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ISPOR

Improving healthcare decisions

ISPOR Special Interest Group

Medical Devices and Diagnostics Special Interest Group (MDD SIG)

Regional Differences Across HTA & Procurement of Medtech Solutions: ‘Crossing the Pond’ of Differing Roles Across HTA and Procurement.

ISPOR 2023

Monday, May 8, 2023

11:45 AM – 12:45 PM EDT

SECTION

1

Welcome and Session Information

Agenda

- Welcome and Housekeeping Items
- Introduction to Panelists & Audience Polling
- Linking HTA and Device Procurement
- US Perspectives on Device Procurement
- Open Discussion with Panelists and Participants

Antitrust Compliance Statement

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The Antitrust policy is available on the ISPOR website at ispor.org/antitrust.

SECTION

2

Introductions to Panel

Moderator & Panelists:

Richard Charter - Moderator

VP & Partner – MedTech Market Access & Commercial Strategy at Alira Health

Richard Charter is Alira Health's MedTech Market Access and Commercial Strategy Partner, with over 20 years of experience in financial and health economics.

Richard is currently the co-chair of the HTAi Medical Device Interest Group, and the ABHI Sustainability Working Group. His past chair roles include MedTech Europe Evidence & Payers Working Group and the ISPOR Medical Device Special Interest Group. Richard was also the industry advisor for the EU-funded Horizon 2020 COMED initiative on cost and outcomes measurement for medical devices.

Richard holds a master's degree in Healthcare Management, Economics, and Policy from SDA Bocconi. He has also completed the Harvard Business School Intensive Course on Value-Based Healthcare.

Myla Maloney - Panelist

Chief Commercial Officer at PINC AI Applied Sciences

Myla Maloney is the Chief Commercial Officer for PINC AI™ Applied Sciences, a division of PINC AITM, the technology and services platform of Premier. With 22 years of experience in the healthcare industry, Maloney supports Premier's mission of transforming healthcare by leading population health improvement collaboration between PINC AI Applied Sciences and life sciences organizations. Maloney has been with Premier for the last six years and previously served as Premier's Vice President of Strategic Supplier Engagement, where she partnered with leading biopharmaceutical and IT companies.

Myla received her B.S. in business administration and MBA from East Carolina University.

Stephen Hull - Panelist

President at Hull Associates

Stephen Hull is Principal and Founder of Hull Associates LLC, a specialized global reimbursement strategy firm focused on pharmaceutical, medical device, diagnostic and biotech technologies.

Stephen Hull has over 25 years of experience in health policy and medical product strategy, for pharmaceuticals, medical devices, diagnostics, and biotech products.

Stephen has an advanced degree in health policy from the Johns Hopkins Bloomberg School of Public Health, and a bachelor's degree in international relations and French from Colgate University.

Arthi Chandran - Panelist

DVP Health Economics and Reimbursement at Abbott

Arthi Chandran is a recognized leader in Health Economics and Access with nearly two decades of experience in Pharma and MedTech. In her current capacity, she leads a global team of researchers, and reimbursement specialists, responsible for ensuring that patients around the world have an equitable opportunity to experience the benefits of Abbotts portfolio of life enhancing and lifesaving technologies.

Arthi holds an MPH in Chronic Disease Epidemiology from Yale, a MS in Regulatory Affairs from Temple and a Doctorate in Health Policy and Management from the City University of New York.

SECTION

3

Polling Questions for the Audience

Poll 1: How familiar are you with the concept of value-based procurement?

1. Newbie
2. I've heard about it
3. Academic understanding
4. I have, or am, actively engaging in this process

Poll 2: Do you think HTA should have a meaningful role in device procurement?

1. Yes
2. No
3. I don't know

Poll 3: Are you currently a member of ISPORs Medical Device Special Interest Group (SIG)?

