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Uncovering the Impact of HTA on Medical Device and Diagnostic Procurement Process and Outcomes: Insights and Discussion From the ISPOR Medical Devices and Diagnostics SIG Key Project Research

Tuesday May 7, 2024 | 3:15PM – 4:15PM

Discussion Topics

	Topic	Presenter(s)
1	Introductions and Study Background	Michael
2	The US HTA Perspective	Patty
3	The Industry Perspective	Arturo
4	The EU Perspective	Meike
5	Next Steps	All

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Panelist Introductions

Michael Cangelosi, MA, MPH
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Background & Recapitulation of work completed

Mr. Michael Cangelosi

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Systematic Literature Review

Evolving Use of Health Technology Assessment in Medical Device Procurement— Global Systematic Review: An ISPOR Special Interest Group Report

Michael Cangelosi, MA, MPH, Akriti Chahar, PhD,* Simon Eggington, MSc*

ABSTRACT

Objectives: To review the current academic evidence describing how data from health technology assessments (HTAs) informs procurement decisions for medical devices.

Methods: A systematic literature review was performed to identify relevant studies and criteria used in medical device purchasing or procurement decisions. Included articles were screened for relevancy and risk of bias. The included studies were summarized qualitatively.

Results: A total of 292 studies were screened, of which 11 matched the inclusion criteria. Included studies' geographies and HTA maturity varied. Some studies described hospital-level HTA processes, whereas others focused on national-level recommendations. Criteria for procurement decisions included standard HTA factors, such as efficacy, cost, cost-effectiveness, and budget impact; broader issues were also noted, including impact on the organization, ethical aspects, staff workload, and volume. There was little consideration of device-specific characteristics, such as life cycle, learning curve, or incremental technical innovation. Few decisions referred to HTA reports as part of the procurement decision; similarly, few HTA reports included a procurement perspective to help guide the procurement bodies.

Conclusions: There is minimal evidence that notes HTA influencing medical device procurement. Procurement bodies and hospitals may not be incentivized to publish their work and transparency could be improved; further research would better describe the link between HTA and procurement. Such research would enable the HTA agencies to meaningfully assess devices to target procurement bodies and allow device sponsors to prioritize evidence. This could limit redundancy, improve evidence, and ultimately promote savings to healthcare systems and expand access.

Keywords: health technology assessment, medical devices, procurement, purchasing, value assessment frameworks.

VALUE HEALTH 2023; ■(■): ■–■

Introduction

Assessing the value of medical devices is a key element in making adoption and coverage decisions. Several value assessment frameworks (VAFs) have been published with the goal of providing measures to evaluate medical interventions,[1,2] with some acknowledging the challenges in applying value frameworks to medical devices.[3] Medical devices have unique characteristics, such as frequent device iterations and user learning curves, which make it difficult to generalize outcomes, and therefore value to the broader patient population.[4] Additionally, many device types exist, each potentially requiring different assessment criteria, and stakeholders may view the value of any technology differently based on their specific needs.

In 2016, ISPOR created a Special Task Force to examine recent US VAFs and provide guidance on best practices for assessing the value of healthcare interventions from a payer's perspective.[5] The Special Task Force recommended the use of the cost per quality-adjusted life-year for payer coverage and reimbursement decisions, a measure rarely used till date by US payers.[6] Nevertheless, the growing influence of organizations such as the Institute for Clinical and Economics Review may change this in the coming years. One recent review compared value-based frameworks from around the world, identifying differences in the conception of value and a need for more systematic use of value-based care and joint action between jurisdictions.[7]

Elsewhere, cost-effectiveness analysis is an established component of funding decisions via bodies such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom. In 2009, NICE introduced a new program, the Medical Technologies Evaluation Programme, focused on medical devices and diagnostics expected to be cost saving or cost neutral.[8] In Germany, the Institute for Quality and Efficiency in Healthcare prefers the use of an efficiency frontier for comparing the costs

*All authors contributed equally to the overall project and should be considered co-first authors.

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Takeaways:

- Minimal published evidence of HTA influencing MedTech procurement
- Few procurement decisions referencing HTA; similarly, few HTA reports include a procurement perspective.
- Procurement may not publish
- Procurement may include broader issues than HTA – organization impact, staff workload, volume
- HTA not considering life-cycle, learning curve, incremental tech innovation

