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Health Solutions

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Navigating the Complex HTA Landscape for Medtech Success



Presenters



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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?



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?

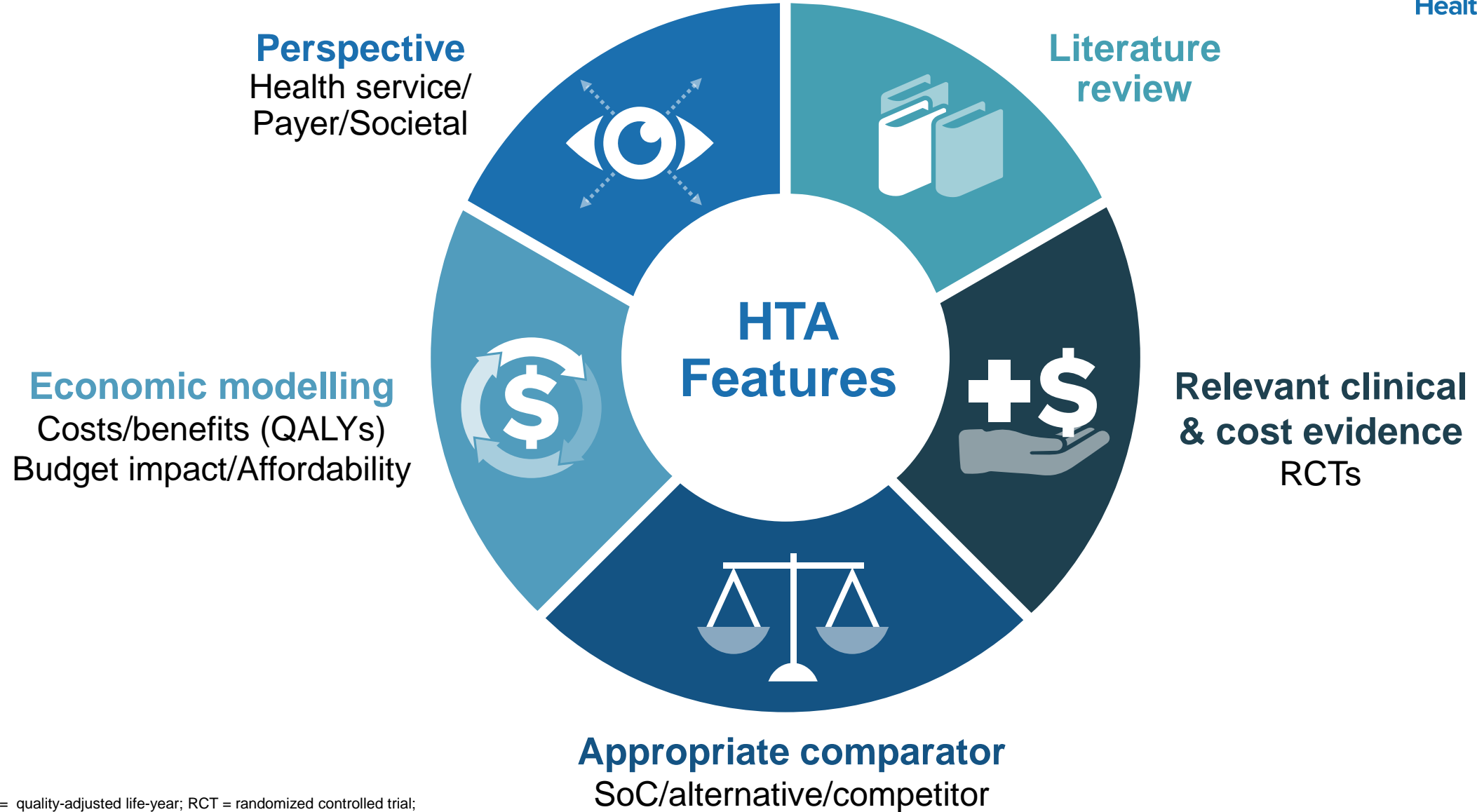
Linked to reimbursement?



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 ...



QALY = quality-adjusted life-year; RCT = randomized controlled trial;
SoC = standard of care.

