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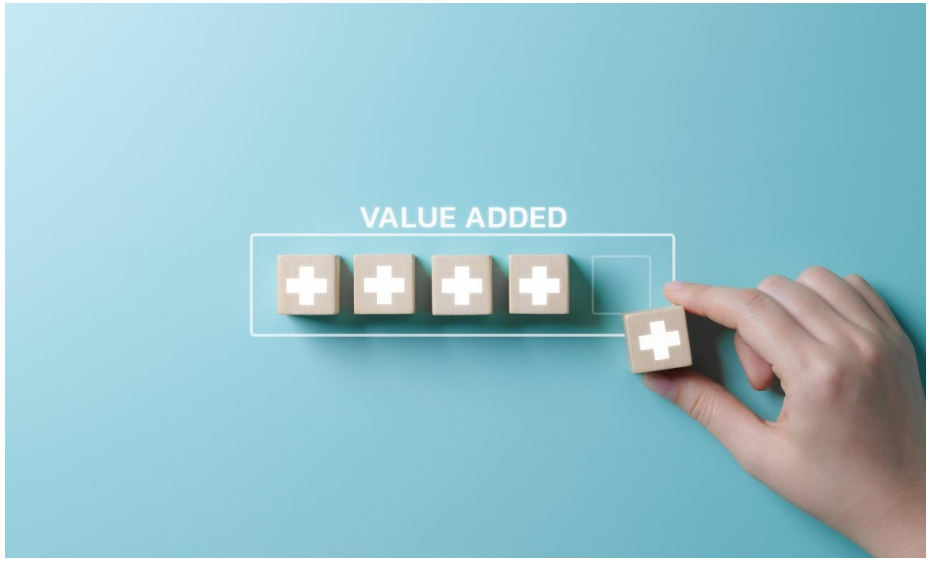
Economic Evaluation and Threshold Values: Conceptual Bases and International Approaches

Christoph Strohmaier

AIHTA Symposium, 17/03/2025



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Opportunity Cost – The Hidden Trade-Offs in Everyday Decisions

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If one abstracts from specific contextual factors, such as economic or political constraints, a **decision** is not just about what one does, but also about what one could do instead – **Weighing alternative or competing courses of action**.

*" […] the **opportunity cost** of making a particular **choice** is the value of the next-best **alternative** that is foregone"* – Turner et al. [2023, p. 2]

*"[…] Health economics is concerned with the **optimum use of [temporarily] scarce economic resources** for the care of the sick and the promotion of health, taking into account **competing uses of these resources.**"* – Mushkin [1958, p. 792]

What does all this have to do with health economic evaluations & threshold values?

Threshold – A decision-making criterion in healthcare

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Decision-makers & policy makers decide on **resource allocation** & prioritise reimbursement decisions **based on specific criteria**:

- Optimal/efficient resource allocation
- "Sustainable" system design & planning criteria
- Additional health care specific decision- & policy-relevant factors (disease severity, orphan designation, equity, etc.)

