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# How can cost-effectiveness thresholds help inform health coverage decisions?

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Red CRITERIA

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# Healthcare expenditure

- Objectives
  - Improve population health
  - Equity?
  - Financial protection?
- Key questions
  - Should a healthcare intervention be provided using collectively pooled funds for healthcare?
  - How should we prioritise scaling up different interventions?
  - How much should we pay for a new healthcare intervention?

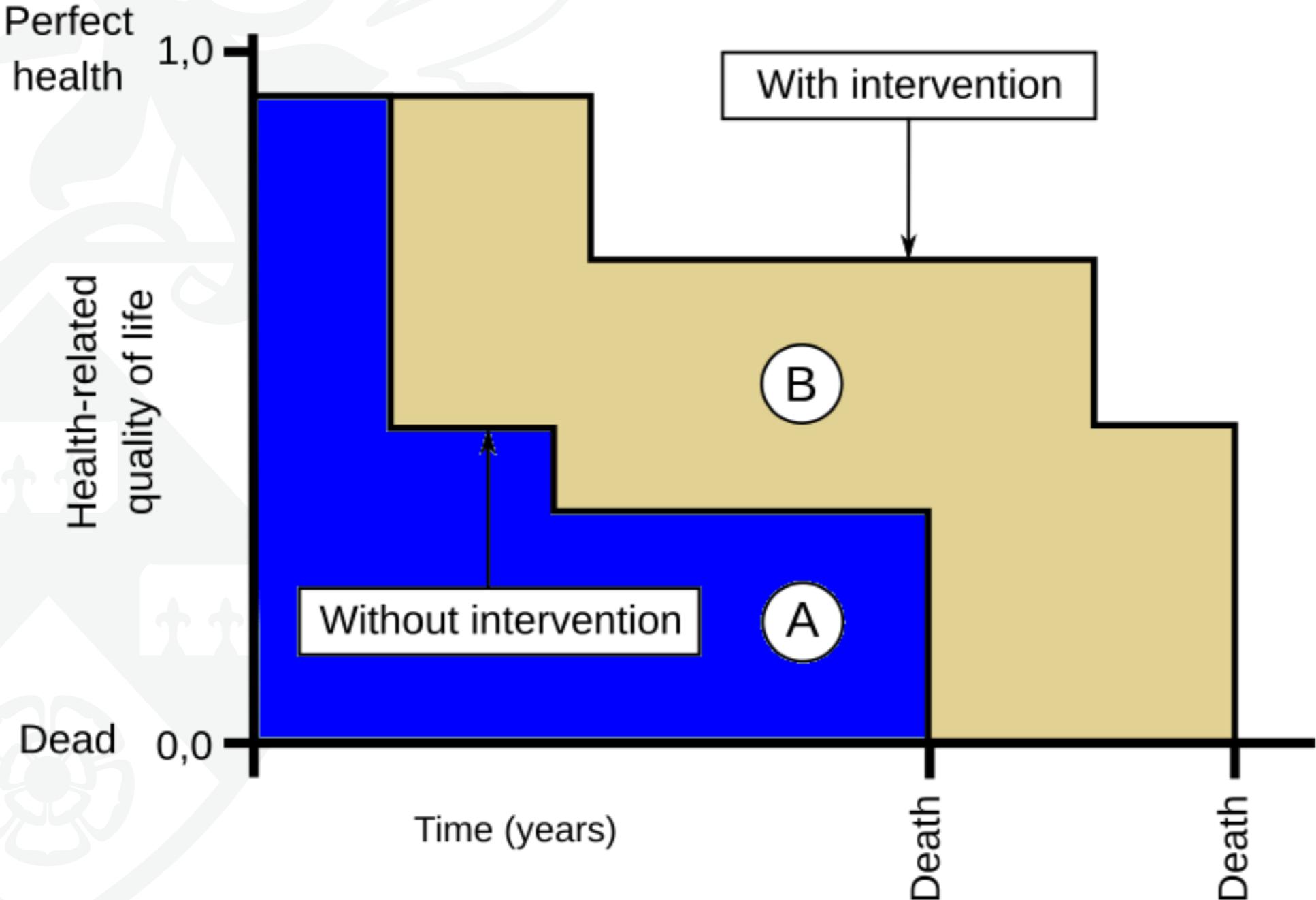
# Improving population health

- Clinically effective treatment
- Orkambi for treating cystic fibrosis (CF)
  - CF is a rare, life shortening disease that gets progressively worse over time and affects about 9,000 people in the UK
  - Orkambi slows the decline in lung function among a sub-population of people with CF (those who have two copies of the F508DE gene mutation - around 50% of people with CF) by 42%
- How to compare the benefits of Orkambi to the benefits from other drugs for other conditions?