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The HTA Perspective

Ms. Patricia Synnott

HTA in the United States

- No national HTA system for pricing, coverage, or adoption decisions

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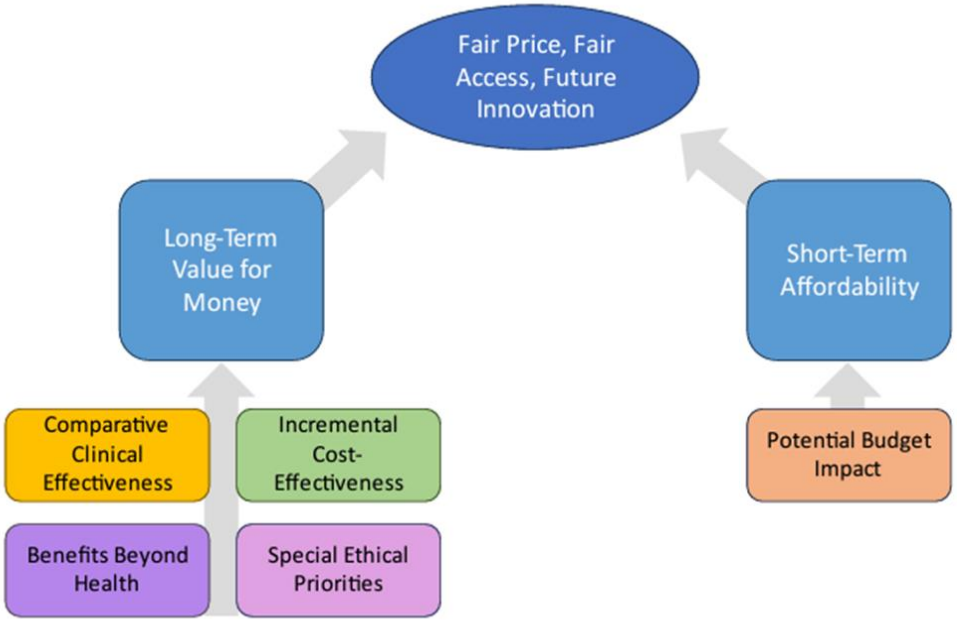
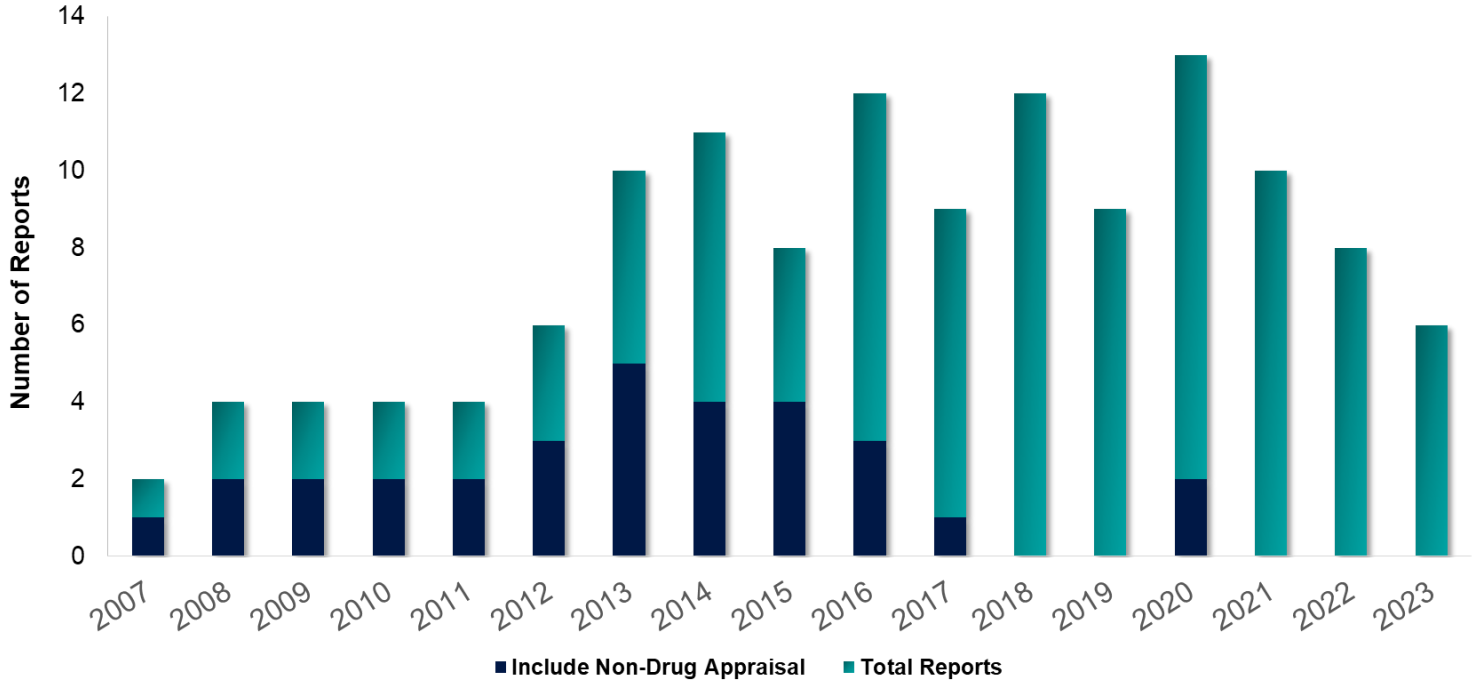
ICER's Value Assessment Framework



ICER Appraisals of Non-Drug Topics



Potential for HTA to Influence Procurement

- Procurement may depend on many factors and stakeholders
    - E.g., Ability to get reimbursed, presence of billing codes, physician preferences
- How does value factor into decisions?

