Missed Signals: The Economic Implications of Current Health Technology Assessment Protocols for Diagnostics

Dr. Ricardo De La Fuente

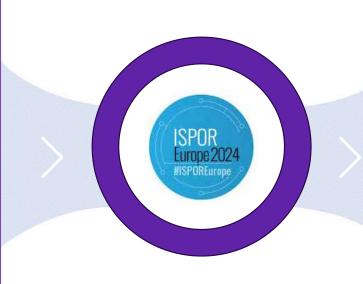
Educational Symposia - ISPOR 2024



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Introduction to the Educational Symposia

- Health technology assessment (HTA) evaluates health technologies to maximize the health of the population while improving the efficiency of the healthcare system
- HTA systems have well
 established methodologies for
 the assessment of
 pharmaceuticals. However,
 that is not the case for medical
 devices and other technologies,
 including in vivo imaging
 diagnostics.
- There is a big unmet need of developing HTA evaluation methods tailored for the assessment of diagnostic technologies



Panel

Alistair McGuire

Professor Health Economics, Dept. Health Policy, London School of Economics

Alexander Natz

Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

Montserrat Chivite

International Market Access Lead, GE HealthCare, Pharmaceutical Diagnostics

Laura Sampietro-Colom

Innovation Deputy Director, Head Evaluation of Innovation and New Technologies, Hospital Clínic Barcelona

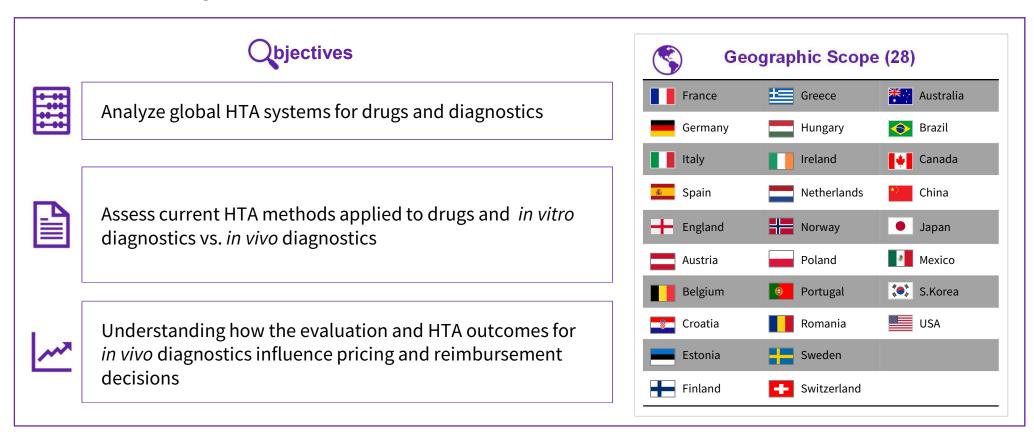
Moderator

Ricardo De La Fuente

Global Market Access Strategy Lead, GE HealthCare, Pharmaceutical Diagnostics



Research objectives



In vivo diagnostic methods are tests that are performed inside the body typically used for imaging vs. *in vitro* tests, which are performed outside the body on samples taken from the subject





Are the HTA methodologies adequate to assess *in vivo* diagnostic technologies?

- a) Yes, they are adequate
- b) They are not adequate because there is an opportunity to improve the evidence analysis?
- c) They are not adequate because there is an opportunity to improve the framework analysis?
- d) They are not adequate at all



HTA methods for the evaluation of pharmaceuticals are applied to evaluate *in vivo* diagnostics with minimum or no modification

HTA METHODOLOGY						
			<i>In vivo</i> diagnostics			
	Drugs	In vitro diagnostics (Medical device)	Molecular Imaging S		Contrast Media (CM) for MRI	
			Tracers	Modality	СМ	
Australia		Molecular Diagnostic	Medical Technology (Tracer & Modality)		Medical Technology (CM & Modality)	
Austria		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Belgium		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Brazil		Medical Technology	Medical Technology (Tracer & Modality)		Medical Technology (CM & Modality)	
Canada		Molecular Diagnostic	Medical Technology (Tracer & Modality)		Pharmaceutical Technology	
China		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Croatia		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
England		Molecular Diagnostic	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Estonia		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Finland		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
France		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Germany		Molecular Diagnostic	Medical Technology (Tracer & Modality)		Pharmaceutical Technology	
Greece		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Hungary	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Ireland		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Italy		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Japan		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Mexico		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
The Netherlands		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Norway		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Poland		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Portugal		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Romania		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
South Korea		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Spain		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Sweden		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
Switzerland		Medical Technology	Pharmaceutical Technology	Medical Technology	Pharmaceutical Technology	
USA		Molecular Diagnostic	Medical Technology (Ti	racer & Modality)	Medical Technology (CM & Modality)	