1. Yes, I am!
2. No, I am not.
3. No, but I would like to be!

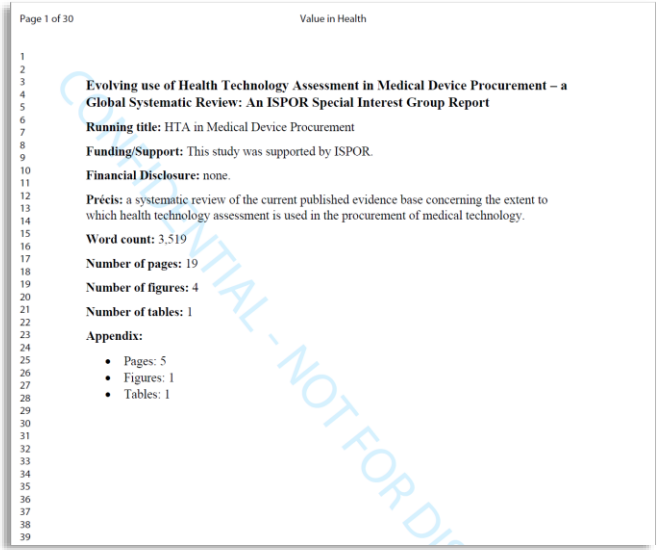
SECTION

4

Linking HTA and Device Procurement

Richard Charter
VP & Partner – MedTech Market Access & Commercial Strategy
Alira Health

Should Joint Clinical Assessments Drive Procurement?



Evolving use of Health Technology Assessment in Medical Device Procurement – a Global Systematic Review: An ISPOR Special Interest Group Report

Running title: HTA in Medical Device Procurement

Funding/Support: This study was supported by ISPOR.

Financial Disclosure: none.

Précis: a systematic review of the current published evidence base concerning the extent to which health technology assessment is used in the procurement of medical technology.

Word count: 3,519

Number of pages: 19

Number of figures: 4

Number of tables: 1

Appendix:

- Pages: 5
- Figures: 1
- Tables: 1

Source: Alira Health Analysis, MedTech Europe, Bocconi University

Paper Conclusion:

"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 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 health care systems and expand access.

Lets discuss this!

Value Based Procurement & HTA, more similar than different…

Health Technology Assessment (HTA)

- Health Technology Assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner.
- The aim is to inform the formulation of safe and effective health policies that are patient focused and seek to achieve the best value for public health.

Value Based Healthcare (VBHC)

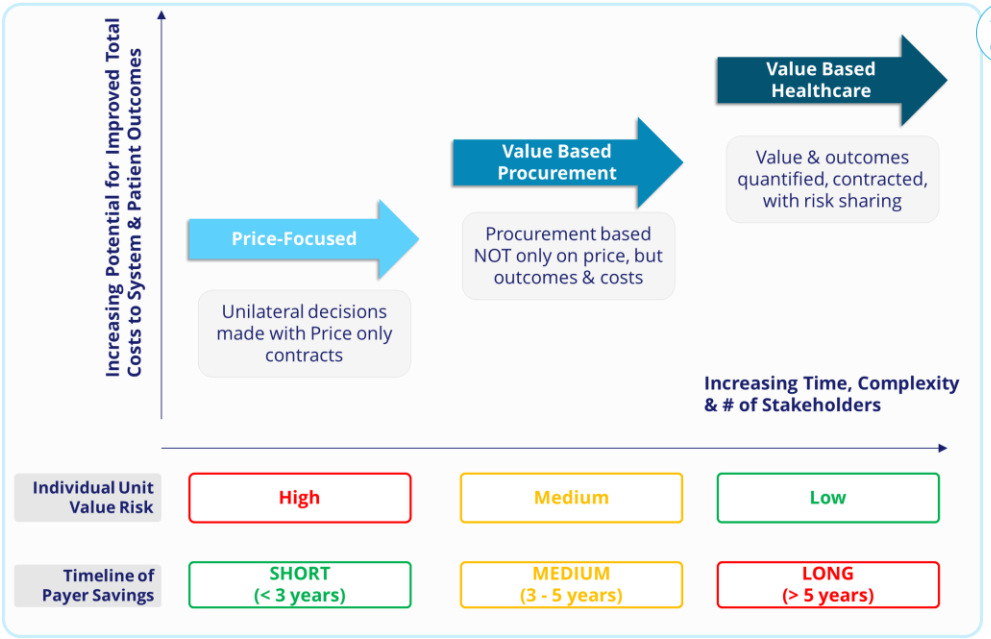
- Value Based Healthcare (VBHC) is a healthcare delivery model where partnerships are built on measuring relationships between:
  - Outcomes that matter to patients, healthcare providers and health systems;
  - Total costs across the entire care continuum, from pre-diagnosis to the time the patient exits the disease state.