Example – Hospital Bed



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

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

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

NICE

National Institute for
Health and Care Excellence

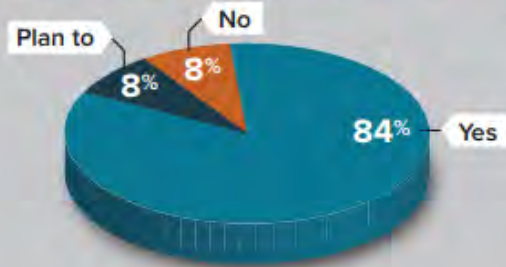
- The National Institute for Health and Care Excellence
- Develops guidance for the NHS in England (and Wales)
- Medtech HTA has evolved over time

Example: NICE and its Medtech HTA Evolution

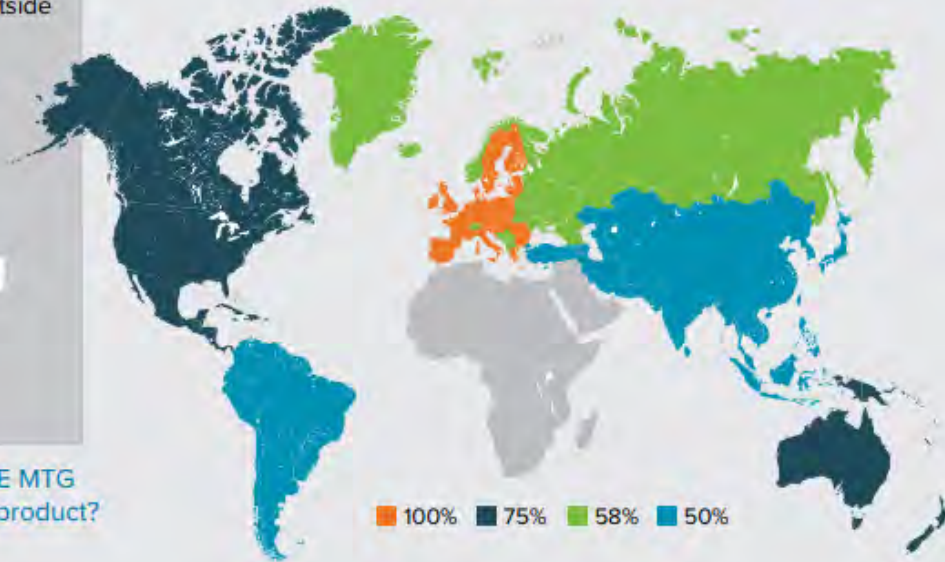
NICE Medical Technologies Guidance Usage Outside the UK

Survey results showed that 92% (12/13) of MTGs are used or are planned to be used by companies outside the UK to promote their technology.

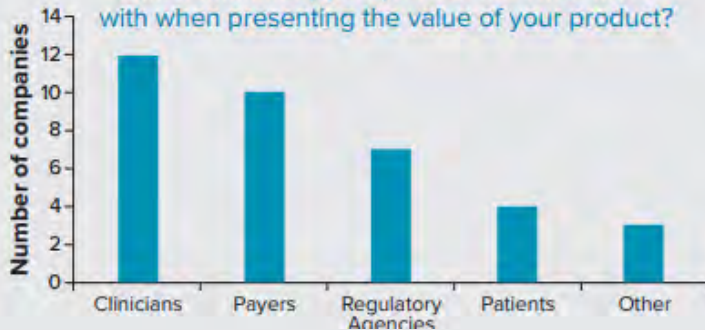
Do you use the NICE MTG to promote your technology outside the UK? (n = 13)



Where have you used the NICE MTG?



Which audience(s) do you use the NICE MTG with when presenting the value of your product?



Outside the UK (n = 12), MTG was predominately used in Europe-EU (100%), North America (75%), and Australasia (75%).

Clinicians (100%) and payers (83%) were the main audiences for which companies used MTG to present the value of their products.

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



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



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

Example: NICE and its Medtech HTA Evolution

Late-stage assessments begin in 2023



- 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
- Continenence wearables
- Slide sheets
- Beds

Summary

Lots of changes in how NICE undertakes HTA on medtech

Reflects learning, feedback, and changes in the wider medtech and HTA environment

But this is just England.....

