



MARKETING *Club* 174th

173th Marketing Club
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HTA Overview Health Technology Assessment

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LIVE WEBINAR

CLUB FOUNDER, HOST
DR. MAHMOUD BAHGAT
LEGENDARY DIRECTOR

25-2

2025
Tuesday

9 pm



10 pm



11 pm

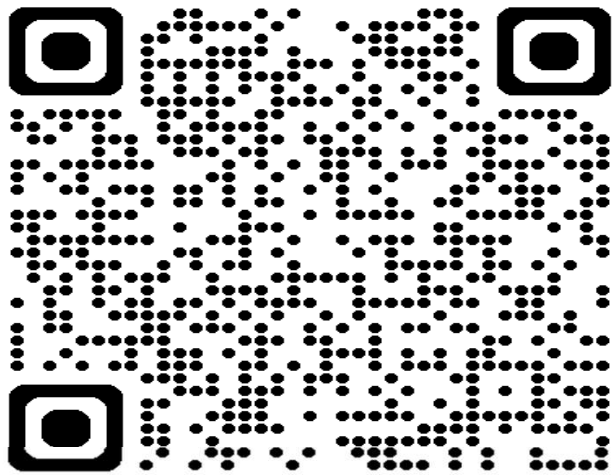


Place
Online
Zoom



Instructor
Dr. Maher Awadallah
Market Access Manager

HTA overview: Marketing Club

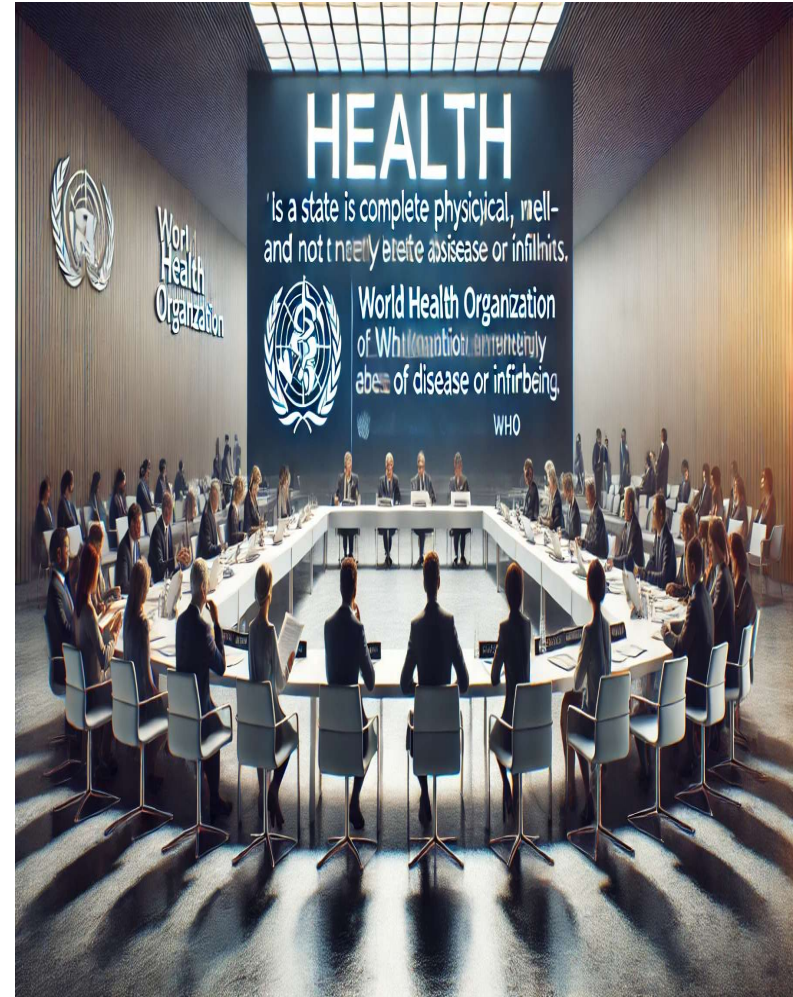


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Introduction:

- **Health (WHO definition)** encompasses a **complete state of physical, mental, and social well-being**, and is not simply the absence of illness.
- The right to achieve the highest possible standard of health is fundamental for every individual, **regardless of their race, religion, political views, or socio-economic status**.
- It is **the duty of governments to ensure the health of their citizens**, which can only be achieved through the implementation of sufficient health and social services.