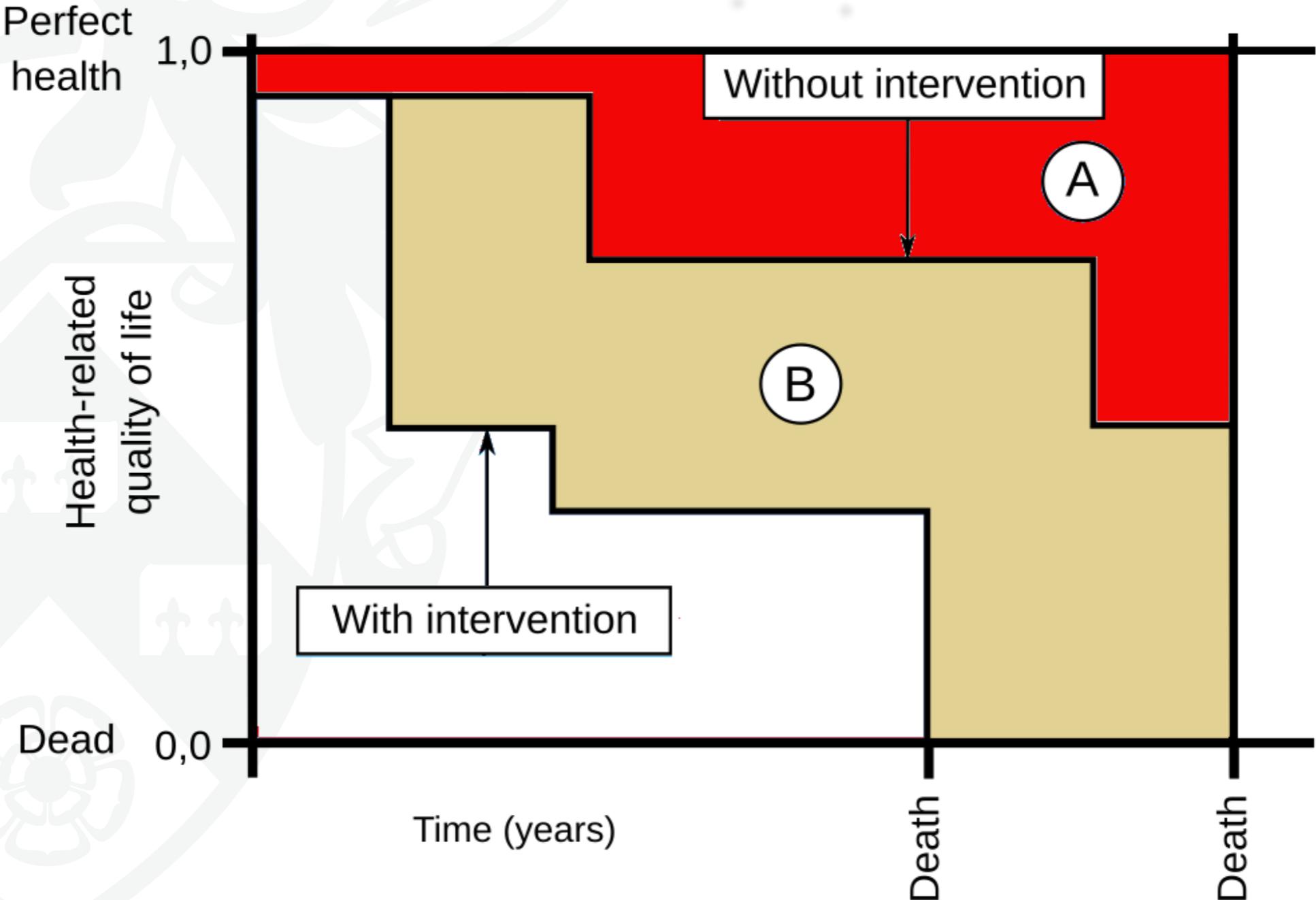
# Improving population health

- Health benefits
  - Impact on length of life and quality of life
  - Comparable across different disease areas
  - Quality adjusted life years (QALYs) gained or disability adjusted life years (DALYs) averted

# Quality adjusted life years (QALYs)



# Disability adjusted life years (DALYs)



Adapted from Jmarchn - Own work, CC BY-SA 3.0, <https://commons.wikimedia.org/w/index.php?curid=67001576>

# Improving population health

- Orkambi is clinically effective
  - 3 QALYs gained per patient compared to standard of care
  - Should it be provided by the UK National Health Service (NHS)?
  - How much should the NHS pay for it?

# Improving population health

- Orkambi is clinically effective
  - 3 QALYs gained per patient compared to standard of care
- Cost £750,000 per patient more than standard of care
- Incremental cost-effectiveness ratio £250,000
  - To gain one additional QALY by funding Orkambi, at the manufacturer's price the NHS must spend £250,000
  - **Should it be provided by the UK National Health Service (NHS)?**
  - **How much should the NHS pay for it?**
- **What are the health opportunity costs of funding Orkambi?**

## Health opportunity cost

- Since resources are scarce relative to needs, the use of resources in one way prevents their use in other ways.
- The opportunity cost of investing in a healthcare intervention is best measured by the health benefits that could have been achieved had the money been spent on the next best alternative intervention or healthcare programme. (Palmer and Raftery, 1999)

# Health opportunity cost – fixed budget

New funding constrained

New intervention

Displaced intervention(s)

Costs <sub>1</sub> Benefits <sub>1</sub>	Costs <sub>2</sub> Benefits <sub>2</sub>	Costs <sub>3</sub> Benefits <sub>3</sub>
Costs <sub>4</sub> Benefits <sub>4</sub>		
Costs <sub>5</sub> Benefits <sub>5</sub>	Costs <sub>6</sub> Benefits <sub>6</sub>	
Costs <sub>7</sub> Benefits <sub>7</sub>	Costs <sub>8</sub> Benefits <sub>8</sub>	Costs <sub>9</sub> Benefits <sub>9</sub>
Costs <sub>10</sub> Benefits <sub>10</sub>	Costs <sub>11</sub> Benefits <sub>11</sub>	Costs <sub>12</sub> Benefits <sub>11</sub>
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Costs <sub>16</sub> Benefits <sub>16</sub>	Costs <sub>17</sub> Benefits <sub>17</sub>	Costs <sub>18</sub> Benefits <sub>18</sub>
Costs <sub>19</sub> Benefits <sub>19</sub>		
Costs <sub>n</sub> Benefits <sub>n</sub>		



**Do the benefits gained outweigh the opportunity costs?**

# Health opportunity cost – flexible budget

Flexible funding

Costs <sub>1</sub> Benefits <sub>1</sub>	Costs <sub>2</sub> Benefits <sub>2</sub>	Costs <sub>3</sub> Benefits <sub>3</sub>
Costs <sub>4</sub> Benefits <sub>4</sub>		
Costs <sub>5</sub> Benefits <sub>5</sub>	Costs <sub>6</sub> Benefits <sub>6</sub>	
Costs <sub>7</sub> Benefits <sub>7</sub>	Costs <sub>8</sub> Benefits <sub>8</sub>	Costs <sub>9</sub> Benefits <sub>9</sub>
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Costs <sub>n</sub> Benefits <sub>n</sub>		

New intervention



Alternative unfunded intervention(s)



**Do the benefits gained outweigh the opportunity costs?**

# Health Opportunity Costs

- Why does it matter?
  - Ensures decisions improve health outcomes overall
  - Decisions made using other thresholds may reduce health outcomes overall
- How can it be done?
  - Typically can't identify specific treatments that will be wholly displaced
  - Instead can try to estimate health effects of increasing/decreasing expenditure

# Evidence to support an assessment of health opportunity costs

- Currently available estimates from within country data
  - UK £12,936 per QALY (Claxton et al 2015)
  - Australia AUS\$28,033 per QALY (Edney et al 2018)
  - Spain €21,000 and €24,000 per QALY (Vallejo-Torres et al 2016)
  - Netherlands, Norway, Sweden, South Africa, Indonesia

