Navigating the Complex HTA Landscape for Medtech Success
Learning Objectives

- Understand medtech HTA and its challenges
- Understand how medtech HTA varies internationally
- Discover the key requirements to consider for medtech HTA

HTA = health technology assessment.
Medtech HTA and its Challenges

Sheryl Warttig
Director
Market Access and Outcomes Strategy
What is Medtech?

Medical technology

Medical device

Hardware

In vitro diagnostics

Health apps

Services

Implantables

Digital health

Software

Health wearables

In vivo diagnostics
What is Health Technology Assessment?

• Means different things to different people

• Different HTA organisations may perform HTA differently and from different perspectives

• Features:
  - Health economic analysis?
  - Mandatory for market access?
  - Linked to reimbursement?

Systematic assessment of the **intended and unintended consequences** of using a technology in a healthcare system

• HTA is being increasingly used to assess medtech
Key Features of HTA …

**Economic modelling**
- Costs/benefits (QALYs)
- Budget impact/Affordability

**Literature review**

**Perspective**
- Health service/
Payer/Societal

**Appropriate comparator**
- SoC/alternative/competitor

**HTA Features**

QALY = quality-adjusted life-year; RCT = randomized controlled trial; SoC = standard of care.
**Medtech – HTA Challenges**

**Evidence**
- Regulatory information usually insufficient for HTA
- Evidence for HTA generated after launch
- Real-world evidence
- Lifecycle: rapid iterations

**Use case**
- Broad indications/use case
  - e.g., wound dressing, robotic-assisted surgical device
- Range of comparators/standard of care
- Different benefits/risks

**Other**
- Benefits/cost impact observed in other areas of disease pathway
  - e.g., diagnostic test used by GPs to avoid a test or procedure performed in secondary care

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**CHALLENGES**

Leads to uncertainties in the clinical and economic evidence

The broader the indication/use, the more evidence is needed

Difficulties demonstrating value to the user

GP = general practitioner.
How much evidence is needed?

It depends on uncertainties e.g.

- how the disease is best managed
- the technology and how it works
- the benefits and their value

The greater the uncertainty, the more evidence needed
Example- Amniotic fluid leak during pregnancy

The condition is well known with a clear and well-established care pathway.

People with a suspected leak during pregnancy are referred to hospital maternity services for a physical examination to see if there is fluid leaking from the cervix.

A diagnostic test can be used at home to rule out amniotic fluid leak, avoiding referral to hospital and physical exam.

Evidence available: 3 diagnostic accuracy studies
Example- Pre-clinical diabetic neuropathy

Diabetic neuropathy is well known, with an established care pathway but it is unclear how pre-clinical diabetic peripheral neuropathy should be managed.

People with diabetes have a routine annual foot check to identify diabetic foot complications.

A diagnostic test assess foot sweat gland activity to predict diabetic foot complications earlier, in its pre-clinical state.

Evidence level: 18 studies of various designs.
Example: NICE and its Medtech HTA Evolution

- The National Institute for Health and Care Excellence
- Develops guidance for the NHS in England (and Wales)
- Medtech HTA has evolved over time
Example: NICE and its Medtech HTA Evolution

69%
Positive commercial impact in the UK (31% unsure)

55%
Positive commercial impact outside the UK (36% unsure)
Example: NICE and its Medtech HTA Evolution

1999
NICE established

2009
Medtech HTA

2014
Medtech innovation briefing

2021
Medtech funding mandate

2022
Early value assessment

2023
Late-stage assessment
Example: NICE and its Medtech HTA Evolution

NICE is established in 1999

1999
NICE established

2009
Medtech HTA

2014
Medtech innovation briefing

2021
Medtech funding mandate

2022
Early value assessment

2023
Late-stage assessment

HTA route = technology appraisal
- Legal requirement for recommended technologies to be made available
- For any technology
- First 10 published included medtech

TA2 Hip prostheses
TA4 Coronary stents
TA5 Liquid-based cytology
TA8 Hearing aids
TA10 Asthma inhalers
Example: NICE and its Medtech HTA Evolution

Bespoke medtech programmes in 2009

1999 2009 2014 2021 2022 2023
NICE established Medtech Medtech Medtech Early value Late-stage
HTA innovation funding assessment assessment
briefing mandate

Bespoke HTA for devices and diagnostics
- MTG (devices, diagnostics, digital; simple health economics)
- Diagnostics guidance (diagnostics only; cost-utility health economics)
- No legal requirement for NHS organisations to make the technology available
- Company request for assessment
Example: NICE and its Medtech HTA Evolution

Medtech innovation briefings in 2014

1999: NICE established
2009: Medtech HTA
2014: Medtech innovation briefing
2021: Medtech funding mandate
2022: Early value assessment
2023: Late-stage assessment

- Guidance takes too long
- Information is needed to support use
- Summary of information
  - Clinical
  - Cost
  - Expert opinion
- No recommendations
- NHS request for assessment

Now discontinued – no new topics since April 2023
Example: NICE and its Medtech HTA Evolution

Medtech funding mandate begins in 2021

• Accelerate adoption of NICE-recommended medtech
• Mandates the use of medtech with the greatest benefits

MedTech Funding Mandate Criteria
• Positive NICE medical technologies or diagnostics guidance
• Will generate cost savings to the NHS within 3 years
• Affordable to the NHS
Example: NICE and its Medtech HTA Evolution

Early value assessments begin in 2022

• Quicker access to promising medtech that addresses unmet needs
• Identifies evidence gaps and supports evidence generation
• Decides whether technology should be used during evidence generation
Medtech evolves over time
Focus on medtech in wide use with a high cost to NHS
- High cost, low volume
- Low cost, high volume
Do incremental changes justify price?

