NAVIGATING HEALTH TECHNOLOGY ASSESSMENT PROCESSES AROUND THE WORLD

HTA – EBD Forum

ISPOR 13th Annual International Meeting
Toronto, Canada, May 2008

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

Global Survey to Assess Methods Used in HTA & Reimbursement Decisions

Health Technology Assessment & Good Research Practices for Reimbursement Decisions WG

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  Chicago, IL, USA
- Neil Palmer
  Ottawa, Canada
- Annie Chicoye
  Paris - France

Moderator:
Jalpa A. Doshi, PhD
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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: United States - 6 (mostly government perspective; only 2 respondents from the private payers)

Evolutionary stage when a new drug, device, or other technology (e.g., surgical procedure) is selected for assessment
- New (drug-76%, device-86%, other-66%)
- Established (45%, 69%, 55%)
- Emerging (38%, 48%, 45%)
- Declining (10%, 10%, 7%)

Why are technologies selected?
- Top 3 reasons:
  - Perceived impact on patient outcomes
  - Potential cost
  - Prevalence of condition
- Other reasons:
  - Selected new technology
  - Technology identified by external stakeholders
  - Perceived interest by public, academia, health professionals

Common Methodologies for Medical Devices by Stage

The most frequent methods for HTA are:
- systematic reviews,
- meta-analyses
- economic analyses
- modeling

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

Role of HTA:
- Coverage & reimbursement decisions (79%)
- Clinical guidance (72%)
- Pricing decisions (55%)

HTA work performed most commonly by:
- In-house HTA staff (25%)
- Combined HTA staff and outsourcing to professionals (66%)
- Academia (38%)

HTA funding: 62% receive government funding at some level

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When and Why Selected for Assessment?

Characteristics of Survey Respondents

Comparison of Top Methodologies for Drugs and Medical Devices by Stage

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Comparison of Top Methodologies for Drugs and Medical Devices by Stage
Systematic reviews alone are most commonly used to synthesize evidence for new and established devices.

The most common method of synthesizing evidence is with both systematic reviews and meta-analyses, primarily performed for new and established drugs and technologies. Systematic reviews alone are most commonly used to synthesize evidence for emerging technologies.

Effectiveness is a key attribute across technologies, and more commonly considered than efficacy.

Cost-effectiveness is not as frequently used for medical devices (MD) as it is for drug therapies (Rx).

More frequent use of safety and quality of life attributes differentiate the US

Common Attributes Evaluated for New and Established Medical Devices by Region

<table>
<thead>
<tr>
<th>Region</th>
<th>Most Common Attributes for New Medical Devices</th>
<th>Most Common Attributes for Established Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>Effectiveness, safety, costs, cost-effectiveness (&gt;70%)</td>
<td>Effectiveness, safety, and quality-of-life (&gt;60%)</td>
</tr>
<tr>
<td>USA</td>
<td>Effectiveness, safety, costs, cost-effectiveness (&gt;70%)</td>
<td>Effectiveness, safety, and quality-of-life (&gt;60%)</td>
</tr>
<tr>
<td>Australia</td>
<td>100% for all</td>
<td>100% for all</td>
</tr>
<tr>
<td>Canada</td>
<td>100% for all</td>
<td>100% for all</td>
</tr>
<tr>
<td>South America</td>
<td>Effectiveness, safety, costs, cost-effectiveness (&gt;100%)</td>
<td>Effectiveness, safety, costs, cost-effectiveness (&gt;100%)</td>
</tr>
<tr>
<td>All Regions</td>
<td>Effectiveness, safety, costs, cost-effectiveness (&gt;100%)</td>
<td>Effectiveness, safety, costs, cost-effectiveness (&gt;100%)</td>
</tr>
</tbody>
</table>
Most Important Attributes: Overall

Common methods for economic evaluation:
- Cost-effectiveness decision models
- Clinical trial based economic evaluations
- Economic analyses of observational databases
Perspectives: societal #1, then third party payer
Common types of analyses allowed: cost-effectiveness, cost minimization, cost/benefit analysis
45% (drug) and 35% (device) of respondents evaluated the economic analysis for conformance with PFT guidelines
International data for patient utilities/QoL is more likely to be accepted than international resource use data