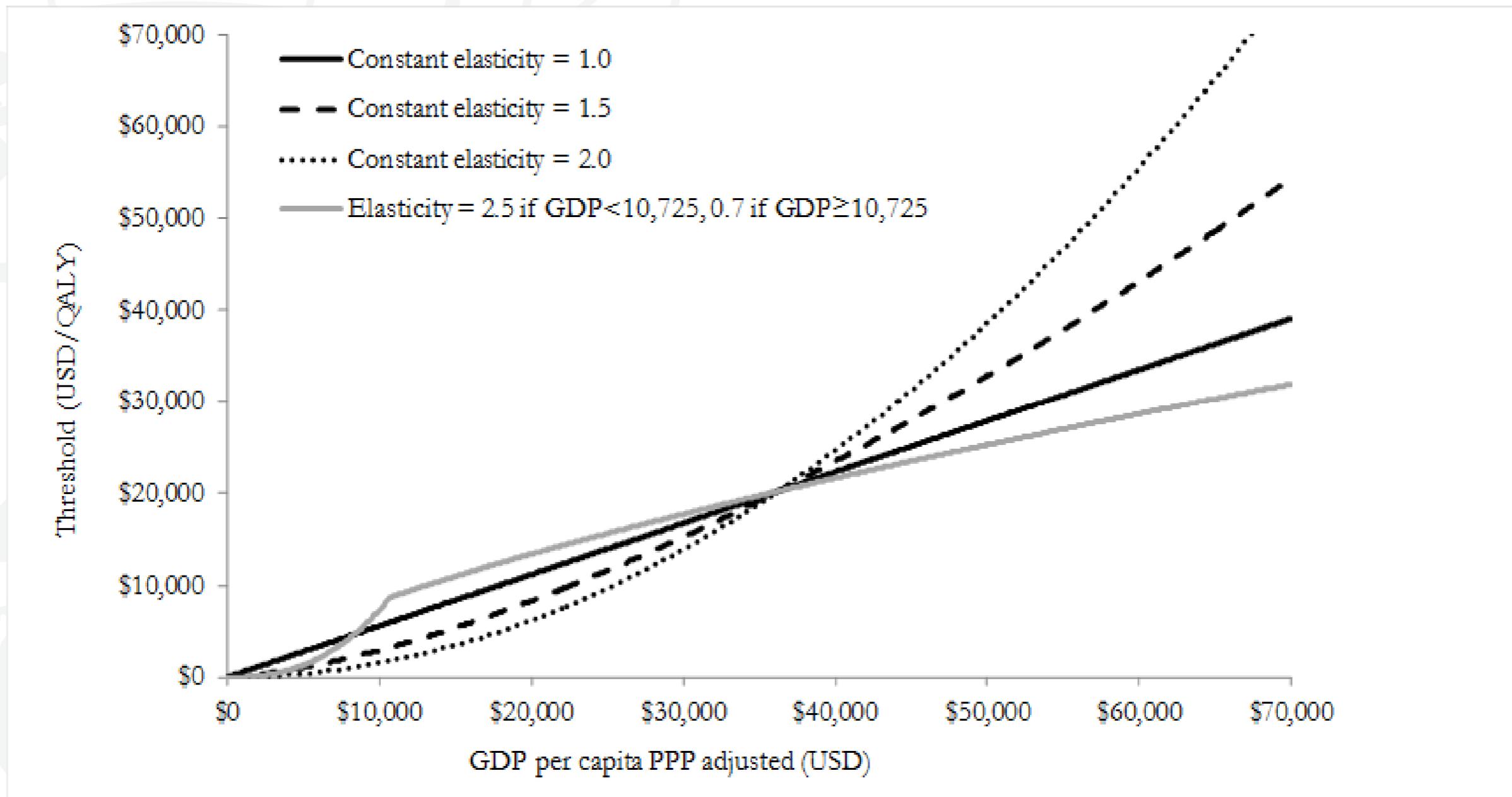
## Orkambi example

- UK £12,936 per QALY (Claxton et al 2015)
- Overall health benefit of providing Orkambi is 3.5 QALYs per patient \* 9,000 patients = 31,500 QALYs
- Overall cost of providing Orkambi is £750,000 per patient \* 9,000 = 6.75 billion
- 6.75 billion could gain 521,800 QALYs in the wider patient population
- Net health benefit of providing Orkambi is the expected health gain of providing it (31,500) net of its health opportunity cost (521,800) = -491,300

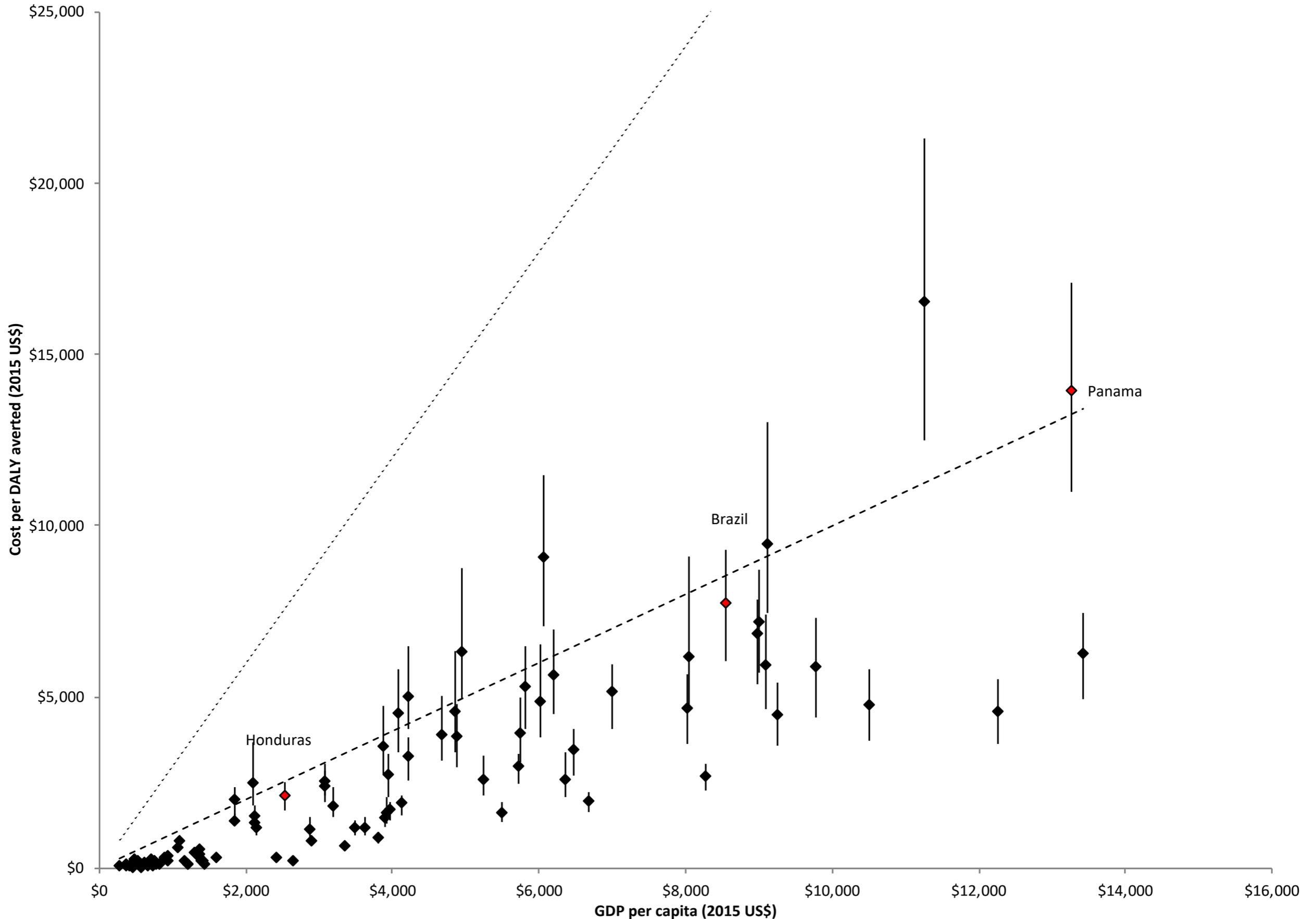
# Evidence to support an assessment of health opportunity costs

- Other available estimates that also reflect health opportunity costs
  - Potential implications for other HCS (Woods et al 2016)
  - Using published estimates of the mortality effect of health care expenditure from country level data (Ochalek et al 2018)