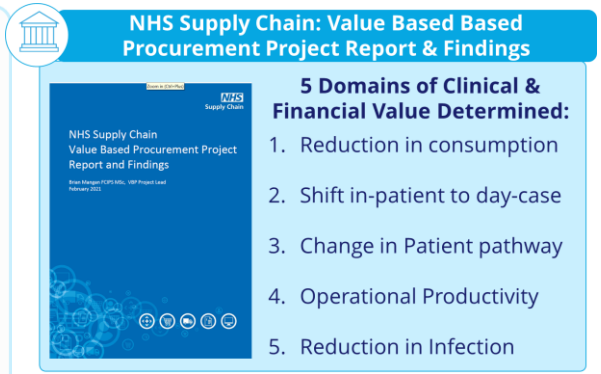
Key Similarities & Differences

Key Similarities	Key Differences
▪ Both attempt to define value with a relationship between outcomes & costs: a common language	▪ VBHC focuses more on the entire patient pathway, which makes it more conducive to Medical Devices
▪ Both utilize a benchmark or comparator to determine improvement / benefit	▪ HTA focuses on economic benefit, VBHC focuses on TDABC[1] (accounting) benefit, which aligns more to procurement decisions.
▪ Both consider value domains beyond just 'economics' or 'accounting'	▪ VBHC implementation is driven more locally, by providers. HTA is more government or policy oriented. This is changing (e.g. Wales, France).
▪ Both involve multi-stakeholder collaborative dialogues	▪ VBHC is more clearly structured around medical conditions, instead of specific technologies or interventions
▪ Both attempt to reduce variation in care	

Source: Alira Health Analysis

Conventional Procurement is maturing towards value based and HTA based decision making…





Adapted from: Mangan, B Kelley T, McGough R, & Meehan J. Value Based Procurement An alternative approach to total cost reduction, improved efficiency and enhanced patient outcomes in the NHS: A Framework for Delivery. NHS Northwest Procurement Development, 2018. University of Liverpool.

Decision criteria that can be considered by HTA & Procurement are converging.

A University Hospital Infusion Pump Tender

In 2014, a University Hospital tendered a medical device:

- Advanced model to include the total cost over the product life span for **40 units**
- High basic quality requirements, with theoretical price markups for suppliers not fulfilling all quality requirements

3 suppliers participated, only 2 fulfilled all basic requirements for final assessment

Total Assessment Incl. Function & Quality		
Supplier	Points	Missing
Company C	Failed	
Company B	343	201
Company A	439	105

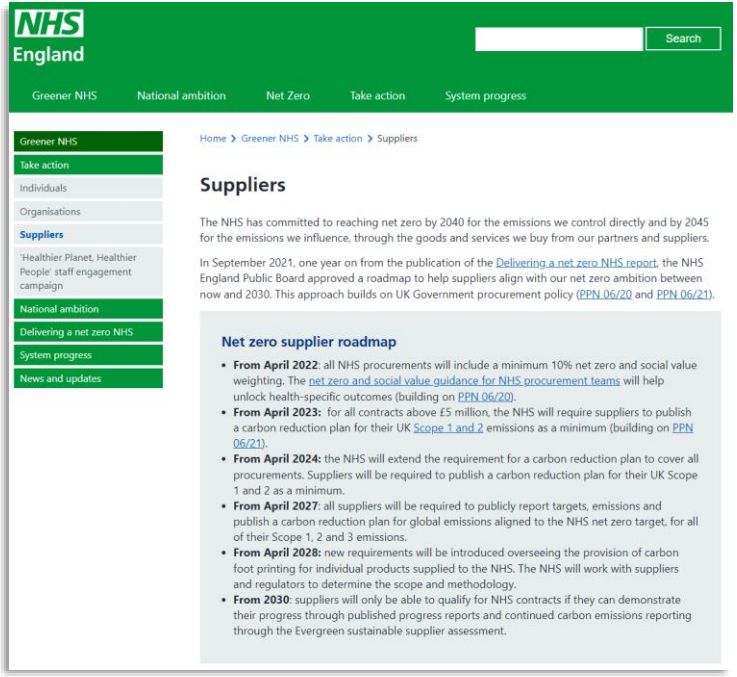
- Max points 544.
- Price markup per missing point: 13,000 local currency