Practical (but not insurmountable) Challenges for HTA

- Adequacy of clinical evidence
- Learning curve
- Rapid, incremental product iterations
- Integration in care pathway

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The Industry Perspective

Mr. Arturo Cabra

Industry Perspective

- Duplicative actions may increase costs to market access
  - Two agencies with different information needs
- Duplicative actions may give 'more bites at the apple'
  - A loss in HTA, doesn't necessarily mean a loss in procurement
- Procurement focus on price may be underestimating value
- Lack of transparency in procurement creates privileged knowledge of experience
  - Startups can learn from prior HTA reports
  - No such reports generally exist for procurement. Relationship driven knowledge

Industry Perspective

- Sharing the same challenges:

- Devices possess unique characteristics (lifecycle, regulatory environment, user-device interactions, learning curves device iterations: challenge to generalize outcomes.

- Diversity on the devices: require different assessment criteria and differences on the value recognition and stakeholder perspective and needs.
  - value is in the eye of beholder"

- Lack of Incentives from hospitals:
  - Purchasing Mechanism: Payments, DRG's, rebates and discounts are strong incentives in the short term.
  - Confidentiality against sharing knowledge.

Opportunities

- Lack of standardization on the HTA means a more complex evidence generation plan (increase costs to market access).

- Duplicative actions may increase costs to market access
  - Two agencies with different information needs
- Duplicative actions may give 'more bites at the apple'
  - A loss in HTA, doesn't necessarily mean a loss in procurement
- Procurement focus on price may be underestimating value
- Lack of transparency in procurement creates privileged knowledge of experience
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The view from the EU
Next Steps:
Beyond Literature Review
Surveying HTA and Procurement

Ms. Meike Bomhof

EU Perspective
Procurement is fundamentally different in Europe

- Procurement in Europe can take place at national, regional, local or hospital level.

- It usually consists of 3 phases:
    1. **Request for adoption**: Clinician request through dossier submission,
    2. **Evaluation**: By a multidisciplinary committee
        - Evaluation criteria not always transparent
    3. **Procurement**: Following EU public procurement legislation
        - Direct purchasing versus tendering
        - Procurement and tender award criteria

- The process steps, timing and stakeholders involved in this process are not always transparent.

EU Perspective
HTA is more formalized in Europe

- Some 30 European HTA agencies, most members of EUnetHTA:
  - Coordination
  - Involved in JCE process

- Quite formalized HTA processes:
  - **Variability**: Organization at national, regional and local hospital-based
  - **Funding**: Public funding / not for profit. Yearly budgets in general linked to type of activity: primary vs secondary research only
  - **Activities other than HTA**: Horizon scanning, clinical guidelines and health services research.
  - **Relation to decision-making**: Directly linked, or not, to policy decisions at national or regional level. Autonomy of priority setting.

The problem we are here to discuss

National, regional and local procurement agencies

- Cost containment
- Frameworks of legacy product categories
- Low level of understanding of technologies and innovation
- Lack of transparency: Unclear methods and criteria to measure clinical value
- EU tendering legislation helpful but not sufficient to address the issues above

Versus

HTA Agencies

- Structured methods to appraise clinical value and cost effectiveness
- Driven by evidence-based methodologies
- Assesses product value over time from a societal perspective
- Indepth understanding of clinical pathways

EU Perspective
Gap between HTA and Procurement

- ISPOR MD SIG systematic analysis in 2023: **Unclear influence of HTA's on medical device procurement**

- Ongoing research in this area in 2024:
  - **Objective:** Inform on optimal HTA process and content as a basis for – value based – procurement decisions:
    - Provide insights for HTA bodies into drivers of device procurement
    - Understand how HTA can better inform/support medical device procurement
  - **Scope:** USA, Sweden, UK, Spain, Italy and possibly Netherlands
  - **Methodology:** Primary research through personal stakeholder interviews based on a common questionnaire:
    - Members of HTA organizations
    - Persons involved in medical device procurement decisions at national, regional or local hospital / hospital group level

Phase 2 survey actively soliciting participant interviewers and interviewees!

- Opportunity for MDD-SIG members to contribute to key SIG project.
- Opportunity for members of HTA organizations and procurement departments to participate in the research.
- Leverage your existing network
  - HTA
  - Procurement and Purchasing
- For more information, talk to panelists after discussion

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Q & A

Thank You & we encourage you to engage with MDD-SIG

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