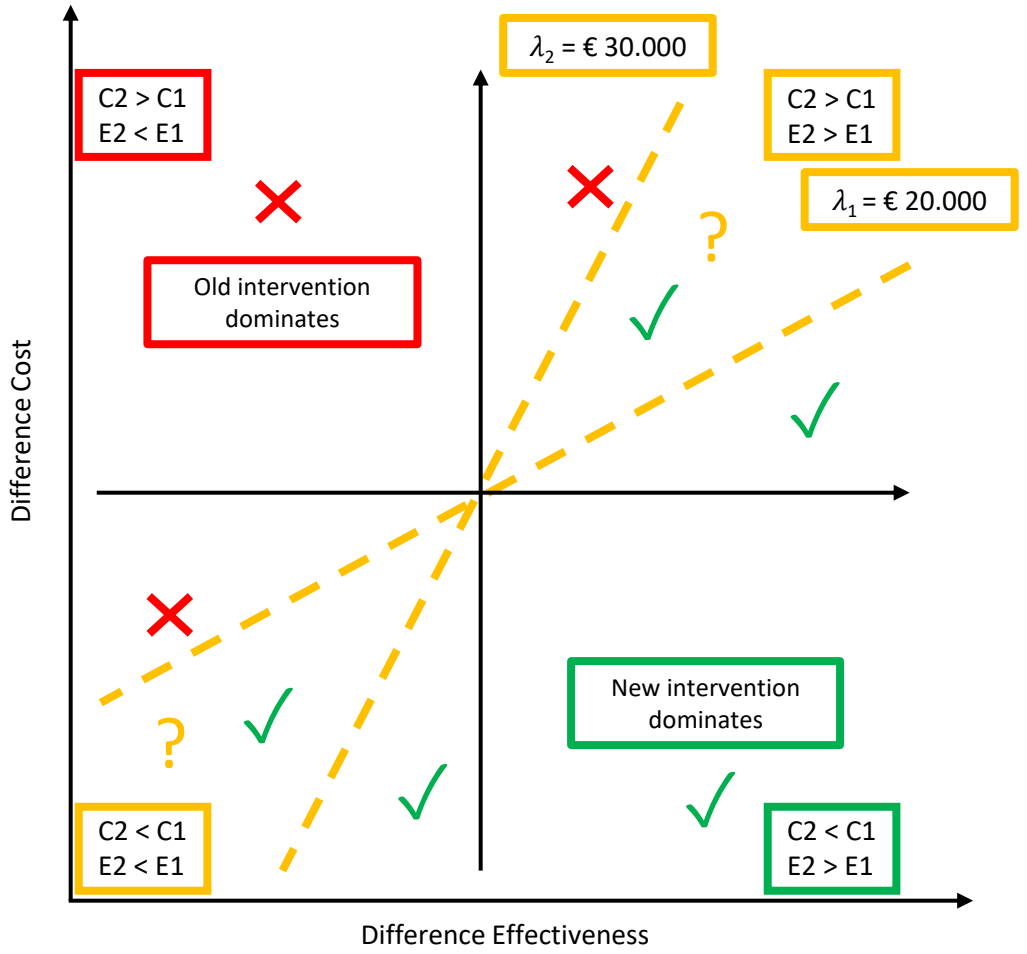
→ Health Economic Evaluations (HEE) & Threshold:

- **Systematic method** to **approximate opportunity costs** in healthcare
- **Support decisions** between alternative interventions for optimal resource utilisation
- Key metric: **Incremental cost-effectiveness ratio (ICER)** → Cost difference per quality-adjusted life year (QALY) of two interventions
- **Comparison of ICER** with **ICER threshold**:

$$ICER = \frac{C_2 - C_1}{E_2 - E_1} = \frac{\Delta C}{\Delta E} \leq \lambda \quad \textbf{(ICER threshold)}$$

C2…new intervention
C1…old intervention ("gold standard")
E2…effect of new intervention
E1…effect of old intervention
λ…ICER threshold/criterion

Cost-Effectiveness Plane



Methods for Calculating & Determining Thresholds

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Empirical ICER Thresholds:

- Basis/Concept: **Past reimbursement decisions** & outcome data (e.g., mortality, QALYs) serve as the foundation for calculation
- Advantage: Some approaches are less data-intensive → calculation using macro-level data, considering a given budget & "desired" life expectancy (aggregated health expenditures & life expectancy → Pichon-Riviere et al., 2022)
- Disadvantage: Most approaches require extensive data (past decisions, compared interventions, costs & benefits), are methodologically complex (Claxton et al., 2015) & may not reflect societal values

Gross Domestic Product (GDP)-Based ICER Thresholds ("WHO Approach"):

- Basis/Concept: Uses a country's **GDP per capita** as a benchmark to determine cost-effectiveness thresholds (WHO: 1 – 3x GDP per capita per QALY)
- Advantage: Simple & widely applicable, especially in low- & middle-income countries
- Disadvantage: May not reflect country-specific healthcare priorities, budget constraints, or societal values

Societal Willingness to Pay (WTP) Thresholds:

- Basis/Concept: Involvement of a **representative population** → Reflects the maximum amount society is willing to pay for additional health gains (e.g. QALY)
- Advantage: Standardised methods to incorporate societal values & preferences, ensuring decisions align with public priorities
- Disadvantage: A representative universal threshold may be ethically questionable ("high-cost medications")