Introduction:

- **Health Technology** is a broad concept that encompasses any intervention that can impact health.
- This includes medical devices, pharmaceuticals, procedures, and organizational systems used in healthcare.



Introduction:

Definition and Purpose of HTA

1 Scientific Research

HTA is defined as a field of scientific research focusing on the **medical, social, ethical, and economic** implications of development, diffusion, and use of health technology.

2 Wide Range of Technologies

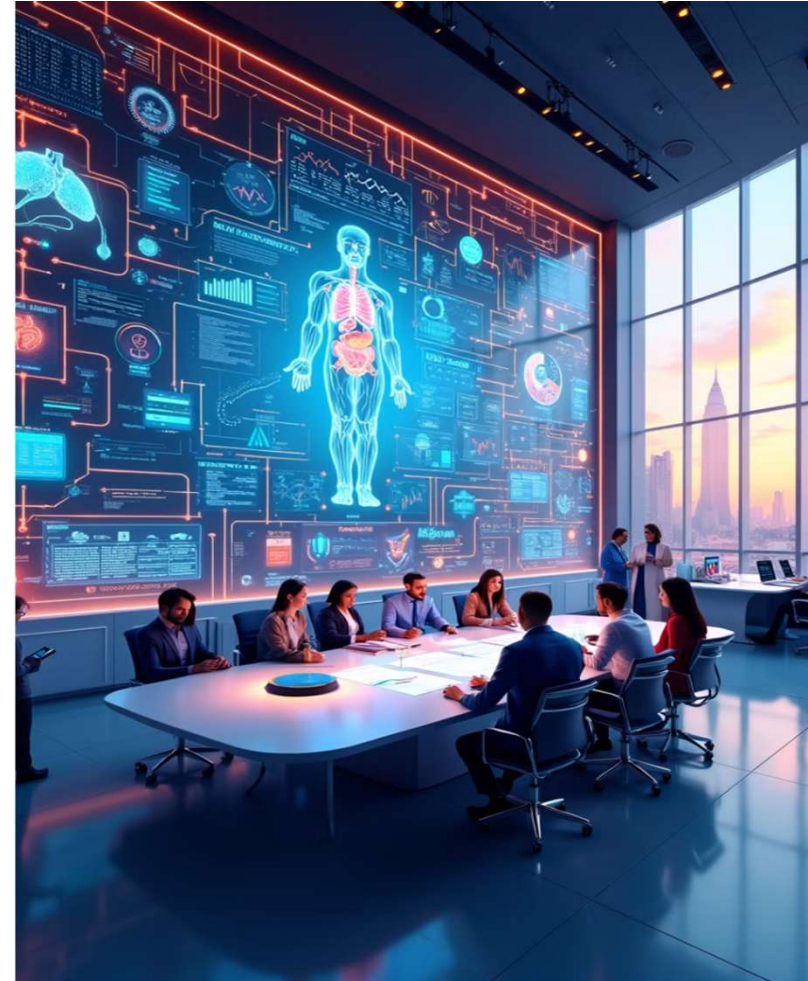
Drugs, medical devices, procedures, and systems developed to solve a health problem and improve quality of lives.

3 Evidence-Based Information

To provide evidence-based information on the effectiveness, safety, and cost-effectiveness of health technologies.

4 Guide Decision-Makers

To guide decision-makers in healthcare policy, practice, and investment decisions, ensuring that **resources** are used **efficiently and effectively**.



Introduction:

WHY HTA ?

The Rise in healthcare cost

- Increase in number of Chronic diseases.
- Enhanced diagnosis of rare diseases.
- Launches of novel therapies with high impact on budget.



**Budget limitations
and need for Proper
resources allocations**

Traditional stakeholders

Clinicians - Pharmacists -
Authorities

- Efficacy
- Safety
- Price

Emerged stakeholders

Payors - Patients

- Cost effectiveness
- Evidence based trials
- Value of medicines
 - Affordability.
 - Reimbursement
 - RWE.

HTA is important beyond safety and efficacy



Top 10 HTA bodies



Defines scope and key questions; invites evidence submissions; conducts systematic reviews and economic evaluations; holds public and stakeholder consultations before issuing guidance.



Receives submissions; performs systematic clinical and economic reviews; engages with stakeholders through consultations; and develops recommendations for public payers.



