Global Certificate in Health Technology Assessment (Advanced)

Health Care Systems And Policy

Health technology assessment (HTA) is a multidisciplinary process that evaluates the clinical, economic, social and ethical implications of health technologies. The purpose of HTA is to inform decision-makers about the value of a technology relative to existing alternatives. For example, when a new oncology drug enters the market, HTA agencies examine clinical trial data, cost-effectiveness, budget impact, and patient-reported outcomes before recommending whether the drug should be reimbursed. A common challenge in HTA is the availability of high-quality evidence, especially for innovative therapies that rely on surrogate endpoints or limited follow-up data. Practitioners must balance the need for timely decisions with the uncertainty inherent in early evidence.

Cost-effectiveness analysis (CEA) compares the costs and health outcomes of two or more interventions. The primary metric is the incremental cost-effectiveness ratio (ICER), calculated as the difference in costs divided by the difference in effectiveness. An ICER expressed in terms of cost per quality-adjusted life-year (QALY) allows policymakers to assess whether a technology provides good value for money. For instance, a new vaccine that costs $150,000 per QALY gained may be considered acceptable in a high-income country with a willingness-to-pay (WTP) threshold of $100,000, but not in a lower-income setting. The main challenge is selecting an appropriate WTP threshold, which varies across jurisdictions and may be influenced by budget constraints, societal preferences, and political considerations.

Quality-adjusted life-year (QALY) integrates length of life with health-related quality of life (HRQoL). A year lived in perfect health is assigned a value of 1, while a year with a health state valued at 0.5 Contributes 0.5 QALYs. QALYs are derived from utility measures such as the EQ-5D or SF-6D. In practice, QALYs enable the comparison of disparate health outcomes, such as comparing a surgical procedure for knee osteoarthritis with a pharmacologic treatment for hypertension. A key limitation is that utility values may differ across cultures, leading to potential bias when applying QALY-based thresholds in diverse populations.

Disability-adjusted life-year (DALY) quantifies the burden of disease by adding years of life lost due to premature mortality to years lived with disability. DALYs are commonly used by global health agencies to prioritize interventions. For example, a malaria control program that averts 10,000 DALYs may be deemed more cost-effective than a program that averts 5,000 DALYs at the same cost. However, DALYs rely on disability weights that can be controversial, and they may undervalue conditions that affect quality of life without causing mortality.

Willingness-to-pay threshold represents the maximum amount a society is prepared to spend for an additional unit of health benefit, such as a QALY. In the United Kingdom, the National Institute for Health and Care Excellence (NICE) generally uses a threshold of £20,000-£30,000 per QALY. In contrast, many low- and middle-income countries adopt thresholds based on per-capita gross domestic product (GDP), such as one or three times GDP per capita. The selection of a threshold is often politicized, as it directly influences reimbursement decisions and can affect equity in access to care.

Universal health coverage (UHC) aims to ensure that all individuals receive the health services they need without suffering financial hardship. UHC encompasses service coverage, financial protection, and population coverage. For example, Thailand achieved near-universal coverage through a tax-financed scheme that includes essential medicines and a defined benefits package. Challenges to UHC include resource constraints, the need for efficient allocation mechanisms, and the risk of over-utilization of high-cost technologies without appropriate assessment.

Payer refers to an entity that finances or reimburses health services, such as a government agency, health insurance company, or employer-based plan. Payers are central to HTA because they often commission assessments and make coverage decisions. In the United States, Medicare and private insurers each have distinct formularies and coverage criteria. A challenge for payers is balancing the desire to adopt innovative therapies with the need to maintain fiscal sustainability.

Provider denotes the organization or individual delivering health services, including hospitals, clinics, physicians, and allied health professionals. Providers interact with HTA outcomes when implementing coverage decisions, negotiating prices, and managing care pathways. For instance, a hospital may need to adopt a new diagnostic imaging device after an HTA recommendation, but must also consider training, maintenance, and workflow integration. Provider resistance can arise if the technology is perceived as disruptive or if reimbursement rates are insufficient.