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:

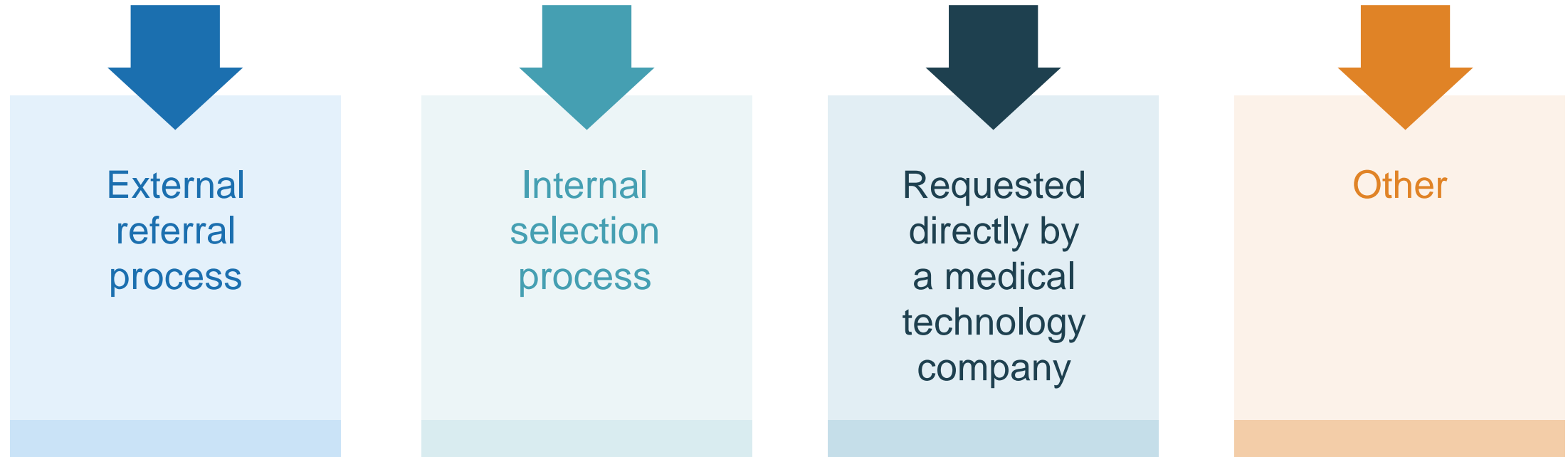
- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- Columbia
- Denmark
- England
- Finland
- France
- Germany
- Italy
- Japan
- Malaysia
- Norway
- Peru
- Poland
- Portugal
- Republic of Ireland
- Scotland
- Singapore
- South Korea
- Spain
- Sweden
- Switzerland
- the Netherlands
- Tunisia
- United States
- Uruguay
- Wales

What Types of Medical Technologies Can Undergo HTA at Your Organisation?













Country	HTA organisation	Digital	Non-invasive devices	Invasive devices	Diagnostics
Canada	CADTH	✓	✓	✓	✓
Denmark	DEFACTUM	✓	✓	✓	✓
Denmark	DHTC	✓	✓	✓	✓
Finland	FinCCHTA	✓	✓	✓	✓
Germany	G-BA	✓	✓	✓	✓
Japan	NIPH	✗	✗	✓	✗
Norway	Nye Metoder	✓	✓	✓	✓
Spain	AQuAS	✓	✓	✓	✓
Sweden	TLV	✓	✓	✓	✓
Tunisia	INEAS	✓	✓	✓	✓
UK: England	NICE	✓	✓	✓	✓
US	AHRQ	✓	✓	✓	✓

AHRQ = Agency for Healthcare Research and Quality; AQuAS = Agency for Health Quality and Assessment of Catalonia; CADTH = Canadian Agency for Drugs and Technologies in Health; DHTC = Danish Health Technology Council; FinCCHTA = Finnish Coordinating Center for Health Technology Assessment; G-BA = Federal Joint Committee; INEAS = National Authority for Evaluation and Accreditation in Health; NICE = National Institute for Health and Care Excellence; NIPH = National Institute of Public Health; TLV = Dental and Pharmaceutical Benefits Agency.

