Health Technology Assessment and Evidence-Based Decisions (HTA-EBD) Special Interest Group (SIG)

Working Groups (WG)

- HTA & Good Research Practices for Reimbursement Decisions
- HTA of Emerging New Technologies
- Global HTA Used in Healthcare Reimbursement

ISPOR Liaison
Nadia Naaman - Randa Eldessouki

Moderator
Kevin Mayo PhD
Denville, NJ, USA

Speakers
- Karl Matuszewski MS, PharmD
  Chicago, IL, USA
- Marcin Czech PhD, MD, MBA
  Warsaw, Poland
- Angeliki Angeli MSc
  Athens, Greece
- Bonnie Handke RN, MBA
  Minneapolis, MN, USA

The Road Map provides an overview of country-specific health care delivery systems, reimbursement and pricing approval processes, reimbursement terminology, and contact information for the most relevant HTA and other government organizations.

http://www.ispor.org/HTARoadMaps/Default.asp
Project Objective:
To provide a comprehensive, validated decision model for each country* that defines decision-makers and the decision-making process for coverage and payment of new and emerging technologies in pharmaceuticals, medical devices and diagnostics.

Project Goal:
- Level 1: (visual or narrative)
  - Name of Decision-Maker
  - Name of Evaluator/Advisory Organization
  - Primary factors included in the decision-making process.
  - A very brief description of the Decision-Maker should be included in the "Notes" section of this slide to include the coverage population or # of covered lives (reflecting the size of our chosen Decision-Maker).
- Level 2: (visual or narrative)
  - Leadership structure of Decision-Maker (decision-making organization)
  - History of Decision-Maker
  - Geographic coverage map
  - Tools required (i.e. HTA, health economic analysis, etc.)
  - Website address

*The countries being evaluated will be determined based upon resources available. We will begin with U.S., Australia, France, Germany, Sweden, Spain, Canada and the U.K. The long-term plan for the SIG is to develop a model for every country, in collaboration with the 2 other working groups, and post on the ISPOR website.

Definitions:
- **Decision-Maker (DM):** Defined as the payer (person or organization) who makes final decisions for coverage and payment of a product or technology.
- **Evaluator:** Defined as a person or organization who provides input into the decision-making process via HTA development but does not make final decisions for coverage and payment.
- **Decision-Making Process:** The HTA evaluation process, as defined in the public domain, for emerging new technologies (i.e. medical device, pharmaceutical, diagnostic) in consideration for coverage and payment.
Australia – Medical Devices

1. Australian Government / Minister for Health and Aging / Department of Health and Aging (DoHA)
2. Prostheses List
3. Medical Benefits Schedule
4. Medical Services Advisory Committee (MSAC)
5. HealthINPACT (sub-committee of MSAC)
6. Consultative Committees: Pathology Services Table (CPCST) / Diagnostic Imaging (CPCDI)
7. Executive Health Services Committee (EHSC)
8. Consultative Committees: Therapeutic Goods Administration (TGA)
9. Medical Devices Evaluation Committee (MDEC)
10. Australian Register of Therapeutic Goods (ARTG)
11. Australian Government / Minister for Health and Aging / Department of Health and Aging (DoHA)
12. Medl participating on these committees
13. Australian Health Ministers’ Advisory Council (AHMAC)
14. Nationally Funded Centers
15. Australian Register of Therapeutic Goods (ARTG)
16. Medicare Benefits Schedule
17. HealthPACT (sub-committee of MSAC)
18. Overseas HTA agencies
19. Australia and New Zealand Horizon Scanning Network (ANZHSN)
20. More details @ http://www.ispor.org/HTARoadMaps/Default.asp

France

Level 1

1. Ministry of Health
2. Comité Economique des produits de Santé (CEPS)
3. Transparency Commission (TC)
4. Marketing Authorization

Level 2

1. Ministry of Health
2. Comité Economique des produits de Santé (CEPS)
3. Economic dossier
4. Transparency Commission (TC)
5. Marketing Authorization
6. Price
7. ASMR Therapeutic Benefit

Spain

1. Central Government
2. Ministry of Health (Ministerio de Sanidad y Consumo)
3. HTA Agency Instituto de Salud Carlos III
4. National Health System / Interterritorial Council (Consejo Interterritorial del Sistema Nacional de Salud)
5. Regional HTA Agencies: Andalusia, Catalonia, Basque Country, Galicia, Madrid
6. Regional Departments of Health

More details @ http://www.ispor.org/HTARoadMaps/Default.asp
Germany

Federal Ministry of Health

Statutory Health Insurance (SHI)

Federal Joint Committee - Gemeinsamer Bundesausschuss (G-BA)

German Institute for Health Technology Assessment (DAHTA)

Institute for Quality and Efficiency in Health Care (IQWiG)

Sweden

18 County Councils (providers)

Swedish Council on Technology Assessment in Health Care (SBU)

National Corporation of Swedish Pharmacies (Apoteket AB)

Medical Products Agency (Läkemedelsverket)

External clinical consultants

TLV (Pharmaceutical Benefits Board) base the decision of reimbursement of prescription drugs on a HTA submission from the pharmaceutical company and external recommendations

We will diagram the major health systems of the world... one country at a time.

