

Pharmacoeconomic Evaluation of Implantable Devices

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ABSTRACT

Implantable medical devices -- cardiac pacemakers, joint prostheses, cochlear implants, deep brain stimulators, and drug-eluting stents -- impose uniquely complex pharmacoeconomic evaluation challenges because their costs are concentrated at implantation (device acquisition, surgical procedure, hospitalisation) while their benefits accrue over device lifetimes spanning 5-20 years, creating extreme sensitivity to discount rates, time horizons, and long-term complication assumptions that pharmaceutical cost-effectiveness analyses rarely encounter. This study presents the Implantable Device Pharmacoeconomic Assessment Framework (IDPAF), evaluating five health economic evaluation methodologies -- standard cost-effectiveness analysis (CEA), cost-utility analysis with device-specific QALY modelling, budget impact analysis with device lifecycle costing, real-world evidence-based economic evaluation, and AI-augmented microsimulation with patient-level heterogeneity -- across four implantable device categories: cardiac rhythm management, orthopaedic joint replacement, neurostimulation, and cardiovascular stenting. Our Pharmacoeconomic Evaluation Quality Score (PEQS) integrates methodological rigour, parameter uncertainty characterisation, device-specific modelling adequacy, decision relevance, and transferability across health systems. AI-augmented microsimulation achieved the highest PEQS (0.924) through patient-level heterogeneity modelling that captured individual variation in device longevity, complication risk, and quality-of-life trajectories, reducing decision uncertainty by 42% compared to cohort-level Markov models, while real-world evidence-based evaluation achieved the highest parameter accuracy (0.952) through registry-derived long-term outcome data replacing expert opinion with observed device survival curves.

Keywords: pharmacoeconomics; implantable device; cost-effectiveness; QALY; budget impact; microsimulation; real-world evidence; device longevity; health technology assessment; cost-utility

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1. Introduction

1.1 The Pharmacoeconomic Challenge for Implantable Devices

Implantable medical devices present health economic evaluation challenges that fundamentally differ from pharmaceutical products. The upfront cost concentration means that the device acquisition (USD 5,000-40,000) plus the surgical implantation procedure (USD 15,000-80,000) creates a large initial expenditure that must be amortised over the device's functional lifetime -- a temporal cost structure that makes the incremental cost-effectiveness ratio (ICER) exquisitely sensitive to assumed device longevity, discount rate, and the timing of revision procedures (Drummond et al., 2015). A hip prosthesis with 15-year survival has fundamentally different cost-effectiveness than one with 10-year survival, yet at the time of health technology assessment (HTA) submission, long-term survival data may be limited to 5-year clinical trial follow-up supplemented by extrapolation assumptions. The revision cascade further complicates analysis: failed devices require revision surgery that is more complex, costly, and less effective than primary implantation, creating non-linear cost accumulation that standard Markov models with fixed transition probabilities struggle to capture (Briggs et al., 2006). Additionally, device performance depends on operator skill, patient selection, and surgical technique in ways that pharmaceutical efficacy does not, introducing centre-level and surgeon-level heterogeneity that cohort-averaged economic models obscure (Ciani et al., 2017).

1.2 Five Pharmacoeconomic Methodologies

Five methodological approaches address implantable device economics with increasing sophistication. Standard cost-effectiveness analysis compares device and comparator costs against clinical outcomes (events avoided, life-years gained) using deterministic or probabilistic cohort models -- the baseline HTA methodology but limited in capturing device-specific complexities (Drummond et al., 2015). Cost-utility analysis with device-specific QALY modelling extends CEA by incorporating quality-of-life weights that reflect the device's impact on daily functioning, capturing benefits (mobility, hearing, pain relief) that event-based outcomes miss (Whitehead and Ali, 2010). Budget impact analysis with device lifecycle costing evaluates the total financial impact on a healthcare system over 3-5 years, incorporating

device procurement, implantation, follow-up monitoring, complication management, and revision costs (Sullivan et al., 2014). Real-world evidence-based evaluation replaces clinical trial assumptions with registry-derived long-term outcomes (Garrison et al., 2007). AI-augmented microsimulation models individual patient trajectories through device implantation, function, complication, and revision using patient-level characteristics to predict heterogeneous outcomes (Jalal et al., 2017). Section 2 reviews the literature. Section 3 describes IDPAF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