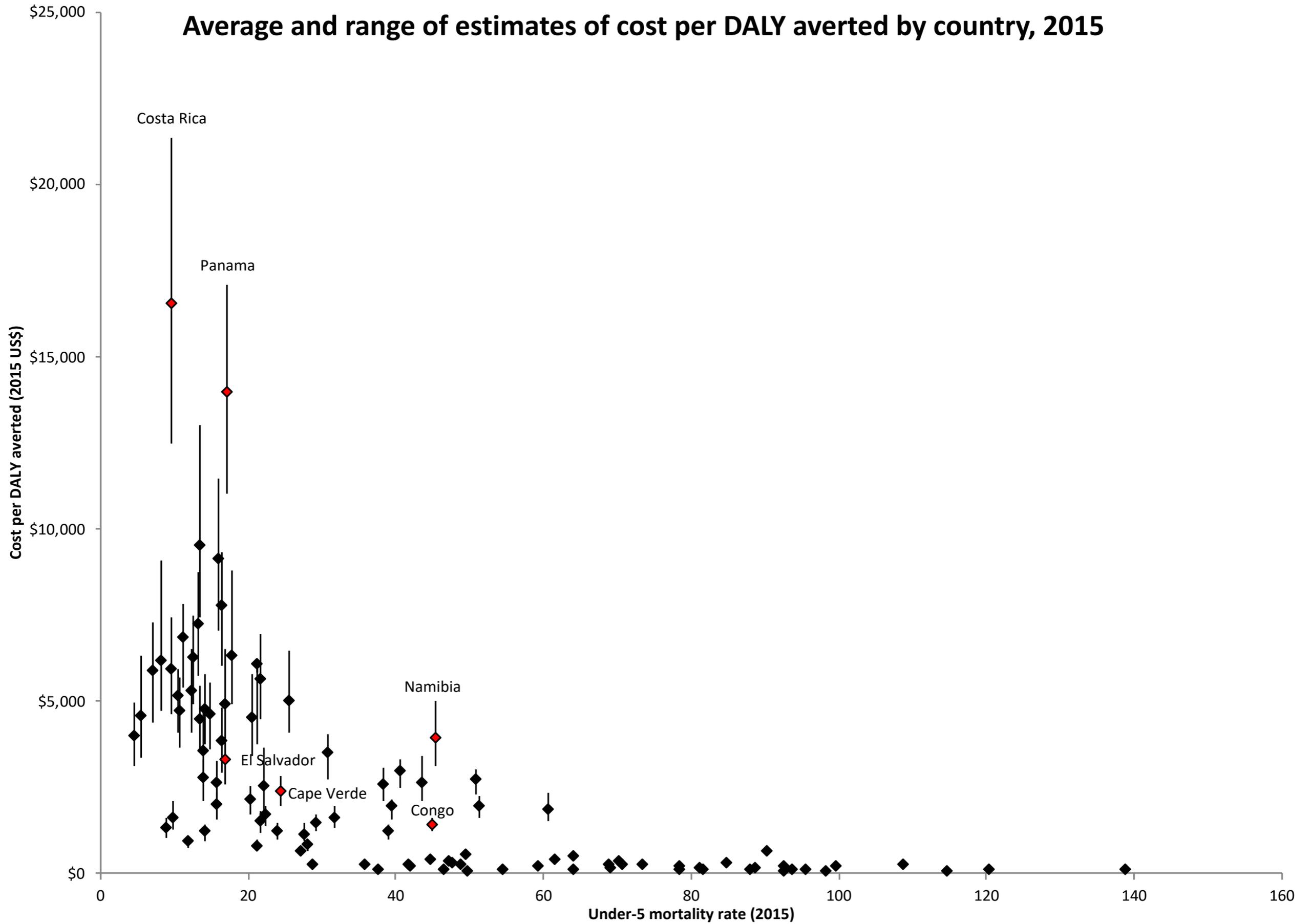
# Possible implications for other countries



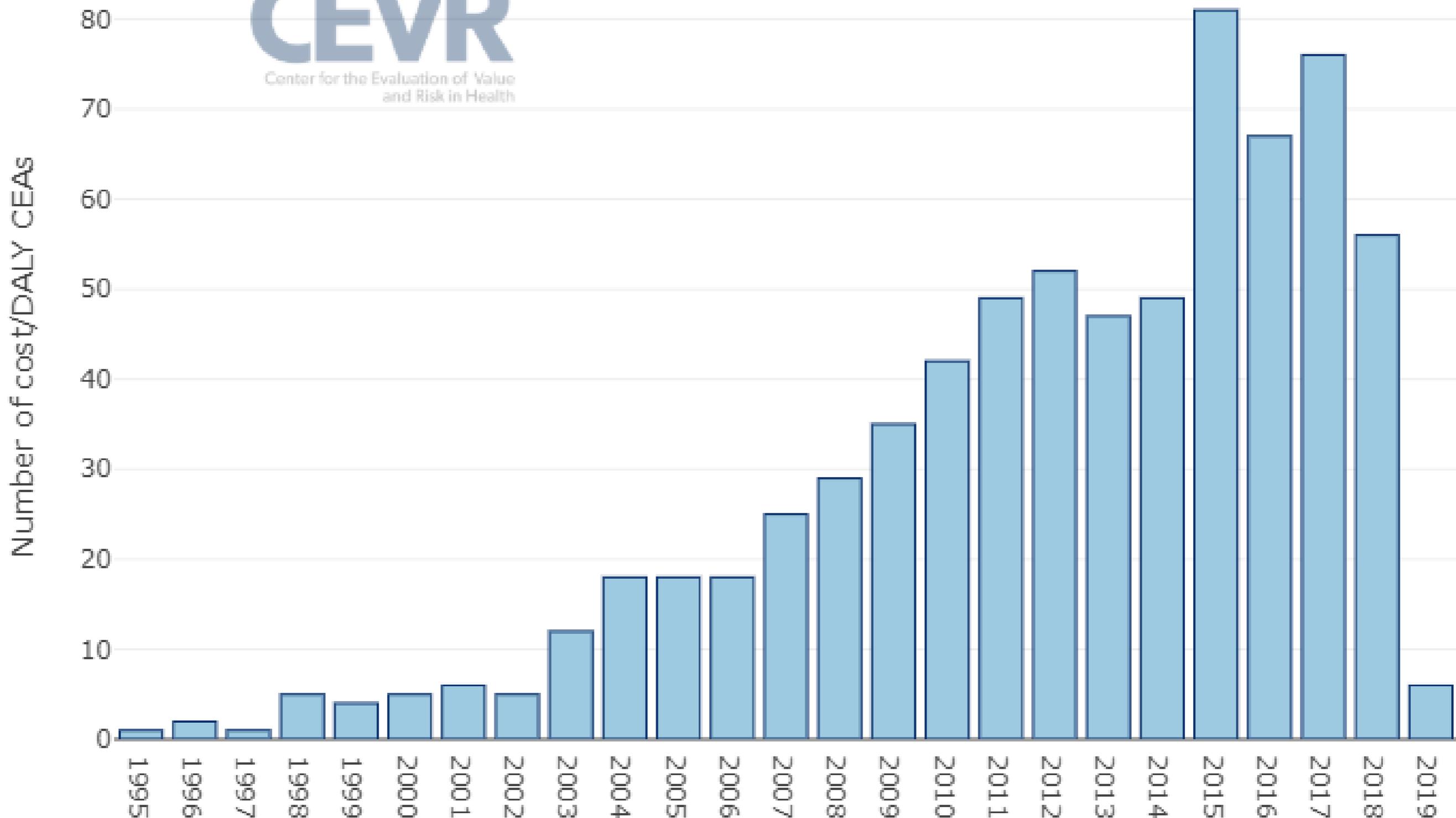
# Average and range of estimates of cost per DALY averted by country, 2015



# Average and range of estimates of cost per DALY averted by country, 2015



# Cost-effectiveness analysis (CEA) studies by year of publication.



# Cost-effectiveness analysis (CEA) studies by location.



# Cost-effectiveness threshold

- What thresholds are used in published CEAs (Leech et al 2018)

“Rather than relying on generic global benchmarks, we encourage practitioners to develop context-specific values reflecting the health care system and local priorities.”

