

Advancing Evidence Generation Through HTA for Enhanced Health Outcomes: A Global Perspective

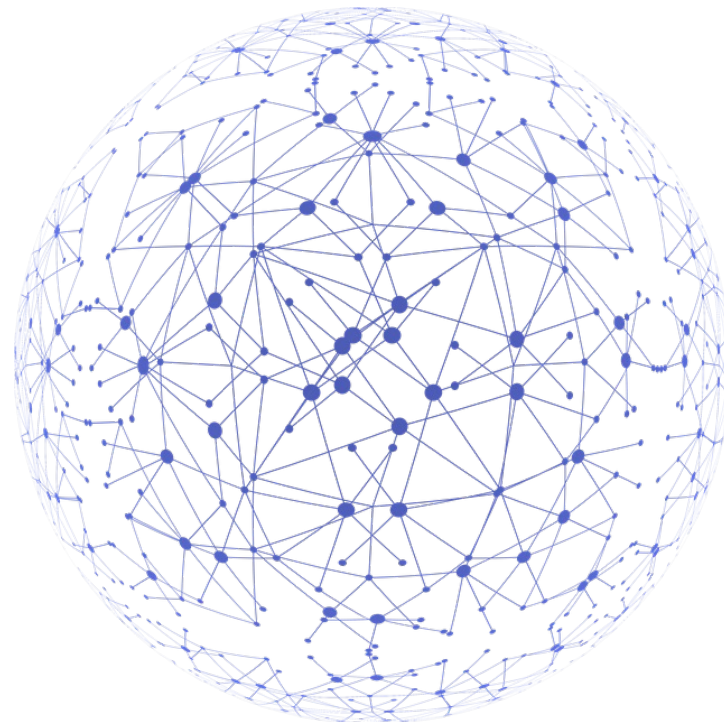
Student Network Session

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Health Technology Assessment (HTA)

- What is HTA?
 - Multidisciplinary process evaluating the **medical, social, economic and ethical aspects** related to the use of a health technology in a **systematic, transparent, unbiased, and robust** manner --- *Appl Health Econ Health Policy* 2021;19(3):281-304.
 - “HTA is a multidisciplinary process that uses explicit methods to determine the **VALUE** of a health technology at different points in its lifecycle. The purpose is to inform decision making in order to promote an equitable, efficient, and high-quality health system.” --- International Network of Agencies for HTA (INAHTA)
- **Considers a wide range of factors**, including clinical efficacy, patient outcomes, cost-effectiveness, budget impact, ethical considerations, and social implications
- Involves **multiple stakeholders**, including healthcare professionals, patients, industry representatives, and policymakers

Why do we need health technology assessment (HTA)?



Evidence-based
decision-making
(adoption, reimbursement & use)