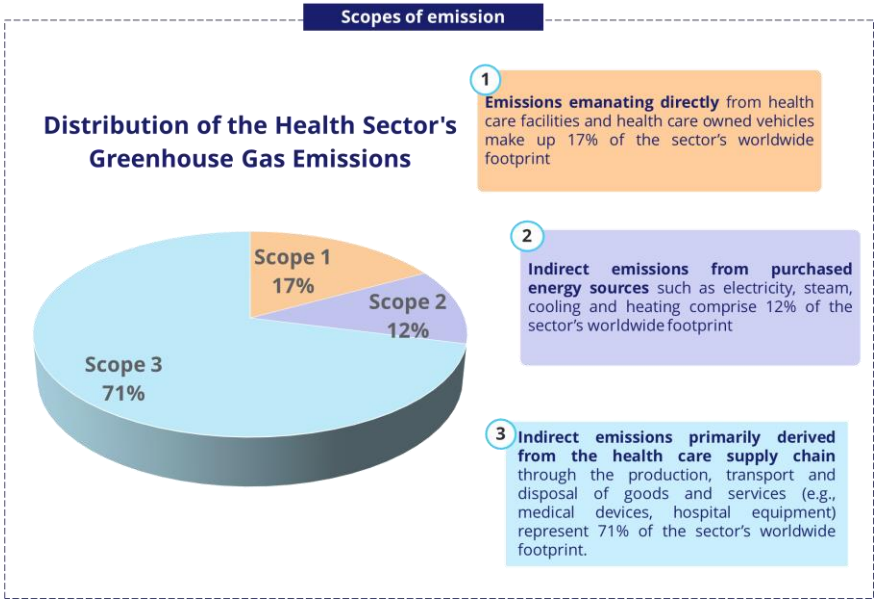
Tender Breakdown	Company B		Company C
Equipment	596,000		831,200
Supplies for 6 years	180,000		630,000
Service equipment	17,032	Higher price than Company B	0
Additional functionality and service agreement	252,270		177,325
Total Cost	**1,045,302**		**1,638,525**
Markup after quality assessment	2,616,900		1,365,000
Adjusted Cost	**3,662,202**		**3,003,525**

**prices in local currency*

Source: Alira Health Analysis

‘Social’ criteria, especially “environmental” criteria are becoming mandatory for both HTA & Procurement





Source: Alira Health Analysis; NHS England website: Greener NHS » Suppliers (england.nhs.uk)

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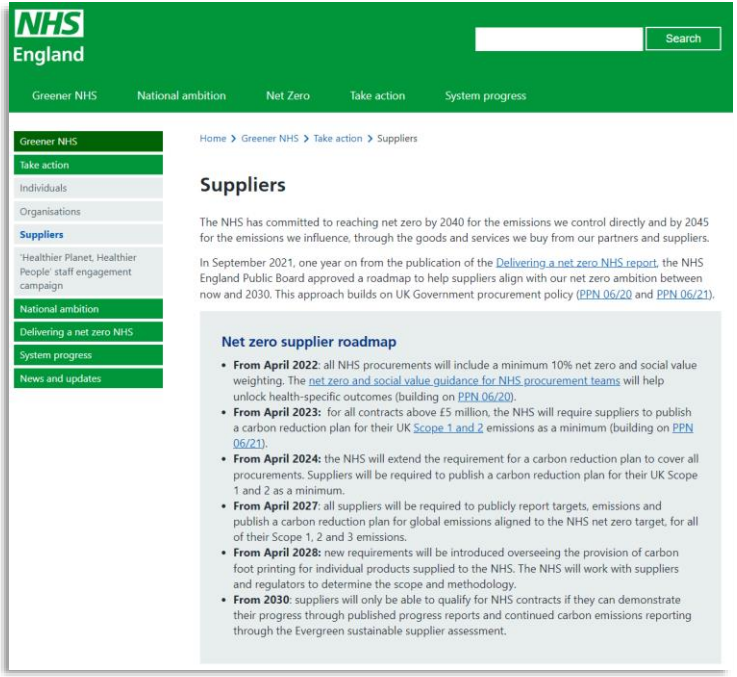