**Table 1 – Characteristics of published cost-per-DALY studies for LMICs, 2000–2015.**

By threshold	2000–2015 analyses (N = 381) (%)
1–3 times country's GDP only	250 (66%)
WB/WHO 1990s only	15 (4%)
Country-specific only	0 (0%)
None	89 (23%)
Other*	27 (7%)
<b>By region</b>	
Latin America and Caribbean	44 (12%)
Sub-Saharan Africa	156 (41%)
Southeast Asia, East Asia, and Oceania	58 (15%)
South Asia	42 (11%)
North Africa and Middle East	10 (3%)
Central Europe, Eastern Europe, and Central Asia	9 (2%)
Other†	62 (16%)

Source: Leech AA, Kim DD, Cohen JT, Neumann PJ. Use and misuse of cost-effectiveness analysis thresholds in low- and middle-income countries: trends in cost-per-DALY studies. *Value Heal.* 2018;1–3. 10.1016/j.jval.2017.12.016.

## Incremental cost-effectiveness ratios (ICERs)

	Expected cost (£)	Expected QALY
B	70,000	5
A	50,000	4

- Incremental cost of A compared to B =  $C_B - C_A = £20,000$
- Incremental benefit of A =  $H_B - H_A = 1$
- $ICER = (C_B - C_A) / (H_B - H_A) = £20,000 / 1 = £20,000 / QALY$
- Should we change to B or keep A?

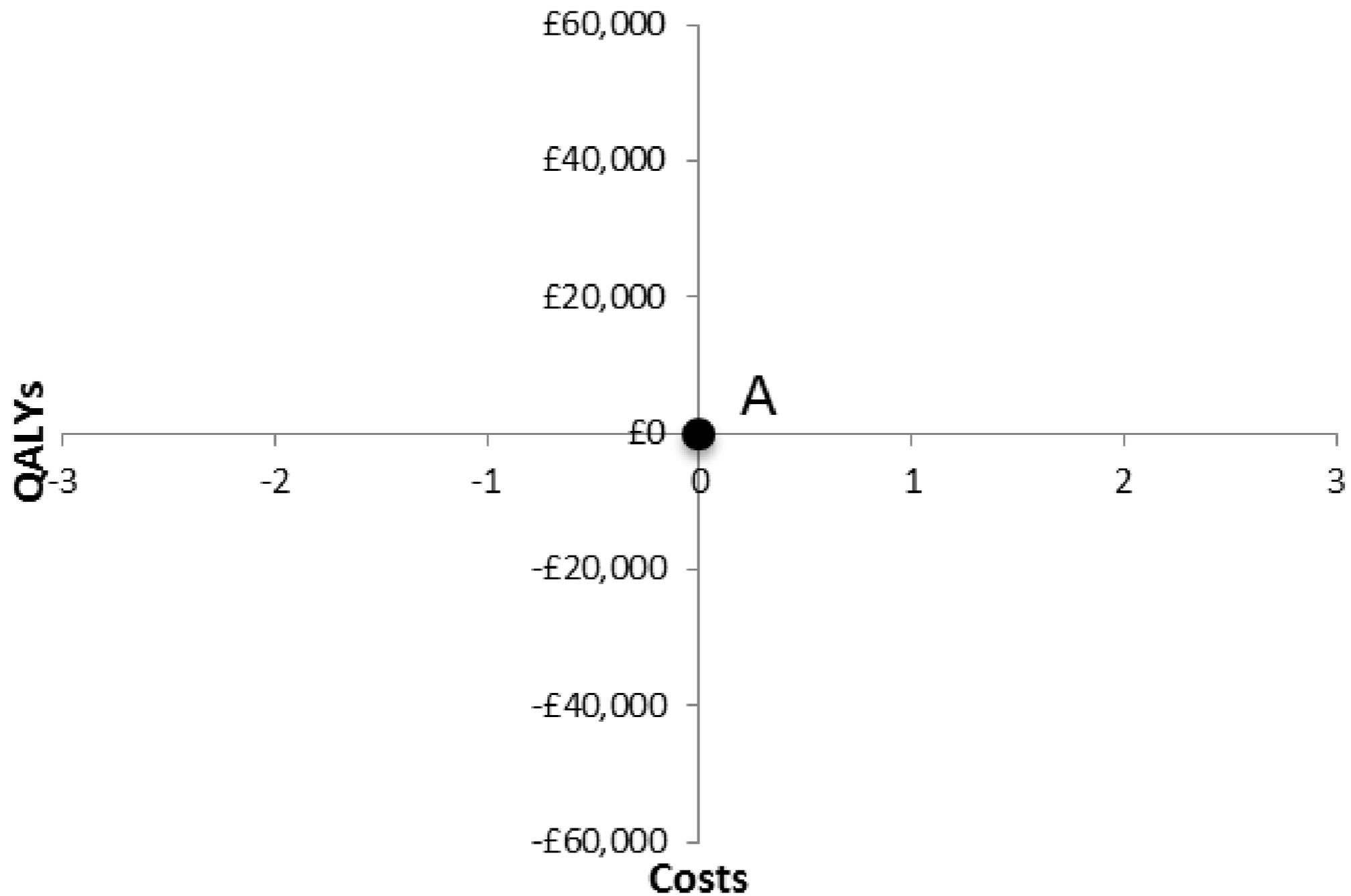
## Incremental cost-effectiveness ratios (ICERs)

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# Cost-effectiveness analysis

