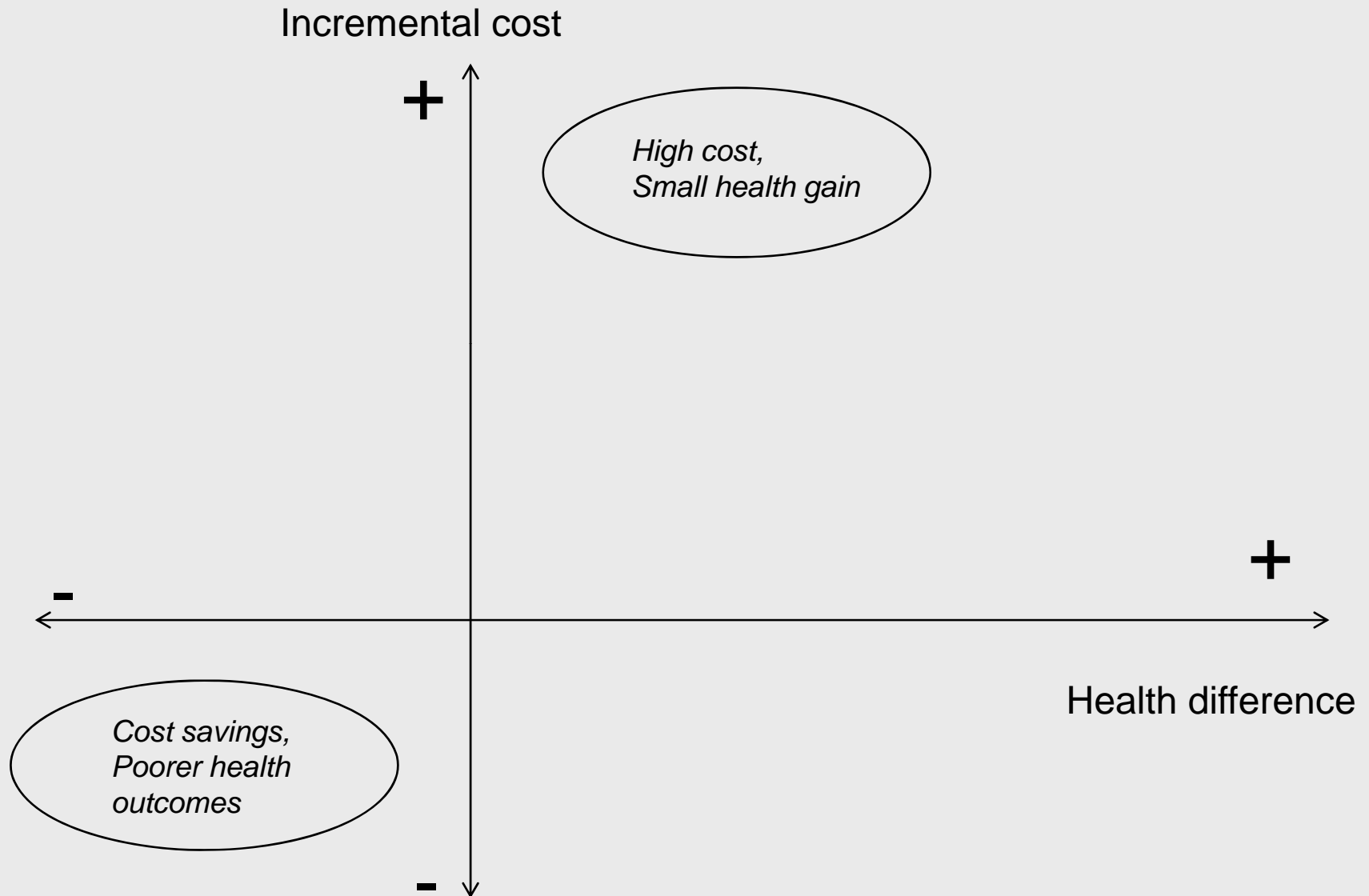
When is health innovation not a challenge?



When is health innovation a challenge?



When is health innovation a challenge?



