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# Critical Analysis of the History and Impact of Cost Effectiveness Thresholds (CETs)

## Emerging Lessons and Insights for Decision-Makers


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## Disclaimer

Here we report findings emerging from the first phase of an ongoing project on cost effectiveness thresholds (“CETs”). It was supported by Johnson & Johnson.

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# The Project

- **Rationale**:
  - Few (if any) HTA agencies have adopted the logic of cost effectiveness without modifications
  - Reliance on cost effectiveness thresholds (CETs) varies greatly
  - A number of HTA agencies do not use CETs at all, some of them having explicitly rejected the underlying logic
- **Objectives**:
  - To provide a comprehensive account of the origins, actual use, and the roles and limitations of CETs in the context of HTAs
  - To contribute to the worldwide dialogue about the appropriate use and unresolved issues surrounding the adoption of CETs
- **Approach**:
  - Critical or integrative review method


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# Analysis Uncovered Six Dominant Themes

- **Historical CET Experiments**
  - Substantial variability in acceptance and implementation
- **Establishing a CET**
  - No uncontroversial scientific basis
- **Ethical Considerations**
  - CETs drive equality of QALYs, but do not treat patients as persons equally; collectively financed health schemes as social institutions
- **Usefulness in Decision-Making**
  - CETs do not account for rights-based reasoning, inherent in constitutional provisions across nations
- **Empirical Issues**
  - CETs are, by definition, blind to budget impact
- **Real-World Implications**
  - CETs, if not modified or supplemented by alternative pathways, can lead to delayed or reduced access to effective medicines


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# The Logic of Cost Effectiveness

## Some International Milestones

**Oregon Health Plan** (OHP, since **1989**)
- debate about the "rule of rescue"
- legal ban of cost/QALY use in the United States (ADA, ACA / PCORI, IRA, …)

**New Zealand** (PHARMAC Core Service Committee, since **1992**)

**Australia** (PBAC / PBS, since **1993**)

**Canada** (CDA-AMC / INESSS, since 2024)
- established as CCOHTA in 1989 (CADTH, since 2006)
- first cost effectiveness guidelines for pharmaceuticals issued in **1994**

**England and Wales** (NICE, since **1999**)

**Germany** (IQWiG, since 2004)
- proposing "efficiency frontier analysis" as an alternative approach (**2009/2010**)

ACA, Affordable Care Act; ADA, Americans with Disabilities Act; CADTH, Canadian Agency for Drugs and Technologies in Health; CCOHTA, Canadian Coordinating Office for Health Technology Assessment; CDA-AMC, Canada's Drug Agency - L'Agence des médicaments du Canada; INESSS, Institut national d'excellence en santé et services sociaux; IQWiG, Institute for Quality and Efficiency in Health Care; IRA, Inflation Reduction Act; NICE, National Institute for Health and Care Excellence; PBAC, Pharmaceutical Benefits Advisory Committee; PBS, Pharmaceutical Benefits Scheme; PCORI, Patient-Centered Outcomes Research Institute; PHARMAC, Pharmaceutical Management Agency.


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# Cost Effectiveness Thresholds – Example

**The NICE Cost Effectiveness Threshold**
- NICE Methods Guide and Reference Case (**2004**)
- official benchmark (CET) and Social Value Judgments (**2004/2005**; **2008**)

**NICE End-of-Life Guidance** (**2009**)
- permitting violation of NICE's CET if treatment is limited to a small terminally ill patient population, primarily addressing new cancer treatments

**NICE Severity Modifier (2022)**
- replacing end-of-life guidance

**Cancer Drugs Fund** (**CDF**, **2011**)
- reconfigured in 2016, essentially converted into a managed access scheme

**NICE Single Technology Appraisal Process** (**STA**, **2005**)

**Highly Specialised Technology Process** (**HST**, **2013**)
- new restrictive routing criteria introduced in **2025**

**Ethical principles officially adopted by NICE**
- fundamental equity position (QALY egalitarianism, **2004**)
- submission to Daniels & Sabin (accountability for reasonableness, A4R) in **2005**
- submission to Beauchamp & Childress (Medical Ethics, 1979) in **2008**

**Budget Impact Threshold** (**BIT**, **2017**)

**Adjustment of BIT and CET (2026)**

A4R, accountability for reasonableness; CET, cost effectiveness threshold; QALY, quality-adjusted life year; NICE, National Institute for Health and Care Excellence.