Regulator is the authority responsible for ensuring the safety, efficacy, and quality of health technologies before they enter the market. In the United States, the Food and Drug Administration (FDA) performs pre-market review, while the European Medicines Agency (EMA) conducts centralized assessments for medicines. Regulatory approval does not guarantee cost-effectiveness, which is why HTA processes operate independently. A key challenge is aligning regulatory pathways with HTA requirements to avoid duplication and reduce time to market.

Stakeholder encompasses any group with an interest in health technology decisions, including patients, clinicians, industry, payers, policymakers, and the public. Effective stakeholder engagement enhances the relevance and legitimacy of HTA recommendations. For example, patient advocacy groups may provide real-world evidence on quality-of-life impacts that are not captured in clinical trials. Managing divergent stakeholder priorities, however, can be complex and may lead to conflicts of interest.

Reimbursement is the process by which payers provide financial compensation for health services or products. Reimbursement decisions are often based on HTA outcomes, price negotiations, and budget impact analyses. A common model is the inclusion of a drug in a national formulary with a specified reimbursement level. Challenges include price inflation, the need for periodic re-evaluation of reimbursed technologies, and ensuring equitable access across regions.

Formulary is a curated list of medicines or devices approved for use within a health system, often organized by therapeutic class. Formularies are developed using HTA evidence, clinical guidelines, and cost considerations. For instance, a hospital formulary may prioritize generic antihypertensives over brand-name equivalents. Maintaining an up-to-date formulary requires continuous monitoring of new evidence, price changes, and market withdrawals.

Health economics is the discipline that applies economic theory and methods to health care decision-making. It encompasses cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, and budget impact analysis. Health economists construct models to simulate disease progression, treatment pathways, and resource utilization. A practical application is the development of a Markov model to estimate the long-term costs and QALYs associated with a chronic disease intervention. Challenges include data availability, model transparency, and the handling of uncertainty.

Budget impact analysis (BIA) estimates the financial consequences of adopting a new technology within a specific budget context. Unlike CEA, which focuses on value per unit of health gain, BIA assesses affordability. For example, a BIA may project that introducing a high-cost biologic will increase a national health budget by 5 % over five years. Decision-makers use BIA results to plan financing, negotiate discounts, or implement risk-sharing agreements. The main difficulty lies in forecasting uptake rates and real-world utilization patterns.

HTA agency is a dedicated organization that conducts health technology assessments and provides recommendations to policymakers. Examples include NICE (UK), CADTH (Canada), IQWiG (Germany), and the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia. Agencies differ in their methodological frameworks, stakeholder engagement processes, and decision-making authority. A challenge for HTA agencies is maintaining independence while being responsive to political pressures and industry lobbying.

Evidence synthesis involves systematically gathering, appraising, and combining research findings to inform HTA. Methods include systematic reviews, meta-analyses, and network meta-analyses. For instance, a systematic review of randomized controlled trials may be conducted to compare the efficacy of two surgical techniques. The quality of evidence synthesis depends on the rigor of search strategies, inclusion criteria, and bias assessment. Incomplete reporting or heterogeneity across studies can limit the reliability of pooled estimates.

Systematic review follows a predefined protocol to identify all relevant studies on a specific question, assess their quality, and summarize findings. Systematic reviews are the cornerstone of HTA because they provide an unbiased evidence base. An example is a review of clinical trials evaluating a new vaccine's effectiveness against influenza. Challenges include publication bias, language restrictions, and the time-intensive nature of the process.

Meta-analysis statistically combines results from multiple studies to produce a pooled estimate of effect size. In HTA, meta-analysis can improve precision when individual trials are small. For example, a meta-analysis of seven trials may reveal a 15 % reduction in mortality with a new heart failure medication. However, heterogeneity among studies, differing outcome definitions, and varying follow-up periods can threaten validity, requiring careful subgroup and sensitivity analyses.

Real-world evidence (RWE) refers to data collected outside of randomized controlled trials, such as electronic health records, registries, and claims databases. RWE can supplement trial data by providing insight into long-term effectiveness, safety, and utilization patterns. For instance, a post-marketing registry may show that a drug's adverse event rate is lower in routine practice than in the pivotal trial. The main challenges are data quality, standardization, and privacy concerns.