Reviews manufacturer submissions; assesses clinical evidence and cost-effectiveness; convenes expert panels; and issues funding recommendations based on committee deliberations.



Establishes evaluation criteria and scope; conducts systematic literature and economic assessments; consults experts and the public; and publishes recommendations that inform reimbursement.



Performs systematic reviews and meta-analyses; appraises benefits and harms; engages with clinical experts; and produces detailed reports that inform decision-making on healthcare services.



Solicits submissions; conducts clinical and economic evaluations with a focus on cost-minimization; holds stakeholder consultations; and makes final funding decisions based on these assessments.



Collects data and submissions; undertakes systematic evidence reviews and budget impact analyses; convenes expert panels; and recommends reimbursement levels through a formal review process.



Defines the scope of assessments; performs systematic literature reviews and economic evaluations; engages stakeholders; and formulates policy recommendations based on comprehensive analyses.



Reviews clinical and economic evidence; convenes expert committees; conducts public consultations; and issues recommendations for technology incorporation into the public system.



Invites submissions; conducts systematic reviews and cost-effectiveness analyses; engages with stakeholders and experts; and provides recommendations to inform national health policy.



Overview of the HTA Process:

- **Defining the Decision Problem:**
 - ❑ Work with **stakeholders (e.g., NICE)** to clarify current clinical practice.
 - ❑ Identify where a new technology fits into the care pathway.
- **Search for Evidence:**
 - ❑ Conduct extensive searches across research **databases, registers, and the web.**
- **Systematic Review of the Evidence:**
 - ❑ Critically appraise and synthesize retrieved studies.
 - ❑ Evaluate potential biases using statistical methods (e.g., meta-analysis) or narrative synthesis.
 - ❑ Summarize key findings on the clinical effectiveness of the new technology.
- **Economic Evaluation.**
- **Production of the Final HTA Report.**
- **Continuous monitoring of the Impact.**



Overview of the HTA Process:

RCT is not enough!

- ☐ The Crash 2 Trial was a large, well-conducted trial of over 20,000 patients which assessed the use of tranexamic acid (TXA) for bleeding related to trauma in the emergency department.
- ☐ The results showed that the overall risk of death was reduced by 9% using TXA vs Placebo.
- ☐ Risk of death due to bleeding was reduced by 15%.

The missing piece of the puzzle

- ☐ Is placebo the only comparator in the evaluation?
- ☐ How well does TXA perform compared to other existing treatments?
- ☐ Will TXA be a cost- effective option?



Overview of the HTA Process:

Defining the Decision Problem:

•Population: 🧑

- ☐ Clearly define which patients are being considered.
- ☐ Example: Certain age group or Newly diagnosed cases., Or patients with certain complication.

•Intervention: 💊

- ☐ Describe the treatment in detail (dose, frequency, formulation, administration).
- ☐ Example: In HA Market the EHL vs SHL factors.

•Comparators: ⚖️

- ☐ Identify relevant alternatives in clinical practice.
- ☐ Example: in SCD (Comparator could be HU or Blood transfusion).

•Outcomes: 📊

- ☐ Define what needs to be measured to evaluate effectiveness.
- ☐ Example: in SCD (Pain episodes or Hb level).



HA= Hemophilia A EHL = Extended Half Life SHL= Standard Half Life HU =Hydroxyurea SCD= Sickle Cell Disease





Components of HTA:

Clinical Effectiveness

Definition

- ❑ Clinical Effectiveness evaluates how well a technology improves health outcomes compared to current standard care.

Data Analysis

- ❑ This involves analysing data from clinical trials, observational studies, and other research to determine the technology's impact on disease progression, symptom relief, and overall survival.





Components of HTA: Systematic review

1. Develop protocol
2. Literature search
3. Study selection
4. Data extraction
5. Critical appraisal and quality assessment
6. Data synthesis
7. Internal and external validity
8. Report writing





Components of HTA:

Sources of Bias

Type of Bias	Description	Mitigation Strategy
Selection Bias	Systematic differences in baseline characteristics between study groups.	Randomization to ensure equal allocation.
Performance Bias	Differences in care delivery due to awareness of treatment allocation.	Blinding/masking of participants and providers.
Detection Bias	Differences in outcome measurement influenced by knowledge of treatment assignment.	Blinding outcome assessors and using objective outcome measures.
Attrition Bias	Bias arising from unequal dropout or incomplete follow-up among groups.	Intention-to-treat analysis and robust follow-up protocols.
Reporting Bias	Selective reporting of outcomes that favor significant findings.	Pre-registration of study protocols and transparent reporting.
Publication Bias	Tendency for studies with positive results to be published more frequently.	Encouraging publication of all results, regardless of outcome.





