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Principles on Health Technology Assessment and other Value Frameworks

Health technology assessment (HTA) is a multidisciplinary process that applies scientifically based methods to assess the value of a health technology across different stages of its life cycle.[1] HTA can also refer to value frameworks used by payer organizations, clinicians, and private entities to assess the value of a technology.[2,3]

Our company supports the use of HTA and other value frameworks, alongside collaboration with HTA agencies and other stakeholders to enable the optimal use, design, and governance of HTA that accelerates and expands equitable patient access and promotes sustainability of health care systems.

Background

The goal of HTA is to inform health care decision-making and improve access to and utilization of technologies that improve health care outcomes effectively and efficiently.[1] As such, HTA should provide a comprehensive analysis that considers the medical or clinical benefits of the technology, as well as the ethical, economic, and societal factors. Such factors might include improved patient health outcomes, quality of life, treatment experience and adherence, and ability to return to work.

Globally, HTA policies and methodologies have been rapidly evolving. National HTA agencies are seeking to foster greater collaboration such as the European Union's HTA Regulation[i] and the cross-border alliance of HTA including Australia, Canada, the United Kingdom, Ireland, and New Zealand, among others. As collaboration and cooperation grow, the evolution of HTA should be guided by alignment on shared principles, rooted in evidence-based practices and established methodologies, while ensuring accessible, transparent dialogue among multi-sectoral stakeholders including clinicians, patients, regulators, payers, HTA agencies, and developers of medicines and technology. Moreover, it is crucial to maintain clear understanding of the needs of HTA agencies at the local level during interactions.[4]

[i] See also MSD policy statement on the European Union health technology assessment regulation. https://www.msd.com/wp-content/uploads/sites/9/2023/12/EU-HTA_MSD_NOV23.pdf

HTA principles

Our company supports the following principles for HTA and other value frameworks, and we are committed to collaborating with HTA agencies and other stakeholders to enable the optimal use, design, and governance of HTA that accelerates and expands equitable patient access and promotes the sustainability of healthcare systems.

Value assessment

HTA should enable efficient resource allocation to prioritize technologies that provide optimal value and benefits for patients and health care systems. It is important to have transparent methods to conduct value assessment.

- **Assess the full value of health technologies and their full range of benefits, risks, and costs.** This includes:
    - Direct medical effects to the patient (e.g., health benefits on disease and quality of life, adverse events, hospitalization rates),
    - Impact on caregivers and families (e.g., reducing caregiver burden, improving patient independence and autonomy) and society (e.g., improving productivity by reducing absenteeism, improving equity through addressing racial, ethnic disparities in access to health care),
    - Impact on healthcare systems (e.g., improving health care efficiency, shifting service delivery from in-patient to out-patient settings, addressing non-medical effects), and
    - Economic and fiscal impacts (e.g., generating savings beyond the health system budget).
- **Maintain independent assessments of the value from the budget impact**. We recognize that affordability is a central concern for health care systems, and we support the use of strategies and solutions such as innovative financing models, market access agreements, and price-volume or outcomes-based agreements. However, HTA focused solely on cost and cost containment does not prioritize the broader value of health technologies.
- **Conduct an independent analysis.** To ensure independence, the individuals or organizations conducting the HTA analysis should be separate from those making decisions related to clinical practices, budgeting, pricing, and reimbursement. This separation provides a clear division that enables impartial assessment of the health technology under review.
- **Apply HTA across technologies**. While acknowledging that in some jurisdictions, HTA primarily focuses on medicines, we advocate for a broader adoption of HTA methodology to assess both high value and new technologies.

Methodology

- **Meaningful use of comparators**. HTA should follow a clear, evidence-based methodology with well-defined objectives and research questions, meaningful use of potential comparators, relevant and reliable data, and acknowledge limitations and uncertainties. Potential comparators across all types of current clinical practice for a health condition, include medical devices therapeutic procedures, diagnostics, different medicines, and broader approaches including lifestyle and behavioral therapies.
- **Consider all relevant and reliable data.** HTA should collect data from all relevant sources including real world data (RWD) and evidence (RWE), observational research and patient generated data. Data ranking should be based on study quality, with clear disclosure of assessment standards and not be limited to peer-reviewed publications or publicly available data. Consensus approaches to handle uncertainty in these data are crucial for effective HTA utilization.
- **Acknowledge data and methodological limitations,** recognizing all sources of potential bias and uncertainty. Sufficient sensitivity analyses should be conducted to understand any uncertainty in the evidence that may be important to the decision.

Structural elements

While there is no single definitive model for value assessment within HTA frameworks, it is essential for HTA to align with the local health care system's context. HTA agencies should consider the following principles to govern their processes.

- **Ensure broad stakeholder engagement.** HTA should include health care providers, patients, citizens, technology developers, payers, government decision-makers, and others as appropriate. The unique needs for each stakeholder, especially patients, can help define the perspective on a condition in the value assessment. To ensure these stakeholders can effectively contribute to the HTA process, agencies should consider the time and training needs of each stakeholder.[5,6]
- **Align the HTA process within its local mandate**. To maximize societal impact and integration, HTA should align with local mandates, guidelines, and priorities. This involves considering key factors like disease burden, treatment effectiveness, practice variations, and resource allocation. HTA should prioritize timely access to innovation, cost-effective population health recommendations, evidence-based decision-making, and transparent processes as guided by the local country.
- **Ensure governance and processes are transparent and relevant.** To maintain trust and relevance, HTA processes should be transparent about their methodology, structures, timelines, and decision criteria. Agencies should also regularly review and update their findings considering substantial new evidence.
- **Ensure adequate expertise and infrastructure.** Where HTA processes are in place, the

system should ensure there is adequate expertise to appropriately interpret the HTA to inform decision-making.

Additional considerations for HTA collaborations

- **Any collaboration and joint work between HTA agencies** should focus on the common aspects of the countries and regions involved, since key elements of HTA analyses vary across health care systems, including current treatment options, patient population, cultural norms and values, health care costs, individual willingness to pay, and disease burden. Moreover, the assessment of economic value should remain at the country level since certain questions are specific and cannot be transferred across different healthcare systems.

References

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