Resource allocation
& cost containment

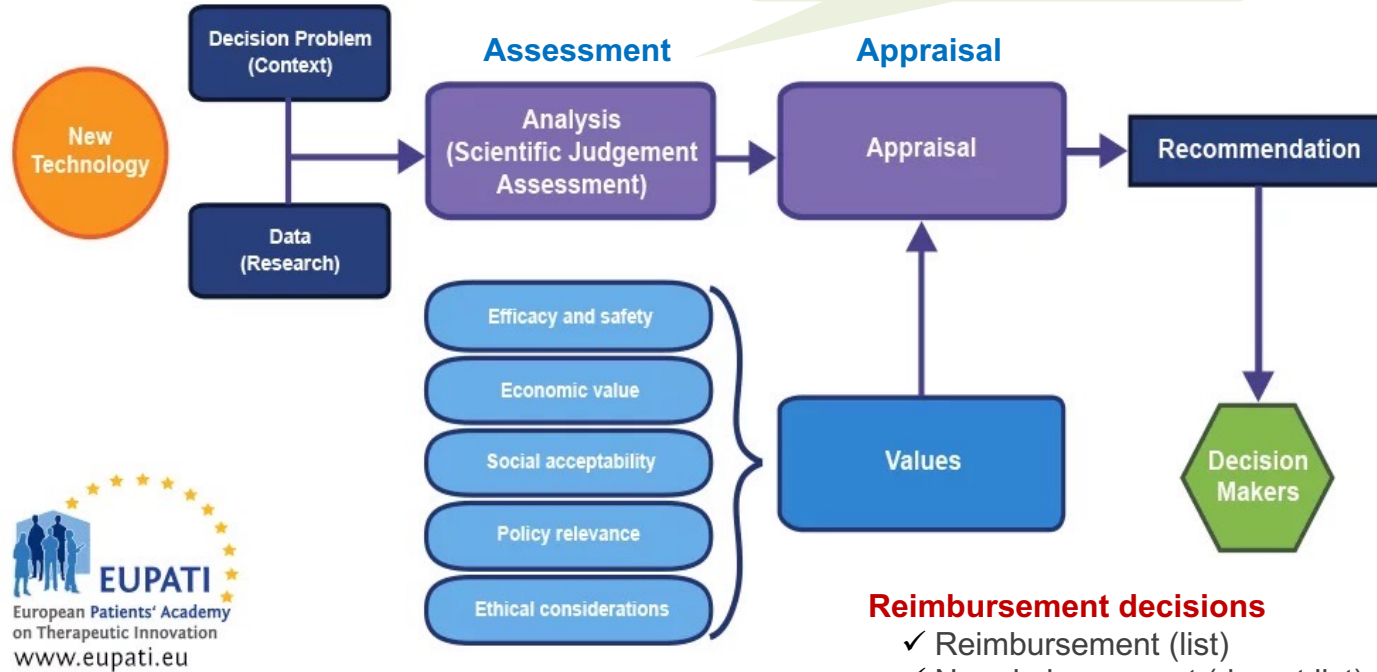
Patient safety and
quality of care

Equity & access



	Regulatory approval	HTA (to inform reimbursement decisions)
Primary role	Provide market authorization	Support for clinical and coverage decisions within a particular healthcare system
Decision	Evaluate whether the clinical benefits outweigh the risks Should this technology be available?	Evaluate whether the technology offers useful, appropriate (and affordable) benefits for all or a select subgroup of patients in the particular healthcare system compared to what is most commonly used in the disease area
Assessment focus	Safety, efficacy, quality (e.g., GMP)	(Comparative) effectiveness, safety, quality of life, economics, budget impact, social, ethical, legal, organizational
Characteristics of studies they prioritize		
Comparator	Placebo (when no head-to-head comparison)	Active control, ideally standard of care
Endpoint	Surrogate endpoints	Final clinical “hard” outcomes such as death; quality of life
Time horizon	Trial duration	Lifetime or at minimum the time needed to capture all risks and benefits of therapy

Arriving at an HTA recommendation (health technology assessment)



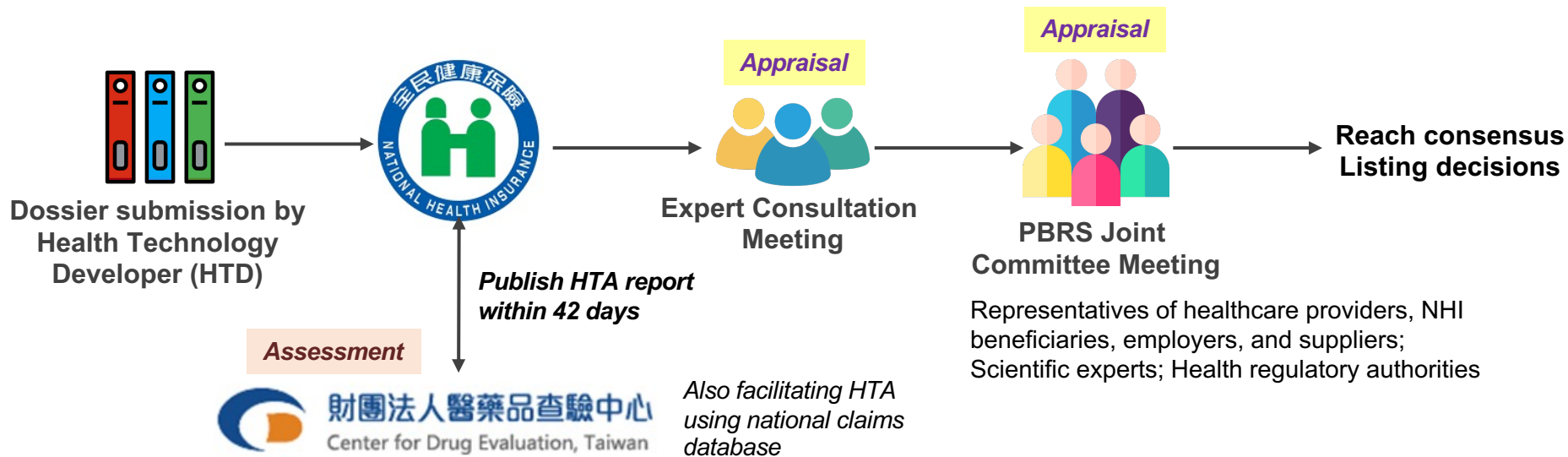
Reimbursement decisions

- ✓ Reimbursement (list)
- ✓ No reimbursement (do not list)
- ✓ Conditional reimbursement (list with restrictions)

Pricing decisions

Access restrictions for sub-populations or sub-indications

Process for listing in the NHI Pharmaceutical Benefits and Reimbursement Scheme (PBRs) in Taiwan (simplified version)



With mechanisms to notify HTD, receive feedback/response, and negotiation regarding agreement


How to determine the value of health technology?