Markets also differ in the impact level of the HTA outcomes on P&R decisions

In vivo Diagnostics – HTA outcomes impact						
Role HTA body	HTA recommendations & funding	HTA embedded into decision-making process	Markets			
Mandatory	Binding Purchasers/ commissioners of care are legally obliged to consider the HTA outcome when deciding on coverage	Integrated	Australia, Belgium, England, Estonia, Germany, Hungary, Japan, Norway, Portugal, South Korea, Spain, Sweden			
HTA bodies are directly accountable to the MoH and are responsible for the pricing	Binding	Not integrated Only in certain cases	China, Croatia, Finland, Italy-Veneto			
and reimbursement of new technologies	Non-binding Negative recommendation is not necessarily associated with a negative coverage decision	Integrated	England, Poland			
Advisory Advisory HTA bodies offer		Integrated	Brazil, Canada, France, Germany, Ireland, Norway, South Korea, Sweden			
coverage recommendations, but decision-makers aren't required to follow them or	Non-binding	Not integrated Only in certain cases	Austria, Belgium, Croatia, Estonia, Italy-Regions, Netherlands, Spain, Sweden, USA			
consider them during negotiations with manufacturers		Not integrated Only in certain cases	Finland, Italy			

Note: one country could have multiple HTA bodies with different archetypes

Non-exhaustive



Suboptimal evaluation of *in vivo* diagnostic methods has an impact on pricing, access, and reimbursement decisions

Hurdle	Learning/Limitation	Implications	
HTA methods are	Assessment of <i>in vivo</i> tracers as drugs is inadequate because it is focused on treatment effectiveness to determine the degree to which improvements in therapeutic yield will result in improved patient outcomes	Insufficient value evaluation because assessing test effectiveness is completely different than evaluating clinical effectiveness of a drug	
inadequate to evaluate in vivo diagnostics	HTA methods for drugs strongly recommend demonstrating effectiveness by conducting randomized clinical trials (RCT)	RCTs are not the best option for <i>in vivo</i> diagnostic technologies trials impacting value demonstration and results of the evaluation	
	HTA methods for drugs do not allow strong value demonstration for <i>in vivo</i> diagnostic technologies	Major difficulties to demonstrate the clinical impact that <i>in vivo</i> diagnostics bring to patients, impacting future pricing and reimbursement decisions	
Lack of	HTA organizations do not provide consistent parameters of acceptability in terms of clinical and analytic performance, clinical utility, and economic impact	HTA is left to subjective judgment rather than objective assessment as to which tests meet, exceed, or fail to meet standards	
standardization for	There is a substantial variation in evidence requirements at the time of evaluating <i>in vivo</i> diagnostics (HTA Pharma)	Risk of getting an insufficient HTA outcome will impact P&R decisions	
HTA evaluations	HTA for pharma technologies compares patient outcomes but it may not always be feasible depending on the specific interventions	Substantial variation in evidence requirements for HTA methodologies to evaluate pharma technologies	
Disparities in impact of HTA recommendations	Almost half of markets (from this study) are issuing non-binding recommendations ; however, the importance and the weight of these recommendations may vary across countries	Non-binding recommendations are not so strict in practice so they could have strong weight on pricing & reimbursement decisions	
Tra recommendations	Disparities regarding impact of HTA pharma outcomes	Different levels of influence makes it difficult to prepare HTA submissions	





What is the most important limitation impacting the HTA assessments of *in vivo* diagnostic methods?