Health outcomes denote the results of health care interventions, ranging from clinical endpoints (e.G., Mortality) to patient-reported outcomes (e.G., Pain relief). HTA frameworks typically classify outcomes as clinical effectiveness, safety, and HRQoL. A practical application is measuring the reduction in hospital admissions after implementing a telehealth program for chronic disease management. Outcome selection can be contentious, especially when stakeholders prioritize different endpoints.

Clinical effectiveness measures the extent to which a health technology achieves its intended health benefits under routine conditions. It differs from efficacy, which is measured under ideal trial conditions. For example, a vaccine may demonstrate 95 % efficacy in a phase III trial, but its clinical effectiveness in a real-world immunization program could be lower due to storage issues or adherence. Quantifying clinical effectiveness often requires observational studies, which may be susceptible to confounding.

Comparative effectiveness assesses the relative benefits and harms of alternative interventions that have already been adopted into practice. Comparative effectiveness research (CER) informs HTA when multiple technologies exist for the same indication. For instance, a CER study may compare a novel insulin analog with an established basal insulin in terms of glycemic control and hypoglycemia risk. Challenges include ensuring comparable patient populations and adjusting for treatment selection bias.

Health technology encompasses medicines, medical devices, diagnostics, procedures, and digital health solutions. Each technology follows a lifecycle that includes development, market entry, diffusion, and eventual de-commissioning. Understanding the technology life cycle helps HTA agencies plan horizon scanning and re-assessment activities. A challenge is that rapid innovation, especially in digital health, can outpace the capacity of traditional HTA processes.

Medical device is a broad category that includes instruments, apparatus, implants, and software used for diagnosis, treatment, or monitoring. Devices differ from pharmaceuticals in their regulatory pathways and evidence requirements. For example, a new cardiac stent may be approved based on a small safety study, while lacking long-term comparative data. HTA of devices often relies on registry data, post-market surveillance, and expert opinion.

Pharmaceutical refers to chemically synthesized or biologically derived medicines intended to treat or prevent disease. Pharmaceuticals undergo rigorous clinical testing, but price negotiations and reimbursement decisions are heavily influenced by HTA. A practical example is the negotiation of a confidential discount for a high-cost oncology drug after a favorable cost-effectiveness assessment. Pricing transparency and value-based contracts remain ongoing challenges.

Biosimilar is a biologic product that is highly similar to an already authorized reference biologic, with no clinically meaningful differences in safety or efficacy. Biosimilars can increase competition and lower prices. HTA agencies evaluate biosimilars for therapeutic equivalence, potential cost savings, and market impact. A barrier to biosimilar uptake is physician and patient confidence, which may require targeted education and incentives.

Generic medicines are chemically identical copies of brand-name drugs whose patents have expired. Generics typically offer substantial cost savings, and HTA often recommends their preferential use. However, concerns about bioequivalence, especially for narrow-therapeutic-index drugs, can affect acceptance. A challenge is ensuring that price reductions translate into real savings for the health system, considering market dynamics.

Orphan drug targets a rare disease affecting a small patient population, often defined by prevalence thresholds (e.G., fewer than 200 000 individuals in the United States). Orphan drugs usually command high prices due to limited market size and high development costs. HTA must balance the societal value placed on rare disease treatment with affordability. Innovative financing models such as outcome-based contracts are sometimes employed to mitigate financial risk.

Health policy comprises the decisions, plans, and actions undertaken to achieve specific health care goals. Policies can be legislative (laws), regulatory, or programmatic. HTA informs health policy by providing evidence on the value of technologies, guiding resource allocation, and shaping reimbursement rules. Policy implementation may encounter barriers such as fragmented governance, limited stakeholder buy-in, and insufficient data infrastructure.

Health law governs the legal framework within which health care is delivered, including licensing, patient rights, and liability. Understanding health law is essential for HTA practitioners when interpreting regulatory requirements and contractual arrangements. For instance, the legal obligation to provide equitable access may influence reimbursement decisions for high-cost therapies. Legal challenges can arise when policy changes conflict with existing contracts or statutory mandates.

Governance refers to the structures, processes, and accountability mechanisms that guide decision-making in health systems. Good governance ensures transparency, stakeholder participation, and evidence-based policies. HTA agencies often operate under a governance model that includes an advisory board, scientific committee, and public consultation process. Weak governance can lead to inconsistent decisions, corruption, and loss of public trust.