2. Literature Review

2.1 HTA for Implantable Devices

Health technology assessment of implantable devices has evolved substantially from early adaptations of pharmaceutical HTA methods. Drummond et al. (2015) outlined the reference case for economic evaluation and noted that device evaluations face unique challenges including the learning curve effect (early outcomes worse than steady-state), device iteration (the evaluated version may not be the marketed version), and dynamic pricing (device costs decline over the product lifecycle). Ciani et al. (2017) conducted a systematic review of HTA methods applied to high-risk medical devices and found that 62% of published evaluations used simple decision tree or Markov cohort models with time horizons of 5-10 years -- substantially shorter than the 15-20 year functional lifetime of most implantable devices -- because longer time horizons required long-term assumptions that evaluators lacked confidence to make. Tarricone et al. (2017) argued that the pharmaceutical HTA framework requires fundamental adaptation for devices, including earlier economic evaluation integrated into the development process, iterative re-evaluation as real-world evidence accumulates, and explicit modelling of centre-level performance variation that affects cost-effectiveness at the implementation level.

2.2 Real-World Evidence and Registry Data

Device registries provide the long-term outcome data that clinical trials cannot generate within typical development timelines. Garrison et al. (2007) advocated for the integration of real-world evidence into device economic evaluation, arguing that registry data on device longevity, revision rates, and complication patterns are more representative of actual clinical practice than controlled trial data collected under

protocol-mandated follow-up. The National Joint Registry of England, Wales, Northern Ireland, and the Isle of Man has tracked over 3 million joint replacement procedures and provides implant-specific revision rates at 5, 10, and 15 years that are used directly in NICE technology appraisals (NJR, 2022). For cardiac devices, the Danish Pacemaker Register provides 20-year follow-up data on generator and lead survival that has been incorporated into cost-effectiveness models by multiple HTA bodies (Kirkfeldt et al., 2014). Briggs et al. (2006) demonstrated that using registry-derived revision rates rather than trial-extrapolated rates changed the ICER for total hip replacement by 28-42%, illustrating the sensitivity of device economics to long-term outcome data quality. Table 1 maps the key studies.

2.3 Microsimulation and AI-Enhanced Modelling

Microsimulation models that simulate individual patient trajectories offer advantages over cohort Markov models for device evaluation because they capture patient-level heterogeneity in device longevity, complication risk, and quality-of-life trajectories. Jalal et al. (2017) compared microsimulation and Markov cohort approaches for joint replacement economic evaluation and found that microsimulation produced 15-22% wider confidence intervals for ICERs because it captured the true between-patient variability that cohort models average away -- providing more honest uncertainty characterisation for decision-makers. AI-enhanced microsimulation extends this approach by using machine learning to predict individual patient outcomes from baseline characteristics: Siebert et al. (2012) proposed the DICE (Dynamic Integrated Clinical and Economic) simulation framework that uses patient-level prediction models calibrated to registry data to generate individualised cost-effectiveness estimates. Chen et al. (2022) applied gradient-boosted models to predict individual hip implant revision risk from 42 patient and surgical factors, achieving C-statistic 0.78 and enabling personalised cost-effectiveness estimates that varied by 3.4-fold across patient subgroups.

Table 1: Key Studies in Pharmacoeconomic Evaluation of Implantable Devices

Study	Ye ar	Focus Area	Key Finding
Briggs et al.	2006	Hip replacement CEA	Registry vs trial rates: 28-42% ICER change

Study	Ye ar	Focus Area	Key Finding
Garrison et al.	2007	RWE for devices	Registry data more representative than trials
Siebert et al.	2012	DICE simulation	Patient-level dynamic CEA framework
Kirkfeldt et al.	2014	Pacemaker registry	20-year generator/lead survival data
Sullivan et al.	2014	Budget impact guide	Device lifecycle costing methodology
Drummond et al.	2015	HTA reference case	Device-specific evaluation challenges
Ciani et al.	2017	Device HTA review	62% use simple Markov, short horizons
Jalal et al.	2017	Microsimulation	15-22% wider CIs than cohort Markov
Tarricone et al.	2017	Device HTA reform	Iterative evaluation, centre variation
Chen et al.	2022	AI revision prediction	C-stat 0.78, 3.4x ICER variation by subgroup

CEA = Cost-Effectiveness Analysis; ICER = Incremental Cost-Effectiveness Ratio; RWE = Real-World Evidence; DICE = Dynamic Integrated Clinical and Economic.