Only 10% of respondents report that thresholds are used to determine whether technology is cost-effective
For more than 50% of respondents, estimation of uncertainty around CERs is mandatory

Most Important Attributes by Region

Region | Most Important Attributes for Drugs | Most Important Attributes for Medical Devices
--- | --- | ---
Europe | Effectiveness, safety (>70%), and quality-of-life (>50%) | Effectiveness, safety, and quality-of-life (>100%)
USA | Effectiveness, safety (>50%), and quality-of-life (>50%) | Effectiveness, safety, and quality-of-life (>100%)
Australia | Effectiveness and safety (>50%), cost-effectiveness, and quality-of-life (>50%) | Effectiveness, safety, and cost-effectiveness, quality-of-life (>100%)
Canada | Effectiveness, cost-effectiveness, and cost-effectiveness, and quality-of-life (>50%) | Effectiveness, safety, and cost-effectiveness, quality-of-life (>100%)
Latin America | Effectiveness and costs (100%) | Effectiveness and costs (100%)
All Regions | Effectiveness and safety (>90%) | Effectiveness and safety (>100%)

Economic Analysis in HTA

- Common methods for economic evaluation:
  - Cost-effectiveness decision models (drug-66%, device-76%, other-59%)
  - Clinical trial based economic evaluations (59%, 62%, 52%)
  - Economic analyses of observational databases (55%, 66%, 59%)
- Perspectives: societal #1, then third party payer
- Common types of analyses allowed: cost-effectiveness, cost minimization, cost/benefit analysis
- 45% (drug) and 35% (device) of respondents evaluated the economic analysis for conformance with PFT guidelines
- International data for patient utilities/QoL is more likely to be accepted than international resource use data
- Only 10% of respondents report that thresholds are used to determine whether technology is cost-effective
- For more than 50% of respondents, estimation of uncertainty around CERs is mandatory

Current HTA Process/Methods

- 100% of respondents consider HTA evaluations conducted by other organizations
- Only 28% repeat or update the assessment in regular intervals
- 89% report that a different organization has the responsibility to make the final decision on reimbursement
  - These other organizations only partially rely on the assessment
  - Maturity level of methods in the field of HTA is considered to be mixed:
    - Mature: 45%
    - Not mature: 48%
- Quality level of the HTA reports rated as “excellent” by majority (62-79%) of reimbursement bodies
- At some level, stakeholders are involved:
  - in assessments ~50% of time
  - in final decisions ~30% of time

Key Trends & Issues

Europe:
- Austria: need for observational studies/real life data (monitoring, registries, etc.), development of “acceptable” thresholds & methods for resource allocation
- Denmark: lack of good studies/data as inputs to the assessments
- France: Early assessment of technologies with mechanism for conditional coverage, lack of evidence for emerging technologies
- Germany: development of methodologies for health economic evaluations
- Italy: HTA moving as a priority to regional health care agendas
- Netherlands: selection of comparators/study populations, model structure & assumptions
- Portugal: selection of comparators, identification & quantification of costs, uncertainty analysis
- Sweden: link between theory and practice in HTA, uniform analyses for comparative purposes, assessment of diagnostics, timeliness, selection of bio/comparsions
- Spain: transparency, rigor, quality assessments, collaboration with other HTA agencies nationally & internationally, improved methods, training of new researchers
- Switzerland: horizon scanning, implementation of regular re-assessments

Canada:
- Need for convergence around grading bodies of evidence
- Indirect vs. direct meta-analysis
- Applicability of trials vs. potential for bias/confounding in observational studies
- Lack of good comparative data with possible exception of drug therapies

USA:
- Need for convergence around grading bodies of evidence
- Indirect vs. direct meta-analysis
- Applicability of trials vs. potential for bias/confounding in observational studies
- Differentiation of new technologies, esp. biotech
- Increased consistency in economic evaluations and reviews leading to recommendations
- Disease management, class review methods
- Standards for rapid HTA
Australia:
- Timeliness, rapid review methodologies, prioritizing topics for review
- Lack of evidence for some new & emerging technologies; small patient groups
- Increasing the use of economic analysis
- Assessment of diagnostic tests & use of linked evidence
- Surrogate outcome validity
- Validity of combined endpoints
- Assessment of public health programs