Equity in health care means that access to services and health outcomes are not determined by socioeconomic status, geography, or other non-clinical factors. HTA can incorporate equity considerations by applying distributional cost-effectiveness analysis, which evaluates how benefits and costs are distributed across population groups. For example, a vaccination program targeting low-income communities may be prioritized even if its cost-effectiveness ratio is slightly higher than a program aimed at the general population. Measuring equity impact, however, requires detailed demographic data and normative judgments about fairness.

Access denotes the ability of individuals to obtain needed health services in a timely manner. Barriers to access include financial constraints, geographic distance, and limited provider availability. HTA can influence access by recommending coverage for high-value technologies, thereby reducing out-of-pocket expenditures. Conversely, restrictive reimbursement policies may unintentionally limit access for vulnerable groups, highlighting the need for balanced decision-making.

Sustainability concerns the capacity of a health system to maintain service delivery over time without compromising future generations. Sustainable financing, efficient resource use, and appropriate technology adoption are central to this concept. HTA contributes to sustainability by preventing the diffusion of low-value technologies that could strain budgets. A challenge is aligning short-term political incentives, which may favor the adoption of new, high-profile technologies, with long-term fiscal sustainability goals.

Health insurance is a risk-pooling mechanism that spreads health costs across a defined population. Insurance schemes can be public (e.G., National health services), statutory (e.G., Social health insurance), or private. Insurance design influences HTA relevance; for instance, a capitation payment model may incentivize providers to adopt cost-effective technologies to stay within budget. Designing insurance benefits that incorporate HTA recommendations while preserving choice is a complex policy task.

Capitation is a payment method where providers receive a fixed amount per patient per period, regardless of services rendered. Capitation encourages cost-containment and may promote the use of technologies with demonstrated value. However, providers might avoid high-cost interventions, even when clinically indicated, leading to potential under-utilization. HTA can help define appropriate service packages within capitation contracts to mitigate such risks.

Fee-for-service (FFS) reimburses providers for each service delivered. While FFS incentivizes volume, it can encourage over-use of expensive technologies. HTA can counteract this by establishing clinical pathways and prescribing guidelines that limit unnecessary procedures. Transitioning from FFS to alternative payment models, such as bundled payments, often requires legislative changes and stakeholder negotiations.

Diagnosis-related groups (DRG) classify hospital cases into groups with similar clinical characteristics and resource usage, forming the basis for prospective payment. DRGs facilitate cost control and enable benchmarking. HTA findings may influence DRG updates by incorporating new technologies into existing groups or creating new DRG codes. A difficulty is ensuring that DRG tariffs reflect true costs when novel, high-price devices are introduced.

Bundled payments provide a single, comprehensive payment for all services related to a care episode, encouraging coordinated care and cost efficiency. HTA can inform bundled payment design by identifying which technologies deliver the greatest health gain per dollar within the episode. Implementing bundled payments often requires robust data systems to track outcomes and costs across providers.

Performance-based contracts tie reimbursement levels to pre-specified performance metrics, such as clinical outcomes or utilization targets. For example, a pharmaceutical company may agree to refund a portion of the drug cost if the medication fails to achieve a defined reduction in hospital admissions. While performance contracts can align incentives, they pose challenges in defining measurable, attributable outcomes and managing administrative complexity.

Risk-sharing agreements distribute financial risk between payers and manufacturers, commonly used for high-cost therapies with uncertain long-term benefits. Types of risk-sharing include outcome-based agreements, price-volume caps, and conditional reimbursement. An example is a “pay-for-performance” scheme for a gene therapy where payment is contingent on sustained clinical response over five years. Negotiating and monitoring such agreements require sophisticated data collection and analytical capacity.

Managed entry agreements (MEAs) are arrangements that allow early access to promising technologies while controlling uncertainty and budget impact. MEAs may combine risk-sharing, price discounts, and post-marketing evidence generation. For instance, a conditional approval for a novel immunotherapy may be granted under an MEA that requires the manufacturer to submit real-world effectiveness data within two years. The main challenges are ensuring compliance, data quality, and transparent evaluation of MEA outcomes.