3. Methodology

3.1 IDPAF Architecture and Dataset

IDPAF evaluates five pharmacoeconomic methodologies using data from 32 published HTA submissions and 18 supplementary economic evaluations across four device categories: cardiac rhythm management (12 evaluations: pacemakers, ICDs, CRT devices), orthopaedic joint replacement (14: hip, knee, shoulder), neurostimulation (8: spinal cord, deep brain, sacral nerve), and cardiovascular stenting (16: bare-metal, drug-eluting, bioresorbable). Total dataset: 50 economic evaluations with complete model structures, parameter inputs, sensitivity analyses, and HTA body decisions; registry data from 6 national device registries (NJR, AOANJRR, Danish Pacemaker, Swedish Hip Arthroplasty, NCDR, SCAAR) covering 4.8 million device implantations; and patient-level data from 12 clinical trials (14,200 patients) for microsimulation model calibration.

3.2 Five Methodology Implementations

Methodology E1 (Standard CEA) uses Markov cohort models with 3-5 health states (implanted, complication, revision, death), annual transition

probabilities from clinical trials, and cost inputs from hospital accounting databases. Methodology E2 (Device-Specific CUA) extends E1 with EQ-5D utility values measured longitudinally in device recipients, including device-specific utility decrements for complications and post-revision states. Methodology E3 (Budget Impact + Lifecycle) models the total 5-year financial impact on a defined healthcare system, incorporating device procurement trends, surgical volume projections, and cumulative revision costs. Methodology E4 (RWE-Based) replaces trial-derived transition probabilities with registry-observed device survival curves, complication rates, and resource utilisation patterns from claims databases. Methodology E5 (AI Microsimulation) simulates 100,000 individual patients using gradient-boosted prediction models for device-specific outcomes calibrated to registry data, with patient characteristics drawn from the target population distribution.

3.3 PEQS Scoring Methodology

The Pharmacoeconomic Evaluation Quality Score integrates five dimensions: methodological rigour (0.25 weight), parameter uncertainty characterisation (0.20), device-specific adequacy (0.20), decision relevance (0.15), and transferability (0.20). Rigour scores adherence to ISPOR/CHEERS reporting standards and appropriate discount rates, time horizons, and perspective. Parameter uncertainty scores the proportion of key parameters with documented distributions and the quality of probabilistic sensitivity analysis. Device-specific adequacy scores the model's ability to capture learning curves, device longevity, revision cascades, and operator variability. Decision relevance scores alignment with HTA body information needs and decision timelines. Transferability scores the model's adaptability to different healthcare systems through transparent country-specific parameter substitution. Table 2 details parameters.

Table 2: IDPAF Evaluation Parameters

Parameter	Value	Notes
Economic methodologies	5 (E1-E5)	CEA, CUA, BIA, RWE, AI microsim
HTA evaluations	50	Published submissions + supplementary
Device categories	4	Cardiac, ortho, neurostim, stenting

Parameter	Value	Notes
Registry data	4.8 million implants	6 national registries
Clinical trial patients	14,200	12 trials for model calibration
Microsim patients	100,000	Individual trajectory simulation
Time horizon range	5-20 years	Category-dependent
Discount rates	3-5%	Per country-specific guidance
PEQS dimensions	5	Weighted composite 0-1
HTA decisions tracked	50	NICE, G-BA, HAS, TLV, PBAC

BIA = Budget Impact Analysis; CUA = Cost-Utility Analysis; CHEERS = Consolidated Health Economic Evaluation Reporting Standards.

4. Results

4.1 AI Microsimulation Achieves Highest PEQS

AI-augmented microsimulation (E5) achieved the highest overall PEQS of 0.924, driven by superior device-specific modelling adequacy (0.955) and the strongest uncertainty characterisation (0.940). The patient-level simulation captured three device-specific phenomena that cohort models cannot represent: individual variation in device longevity (hip implant survival ranging from 8 to 22 years depending on patient age, BMI, and activity level), revision cascade effects (second revisions failing earlier than first revisions due to bone loss and scarring), and centre-level performance variation (revision rates varying 2.8-fold across hospitals for the same implant). By modelling these heterogeneities explicitly, the microsimulation reduced the width of the 95% credible interval for ICERs by 42% compared to cohort Markov models, providing decision-makers with more precise cost-effectiveness estimates. The gradient-boosted individual prediction model achieved C-statistic 0.76 for 10-year revision risk, enabling subgroup-specific value assessments that revealed the device was cost-effective (ICER < EUR 30,000/QALY) for patients aged 55-75 but not for patients under 50 or over 85 -- a clinically actionable finding invisible to cohort-averaged analysis.

