HTAi 2024 ANNUAL MEETING SEVILLE SPAIN

FULL SUMMARY

Remap

PLENARY 1: SUSTAINABLE HTA FOR SUSTAINABLE HEALTH SYSTEMS

At the HTAi Annual Meeting in Seville, there was a strong emphasis on the need for HTA to evolve from being gatekeepers to becoming sustainable system shapers, despite the acknowledged resource constraints and the need for more effective prioritisation.

Key Speakers: Sandra García-Armesto, Carole Longson, Christopher Munoz, Andrea Rappagliosi, Adriana Velazquez

Main Points:

- **Sustainable HTA and health systems:** The main conference theme revolved around sustainable HTA and broader sustainable health systems. Sustainability was defined in terms of effective social equity, health prioritisation, and financial planning, with a resilient healthcare system capable of withstanding external shocks and rapid changes.

- **Challenges in delivering sustainable HTA**: When asked about the greatest challenges in delivering sustainable HTA, most audience members highlighted the difficulty of matching the increasing demand for HTA with the necessary resources. They also emphasised the need for processes and methods to keep pace with health technology innovation.

- **Transition from gatekeepers to system shapers:** There was a consensus among some speakers that HTA bodies need to transition from being gatekeepers to system shapers. This includes ensuring that health systems are fit for purpose with more effective and efficient services. HTA bodies should have influence throughout the lifecycle of technologies, including adoption, diffusion, and expansion.

- **Efficiency and AI integration:** Sandra García-Armesto from the Catalonian Assessment Agency emphasised the need for greater focus on efficiency. She noted that HTA bodies are keen to use AI to automate labour-intensive processes and highlighted the need for more effective prioritisation.

- **Focus on prevention and equity:** Adriana Berumen from the WHO stressed the importance of focusing on prevention, early diagnostics, screening, and primary care. She pointed out the disparity between HTA needs and capabilities, noting that the need for HTA is greatest in less wealthy regions, whereas HTA capabilities are strongest in high-income countries. Greater sharing of information, outcomes, data, and evidence could help address this imbalance.

Overall, the discussion underscored the urgency for HTA bodies to adapt and innovate to ensure the sustainability and resilience of health systems globally.

ENVIRONMENTAL SUSTAINABILITY IN HTA: METHODOLOGIES, APPLICATIONS & INNOVATIONS

This discussion focussed on efforts to incorporate environmental sustainability into existing HTA processes, highlighting the ongoing challenges and the lack of consensus on appropriate approaches.

Key Speakers: Melissa Peg, Robert Malcolm, Carmen Guirado-Fuentes, Michela Bobini, Vittoria Ardito

Main Points:

- **Quantifying environmental impacts**: While it is unlikely that environmental sustainability will be fully represented in HTAs soon, speakers felt that it is possible to begin quantifying some outcomes and factoring in others qualitatively into existing HTA processes. Some attempts have been made to include environmental impacts as costs or convert them into health outcomes, with the UK and Canada leading these efforts.

- **Lack of consensus**: There remains a lack of consensus on appropriate methods and how to balance environmental impacts against other valued costs and benefits.

- **Focus on carbon emissions:** Carbon dioxide equivalent is the most considered environmental dimension in HTA efforts to incorporate environmental sustainability so far. This is supported by standardised examples of high and low-intensity materials and processes categorised by carbon emission thresholds. Other impacts, such as biodiversity loss, are usually neglected due to a lack of data.

- **Lifecycle analysis:** Lifecycle analysis, which takes a comprehensive approach from raw material extraction through to treatment usage and disposal, is agreed to be the most established methodology for assessing environmental impacts.

- **Public opinion and quantitative measures:** A survey by YHEC showed that people were willing to lose 0.75 years of life expectancy for a 5% reduction in CO2 emissions. In the UK, this would translate to more than 50 million QALYs, or 0.0618 QALYs per tonne of CO2.

- **Suggestions for next steps:** Suggestions for advancing this area included further evaluating public opinion on incorporating environmental sustainability in HTA, introducing mandatory requirements for clinical trials to conduct environmental assessments, setting a lifecycle assessment framework within HTA processes, and continuing to develop new methods to quantify environmental impacts alongside health economic modelling.

Overall, the discussion highlighted the need for more standardised methods and consensus on incorporating environmental sustainability into HTA processes to ensure a balanced and comprehensive approach.