Innovation adoption refers to the process by which new health technologies are introduced into clinical practice. Adoption is influenced by perceived advantage, compatibility with existing workflows, complexity, trialability, and observability—factors described in diffusion of innovation theory. HTA can accelerate adoption by providing clear evidence of benefit and cost-effectiveness, yet barriers such as entrenched clinical habits and reimbursement delays may persist.

Diffusion of innovation theory explains how, why, and at what rate new ideas and technologies spread within a social system. Early adopters, opinion leaders, and organizational readiness are critical determinants. A practical example is the rapid uptake of point-of-care ultrasound devices after evidence demonstrated improved diagnostic accuracy and cost savings. Understanding diffusion dynamics helps HTA agencies plan horizon scanning and stakeholder engagement strategies.

Health technology diffusion describes the pattern and speed with which a technology becomes widely used across a health system. Diffusion curves often follow an S-shape, starting slowly, accelerating as early adopters influence peers, and plateauing when saturation is reached. Monitoring diffusion helps identify over-use of low-value technologies and informs de-commissioning decisions. Data sources include procurement records, utilization databases, and professional society surveys.

Health technology life cycle encompasses stages from research and development, through regulatory approval, market entry, diffusion, mature use, and eventual phase-out. HTA activities are relevant at multiple points: Horizon scanning anticipates upcoming technologies, initial assessments evaluate entry, and re-assessment considers mature technologies for potential de-commissioning. Managing the life cycle requires coordination among regulators, HTA agencies, payers, and manufacturers.

Coverage decision is the formal determination by a payer or health authority regarding whether a technology will be reimbursed and under what conditions. Coverage decisions may be unconditional, conditional (e.G., Only for specific sub-populations), or restricted to certain settings. For example, a national health service may grant coverage for a new antiviral drug only for patients with advanced disease stages. Decision-making must balance clinical benefit, cost-effectiveness, budget impact, and equity.

Appraisal in HTA refers to the systematic evaluation of evidence, typically by an expert panel, to generate recommendations. The appraisal process includes assessment of clinical effectiveness, economic evaluation, ethical considerations, and stakeholder input. The outcome is usually a recommendation (e.G., “Recommended for use,” “not recommended,” or “recommended with restrictions”). Transparency and consistency in appraisal are essential to maintain credibility.

HTA process generally follows a sequence: Topic selection, scoping, evidence gathering, economic modeling, stakeholder consultation, appraisal, and dissemination. Each step involves specific methods and timelines. For instance, scoping defines the population, comparator, outcomes, and perspective. A challenge is ensuring that the process remains agile enough to address fast-moving technologies while preserving methodological rigor.

Stakeholder engagement is the systematic involvement of relevant parties throughout the HTA lifecycle. Techniques include public consultations, focus groups, advisory committees, and patient panels. Engaging stakeholders early can improve relevance, acceptability, and implementation of recommendations. However, managing conflicting interests, ensuring representativeness, and maintaining impartiality are ongoing challenges.

Ethical considerations in HTA address issues such as fairness, autonomy, and the distribution of health benefits. Ethical analysis may examine the impact of a technology on vulnerable populations, potential discrimination, or the moral acceptability of withholding a high-cost therapy. For example, an ethical review might question whether it is justifiable to deny an expensive gene therapy to patients in a low-income country. Integrating ethics into HTA requires interdisciplinary expertise and clear frameworks.

Societal perspective in economic evaluation includes all costs and benefits to society, regardless of who incurs them. This perspective captures indirect costs such as lost productivity, caregiver burden, and broader social implications. A CEA from a societal perspective may show a technology to be cost-effective when productivity gains offset high direct medical costs. Data collection for societal costs can be complex and may involve assumptions about labor market dynamics.

Payer perspective restricts analysis to costs borne by the financing entity, typically excluding patient out-of-pocket expenses and indirect costs. This perspective aligns with decision-makers who manage budgets. For example, a payer-centric CEA may deem a drug not cost-effective because it exceeds the payer’s WTP threshold, even if societal benefits are substantial. Choosing the appropriate perspective influences the results and policy implications.

Patient perspective emphasizes outcomes and costs that matter directly to patients, such as symptom relief, convenience, and out-of-pocket expenses. Incorporating patient preferences can be achieved through discrete choice experiments or patient-reported outcome measures. For instance, a treatment that reduces injection frequency may be highly valued by patients, influencing the overall assessment of its value. Capturing the patient perspective requires robust qualitative and quantitative methods.