More details @ http://www.ispor.org/HTARoadMaps/Default.asp
Objective:
- To develop a global review of available health technology assessment information
- To develop a roadmap of health technology assessment information at the ISPOR website for health care decision-makers and payers.

Achievements:
- The ISPOR Global Health Care Systems Road Map

The Road Map provides an overview of country-specific health care delivery systems, reimbursement and pricing approval processes, reimbursement terminology and contact information for the most relevant HTA and other government organizations.

http://www.ispor.org/HTARoadMaps/Default.asp
The Greek Health Care System

- Mixed system of public-private funding and provision of health care services. Constitutes of:
  - The National Health System (ESY) (Public hospitals, Health Centers and the National Centre of Emergency Care)
  - The Social Insurance Funds
  - The Private sector (diagnostic centers, private clinics, laboratories, infirmaries etc.)
- Health care is funded by the governmental budget (general taxation), the social insurance (insured premiums) and private expenditure

Health Insurance

- Health Insurance in Greece is compulsory
- Assignment to a Fund depends on the occupation of the insured and not on his/her income level
- Insurance Funds are mainly funded through insured and their employers’ premiums as well as by the governmental budget, through social levies and subsidization of deficits.

The Pharmaceutical Policy

- Fragmented in 3 Ministries:
  - Pricing policy ➔ Ministry of Development  
    - 11-member Pricing Committee
  - Reimbursement policy ➔ Ministry of Health & Social Solidarity
  - Sick Funds ➔ Ministry of Employment & Social Protection

Pricing Policy

- Strict control
- Uniform retail price across the country (with the exception of areas where low VAT rate applies)
- Generics priced at 80% of branded

Prices

- Pharmacy Purchase Price (PPP)  
  Ex-factory price + wholesaler profit
- Retail price (RP)  
  PPP + pharmacist’s profit + VAT
- Hospital price (HP)  
  PPP - 13%

Retail Price Structure

Retail price= 100%
Pricing System
Market Decree 6/12.12.2005
- Average of the 3 lowest prices in Europe (2+1)
  - 2 are selected from the 15 EU original member states + Switzerland and one from the 10 countries joining the EU on 1/5/2004
- Once a price has been set, a 4-year monitoring period begins, during which the Ministry of Development investigates prices every year. If the verification price has changed, price readjustment
- Price bulletins are issued every 90 days
- Domestically produced medicines to be priced as the imported
- Patent expiry: Price of original to be reduced by 20% when generic reaches 5% of the market

Reimbursement System
- All marketed prescription medicines are reimbursed by Social Insurance (Law 3457/2006)
- Reimbursement rates
  - The standard reimbursement rate is 75%
  - 90% reimbursement for treatments for chronic conditions (such as osteoporosis, Parkinson’s disease, coronary heart disease, etc.)
  - 100% reimbursement for treatments for severe, debilitating or life-threatening disease (such as cancer, multiple sclerosis, hormone deficiency, etc.)
- Average co-payment rate: 15%
- Public hospitals dispense medicinal products to the poor at no charge

The New Reimbursement System
Law 3697/2008
Implemented from 1/1/2009 onwards
- Social Insurance Funds will reimburse the Reference Price (excluding co-payment)
- Reference Price = Retail Price – 3%
- The difference between the Reference Price and the Retail Price will be incurred by the pharmaceutical industry

Conclusions
- Recent reforms of pricing and reimbursement systems have:
  - Improved access to new medicines
  - Controlled parallel exports
- Reforms in Greece are implemented very slowly
- Fragmented regulatory framework
- No incentives to conduct R&D
- Economic evaluation: not included in decision making

Health Care System
- Insurance-budgetary model
- Services provided free at the point of service in case of sickness, injury, pregnancy, child-birth and confinement, as well as in prevention of diseases and health promotion
- The National Health Fund (NHF) – a non-profit body provided with legal personality - collects funds from premiums paid by citizens (with a total annual budget at the level of 15.3 bl.€ in 2008)
- NHF manages the funds and contracts providers to render health services

Insurance-budgetary model
Services provided free at the point of service in case of sickness, injury, pregnancy, child-birth and confinement, as well as in prevention of diseases and health promotion
The National Health Fund (NHF) – a non-profit body provided with legal personality - collects funds from premiums paid by citizens (with a total annual budget at the level of 15.3 bl.€ in 2008)
NHF manages the funds and contracts providers to render health services
Majority of resources are allocated for inpatient treatment (hospitals), followed by reimbursement of medications (~20%), outpatient general care and specialized outpatient care.