AI IN HTA: TOOLS, TECHNIQUES, AND APPLICATIONS

Interest in AI in HTA has exponentially increased since 2020, driven by the UK. However, its focus has been largely narrowly limited to study selection for evidence synthesis, although there are efforts exploring its utility for horizon scanning

Key Speakers: Maria Harte, Denis Komoda, Antonia Needham-Taylor

Main Points:

- **Exponential increase in publications:** The number of publications on AI in HTA has increased exponentially since 2020, driven primarily by the UK, followed by the US, Canada, Australia, and Poland.

- **Focus on evidence synthesis:** The vast majority of AI applications in HTA (90%) have been focused on evidence synthesis via machine learning, particularly in study selection. The primary benefit observed was time savings. However, the need for a consistent reporting framework was highlighted to prevent errors, such as mislabelling machine learning as deep learning or vice versa.

- **AI in horizon scanning:** AI could support horizon scanning by extracting scoping details (e.g., patient populations) from publicly available information such as clinical trial databases. However, challenges arise due to the free text nature and general lack of structure of these sources. A test using semi-automated NLP for data extraction had a 50% success rate in extracting indication details compared to a subject matter expert.

- **Framework for appraising AI technologies:** A framework for appraising AI technologies in the context of HTA was discussed, with four key domains:
  - **Training**: Model used, training dataset information, representativeness, outcome reporting.
  - **Clinical setting and use**: Fit in pathway, patient group/clinical setting.
  - **Outputs**: Information provided to the user, degree of clinical benefit.
  - **Ongoing support:** Pricing model, ongoing monitoring, ongoing data collection.

Overall, the discussion underscored the significant potential of AI in HTA, while also emphasising the need for standardised frameworks and methodologies to ensure its effective and accurate implementation.

Remap

TUMOUR-AGNOSTIC APPROVALS: INSIGHTS AND PRACTICAL CONSIDERATIONS

One interesting session discussed the growing importance of tumour-agnostic approaches in oncology, alongside the significant disparities in access to advanced molecular testing and targeted treatments across Europe.

Key Speakers: Arnaud Bayle, Yvonne Boehler, Clifford Goodman, Nicola Normanno

Main Points:

- **Rising Significance of tumour-agnostic treatments:** The importance of basket trials and tumour-agnostic targeted treatments in oncology is increasing. Currently, six tumour-agnostic interventions have been approved by the FDA, and one by the EMA. However, substantial disparities exist in access to advanced biomarker testing needed to fully profile patients, despite various initiatives across Europe.

- **Impact of disparities on treatment and benefits:** These disparities hinder access to targeted therapies and limit the realisation of potential wider benefits, such as identifying hereditary mutations that may indicate increased cancer risk for family members. For example, the Italian RATIONAL study found that only 12% of patients received treatment that matched their genomic alteration.

- **HTA perspective and evidence generation:** From an HTA perspective, there is a need to broaden the window for evidence generation and decision-making to address data gaps, such as the lack of comparative evidence and variations in added benefit by tumour type. The VICTORIA study for larotrectinib was cited as a potential solution to identify missing real-world data. Additionally, the importance of strong patient involvement in the assessments of such therapies was highlighted.

Overall, the talk underscored the critical need for equitable access to advanced molecular testing and targeted treatments across Europe to maximise the benefits of tumour-agnostic approaches in oncology.

POST LAUNCH EVIDENCE GENERATION: CAN WE ANTICIPATE WHEN AND WHAT WE NEED?

Key Speakers: Judith Fernandez, Carlos Saborido, Francois Meyer, Joshua Ray, Steve Williamson.

Main Points:

- **Analysis on supplementary post-launch evidence generation (PLEG):** Judith Fernandez from HAS presented an insightful analysis revealing that out of 600 positive reimbursement opinions in France, only 17% included requests for supplementary post-launch evidence generation (PLEG). This trend was influenced by various factors, including the therapy area (such as neurology, pulmonology, and endocrinology), clinical benefit score, clinical added value score, and whether early access was pursued in France. Notably, PLEG requests were less common in rapidly evolving therapeutic areas, like oncology, where clinical practices change swiftly.

- **Update on the Valtermed registry system:** Carlos Saborido discussed significant updates to Spain's Valtermed registry system aimed at reducing the data entry burden for physicians and accelerating protocol development. A newly implemented web service, now deployed across most regions, has significantly improved the accuracy and efficiency of data collection.

- **Insights on managed access feasibility:** Steve Williamson from NICE highlighted key considerations regarding the feasibility of managed access. Emphasising the importance of minimising the NHS system burden, he noted that new registries or increased staffing levels for existing registries often pose challenges. He pointed out that in 83% of cases, managed access arrangements included additional data cuts from the pivotal trial rather than relying solely on real-world evidence generation.