## Incremental cost-effectiveness plane



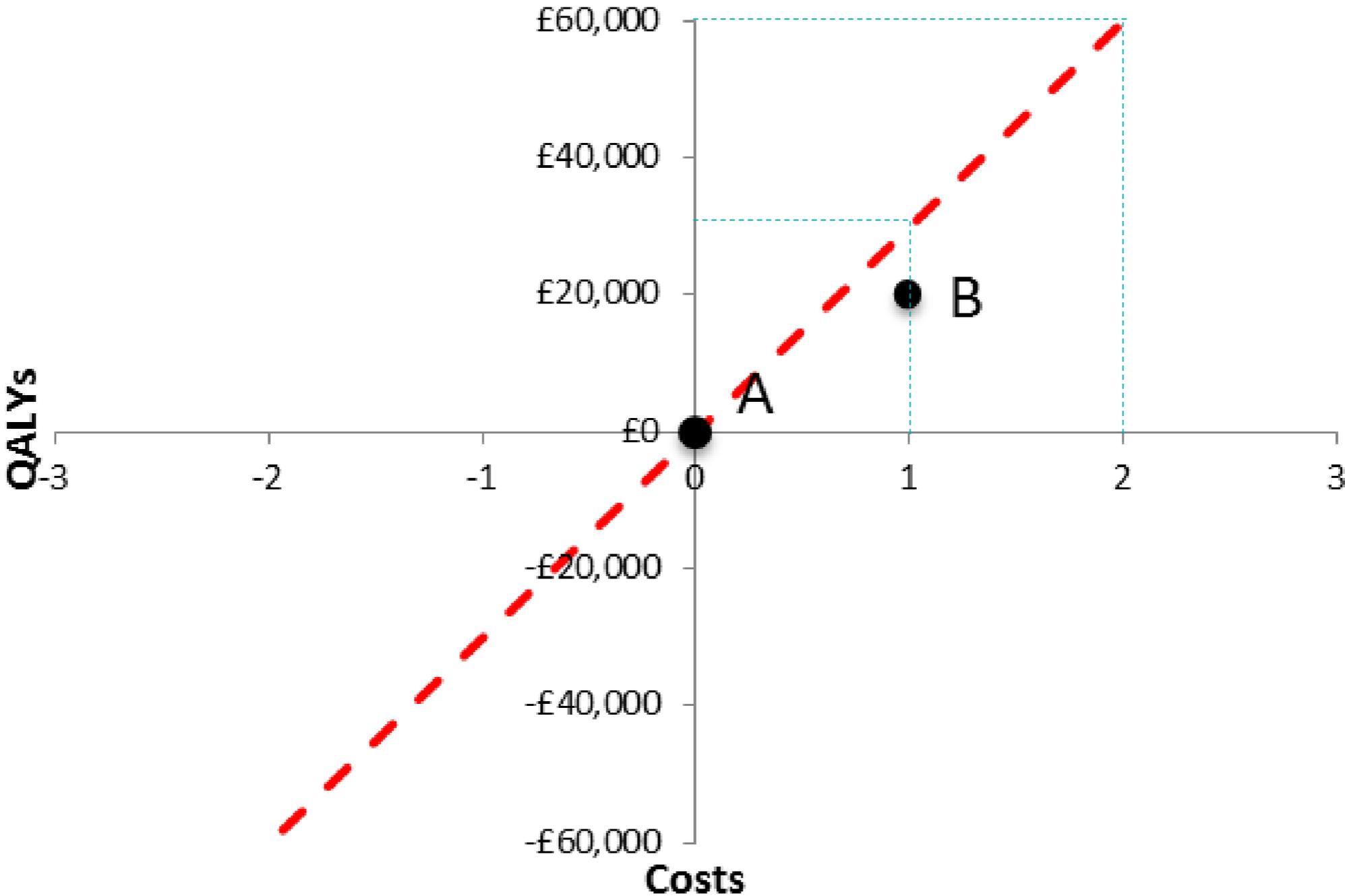
# Cost-effectiveness analysis

## Incremental cost-effectiveness plane



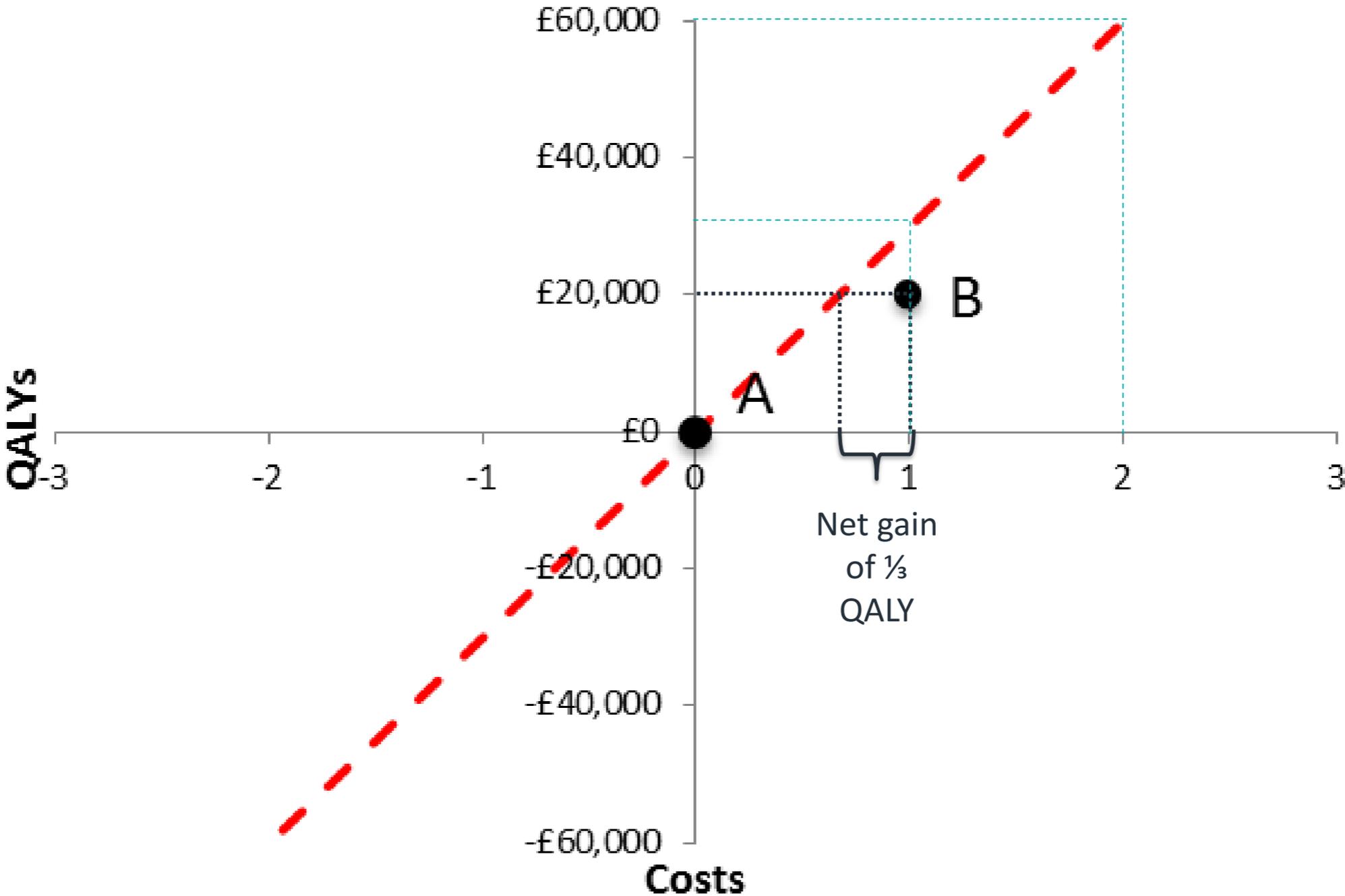
# Cost-effectiveness analysis

## Incremental cost-effectiveness plane



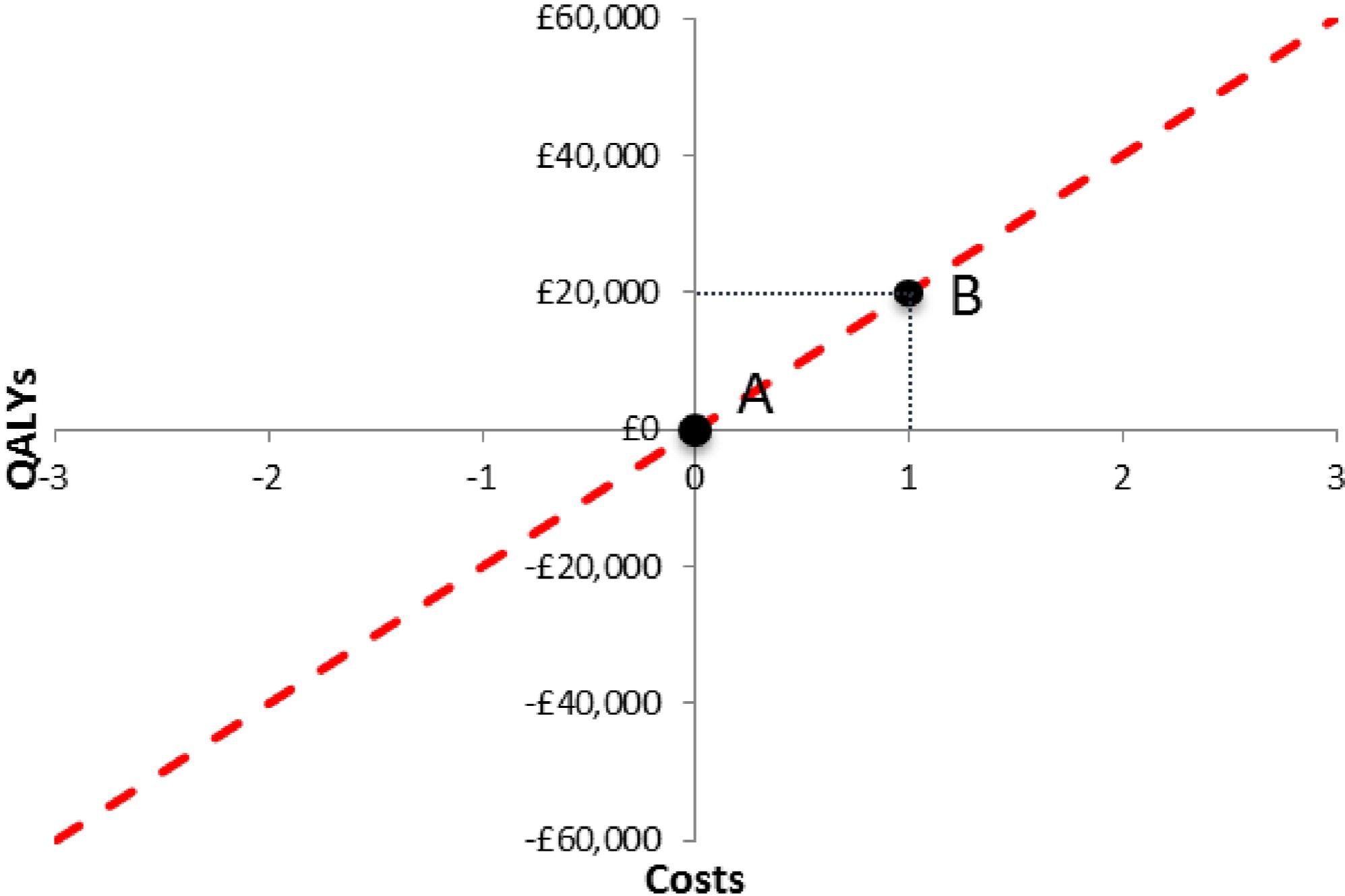
# Cost-effectiveness analysis

## Incremental cost-effectiveness plane



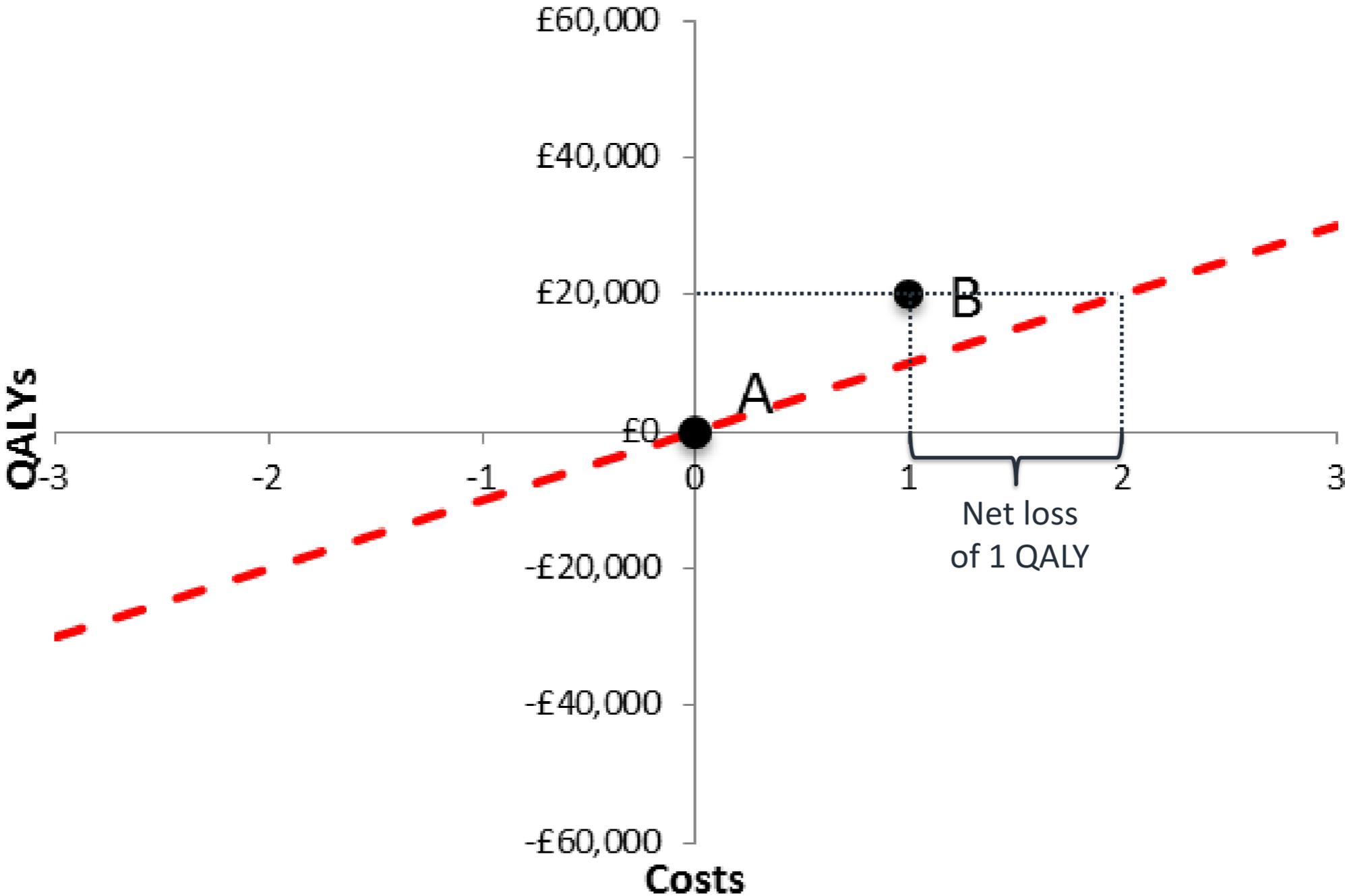
# Cost-effectiveness analysis

## Incremental cost-effectiveness plane



# Cost-effectiveness analysis

## Incremental cost-effectiveness plane



## Consequences of using a “threshold” that is too high

- Does not reflect how much health the health care system currently delivers
  - Reduce health outcomes
  - Underestimates the value of increased health expenditure
- World Health Organization no longer recommends the use of 1 and 3x GDP per capita as thresholds (Bertram et al, 2016)