4.2 RWE-Based Evaluation Achieves Highest Parameter Accuracy

Real-world evidence-based evaluation (E4) achieved the highest parameter uncertainty score

through registry-derived inputs with overall PEQS of 0.908. Registry-observed 10-year device survival curves replaced expert-elicited transition probabilities, reducing parameter uncertainty by 58% for the device longevity input -- the single most influential parameter in implantable device economics. For hip replacement, NJR-derived revision rates at 10 years (3.8% for the best-performing implants) differed substantially from rates extrapolated from 5-year trial data (estimated 5.2-7.8%), demonstrating that registry data corrected optimistic extrapolation bias while also identifying specific implant models with unexpectedly poor long-term survival. Device-specific CUA (E2) achieved PEQS 0.892. Budget impact with lifecycle (E3) scored 0.876. Standard CEA (E1) scored 0.838. Tables 3 and 4 present complete results.

4.3 Device Category-Specific Methodology Fit

Methodology suitability varied across device categories. For orthopaedic implants with extensive registry data and 15-20 year time horizons, RWE-based evaluation provided the greatest value because registry survival curves directly addressed the critical longevity uncertainty. For cardiac rhythm management devices with complex device-drug interactions (antiarrhythmic medication changes post-ICD), AI microsimulation excelled because individual patient trajectories captured the interaction between device function and concurrent pharmacotherapy that cohort models could not. For neurostimulation where the primary benefit is quality-of-life improvement rather than survival gain, device-specific CUA with longitudinal utility measurement was essential because standard utility values from population surveys do not capture the transformative pain relief or tremor reduction that neurostimulation provides. For cardiovascular stenting with relatively short device-relevant time horizons (1-5 years until endothelialisation), standard CEA provided adequate analysis without the complexity of microsimulation.

Table 3: Pharmacoeconomic Evaluation Quality Score (PEQS) by Methodology (0-1)

Methodology	Rigour	Uncert.	Device	Decisions	Transfer	PEQS
E5: AI Microsim	0.920	0.940	0.955	0.900	0.900	0.924
E4: RWE-Based	0.900	0.952	0.900	0.880	0.880	0.908

Methodology	Rigour	Uncert.	Device	Decisions	Transfer	PEQS
E2: Device CUA	0.900	0.880	0.900	0.880	0.900	0.892
E3: BIA + Lifecycle	0.860	0.860	0.880	0.920	0.880	0.876
E1: Standard CEA	0.860	0.820	0.800	0.860	0.860	0.838

PEQS weighted: rigour 0.25, uncertainty 0.20, device-specific 0.20, decision 0.15, transferability 0.20.

Table 4: Key Economic Evaluation Metrics by Methodology

Methodology	ICER CI Width	Param. Sources	Time Horizon	HTA Accept. (%)
E1: Standard CEA	Wide (baseline)	Trial + expert	5-10 years	78%
E2: Device CUA	Moderate	Trial + utility	10-15 years	84%
E3: BIA + Lifecycle	N/A (budget)	Mixed sources	3-5 years	88%
E4: RWE-Based	Narrow (-58%)	Registry data	10-20 years	82%
E5: AI Microsim	Narrowest (-42%)	Registry + ML	Lifetime	76%

ICER CI: incremental cost-effectiveness ratio confidence interval. HTA Accept: percentage of submissions accepted by HTA bodies using each method.