Efficiency Frontier Approach (EFA) → Price Ceiling:

- Basis/Concept: **No fixed threshold**, but rather alignment with the efficiency frontier in a specific therapeutic area
- Advantage: EFA follows a strict rule where costs/expenditures increase proportionally to health improvements → efficient combination of currently available interventions in a specific therapeutic area
- Disadvantage: No explicit threshold, but a price ceiling + focus on individual therapeutic areas

Threshold – Relevance in the Austrian Healthcare System

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Thresholds: Two Interpretations, but two sides of the same coin – "We live in a society governed by a state."

- Consideration of **forgone benefits** through alternative resource use
- **Society's willingness to pay** for "health gains"

Reference value for assessing the **"appropriateness of the cost-effectiveness ratio"** of interventions

At least five legal texts in Austria related to **Efficiency** or **Cost-Effectiveness ("Wirtschaftlichkeit")** in the healthcare system:

- **General Social Insurance Act (ASVG):** *"The medical treatment must be sufficient and appropriate but must not exceed what is necessary."* (**„Wirtschaftlichkeitsgebot"** in §133 & § 351g ASVG/ VO-EKO + *"Application of Health Economic Evaluations"*)
- **Federal Hospitals Act (KAKuG):** *"The assessment of the additional medical-therapeutic benefit…**according to predefined cost-effectiveness criteria**) & potential application criteria." & "The expected budget impact & the comparability of the price within the context of international price structures must certainly be taken into account.".*
- **Federal Act on the Quality of Health Care:** *"**Efficiency:** The ratio between the input & the outcome of a service according to the principle of cost-effectiveness, while considering cost containment".*
- **Federal Constitutional Law 15a (Bundesverfassungsgesetz/Zielsteuerung-Gesundheit):** *"The responsibility for the use of taxes & contributions provided by the population calls for tools to **enhance the effectiveness & efficiency** of healthcare".*
- **Federal Budget Act:** *"In the interest of citizens & patients, the quality, effectiveness, & **cost-effectiveness ["Wirtschaftlichkeit"]** of healthcare must be sustainably ensured for the future".*
- **Further acts:** Medicinal Products Act, Federal Act on Health Telematics...

International Practice – Country Overview

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- 24 out of 39 (62%) surveyed countries use thresholds
- 7 countries (30%) with **explicit thresholds**: EST, E&W, IRE, POL, SVK, SVN, THA
- 17 countries (70%) with **implicit thresholds** (reference value or "rule of thumb")
- Majority are high-income countries
- Baseline thresholds:
  - Average baseline threshold: €28,500 per QALY
  - Range of baseline thresholds: ~€4,000 (THA) to €50,000 (SVK) per QALY

- 11 out of 24 countries (46%) use more flexible approaches for baseline thresholds:
  - Threshold ranges & multiple baseline thresholds
  - Example Canada: Different baseline thresholds for oncological & non-oncological interventions
  - Average upper threshold: €54,200 per QALY (n = 11 countries)
  - Highest threshold overall: USA (~€142,450 per QALY)

Calculation approach		
No method reported (n=12)	**GDP-based (n=9)**	**Empirical (n=3)**
• Canada (CAN) • England and Wales (E&W) • Ireland (IRL) • Japan (JPN) • Netherlands (NLD) • Norway (NOR) • Portugal (PRT) • Scotland (SCT) • Slovenia (SVN) • Sweden (SWE) • Thailand (THA) • United States of America (USA)	• South Korea (KOR): 1 × GDP • Brazil (BRA): 1–3 × GDP • China (CHN): 1–3 × GDP • Czech Republic (CZE): 1–3 × GDP • Estonia (EST): 1–3 × GDP • Greece (GRC): 1–3 × GDP • Hungary (HUN): 1.5–3 × GDP • Poland (POL): 3 × GDP • Slovak Republic (SVK): 3 × GDP	• Australia (AUS) • Latvia (LVA) • Spain (ESP)