National Institute for Health & Clinical Excellence (NICE)

“The Institute's purpose is to offer health professionals guidance on the use of technologies, based on rigorous reviews of the available evidence”

“In doing so, it takes the following six matters into account:

- The clinical needs of patients ...
- NHS priorities ...
- The broad balance between benefits and costs, incorporating both clinical and cost effectiveness
- The potential impact on other NHS resources
- The encouragement of innovation
- Guidance from ministers on the resources available.”

Rawlins (BMJ, 2001)

NICE Programmes

Technology appraisals

- Criteria include both clinical and cost effectiveness

Clinical guidelines

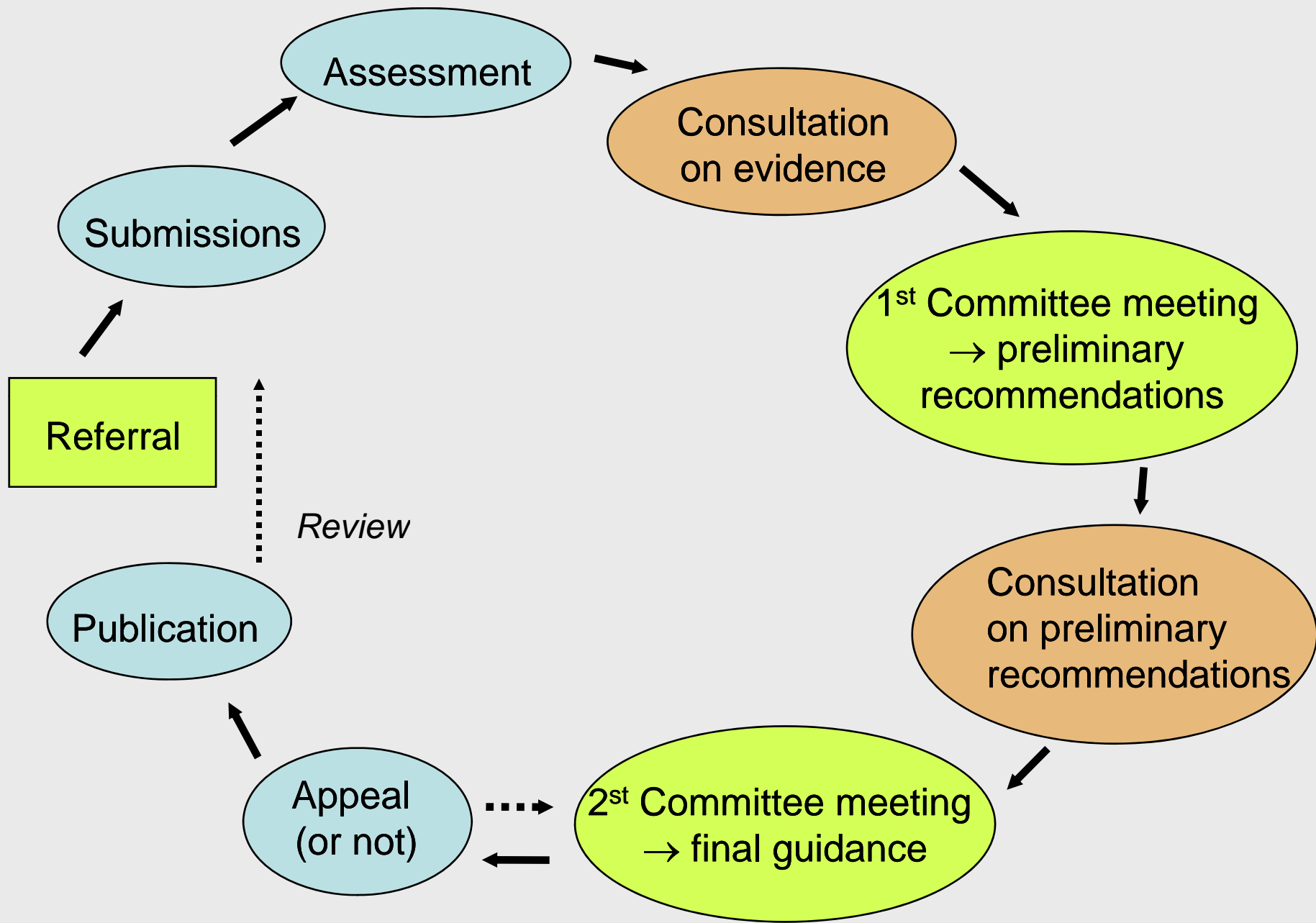
- Criteria include both clinical and cost effectiveness