# National Institute for Health and Care Excellence, UK

Guide to the methods of technology appraisal 2013 (PMG9)

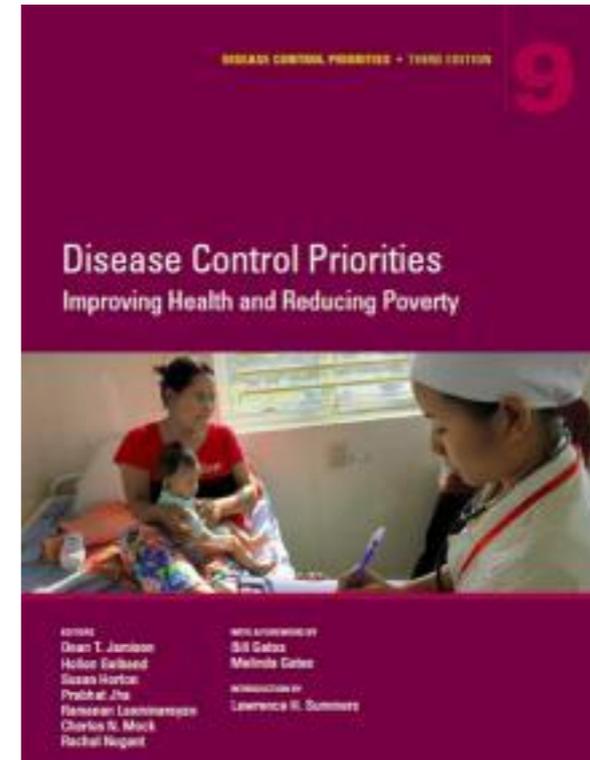
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- 1.4.2 In general, a technology can be considered clinically effective if, in normal clinical practice, it confers a health benefit, taking account of any harmful effects and opportunity costs. A technology can be considered to be cost effective if its health benefits are greater than the opportunity costs of programmes displaced to fund the new technology, in the context of a fixed NHS budget. In other words, the general consequences for the wider group of patients in the NHS are considered alongside the effects for those patients who may directly benefit from the technology.

# Patented Medicine Prices Review Board, Canada

- Canadian draft guidelines on assessing pharmacoeconomic value
  - \$60,000/QALY threshold
  - Based on estimates of the marginal cost of a QALY in the Canadian health system (Ochalek et al, 2018), empirical estimates of supply-side thresholds from other relevant jurisdictions, and evidence of historical trends in cost effectiveness assessments by Canadian HTA agencies.

# Disease Control Priorities



- A threshold of \$200 per DALY is used to identify priority interventions for consideration in low-income countries (Horton et al, 2017)
  - Aims to reflect what people are able and willing to spend from the public budget
  - All but four countries in the World Bank database had per capita income above \$400 in 2013

# Ministry of Health Malawi

## 4

### The Essential Health Package (EHP)



**BMJ Global Health** Supporting the development of a health benefits package in Malawi

Jessica Ochalek,<sup>1</sup> Paul Revill,<sup>1</sup> Gerald Manthala,<sup>2</sup> Finn McGuire,<sup>2</sup> Dominic Nkhoma,<sup>4</sup> Alexandra Rollinger,<sup>3</sup> Mark Sculphar,<sup>3</sup> Karl Claxton<sup>1</sup>

**ABSTRACT**  
Malawi, like many low-income and middle-income countries, has used health benefits packages (HBPs) to allocate scarce resources to key healthcare interventions. With no widely accepted method for their development, HBPs often prohibit more that can be delivered, given available resources. An analytical framework is developed to guide the design of HBPs that can identify the potential value of including and implementing different interventions. It provides a basis for informing meaningful discussions between governments, donors and other stakeholders around the trade-offs implicit in package design. Methods of value, founded on an understanding of the health opportunity costs of the choices faced, are used to quantify the scale of the potential net health impact (net disability-adjusted life years averted) or the amount of additional healthcare resources that would be required to deliver similar net health impacts with existing interventions (the financial value to the healthcare system). The framework can be applied to answer key questions around, for example, the appropriate scale of the HBP, which interventions represent 'best buys' and should be prioritised, where investments in scaling up interventions and health system strengthening should be made, whether the package should be expanded, costs of the consequences of donor funding and how objectives beyond improving population health can be considered. This is illustrated using data from Malawi. The framework was successfully applied to inform the HBP in Malawi, as a core component of the country's Health Sector Strategic Plan II 2017-2022.

**INTRODUCTION**  
Sustainable Development Goal target 3.8 is to 'achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all' by 2030.<sup>1</sup> However, the resources available for healthcare are limited, so not all services can be

**Summary box**  
**What is already known about this topic?**  
• Health benefits packages (HBPs) are used to set out what should be included in a publicly subsidised package of health interventions to make progress toward Sustainable Development Goal target Universal Health Coverage (UHC) in low-income countries (LICs).  
• HBP design has typically failed to take account of all constraints faced (eg, financing, infrastructure and donor aid) and has not been informed by explicit analysis of the potential value of including different interventions. HBPs are rarely fully implemented and the most valuable interventions are not included.  
**What are the new findings?**  
• The analytic framework is founded on an understanding of the health opportunity costs faced and so can offer a principled, principled approach to informing the content and scale of a HBP with existing resources, the value of expanding the HBP and the incremental mobilisation of resources will be the package.  
• An assessment of health opportunity costs makes it possible to report the potential net health impact and disability-adjusted life years averted of including a particular intervention or the amount of additional healthcare resources that would be required to deliver similar net health impacts (financial value) to the healthcare system.  
• This enables interventions that should be prioritised to be identified and the value of implementation efforts and health system strengthening to be assessed and also indicates the value of expanding the package, the costs of the consequences of donor funding and the trade-offs required when considering other objectives.

**Check for updates**

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GOVERNMENT OF THE REPUBLIC OF MALAWI

## Health Sector Strategic Plan II 2017-2022

### Towards Universal Health Coverage

# Accounting for the scale of costs and benefits

- Going beyond a categorical (yes/no) assessment of cost-effectiveness
- Need a measure of the scale of the potential health impact of including an intervention in the Essential Health Package net of associated health opportunity costs
  - Net health impact (net QALYs gained or DALYs averted)
  - Financial value to the health care system (amount of additional healthcare resources that would be required to deliver the equivalent net DALYs averted with other interventions)

# Accounting for the scale of costs and benefits

- Which interventions represent ‘best buys’ for the healthcare system and should be prioritised?
- How can objectives beyond improving population health be considered?
- Where should investments in scaling up interventions and health system strengthening be made?

## Summary

- Cost effectiveness thresholds that reflect evidence of the likely health opportunity costs can be used to help ensure decisions improve population health.
- They can inform on the expected health gains and health forgone by funding an intervention, which can also be traded-off with other objectives.
- Many of the cost-effectiveness thresholds that have been recommended, or have become widely cited, are not founded on an assessment of the likely health opportunity costs, their use is likely to reduce rather than improve health outcomes overall.

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