International Practice – Threshold Associations

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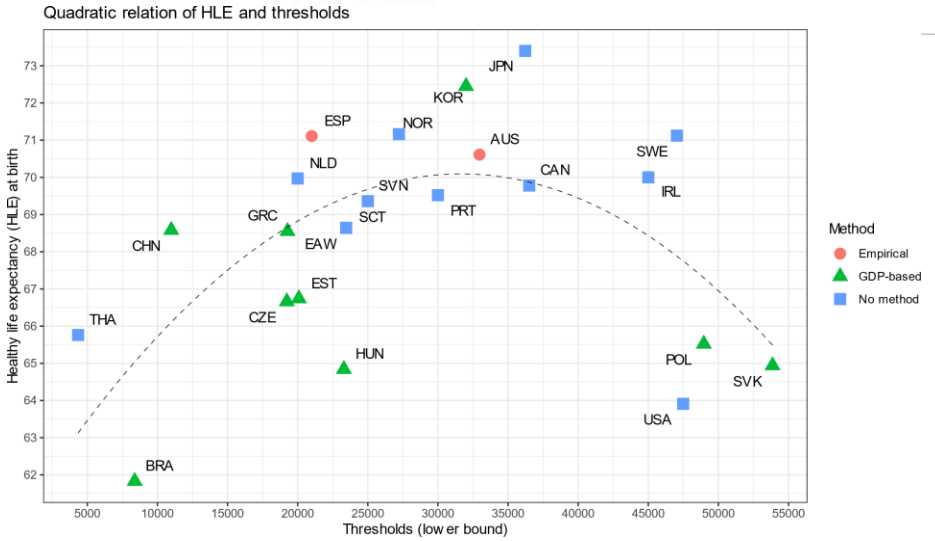
- Relationship Between Thresholds & Healthy Life Expectancy (HLE):
  - Fitted a quadratic function/Inverse U-shaped relationship (Multiple $R^2 = 0.41$):

$$HLE = \alpha + \beta_1 * \text{Threshold} + \beta_2 * \text{Threshold}^2$$

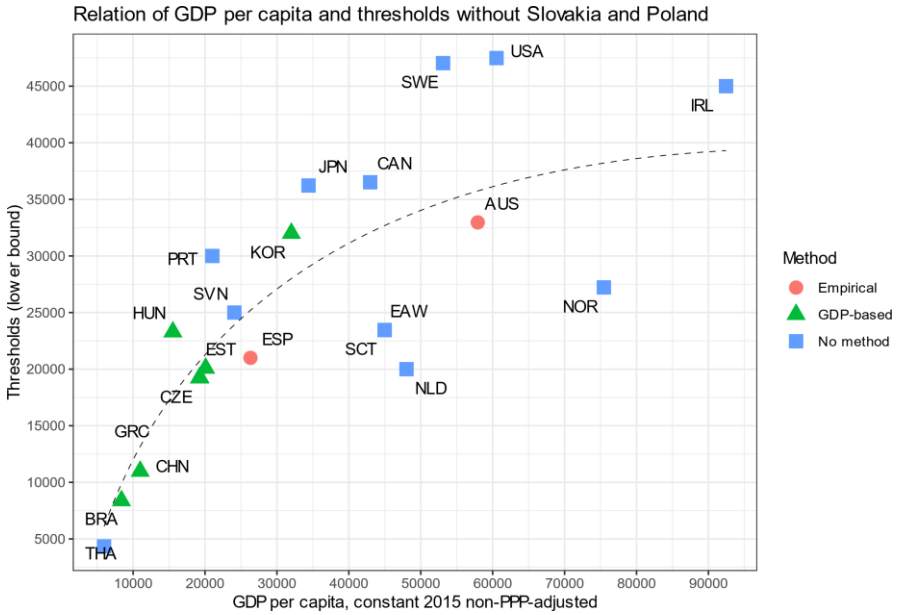
  - Thresholds initially increase with HLE but decline after reaching a peak (Peak: €31,650 per QALY at 70 years of HLE)
  - Higher thresholds do not always correlate with higher life expectancy → other factors (e.g., healthcare quality, lifestyle, socioeconomic conditions) may also be associated with HLE