MedTech Funding Mandate Criteria
- TAVI
- Colostomy bags
- Coronary stents
- Wound dressings
- Continence wearables
- Slide sheets
- Beds

Late-stage assessments begin in 2023
Summary

Lots of changes in how NICE undertakes HTA on medtech

But this is just England…..

Reflects learning, feedback, and changes in the wider medtech and HTA environment
How HTA Varies Internationally, and What Are Key Requirements to Consider for Medical Technologies?

Liesl Gildea
Associate Director
Market Access and Outcomes Strategy
Our Research – Medtech HTA International Survey
### Key Areas of Interest …

- Recognize the types of medtech products HTA bodies assess
- Learn what is involved in creating an HTA submission for medtech
- Understand the types of evidence considered for HTA of medtech
- The role of RWE in decision-making by HTA bodies for medtech products
- Understand the differences and similarities for health economic evaluation of medtech by HTA bodies internationally
Summary of Key Findings
An Online Survey Was Sent to 55 HTA Organisations Worldwide

The survey covered:

- Type of medical technologies (e.g., devices, diagnostics, digital technologies) that undergo HTA
- How technologies are selected for evaluation
- What process is used
- What types of evidence is considered in the review
- Whether and how a medical technology company can submit evidence to the HTA body

- What types of clinical and economic evidence are considered as part of the review
- Requirements for company submissions of clinical and economic literature reviews
- Details of economic evaluations (e.g., perspectives used, discount rates)
- Types of outcomes following HTA of technology
- Timeframes and timelines for reviews
- Who is responsible for reimbursement negotiations
Of the 55 Invitations Sent, 17 Organisations (30.9%) Responded to the Survey

12 confirmed that they assess medical technologies
3 stated they do not assess medical technologies
2 declined participation

HTA organisations contacted from:
- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- Columbia
- Denmark
- England
- Finland
- France
- Germany
- Italy
- Japan
- Malaysia
- Norway
- Peru
- Poland
- Portugal
- Republic of Ireland
- Scotland
- Singapore
- South Korea
- Spain
- Sweden
- Switzerland
- the Netherlands
- Tunisia
- United States
- Uruguay
- Wales
What Types of Medical Technologies Can Undergo HTA at Your Organisation?

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How Are Medtech Products Selected for HTA?

- External referral process
- Internal selection process
- Requested directly by a medical technology company
- Other
# How are Medical Technologies Selected for HTA by Your Organisation?

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<thead>
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What HTA Process Is Used to Assess Medical Technologies by Your Organisation?

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What Evidence Should Medical Technology Companies Expect HTA Bodies to Review?

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<th>Country</th>
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Clinical Evidence Accepted for Medical Technologies
HTAs By Country

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Differences and Similarities of Health Economic Evaluation for Medical Technologies by HTA Bodies

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## Types of Economic Evaluations Conducted by HTAs

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BIA = budget-impact analysis; CBA = cost-benefit analysis; CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis; PCA = price comparison analysis.

The power of knowledge. The value of understanding.
## Perspectives Used in Economic Evaluations

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Conclusions

Summary of Key Findings
The HTA selection process is a critical factor that influences market access for medical technologies.

HTA organisations review a wide range of medical technologies and have varying selection processes.

Most HTA organisations use external or internal processes to select medical technologies for assessment, with little opportunity for companies to request a direct assessment of their medical technologies.

A medical technology’s value proposition is crucial in facilitating topic selection.

Some HTA websites have limited information; therefore, be prepared to contact HTA agencies directly to obtain necessary information.
Case Study
Supporting the Evidence Generation and Market Access Strategy for a Digital Diagnostic

BACKGROUND

Our client’s digital diagnostic technology has previously undergone an HTA and was not recommended for use based on insufficient clinical evidence.

CHALLENGE

The client’s digital diagnostic technology was in a busy disease area with multiple guidelines, which made differentiating their product and demonstrating benefit difficult with the available evidence.
Supporting the Evidence Generation and Market Access Strategy for a Digital Diagnostic

APPRAOH

1. We assembled a team of HEOR and medical technology experts to review the client’s data.

2. Our team reviewed clinical data on the technology that had not previously been assessed and evaluated its relevance for triggering a review of the guidance. Our review included the client’s unpublished evidence as well as protocols for future evidence generation.

3. We developed a summary report that included information on existing evidence gaps, the likelihood that the data assessed would facilitate a change to the current recommendations – and potentially lead to a positive recommendation – and advice on next steps.

VALUE

The client was able to use our summary report to make strategic decisions about additional evidence generation and to refine their approach to market access.
Key Take-Home Messages

Knowing how HTA evaluations vary internationally can help you formulate evidence generation plans to streamline your market access plans and navigate the international HTA maze.

- Medical technologies are subject to HTA evaluation.
- All of the international HTA organizations review all types of medical technology.
- The greatest variation in HTA evaluations centers on economic data.
- Evidence generation plans should be designed to address international HTA organization needs.
Thank You

Questions?

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