Public health guidance

- Criteria include both effectiveness and cost effectiveness

Interventional procedures

- Guidance on safety and efficacy



NICE Appraisal Committee membership

Area of expertise	Number of Committee members (per branch)
Medical (e.g. GP, physician, surgeon)	12 (43%)
Other clinical (e.g. nurse, pharmacist)	4 (14%)
Methodologists (e.g. health economist, statistician)	5 (18%)
Managers	3 (11%)
Patient 'advocate'	2 (7%)
Manufacturer 'representative'	2 (7%)

NICE 'reference case' for CEA

Element of health technology assessment	Reference case
Comparator	Alternative therapies routinely used in the NHS
Perspective on costs	NHS and PSS
Perspective on outcomes	All health effects on individuals
Type of economics evaluation	Cost-effectiveness analysis
Synthesis of evidence on outcomes	Based on a systematic review
Measure of health benefits	Quality-adjusted life-years (QALYs)
Description of health states for calculation of QALYs	Health states described using a standardised and validated generic instrument

Example CEA: anakinra for RA

Results	Cost	QALYs
With Anakinra	£14,523	3.840
Without Anakinra	£2,841	3.729
Difference	£11,682	0.111
ICER (cost per quality-adjusted life-year)	£105,000	

Guidance: “Anakinra should not normally be used as a treatment for rheumatoid arthritis. It should only be given to people who are taking part in a study on how well it works in the long term.”

The importance of CEA at NICE

Secretary of State's Direction to NICE:

- NICE should consider ... “The broad balance of clinical benefits and costs”

Bryan et al (2007):

- “I think economic evaluation was regarded as being important from day one.”
- “It [the CEA] seems to me to be the clincher really. If it's too high then it's not going to get funded.”

NICE social value principle 2:

- NICE “must take into account the relative costs and benefits of interventions (their 'cost effectiveness') when deciding whether or not to recommend them.”



***The drug itself has no side effects ...
but the number of health economists needed to prove its
value may cause dizziness and nausea***

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Rawlins (BMJ, 2001)

TIABIM at NICE

Taking Into Account, Bearing In Mind (TIABIM)

NICE 'takes into account' various other considerations, for example:

- Terminality / End of life use
- Rarity of condition / Orphan drug
- No other therapeutic alternative
- Political priority area
- Innovativeness

“They are dealt with by the application of the [NICE] committee's judgement and discretion”
(Dowie, 2008)

Why positively weight 'innovation'?

What incentives do CEA-based criteria induce for bringing technologies to market?

Would current and future patients be better off through higher prices paid to innovators?

“A technology might be ‘too cost-effective’ if the benefits to patients far outweigh the amount that firms receive - an increase in profits and decrease in cost-effectiveness might be warranted to provide greater incentives for innovation.”

“Technology adoption through cost-effectiveness is a price-control policy in disguise.”

Jena & Philipson (2007, 2008)

Possible solutions

Higher prices for innovatory products

- Patent system (Is it not working well currently?)
- Derive and apply a standard tariff adjustment for 'innovation' (e.g. increase CE threshold from £20k to £25k)
- View CE thresholds as price floors that 'guarantee innovators the social value of their innovations' (Jena & Philipson, 2007)

Use Multi-criteria Decision Analysis (MCDA) as the basis of appraisal (Dowie, 2008)

NICE Appraisal of New Technology

Scores

New technology



0.308

Comparator



0.665

Weightings

pCIEff

pCostE...

Accept...

Termin...

Orpha...

Other...

DHprio...

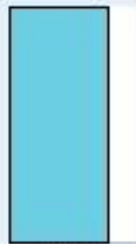
HSFca..

Innova..