- Relationship Between GDP per Capita (constant) & Thresholds:
  - Fitted a linear function with a square root term:

$$GDP = \gamma + \delta_1 * \text{Threshold} + \delta_2 * \sqrt{\text{Threshold}}$$

  - No clear association between GDP per capita & thresholds (Multiple $R^2 = 0.24$)
  - Increasing variation at higher GDP levels: Countries with similar GDP per capita may have significantly different thresholds
  - Influence of unspecified factors: Healthcare system structure, country-specific societal values, disease burden, political priorities etc…



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International Practice – Modifiers

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- Modifiers:
  - Go beyond purely technical efficiency criteria
  - Quantitative modifiers: Adjust the ICER or threshold directly
  - Qualitative modifiers: Influence the decision-making process
  - Example – Norway: The priority of an intervention increases with the expected lifetime health loss (Health-Loss Criterion), reflecting a focus on addressing significant unmet needs
- Usage:
  - 10 modifying criteria for both types of modifiers
  - 15 out of 24 (63%) countries use modifiers
  - 11 countries: Quantitative modifiers
  - 7 countries: Qualitative modifiers
  - 3 countries: Both forms
- "Top 3" Criteria
  - Rare Diseases (n = 9)
  - Disease Burden/Severity (n = 7)
  - Availability of Alternatives (n = 5)

Modifying Criterion	Quantitative Modifier	Qualitative Modifier
Disease burden/severity (including end-of-life treatments)	Netherlands, Norway (Health Loss), Sweden, Czech Republic, England & Wales	Australia ("Rule of Rescue"), Czech Republic, South Korea
Rare diseases (orphan diseases)	England & Wales, Hungary, Ireland, Japan, Slovak Republic, Sweden, USA	Scotland, South Korea
"Equity"	-	Australia, Canada, Thailand
Specific indications and diseases (non-orphan)	Canada (oncology), Japan (pediatric designation, oncology)	-
Availability of alternatives	-	Australia, Czech Republic, England and Wales, Scotland, South Korea
Budget Impact	-	Australia, England & Wales
Uncertainty of ICER/confidence in estimates	-	Australia, England & Wales
Innovation factor	-	Czech Republic
High-Impact single and short-term therapies (SSTs)	USA	-
Public health relevance	-	Australia
∑	∑ 11 Countries	∑ 7 Countries

Thresholds – Wrap Up

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- Health economics & thresholds have their roots in **utilitarianism** (maximisation of happiness or well-being)
- **Efficiency** aspects are **explicitly considered** (approximation of opportunity costs) → "Informed decision-making" & avoidance of displacement effects on healthy life years (Lancet study for UK: Naci et al., 2024 → negative QALY impact at the population level)
- **Non-efficiency aspects** (disease severity, orphan designation, equity, etc.) may not be considered, but…
- **Adjustment** of decision-relevant thresholds based on modification criteria (or multiple thresholds) is possible → should be conducted transparently & not ad hoc
- The application of health economic evaluations & thresholds **promotes transparency** in economic decisions:
  - Allocation of resources becomes traceable (input)
  - Distribution of "health gains" becomes transparent (output)
  - Enables accountability
- Negative aspect of transparency: **"Threshold pricing"** → strategic behaviour by companies
  - Pricing close to the upper limit considered "cost-effective"
  - Before price negotiations: initial price set above the established threshold