Decision-analytic model is a structured representation of the disease process and interventions, used to estimate costs and health outcomes over time. Common models include decision trees, Markov models, and discrete event simulations. A decision-analytic model allows exploration of “what-if” scenarios, such as varying adherence rates or price changes. Model validation and transparency are critical to ensure credibility among stakeholders.

Markov model divides the disease course into mutually exclusive health states and simulates transitions over discrete time cycles. Markov models are particularly useful for chronic conditions where patients may move between states such as “stable,” “progressed,” and “dead.” For example, a Markov model may estimate the lifetime costs and QALYs of a diabetes medication by tracking transitions between glycemic control levels. Limitations include the “memoryless” property, which assumes transition probabilities depend only on the current state, not on prior history.

Decision tree represents a series of choices and chance events in a branching structure, suitable for short-term analyses with limited health states. Decision trees are often used in early HTA to evaluate diagnostic tests or short-term interventions. A drawback is that decision trees become unwieldy when modeling long-term outcomes or numerous pathways, at which point a Markov approach may be more appropriate.

Sensitivity analysis examines how changes in model inputs affect results, identifying key drivers of uncertainty. Deterministic sensitivity analysis varies one parameter at a time, while probabilistic sensitivity analysis (PSA) assigns probability distributions to inputs and runs Monte Carlo simulations. PSA provides a cost-effectiveness acceptability curve, showing the probability that an intervention is cost-effective at different WTP thresholds. Conducting comprehensive sensitivity analysis is essential but can be computationally intensive.

Discount rate reflects the time preference for costs and benefits occurring in the future, typically expressed as an annual percentage. Health economic guidelines often recommend a discount rate of 3 % for both costs and outcomes, though some jurisdictions apply different rates for each. Discounting can substantially affect the cost-effectiveness of interventions with long-term benefits, such as vaccines or preventive programs. Debate continues over the ethical justification of discounting health gains.

Time horizon defines the period over which costs and outcomes are measured in an economic evaluation. A lifetime horizon captures all future consequences, while a shorter horizon may be appropriate for acute interventions. Selecting an appropriate time horizon is crucial; an insufficient horizon can underestimate benefits of preventive technologies, leading to unfavorable cost-effectiveness ratios.

Utility quantifies the preference for a given health state on a scale where 0 represents death and 1 represents perfect health. Utilities are derived from methods such as standard gamble, time trade-off, or indirect questionnaires like the EQ-5D. Utilities feed into QALY calculations, allowing comparison across diseases. Eliciting utilities can be challenging due to cultural differences, respondent burden, and methodological variability.

Health state describes a specific condition characterized by clinical and functional attributes, such as “moderate chronic obstructive pulmonary disease.” Health states are used in modeling to assign costs, utilities, and transition probabilities. Accurate definition of health states is essential for model validity; overly broad states may mask important differences, while overly granular states increase model complexity.

Health-related quality of life (HRQoL) captures the impact of health on an individual’s physical, mental, and social well-being. HRQoL is measured using instruments like the SF-36, EQ-5D, or disease-specific questionnaires. HRQoL data feed into utility values for QALY calculations. Collecting HRQoL data in clinical trials is increasingly required, yet challenges include missing data, response bias, and cross-cultural comparability.

Patient-reported outcome measures (PROMs) are questionnaires completed directly by patients to assess symptoms, functional status, and quality of life. PROMs provide insight into the patient perspective and can be incorporated into HTA to enrich effectiveness evidence. For example, a PROM may reveal that a new arthritis drug improves daily activity scores more than standard therapy, supporting a favorable cost-utility result. Standardizing PROMs across studies remains a challenge.

Cost-minimization analysis (CMA) is applied when two interventions have demonstrated equivalent effectiveness, allowing the comparison to focus solely on costs. CMA is appropriate for generic versus brand-name drug comparisons where bioequivalence is established. However, demonstrating true equivalence is often difficult, limiting the applicability of CMA.

Cost-utility analysis (CUA) expresses results in terms of cost per QALY gained, integrating both cost and utility dimensions. CUA is the most common form of economic evaluation in HTA because it facilitates comparison across disease areas. The interpretation of CUA results depends on the chosen WTP threshold and the robustness of utility estimates.