Components of HTA application dossier or 'submission'

- Burden of disease
- Description of medicine/technology
- Clinical evidence: Efficacy, effectiveness & safety (comparative)
- Economic evidence: Cost-effectiveness analyses & budget Impact analyses
- Assessments of social, ethical, and legal implications

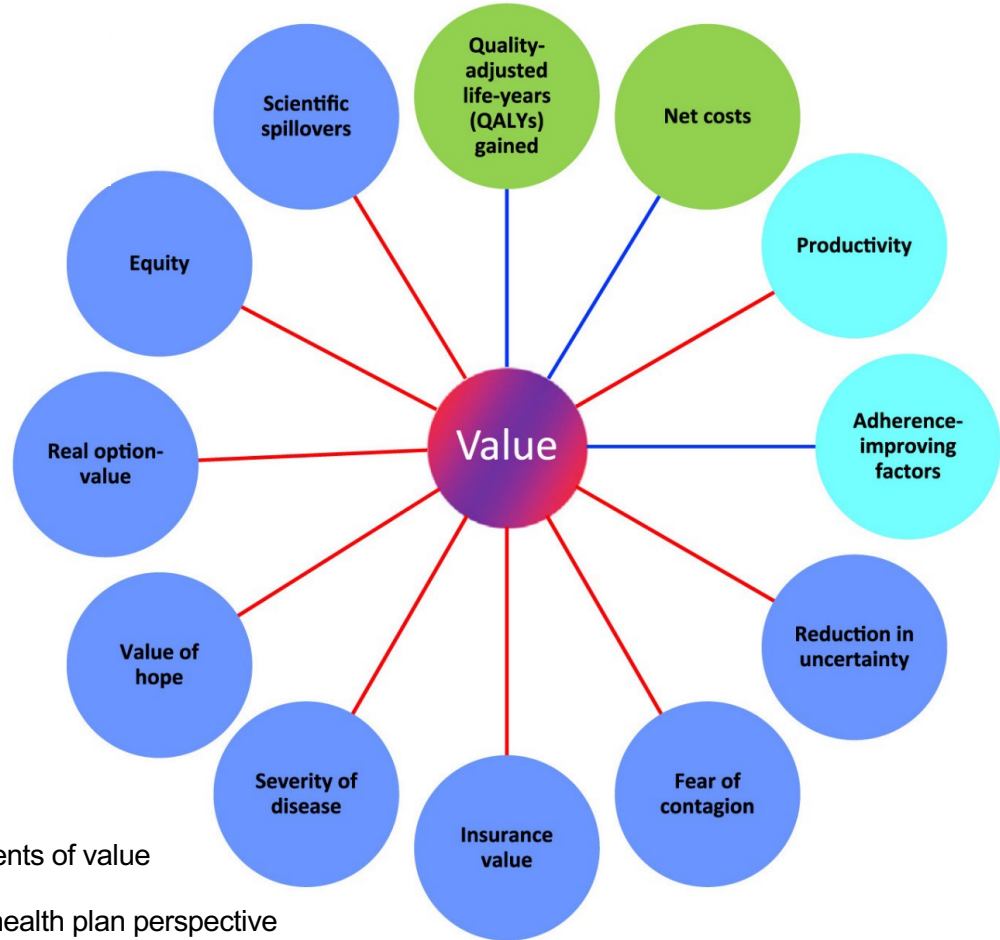
Methodologies for HTA

- Randomized controlled trials (RCTs)
 - Systematic reviews, meta-analyses, network meta-analyses
 - Real-world evidence from observational studies and registries
 - Patient-reported outcomes
 - Cost-effectiveness analysis & economic models projecting long-term costs and outcomes
 - Budget impact analysis
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Evaluation Criteria Considered in HTA

- Criteria that are more common for HTA among different agencies: efficacy or effectiveness, safety, cost-effectiveness, and budget impact
- Some of the criteria are more qualitative than others (e.g., equity, legal, and public health aspects)
 - Included in the appraisal part of HTA rather than the evaluation part
 - Implicit or ad hoc rather than explicit and systematic
- **Unexplained heterogeneity of coverage decisions across countries**
 - Different budget constraints and national priorities, inconsistencies in medicines' eligibility for reimbursement
 - Different HTA processes and methodological frameworks adopted
 - Additional value concerns beyond economic evaluation or clinical benefit assessment are captured to a different extent in the process

Elements of Value



Green circles: core elements of value

Light blue circles: common but inconsistently used elements of value


Dark blue circles: potential novel elements of value

Blue line: value element included in traditional payer or health plan perspective

Red line: value element also included in societal perspective

Evolving HTA activities in Taiwan



- Patient involvement
 - Patients engaged in HTA and reimbursement decision-making processes (since 2015)
 - Educational programs for patients and caregivers (since 2016)
 - International collaboration
 - Actively participate in HTA networks, such as HTAsiaLink, ISPOR, and HTAi
 - Partnered with UK's NICE for knowledge exchange (since 2023)
 - Process improvement
 - Implement a parallel review process to reduce time for new technology inclusion
 - Expand the use of real-world evidence (RWE) in decision-making
 - Introduce provisional listing for selected new drugs and indications
 - Conduct health technology reassessments (HTR)
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If you're interested in this field, what can you start to do?

- Gain a solid foundation in healthcare and related disciplines
 - Understanding healthcare systems, epidemiology, clinical research methods, health economics, health policy
 - Evidence generation (technical skills such as data management, statistical analysis, & economic modeling)
 - Critical appraisal of scientific literature and evidence synthesis
- Consider pursuing advanced degrees or certifications
- Learn about HTA concepts, methods, organizations, and related guidance
- Participate in training programs and workshops
- Gain practical experience through internships or research projects
- Stay updated with the latest research and developments