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Suppliers

The NHS has committed to reaching net zero by 2040 for the emissions we control directly and by 2045 for the emissions we influence, through the goods and services we buy from our partners and suppliers.

In September 2021, one year on from the publication of the Delivering a net zero NHS report, the NHS England Public Board approved a roadmap to help suppliers align with our net zero ambition between now and 2030. This approach builds on UK Government procurement policy (PPN 06/20 and PPN 06/21).

Net zero supplier roadmap

- **From April 2022**: all NHS procurements will include a minimum 10% net zero and social value weighting. The net zero and social value guidance for NHS procurement teams will help unlock health-specific outcomes (building on PPN 06/20).
- **From April 2023:** for all contracts above £5 million, the NHS will require suppliers to publish a carbon reduction plan for their UK Scope 1 and 2 emissions as a minimum (building on PPN 06/21).
- **From April 2024:** the NHS will extend the requirement for a carbon reduction plan to cover all procurements. Suppliers will be required to publish a carbon reduction plan for their UK Scope 1 and 2 as a minimum.
- **From April 2027**: all suppliers will be required to publicly report targets, emissions and publish a carbon reduction plan for global emissions aligned to the NHS net zero target, for all of their Scope 1, 2 and 3 emissions.
- **From April 2028:** new requirements will be introduced overseeing the provision of carbon foot printing for individual products supplied to the NHS. The NHS will work with suppliers and regulators to determine the scope and methodology.
- **From 2030**: suppliers will only be able to qualify for NHS contracts if they can demonstrate their progress through published progress reports and continued carbon emissions reporting through the Evergreen sustainable supplier assessment.

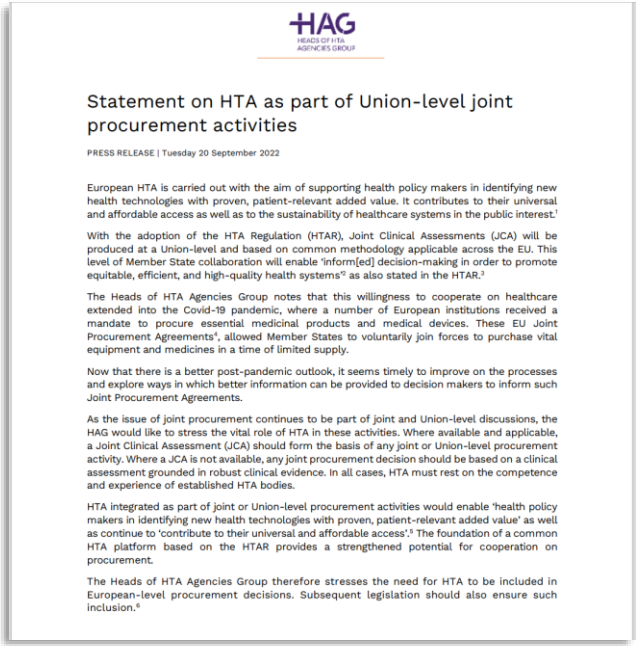
Key principles

The Greenhouse Gas Protocol sets out an internationally recognised methodology for emissions calculation, which divides Scope 3 emissions into 15 categories:

1. Purchased goods and services,
2. Capital goods,
3. Fuel and energy-related activities,
4. Upstream transportation and distribution,
5. Waste generated in operations,
6. Business travel,
7. Employee commuting,
8. Upstream leased assets,
9. Downstream transport and distribution,
10. Processing of sold products,
11. Use of sold products,
12. End-of-life treatment of sold products,
13. Downstream leased assets,
14. Franchises,
15. Investments.