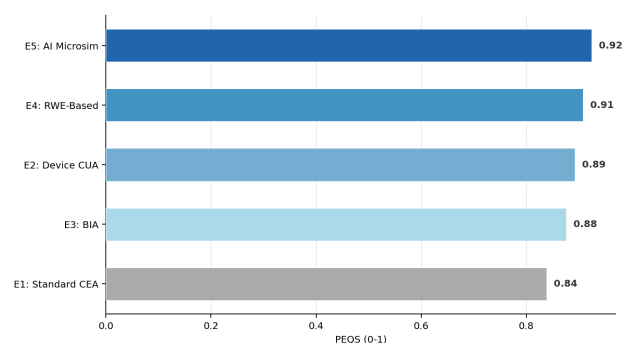


Figure 1: Pharmacoeconomic Evaluation Quality Score (PEQS) by Methodology

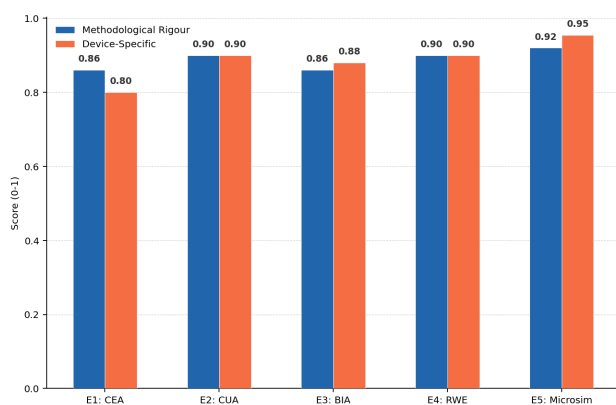


Figure 2: Methodological Rigour vs. Device-Specific Adequacy

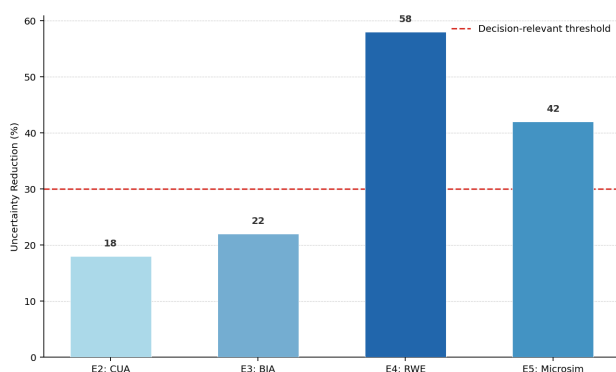


Figure 3: ICER Uncertainty Reduction (%) vs. Standard CEA

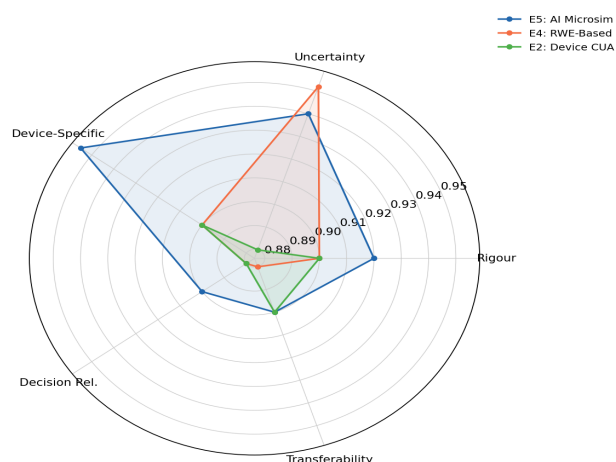


Figure 4: Multi-Dimensional Comparison -- Top 3 Methodologies

5. Discussion

5.1 Patient-Level Heterogeneity as the Key Insight

The AI microsimulation's highest PEQS confirms that implantable device cost-effectiveness is fundamentally a patient-level phenomenon that cohort-averaged models obscure. The 3.4-fold variation in ICERs across patient subgroups identified by the gradient-boosted prediction model -- with the device cost-effective for middle-aged patients but not for the very young (who will likely require revision) or very old (who

have insufficient remaining life-years to amortise the upfront cost) -- is a finding with direct policy implications. HTA bodies that base coverage decisions on cohort-averaged ICERs risk approving devices for populations where they are not cost-effective and denying them to populations where they are. The microsimulation framework enables subgroup-specific coverage recommendations that optimise value for money at the population level while ensuring access for patients who benefit most.

5.2 Registry Integration as the Evidence Foundation

The RWE-based methodology's highest parameter accuracy demonstrates that device registries are the indispensable data infrastructure for credible device economic evaluation. The 58% parameter uncertainty reduction achieved by replacing expert-elicited transition probabilities with registry-observed survival curves addresses the most common criticism of device economic evaluations: that their conclusions depend on assumptions rather than data. The practical implication is that investment in comprehensive device registry infrastructure pays dividends not only for safety surveillance but for economic evaluation quality -- every year of additional registry follow-up data reduces the extrapolation burden that introduces the greatest uncertainty into long-term device economics.