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# The Underlying Premise

"A QALY is a QALY is a QALY – regardless of who gains and who loses it."[1]

"The principal objective of the *National Health Service* ought to be to maximize the aggregate improvement in the health status of the whole community."[2]

"The underlying premise of CEA in health problems is that for any given level of resources available, society (or the decision-making jurisdiction involved) wishes to maximize the total aggregate health benefit conferred."[3]

[1] D. Feeney and G.W. Torrance (1989)

[2] Anthony J. Culyer (1997)

[3] M.C. Weinstein and W.B. Stason (1977)


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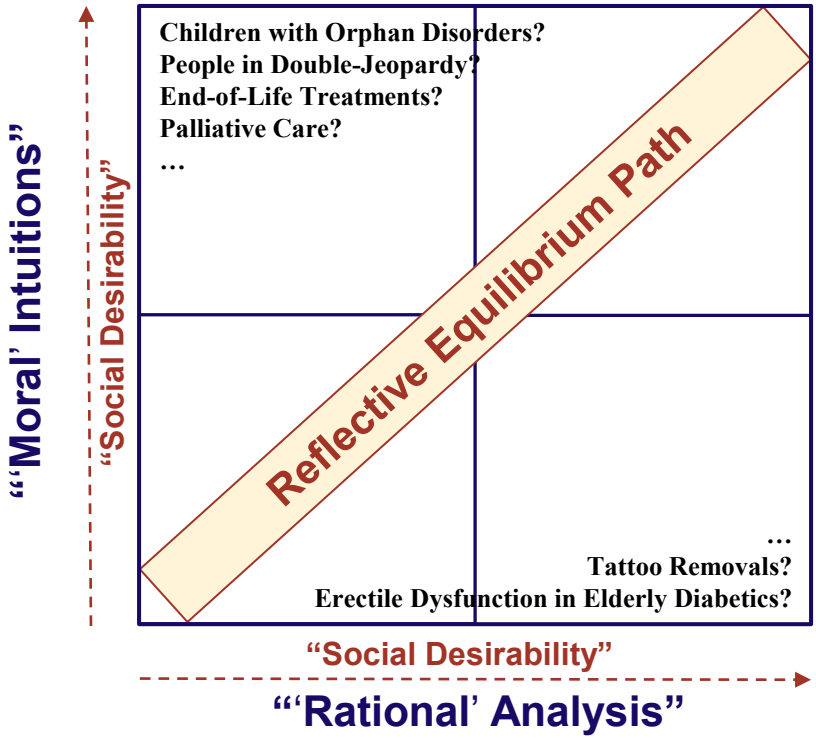
# The Textbook Example: QALY League Table[1]

| **Ranking** [original] | **Intervention** [abbreviated; comparator not stated in original table] | **Cost / QALY [£ (1990)]** |
|---|---|---|
| 3 | G.p. advice to stop smoking | £ 270 |
| 5 | Antihypertensive therapy to prevent stroke | £ 940 |
| 6 | Pacemaker implantation | £ 1,100 |
| 7 | Valve replacement for aortic stenosis | £ 1,140 |
| 8 | Hip replacement | £ 1,180 |
| 9 | Cholesterol testing and treatment | £ 1,480 |
| 11 | Kidney transplant | £ 4,710 |
| 12 | Breast cancer screening | £ 5,780 |
| 15 | Home hemodialysis | £ 17,260 |
| 18 | Hospital hemodialysis | £ 21,970 |
| 20 | Neurosurgery for malignant intracranial tumors | £ 107,780 |
| 21 | Epoetin alfa therapy for anemia in dialysis patients | £ 126,290 |

[1] A. Maynard. *Economic Journal* 1991; 101 (408): 1277-1286


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# Reflective Equilibrium (Issues)





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# Key Findings

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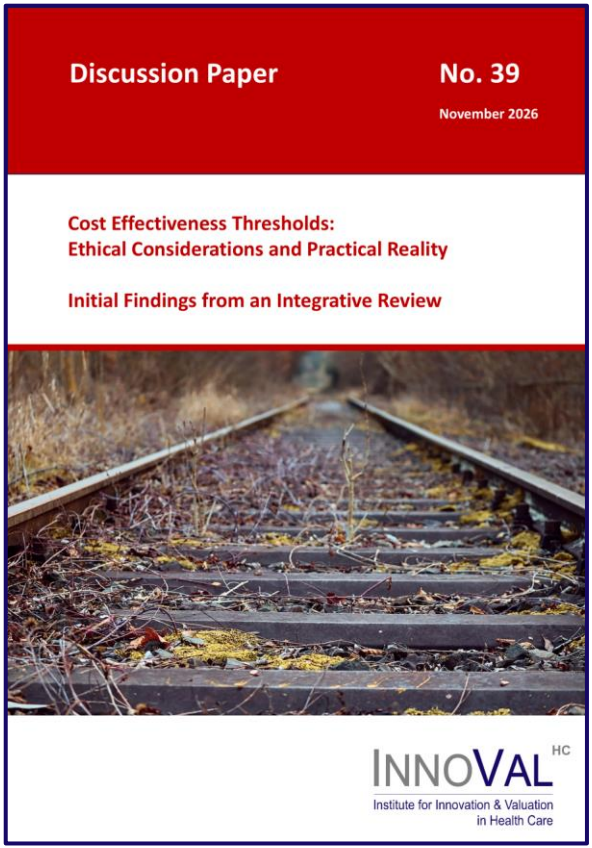
# Next Steps

## Consolidation of Observations

- Appraising the normative status given the technocratic nature of the approach
- Assessing the promise of proposed improvements and the need for alternatives
- Exercising a cautionary approach to simple solutions

## Determining the appropriate role and limitations of CEA

- Completing the analysis; continuing the project into its next phases
- Communicating insights





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