How Are Medtech Products Selected for HTA?



How are Medical Technologies Selected for HTA by Your Organisation?

Country	HTA organisation	Digital	Non-invasive devices	Invasive devices	Diagnostics
Canada	 CADTH	External referral process	External referral process	External referral process	External referral process
Denmark	 DEFACTUM	External referral process	External referral process	External referral process	External referral process
Denmark	 DHTC	Other	Other	Other	Other
Finland	 FinCCHTA	Requested directly by a medical technology company	Other	Other	Other
Germany	 G-BA	Other	Other	Other	Other
Japan	 NIPH	Not applicable	Not applicable	External referral process	Not applicable
Norway	 Nye Metoder	External referral process, internal selection process and requested directly by a medical technology company			
Spain	 AQuAS	External referral process	External referral process	External referral process	External referral process
Sweden	 TLV	External referral process	External referral process	External referral process	External referral process
Tunisia	 INEAS	External referral process	External referral process	External referral process	External referral process
UK	 NICE	Internal selection process	Internal selection process	External referral process	Internal selection process
US	 AHRQ	Internal selection process	Internal selection process	Internal selection process	Not reported

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

Country	HTA organisation	Dedicated HTA process for MT	General HTA process
Canada	CADTH	✗	✓
Denmark	DEFACTUM	✓	✗
Denmark	DHTC	✓	✗
Finland	FinCCHTA	✗	✓
Germany	G-BA	✗	✓
Japan	NIPH	✗	✓
Norway	Nye Metoder	✓	✗
Spain	AQuAS	✓	✗
Sweden	TLV	✓	✗
Tunisia	INEAS	✓	✓
UK: England	NICE	✓	✗
US	AHRQ	✗	✓





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

Country	HTA organisation	Clinical Data	Economic Data	Healthcare Professional Opinion	Patient Opinion
Canada	CADTH	✓	✓	✓	✓
Denmark	DEFACTUM	✓	✓	✓	✓
Denmark	DHTC	✓	✓	✓	✓
Finland	FinCCHTA	✓	✓	✓	✗
Germany	G-BA	✓	✗	✗	✓
Japan	NIPH	✓	✓	✗	✗
Norway	Nye Metoder	✓	✓	✓	✓
Spain	AQuAS	✓	✓	✗	✗
Sweden	TLV	✓	✓	✓	✓
Tunisia	INEAS	✓	✓	✓	✓
UK: England	NICE	✓	✓	✓	✓
US	AHRQ	✓	✗	✗	✗

Clinical Evidence Accepted for Medical Technologies HTAs By Country

Country	Organisation	Clinical trial	RWE	Registry data
Canada	CADTH	✓	✓	✓
Denmark	DEFACTUM	✓	✓	✓
Denmark	DHTC	✓	✓	✓
Finland	FinCCHTA	✓	✓	✓
Germany	G-BA	✓	✗	✗
Japan	NIPH	✓	✓	✓
Norway	Nye Metoder	✓	✓	✓
Spain	AQuAS	✓	✓	✓
Sweden	TLV	✓	✓	✓
Tunisia	INEAS	✓	✓	✓
UK: England	NICE	✓	✓	✓
US	AHRQ	✓	✗	✗

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

Country	HTA organisation	Economic SLR	Topics		
			Utility	Health resource use/cost	Economic evaluations
Canada	 CADTH	✓	✗	✗	✓
Denmark	 DEFACTUM	✓	✓	✓	✓
Denmark	 DHTC	✓	✓	✓	✓
Finland	 FinCCHTA	✓	✗	✓	✓
Germany	 G-BA	✗	NA	NA	NA
Japan	 C2H, NIPH	✗	NA	NA	NA
Norway	 Nye Metoder	✓	✓	✓	✓
Spain	 AQuAS	✓	✓	✓	✓
Sweden	 TLV	✗	NA	NA	NA
Tunisia	 INEAS	✓	✓	✓	✓
UK: England	 NICE	✓	✓	✓	✓
US	 AHRQ	✓	✗	✓	✗











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Types of Economic Evaluations Conducted by HTAs