Conclusion & Outlook

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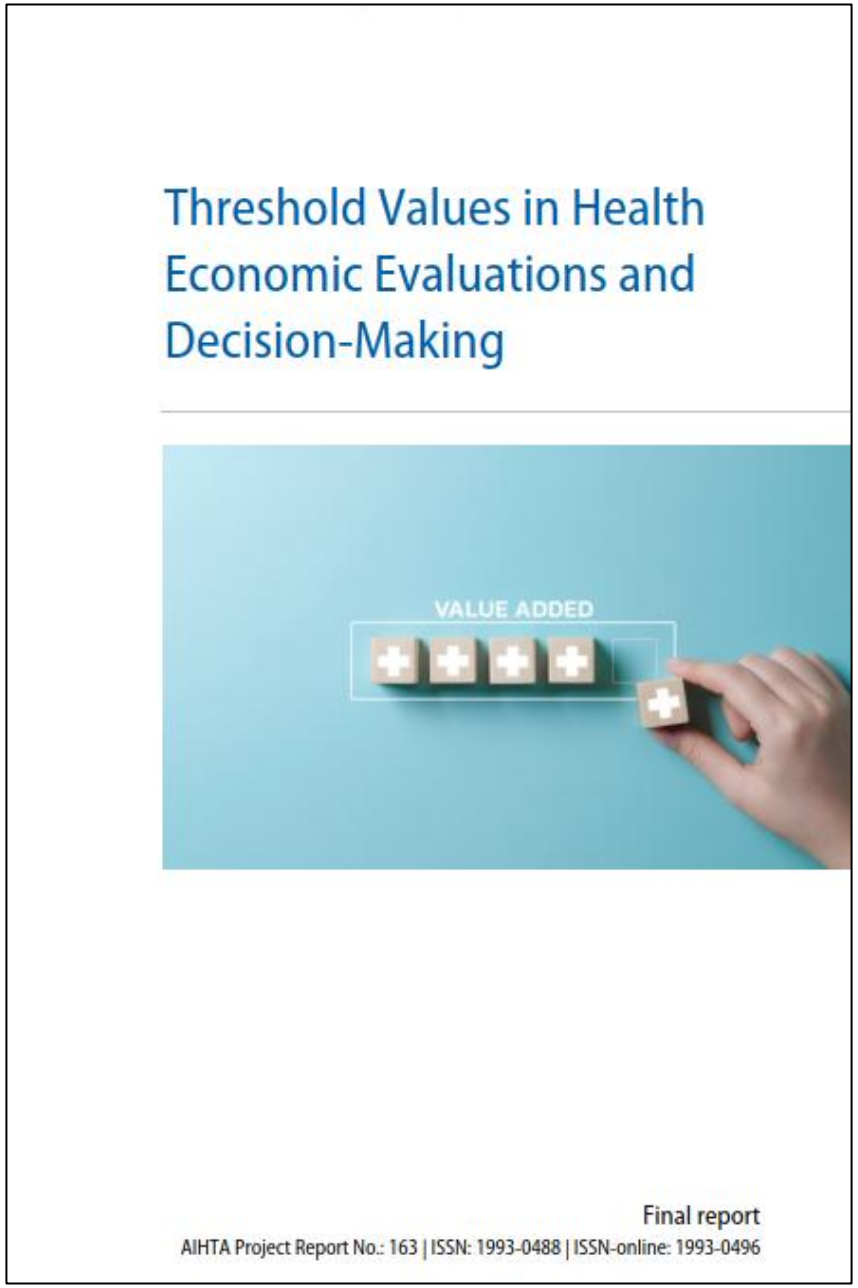
- Efficiency criterion (threshold) as **one of many criteria** in the decision-making process
- **No universal "Gold Standard"** for a specific ICER threshold and/or modifier approach
- **Austria:**
  - Health economic evaluations play, relatively speaking, a subordinate role.
  - The efficiency criterion & opportunity cost thinking deserve more attention (rational decision-making ≠ rationing)
  - Adaptation of health economic methodology to the national context according to the state of research is required
    - ✓ Need of methodological guidelines, including the establishment of appropriate evaluation methods.
    - ✓ Build expertise & capacity, as well as raise awareness among relevant stakeholders (especially decision-makers & policymakers).
    - ✓ Develop transparent processes.
    - ✓ Harmonise legal terminology with scientific language.
    - ✓ Ensure continuous evaluation & adaptation.
- **Commitment from the scientific community**: Further research on methodological aspects & support for evidence-based decision-making.
- **Commitment from decision-makers**: Support through a valid data foundation (Austrian QALYs & unit costs) → prerequisite for evidence-based decision-making.



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https://eprints.aihta.at/1549/

Strohmaier, C. and Zechmeister-Koss, I. (2024): Threshold values in health economic evaluations and decision-making. HTA-Projektbericht 163.