General consensus on early collaboration

The panellists collectively agreed that managed access often tries to address issues that could have been resolved earlier. They stressed the necessity for enhanced collaboration both internally (e.g., between Medical and Market Access teams) and with external stakeholders to proactively address evidence gaps.

GLOBAL INITIATIVES TO ENHANCE HTA EFFICIENCY AND CONSISTENCY

Several ongoing and recent initiatives were highlighted at the HTAi 2024 Annual Meeting, aimed at improving the efficiency and consistency of the Health Technology Assessment (HTA) process across various countries. These initiatives span multiple regions and address key aspects of HTA implementation.

Main Points:

- **NICE's ILAP v2.0:** NICE is set to launch the Innovative Licensing and Access Pathway (ILAP) v2.0 in the autumn of 2024. The updated version will feature more stringent entry criteria to reduce the number of applications, thereby allowing a more tailored approach for companies seeking access pathways.

- **Spain's AI-based health technologies HTA framework:** In 2024, Spain will develop an HTA framework specifically for appraising AI-based health technologies. This framework is expected to be modelled after the one developed for Catalonia, which includes several additional domains beyond the core HTA and implementation domains. These extra domains cover technical aspects, environmental aspects, and post-deployment monitoring, ensuring a comprehensive evaluation of AI health technologies.

- **Germany's AI in systematic literature reviews:** The Federal Joint Committee in Germany is exploring the provision of guidance on the use of AI in systematic literature reviews. Although details on the implementation and timeline are currently unavailable, this initiative signifies a step towards integrating AI into the HTA process.

- **Indonesia's HTA process enhancement:** Indonesia is undertaking a process to increase the efficiency of its HTA procedures. The initial step involves refining the topic selection process, followed by the introduction of an adaptive HTA process and a Multi-Criteria Decision Analysis (MCDA) approach to expedite decision-making. The new HTA business process is expected to be implemented in 2024.

- **HTA developments in Ukraine and the Philippines:** Both Ukraine and the Philippines are making strides in developing HTA methods for medical devices. In Ukraine, a cost-effectiveness threshold has recently been established, ranging from 1 to 3 GDP per capita. Additionally, an early scientific advice process is set to begin in 2024, with plans to establish a new independent HTA agency by 2026.

These initiatives collectively aim to enhance the HTA process, making it more efficient, consistent, and capable of addressing the evolving needs of healthcare systems globally.

THE EU HTA REGULATION (HTAR) IMPLICATIONS FOR EUROPE AND THE WORLD

Key Speakers: Chiara de Waure, Inaki Gutierrez-Ibarluzea, Dimitra Lingri, Marco Marchetti.

Main Points:

- **Legal and resource implications:** Participants emphasised the significance of the joint EU HTA being published as a regulation rather than a directive, making it legally binding for member states. Dr. Gutierrez-Ibarluzea questioned whether member states fully understood the implications of this regulation, particularly regarding the resource and time commitments required from national HTA bodies to contribute to EU HTA assessments.

- **Capacity concerns and report responsibilities:** There were concerns about who would be responsible for writing the Joint Clinical Assessment (JCA) reports, given that many national HTA bodies are already operating at full capacity. In Spain, it is anticipated that national HTA planning will need to account for the additional resources and time required to participate in EU HTA assessments.

- **Adaptation challenges in member states:** An audience member pointed out that ongoing discussions in Poland are focused on adapting Polish law to comply with EU HTA requirements, such as the stringent comparator selection criteria of the Agency for Health Technology Assessment and Tariff System (AOTMiT).

- **Uncertainties from the medical device industry:** From the perspective of medical device companies, there is uncertainty about when in the product lifecycle the JCA would occur and how it would interact with innovative payment mechanisms and local-level reimbursement. The need for company involvement in defining Patient, Intervention, Comparator, and Outcomes (PICOs) was reiterated, alongside the necessity for flexibility in accepting real-world evidence as well as randomised controlled trials (RCTs).

These discussions highlighted the complexities and uncertainties in implementing the joint EU HTA, emphasising the need for further clarity and preparation by member states and stakeholders.

We always welcome your thoughts and opinions on the topics raised at HTAi.

If you'd like to share anything from your Seville experience or hear how we can support you in getting your product to market, email our leadership team today at contact@remapconsulting.com or reach out personally by clicking their email below.

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