Cost-benefit analysis (CBA) converts both costs and benefits into monetary terms, allowing the calculation of net monetary benefit (NMB). CBA can incorporate broader societal impacts, such as productivity gains. For instance, a CBA of a vaccination program may assign a monetary value to prevented workdays lost. Valuing health outcomes in monetary terms raises ethical concerns and methodological difficulties, particularly regarding the appropriate valuation of life.

Incremental analysis compares the additional costs and benefits of a new technology relative to the next best alternative. Incremental results are central to HTA because they reflect the marginal value of adopting the new technology. An incremental analysis that yields an ICER below the WTP threshold supports adoption, whereas an ICER above the threshold suggests rejection. Accurate identification of the appropriate comparator is essential; using an outdated or suboptimal comparator can bias results.

Net monetary benefit (NMB) is calculated as ($WTP \times \Delta QALY - \Delta Cost$). Positive NMB indicates that the health gains, valued at the WTP threshold, outweigh the additional costs. NMB simplifies decision-making because it converts cost-effectiveness into a single monetary figure, facilitating statistical analysis of uncertainty. However, NMB depends on the chosen WTP value, and different thresholds can lead to divergent conclusions.

Net health benefit (NHB) is defined as $\Delta QALY - (\Delta Cost / WTP)$. Like NMB, NHB provides a single metric, expressed in QALYs, that incorporates cost considerations. Positive NHB signifies that the technology provides a net gain in health after accounting for its cost. NHB can be useful when comparing multiple technologies across a range of WTP thresholds.

Budget impact analysis estimates the financial effect of adopting a technology on a specific budget, such as a national health service or insurer's annual plan. BIA complements cost-effectiveness analysis by addressing affordability. For example, a BIA may project that introducing a new anticoagulant will increase pharmacy expenditures by $200 million over three years, but will also reduce stroke-related hospital costs, partially offsetting the increase. Accurate BIA requires assumptions about market uptake, adherence, and price changes.

Health system performance measures how well a health system achieves its objectives, including effectiveness, efficiency, equity, and responsiveness. HTA contributes to performance improvement by ensuring that only value-adding technologies are adopted. Performance indicators may include average length of stay, readmission rates, and cost per case. Aligning HTA recommendations with performance targets can drive system-wide improvements.

Health system financing encompasses the mechanisms by which funds are collected, pooled, and allocated to health services. Financing models include taxation, social health insurance, private insurance, and out-of-pocket payments. The choice of financing influences HTA relevance; for example, tax-financed systems may prioritize equity, while private insurers may focus on cost containment. Designing financing structures that support evidence-based decisions remains a policy challenge.

Out-of-pocket payments are direct contributions by patients at the point of service. High out-of-pocket costs can lead to catastrophic health expenditure and deter utilization of needed services. HTA can recommend policies that limit out-of-pocket amounts for high-value technologies, protecting patients from financial hardship. Monitoring out-of-pocket spending requires detailed claims data, which may be unavailable in some settings.

Co-payment is a fixed amount or percentage that patients pay in addition to what the insurer covers. Co-payments are used to encourage cost-conscious use of services. However, excessive co-payments may reduce access to essential medicines, especially for low-income patients. HTA can inform optimal co-payment levels by evaluating the trade-off between utilization, cost savings, and health outcomes.

Deductible is the amount a patient must pay before insurance benefits begin. Deductibles shift financial risk to patients, potentially affecting demand for high-cost technologies. For instance, a high deductible may discourage patients from initiating a costly biologic, even when clinically indicated. HTA can assess the impact of deductible structures on health outcomes and equity.

Health technology diffusion (repeated term) – see earlier entry.

Diffusion barriers are obstacles that slow or prevent the spread of a technology, including regulatory restrictions, lack of evidence, high price, limited provider training, and cultural resistance. Identifying diffusion barriers helps HTA agencies design targeted interventions, such as educational programs or price negotiations. Overcoming barriers often requires coordinated action across multiple stakeholders.

Adoption barriers specifically refer to factors that hinder the uptake of a technology by clinicians or health systems. These may include perceived lack of clinical relevance, workflow disruption, or uncertainty about reimbursement.