Wider...



0.030



0.730



0.030



0.030



0.030



0.030



0.030



0.030



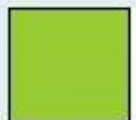
0.030



0.030

Ratings

New technolo...



0.900



0.200



1.000



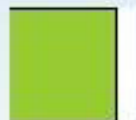
1.000



0.000



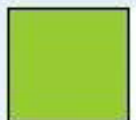
0.000



0.800



0.300



0.500



0.500

Comparator



0.100



0.800



0.500



0.980



0.000



0.000



0.800



0.500



0.000



0.500

NICE Appraisal of New Technology

Scores

New technology



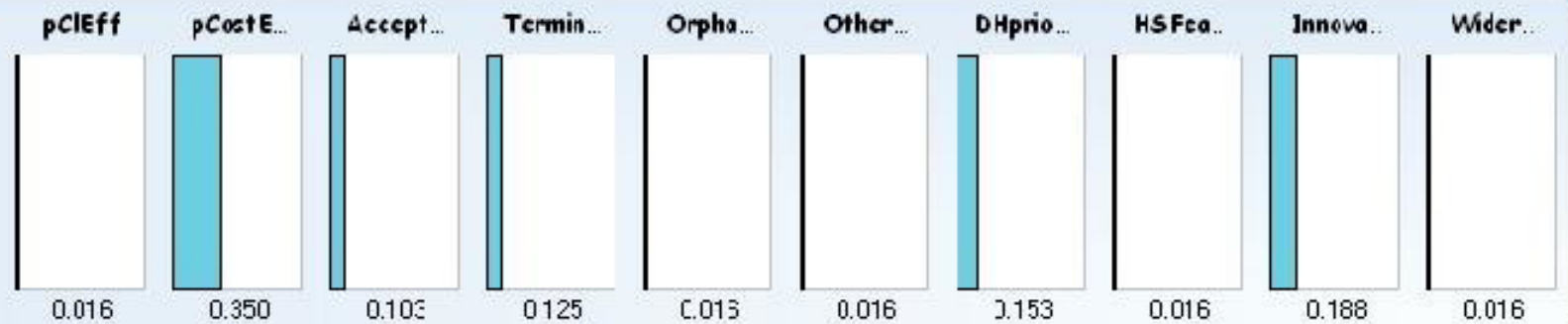
0.617

Comparator

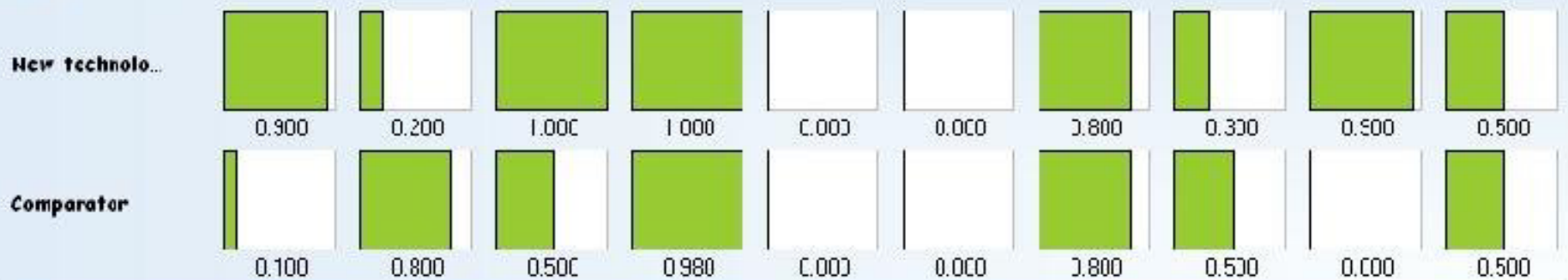


0.555

Weightings



Ratings



Conclusions

Coverage decision by NICE are driven primarily by CEA, with some TIABIM!

Trading-off current patients' benefits and benefits to future patients is necessary and appropriate.

The current patent system is the embodiment of this - is it broken?

Explicit weighting of innovativeness, through a MCDA process, should be explored.