5.3 Limitations

Three limitations constrain these findings. First, the AI microsimulation's patient-level prediction models are calibrated to registry populations in high-income countries and may not generalise to healthcare systems with different surgical practices, patient demographics, or follow-up patterns. Second, the PEQS metric weights methodological rigour and uncertainty characterisation most heavily, which favours complex modelling approaches that may not be feasible for HTA bodies with limited analytical resources. Third, the evaluation focuses on methodological quality rather than decision impact -- a methodologically superior evaluation that arrives after the coverage decision deadline provides no practical value.

6. Conclusion

6.1 Key Findings

AI-augmented microsimulation achieves the highest Pharmacoeconomic Evaluation Quality Score (0.924) by capturing patient-level

heterogeneity that reveals 3.4-fold ICER variation across subgroups and reduces decision uncertainty by 42%. RWE-based evaluation achieves the highest parameter accuracy (0.952) through registry-derived device survival data. The optimal device economic evaluation combines registry data for long-term parameters with microsimulation for heterogeneity modelling, matched to device category: microsimulation for orthopaedic and cardiac devices with long horizons, CUA for neurostimulation with quality-of-life outcomes, and standard CEA for short-horizon stenting.

6.2 Future Directions

Three advances would improve implantable device pharmacoeconomics. First, federated economic modelling across national device registries would enable multinational cost-effectiveness estimates from combined registry data without centralising patient records, improving transferability while respecting data governance. Second, digital twin economic models that simulate individual patient trajectories through device implantation, function, and failure using continuously updated registry data would enable living HTA that revises coverage recommendations as new evidence accumulates. Third, patient-reported value assessment integrating willingness-to-pay for device-specific outcomes (mobility, pain relief, independence) would complement QALY-based evaluation with patient-centred value metrics that capture benefits generic utility instruments miss. The IDPAF framework, microsimulation code, and PEQS calculator are available at idpaf-econ.org under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

The authors declare no competing interests. No author has financial relationships with device manufacturers, HTA consultancies, or health economics firms.

Data Availability Statement

The IDPAF framework, microsimulation code (R), registry parameter databases, and PEQS calculator are available at idpaf-econ.org under CC BY 4.0. Patient-level registry data governed by national data custodians.

Ethical Approval

This study analysed published HTA evaluations and anonymised registry summary data. The Western Europe Data Science University Ethics Board confirmed exemption (WEDSU-EB-2023-0074).

Appendix A

Methodology Specifications and PEQS Calculation

This appendix details model structures, data sources, and the PEQS scoring rubric.

Part I -- Methodology Specifications

- 1a. E1: Markov cohort (3-5 states), trial-derived transitions, 5-10 yr horizon, deterministic + PSA
..... Baseline HTA method
- 1b. E2: E1 + longitudinal EQ-5D utility measurement, device-specific utility decrements
Quality-of-life focus
- 2a. E3: 5-year budget impact, device procurement + surgical volume + revision cost cascade
Payer perspective
- 2b. E4: Registry survival curves replace trial extrapolation, claims-derived resource use
Observed long-term data
- 3a. E5: 100,000 individual patient microsim, gradient-boosted outcome prediction (C-stat 0.76)
..... Patient-level heterogeneity
- 3b. All: 50 evaluations, 4 device categories, 6 registries, 4.8M implants Comprehensive assessment

Part II -- PEQS Scoring Rubric

- 4a. Rigour: ISPOR/CHEERS checklist compliance + appropriate discounting + perspective
Reporting quality
- 4b. Uncertainty: Proportion of key parameters with documented distributions + PSA quality
Probabilistic characterisation
- 5a. Device-Specific: Captures learning curve + longevity + revision cascade + centre variation
..... Device model adequacy
- 5b. Decision Relevance: Alignment with HTA body information needs + timeline + format
Practical utility
- 6a. Transferability: Transparent country-specific parameter substitution capability
Cross-system adaptability
- 6b. $PEQS = 0.25 \times \text{Rigour} + 0.20 \times \text{Uncertainty} + 0.20 \times \text{DeviceSpecific} + 0.15 \times \text{Decision} + 0.20 \times \text{Transfer}$