GPs are paid on a per capita basis.

Referral to specialists is needed with an exclusion of selected specialists and in case of certain diseases.

Dentistry coverage from public funds is limited; patients usually pay out-of-pocket.

In hospitals, where referral is also needed (apart from emergency cases), a DRG system has recently been introduced.

Private sector is in place with an annual turnover of ~200 mln € and market evolution of 20% per year.

Registration of medicinal product is granted either by the European Medicines Agency (EMEA) or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

Reimbursement approval is performed by the Ministry of Health.

Reimbursement criteria are the following:
- Necessity to provide health care for the society
- Making medicines accessible
- Safety
- Importance of a drug in a treatment of conditions associated with high epidemiological threat
- Influence of a drug on direct medical costs
- Affordability for the public payer obliged to finance healthcare services

There are 4 levels of reimbursement: 0% (non-reimbursed), 50%, 70% and 100% with price limits within international names groups and therapeutic groups.

Health Technology Assessment Agency (AOTM) was established as an advisory body to the Ministry of Health.

HTA reports prepared according to official HTA guidelines.

Prices for non-reimbursed drugs are free.

Price for the product submitted for reimbursement is set through a negotiation with a Drug Management Team of the Ministry of Health.

The following criteria are taken into account:
- Production cost (provided by the manufacturer)
- Cost of daily treatment
- Cost of standardized therapy
- Risk-benefit ratio compared to alternative pharmaceuticals for that indication
- Therapy costs per day in comparison to products with the same efficacy
- Evaluation of the economic impact on the national health system
- Estimated sales of the new pharmaceutical product
- Prices in countries with similar GDP

Pricing & reimbursement decisions are made on the national level and published in the official journal.

Reference pricing system:
- Within the group with the same international name (INN)
- Within therapeutic groups based on the same indication, comparable efficacy, the same way of administration and similar adverse effects
Objective: To assess current methods used globally in HTA and health care reimbursement.

On-line survey of 48 items:
- Primary methodologies, importance of attributes
- Breakdown by drugs, medical devices, other technologies
- 30 respondents to date with mix of regions/countries
  - Australia - 3
  - Canada - 2
  - Europe - 17
  - Latin America - 2
  - United States - 6

Type of agency/organization:
- 58% HTA only
- 7% reimbursement only
- 17% both HTA & reimbursement
- 17% other (e.g., 3rd party payers)

Role of HTA:
- Coverage & reimbursement decisions (79%)
- Clinical guidance (72%)
- Pricing decisions (58%)

HTA funding: 62% receive government funding at some level

HTA work performed most commonly by:
- In-house HTA staff (28%)
- Combined HTA staff and outsourcing to professionals (66%)
- Academia (38%)

Application of Drummond et al Principles to Survey Respondents:
- Proposed principles to be used for assessment of existing or establishment of new HTA programs
  - Evaluated adherence to principles across all sections
  - Focus on Methods (principles 5-9)
Effectiveness, RCTs (for clinical

Principle 6: HTAs should consider a wide range of evidence and outcomes

- RCTs (for clinical evidence, efficacy and causal inferences) alone are generally not sufficient for the conduct of HTAs

- Effectiveness, safety, costs, and cost-effectiveness are the most common attributes evaluated across clinical and evolutionary stages (>40% across technologies and evolutionary stage)

Primary Attributes Evaluated for New Drugs

HTAs require use of data from experimental, quasieperimental, observational, and qualitative studies, integrations of both endpoint and validated surrogate data, and assessment of the incremental impact of and trade-offs among multiple clinical, economic and social outcomes in clinically relevant populations.
Principle 7: A full societal perspective should be considered when undertaking HTAs

HTAs should adopt a broad societal perspective to optimize efficiency and societal benefit and to avoid and identify potentially distorted clinical decisions and health policies resulting from adoption of narrower perspectives used by various healthcare system stakeholders.

Principle 8: HTAs should explicitly characterize uncertainty surrounding estimates

All data are imperfect point estimates of underlying distributions that incorporate a variety of errors. All analytical methods are subject to biases and limitations. Thus, extensive sensitivity analyses are required to determine the robustness of HTA findings and conclusions. The limitations of the analysis should always be acknowledged.

Principle 9: HTAs should consider and address issues of generalizability and transferability

Examination of the generalizability and transferability of HTA findings across clinical populations and policy relevant perspectives is required, given the inherent variability of disease, intervention responses, and outcomes across patients, populations, providers, healthcare delivery sites and healthcare systems.