Components of HTA: Cost-Effectiveness

Economic Value

Cost-Effectiveness assesses the economic value of a health technology by comparing its costs (e.g., acquisition, implementation, maintenance) to its health benefits, typically quantified in terms of quality-adjusted life years (QALYs) or other health outcomes.

Value for Money

This analysis helps determine whether a technology provides good value for money spent.





Components of HTA:

Cost-Effectiveness: Example

Patient Group	Cost per Patient (£)
A	10,000
B	20,000
C	30,000
D	40,000
E	50,000

Assumptions:

- Each treatment saves one life.
- Maximum number of treatments per group is 100.
- Total available budget: £3,000,000.





Components of HTA:

Cost-Effectiveness

Option 1: Equal Allocation (Ignoring Cost-Effectiveness)

If we ignore cost differences and treat an equal number of patients in each group, one possible allocation might be treating 20 patients per group:

Patient Group	Cost per Patient (£)	Patients Treated	Total Cost (£)	Lives Saved
A	10,000	20	200,000	20
B	20,000	20	400,000	20
C	30,000	20	600,000	20
D	40,000	20	800,000	20
E	50,000	20	1,000,000	20
Total		100	3,000,000	100





Components of HTA:

Cost-Effectiveness

Option 2: Cost-Effective Allocation

Instead, if we prioritize treatments that save lives at the lowest cost, we start with the most cost-effective groups:

Patient Group	Cost per Patient (£)	Patients Treated	Total Cost (£)	Lives Saved
A	10,000	100	1,000,000	100
B	20,000	100	2,000,000	100
Total		200	3,000,000	200





Components of HTA: Cost-Effectiveness & ICER

Assumptions:

•New Diabetes Treatment:

- Cost per patient: £7,500
- Effectiveness: 0.9 QALYs gained per patient

•Standard Care:

- Cost per patient: £5,000
- Effectiveness: 0.7 QALYs gained per patient

Parameter	New Diabetes Treatment	Standard Care	Difference
Cost per Patient (£)	7,500	5,000	2,500
Effectiveness (QALYs)	0.9	0.7	0.2 QALYs
Incremental Cost-Effectiveness Ratio (ICER)			£12,500 per QALY gained



ICER = Incremental Cost Effectiveness Ratio





Top 10 blockbusters & ICER

Rank	Drug Name	ICER (USD per QALY)	Top 5 Sales Countries
1	Humira (adalimumab) Keytruda	Varies by indication (~\$50,000-\$150,000)	USA, Germany, France, UK, Canada
2	(pembrolizumab)	~\$100,000-\$150,000	USA, China, Germany, France, UK
3	Revlimid (lenalidomide)	~\$100,000-\$200,000	USA, Germany, France, Italy, UK
4	Eliquis (apixaban)	~\$50,000-\$100,000	USA, China, Germany, UK, France
5	Opdivo (nivolumab)	~\$100,000-\$150,000	USA, China, Germany, Japan, UK
6	Imbruvica (ibrutinib)	~\$150,000-\$200,000	USA, Germany, China, France, UK
7	Eylea (aflibercept)	~\$100,000-\$150,000	USA, China, Japan, Germany, France
8	Trulicity (dulaglutide)	~\$50,000-\$100,000	USA, Germany, France, UK, Canada
9	Ozempic (semaglutide)	~\$50,000-\$100,000	USA, China, Germany, UK, France
10	Xarelto (rivaroxaban)	~\$50,000-\$100,000	USA, Germany, France, China, UK



Components of HTA:

Ethical Considerations

1 Moral Implications

Examines the moral implications of adopting or rejecting a technology, considering issues such as equity, access, and patient autonomy.

2 Alignment with Values

Ethical analysis seeks to ensure that health technologies align with societal values and ethical principles, addressing potential disparities and respecting patient rights.