Source: Alira Health Analysis; NHS England website: Greener NHS » Suppliers (england.nhs.uk)

Should Joint Clinical Assessments Drive Procurement?



HAG
HEADS OF HTA AGENCIES GROUP

Statement on HTA as part of Union-level joint procurement activities

PRESS RELEASE | Tuesday 20 September 2022

European HTA is carried out with the aim of supporting health policy makers in identifying new health technologies with proven, patient-relevant added value. It contributes to their universal and affordable access as well as to the sustainability of healthcare systems in the public interest.[1]

With the adoption of the HTA Regulation (HTAR), Joint Clinical Assessments (JCA) will be produced at a Union-level and based on common methodology applicable across the EU. This level of Member State collaboration will enable 'inform[ed] decision-making in order to promote equitable, efficient, and high-quality health systems'[2] as also stated in the HTAR.[3]

The Heads of HTA Agencies Group notes that this willingness to cooperate on healthcare extended into the Covid-19 pandemic, where a number of European institutions received a mandate to procure essential medicinal products and medical devices. These EU Joint Procurement Agreements[4], allowed Member States to voluntarily join forces to purchase vital equipment and medicines in a time of limited supply.

Now that there is a better post-pandemic outlook, it seems timely to improve on the processes and explore ways in which better information can be provided to decision makers to inform such Joint Procurement Agreements.

As the issue of joint procurement continues to be part of joint and Union-level discussions, the HAG would like to stress the vital role of HTA in these activities. Where available and applicable, a Joint Clinical Assessment (JCA) should form the basis of any joint or Union-level procurement activity. Where a JCA is not available, any joint procurement decision should be based on a clinical assessment grounded in robust clinical evidence. In all cases, HTA must rest on the competence and experience of established HTA bodies.

HTA integrated as part of joint or Union-level procurement activities would enable 'health policy makers in identifying new health technologies with proven, patient-relevant added value' as well as continue to 'contribute to their universal and affordable access'.[5] The foundation of a common HTA platform based on the HTAR provides a strengthened potential for cooperation on procurement.

The Heads of HTA Agencies Group therefore stresses the need for HTA to be included in European-level procurement decisions. Subsequent legislation should also ensure such inclusion.[6]

Source: HAG website: Home - HAG (htahag.eu)

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Lets discuss this!
Questions? Comments?

US approach to value appraisal is not guided by a uniform evidence standard or methods.

Medicare Coverage Requirements

- How is Medicare's Reasonable and Necessary standard applied to Medical Devices?
- What is the consistent method applied by Medicare to assess evidence?

Commercial Payer Practices

- What are the current processes and key committees for commercial coverage decisions?
- What can the O'Connor Case in Texas tell us about the future of commercial coverage?

Impact on Purchasing and Contracts

- Medicare competitive bidding is only applied to DME products and has limited connection to HTA and quality.
- Provider and network purchasers apply various frameworks to assess quality and price.
- But overall, there is no "VBP" national framework in play in the USA

SECTION

2

US Perspectives on Device Procurement

Stephen Hull
President
Hull Associates

US approach to value appraisal is not guided by a uniform evidence standard or methods.

Medicare Coverage Requirements	Commercial Payer Practices	Impact on Purchasing and Contracts
▪ How is Medicare's Reasonable and Necessary standard applied to Medical Devices?	▪ What are the current processes and key committees for commercial coverage decisions?	▪ Medicare competitive bidding is only applied to DME products and has limited connection to HTA and quality.
▪ What is the consistent method applied by Medicare to assess evidence?	▪ What can the O'Connor Case in Texas tell us about the future of commercial coverage?	▪ Provider and network purchasers apply various frameworks to assess quality and price. ▪ But overall there is no "VBP" national framework in play in the USA

SECTION

3

Open Discussion with All Panelists

Moderated by:
Richard Charter

Questions for the Audience

- Would anyone in the room like to share an experience of device procurement?
- Do you agree with the panelists regarding pace of HTA integration into key decision-making?
- How could/should ISPOR (and the SIG) continue this research?

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ISPOR Special Interest Group

- Question for the Medical Devices and Diagnostics Special Interest Group email us at:

MedDevices_DiagSIG@ispor.org

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