Country	HTA	Economic evaluations considered	Type of economic evaluation						
			CUA	CEA	CBA	CMA	PCA	BIA	
Canada	CADTH	✓	✓	✓	✓	✓	✓	✓	✓
Denmark	DEFACTUM	✓	✓	✓	✓	✓	✓	✓	✓
Denmark	DHTC	✓	✓	✓	✗	✓	✗	✓	✓
Finland	FinCCHTA	✓	✓	✓	✗	✓	✗	✓	✗
Germany	G-BA	✗	NA	NA	NA	NA	NA	NA	NA
Japan	C2H, NIPH	✓	✓	✗	✗	✗	✗	✗	✗
Norway	Nye Metoder	✓	✓	✓	✗	✓	✗	✗	✓
Spain	AQuAS	✓	✓	✓	✗	✗	✗	✗	✓
Sweden	TLV	✓	✓	✓	✓	✓	✓	✓	✗
Tunisia	INEAS	✓	✓	✓	✓	✓	✓	✓	✓
UK: England	NICE	✓	✗	✓	✗	✓	✗	✗	✓
US	AHRQ	✗	NA	NA	NA	NA	NA	NA	NA

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

Perspectives Used in Economic Evaluations

Country	HTA	Societal	Healthcare system	Individual patient	Institutional	Target group of specific services
Canada 	CADTH	✗	✓	✗	✗	✗
Denmark 	DEFACTUM	✓	✓	✗	✓	✗
Denmark 	DHTC	✓	✗	✗	✗	✗
Finland 	FinCCHTA	✓	✓	✓	✗	✗
Germany 	G-BA	NA	NA	NA	NA	NA
Japan 	C2H, NIPH	✗	✓	✗	✗	✗
Norway 	Nye Metoder	✗	✓	✗	✗	✗
Spain 	AQuAS	✓	✓	✗	✗	✗
Sweden 	TLV	✓	✗	✗	✗	✗
Tunisia 	INEAS	✓	✓	✓	✓	✓
UK: England 	NICE	✓	✓	✗	✗	✗
US 	AHRQ	NA	NA	NA	NA	NA

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

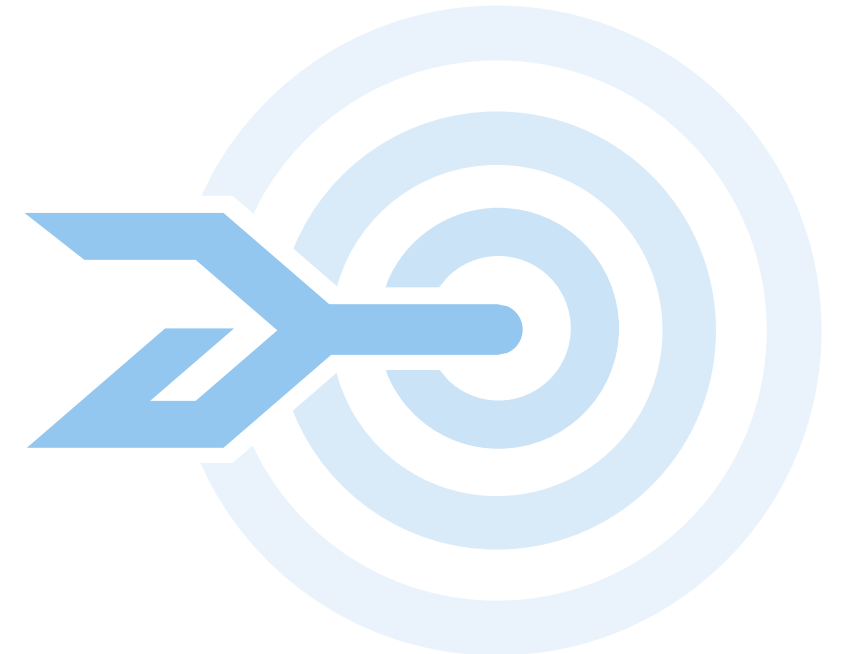
Supporting the Evidence Generation and Market Access Strategy for a Digital Diagnostic

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


APPROACH

- 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

Q&A



Thank You Questions?



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