- a) HTA methods are focused on treatment effectiveness
- b) HTA methods for drugs do not allow strong value demonstration for in vivo diagnostic technologies
- c) Cost of the diagnostic applies to all patients "tested" to identify one
- d) Disparities on the impact of HTA recommendations



Inadequate evaluation of *in vivo* diagnostics results in unfavorable results with economic implications

Learning/Limitation	Economic Implications	
Costs associated with <i>in vivo</i> diagnostic methods could be dominant vs. the short-term economic savings when they are analyzed by conventional HTA methods	Limited efficient use of resources (e.g., avoiding unnecessary imaging and reducing the use of inappropriate therapies) due to restricted access to <i>in vivo</i> diagnostic methods	
HTA analysis does not always properly evaluate the additional economic value associated with the use of <i>in vivo</i> diagnostic methods on the long-term	Lack/limited reimbursement and coverage as the HTA evaluation of does not reflect the additional economic benefits of using <i>in vivo</i> diagnostic methods. The cost associated with them could potentially impact treatment cost-effectiveness when diagnostic testing is identified to be a driver in the health economic model	
In the evaluations for <i>in vivo</i> diagnostics using HTA for drugs, the cost of the therapy only applies to the patients treated, while the cost of the diagnostic applies to all patients "tested"	Restricted coverage because the economic benefits of <i>in vivo</i> diagnostic technologies are diluted as the HTA evaluation aggregates the cost to diagnose one patient	
When diagnostic testing is the SoC to profile all patients, it becomes unclear when and how to incorporate these costs	Diagnostic costs are directly related to the disease and the evaluated technology, meaning that these costs are recognized as direct costs in a health economic model	
Different HTA results were observed from the evaluation of the same <i>in vivo</i> diagnostic technology, even when similar evaluation criteria was applied–e.g., FDG PET/CT evaluation in colorectal cancer in DE (not reimbursed) vs. IT regional (reimbursed)	Potential different reimbursement depending on evaluation (method and criteria) applied, resulting in access disparity to <i>in vivo</i> diagnostics across markets	





What is the most important economic implication as result of inadequate assessment of HTA in vivo methods?

- a) In vivo diagnostic methods could be dominant vs. short-term economic savings
- b) HTA analysis does not always properly evaluate the additional economic value associated with the use of *in vivo* diagnostic methods
- c) When the test is applied to all patients, it becomes unclear when and how to incorporate these costs
- d) Different HTA results from the evaluation of the same *in vivo* diagnostic technology, even when similar evaluation criteria was applied



HTA methods have well established processes to assess drugs but not to assess *in vivo* diagnostic technologies

Diagnostics impact outcomes indirectly

- Patient outcomes depend on the intervention with the diagnostic and subsequent treatments.
- Diagnostic technologies improve health outcomes indirectly by guiding treatment decisions
- Diagnostic's value is based on **changes in patient management and their outcomes**, requiring evaluations of the effect of improved accuracy on decision making

HTA methodology differ across markets

- Although many HTA agencies use largely overlapping assessment criteria with clinical benefit being the main component, they differ in many aspects including the evidence quality, equity, and defining specific cost– effectiveness thresholds
- Heterogeneity across HTA systems makes it difficult to demonstrate value and anticipate assessment outcomes, impacting reimbursement decisions

Lack of specific HTA methods for diagnostics

- HTA assessments for health technologies & medical devices are not well established
- HTA bodies tend to apply general HTA approaches, designed to assess pharmaceuticals, and apply these to diagnostic technologies with little or no modification

Unclear methodology on HTA of diagnostics

- HTA organizations that specifically apply evaluation methods for diagnostics, focus on the evaluation of test accuracy, leaving other test-value benefits outside the assessment
- Lack of consensus on the HTA for medical devices with regard to dimensions, process, criteria, and methods
- There is a **significant uncertainty** about the **minimum evidence** needed to support an HTA submission and/or to get an evaluation result reflective of the test value



Pannel Discussion

- HTA & Evidence Generation:
 - ✓ Disparities on HTA in vivo imaging diagnostics across different evaluation stakeholders
 - ✓ Evidence generation hurdles for a new in vivo imaging diagnostic method
 - ✓ **Evidence planning** and value demonstration to get an optimal HTA outcome for *in vivo* diagnostic technologies
- Real World Setting:
 - ✓ Challenges in HTA evaluations for in vivo diagnostics
 - ✓ Linkage between HTA recommendations and procurement decisions
 - ✓ Insufficient coverage grouping
- Implications:
 - ✓ Lack of value recognition and rewards for new precision imaging diagnostics unlike new precision medicines
 - ✓ Implications of evaluation disparity and ambiguous methodology for *in vivo* imaging diagnostics