Strategies for Positive HTA

Outcomes:

A- Robust Evidence Generation

1

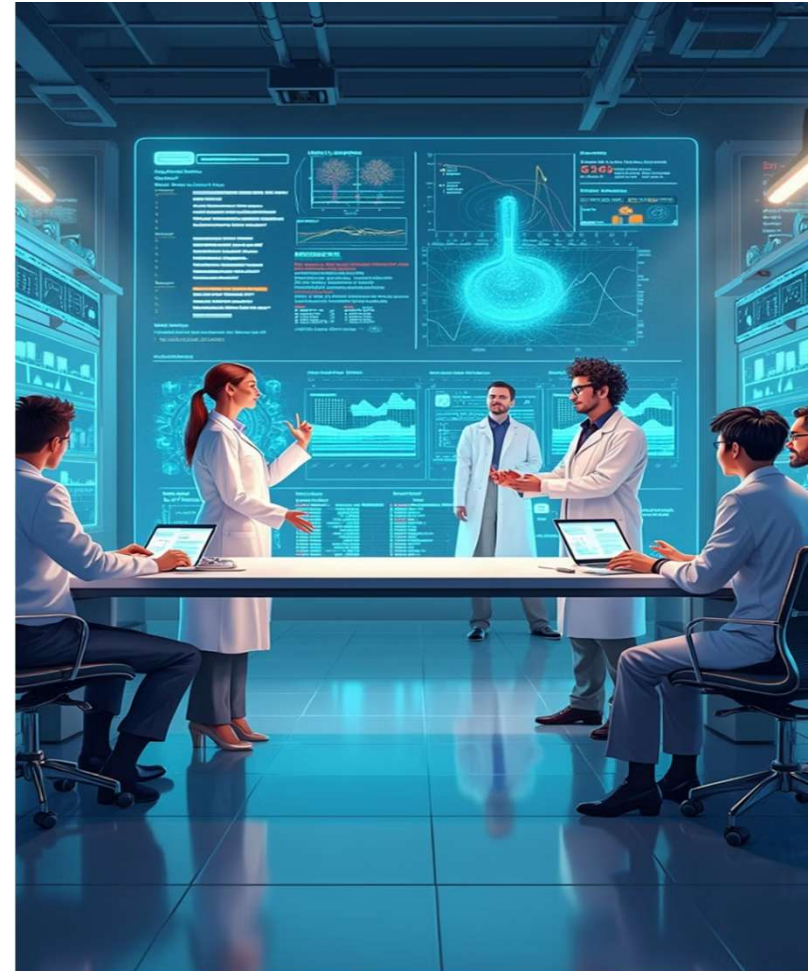
Comprehensive Evidence Package

Developing a comprehensive evidence package that includes robust clinical trial data, real-world evidence, and health economic analyses tailored to HTA requirements.

2

Understanding HTA Criteria

This involves understanding the specific criteria and methodologies used by HTA bodies in different regions and ensuring that the evidence meets these standards.





Strategies for Positive HTA Outcomes:

B-Stakeholder Engagement

1 Early Engagement

Engaging with HTA bodies, payers, healthcare providers, and patient advocacy groups early in the drug development process.



2 Identifying Key Value Drivers

This engagement can help identify key value drivers, inform study designs, and ensure that the evidence generated aligns with stakeholder needs and expectations.



Strategies for Positive HTA Outcomes:

C-Adaptive and Flexible Pricing Models

Value-Based Pricing

Developing pricing and reimbursement strategies that reflect the value demonstrated in HTA assessments and are adaptable to different healthcare systems' needs.

Innovative Approaches

This may include innovative approaches like performance-based agreements or tiered pricing to facilitate access while addressing budget impact concerns.





Conclusion: The Future of HTA in Global Healthcare

1 Ongoing Evolution

Global HTA practices and perspectives highlight the diversity in how health technologies are evaluated and adopted across different healthcare systems.

2 Harmonization Efforts

While there is significant variation in HTA methodologies and their impact on healthcare decision-making, ongoing collaboration and harmonization efforts are crucial for fostering more consistent and efficient HTA processes worldwide.

3 Future Impact

Such initiatives not only improve the comparability of HTA outcomes but also support the global objective of achieving **equitable access to effective and sustainable healthcare**.





Final Thoughts: Redefining Market Access

- **Market access**

- Market Access Is a situation , independent of either regulatory approval or end user preferences.
- Here the payers must agree in making this intervention available for the patients.
- Market access in not about commercialization , nor only market entry.