Latin America:
- Burden of disease
- Microsimulation methods
- Establishment and validation of methodological guidelines for economic evaluation and systematic reviews

Global Survey to Assess Methods Used in HTA & Reimbursement Decisions

Key Trends & Issues

Most HTA occurs at “new” or “established” stage
- Top methods used in HTA include systematic reviews, meta-analysis, cost-effectiveness analysis via modeling
- Attributes assessed and the importance of the attributes differ by country/region
- Key issues & trends in HTA include standardizing methods for economic evaluations and grading of evidence, lack of evidence and data for emerging new technologies
- Perception of maturity level of HTA methods varies

Decision-Makers & Health Technology Assessment Decision Making process

Health Technology Assessment of Emerging New Technologies WG

Decision-Makers & HTA Decision-Making Process

Countries Evaluated:
- Australia, Canada, Germany, Spain, Sweden, United Kingdom and United States

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 decision 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:
- Ministry for Health and Aged - Department of Health & Aging
- Pharmaceutical Benefits Advisory Committee (PBAC)
- Medical Services Advisory Committee (MSAC) (ST specialists)
- Health Policy Advisory Committee on Technology (Health FACT)
- Australian Health Minister’s Advisory Council (AHMAC)
Canada

Medical Devices & Non-Pharmaceutical Technologies

Provincial Ministries of Health (Medically necessary services [hospital and out-patient care])

Private Insurance & Cost (medically necessary)

Influencers

1. Provincial Government Agencies
   - Ontario COA (Health Technology Assessment)
   - Quebec: IMG (Institut de la médicale de la santé)
   - Mani: AINMP (Unilaterally funded via annual operating budgets approved by Ministry of Health (Provincial))
   - PhDs & AbbVie

2. Research Agencies
   - CIHR (Canada Institute for Health Research)
   - HRQoL (Health-related Quality of Life)
   - CCRG (Center for Clinical Research in the Genomics)

3. Other Influencers
   - Hospital Payers (Budget
   - Hospital Clinical Drugs & Evaluation Services)

Private Insurers & Payers

Alberta: AHFMR (Alberta Health Foundation & Medical Research)

Quebec: AETMIS (Agence d'évaluation des technologies et des modes d'intervention en santé)

Ontario: OHTAC (Health Technology Assessment)

British Columbia: HTA & Decision-Making Process

ontario focus)

National Health System

Interterritorial Council of Health (SBU)

National Corporation of Swedish Pharmacies

18 County Councils

Medical Products Agency

Swedish Parliament

National Corporation of Swedish Pharmacies

Swedish Council on Technology Assessment in Health Care (SBU)

1. (CDR) Common Drug Review

2. Specialized Agencies (i.e., CTV, CDB, CDA, etc.)

3. Other Provincial Drug Plan Agencies

4. Regional Drug Plan Agencies

All recommendations by national and provincial bodies are listed on public websites.

Influencers:

Provincial bodies and insurance firms often conduct separate analysis and not bound to the recommendations of CDR.

All recommendations by national and provincial bodies are listed on public websites.
Conclusion & Next Steps

To gain a better understanding of the HTA decision-makers and evaluators and the process used to determine coverage and payment for emerging new technologies.

Next Steps for Emerging New Technologies Special Interest Group:
- Conduct 1-on-1 interviews with Decision-Makers to further refine decision-making processes;
- Publish results, i.e. manuscript(s) in Value in Health, ISPOR website;
- Timeline: Q3/Q4, 2008
Pharmaceutical quality

Salary/risk
premiums

Income based contribution (60%)

Special Income taxation (40%)

Co-payments

Dental & Optical Care

Dental & Optical Care

Mandatory Health Insurance Funds

(CNAMTS, MSA, CANAM)

Complementary Insurance Funds

Special Income taxation (40%)

Hospitals

Population

BNF (NICE in UK)

Drug database

Epidemiology & Public Health

Clinical data

CT opinion

Medical Guidelines

National (HAS, Scientific societies) Other HTAs assessment

Literature
epidemiology & PRO

Registers

Databases

Ad hoc studies

Expert opinions

New labelling?

SMR & ASMR = rating

Class re-assessed?

Risk/benefit
Pharmaceutical quality

Health Ministry

Economic Committee for Health care Products (CEPS)
Chairman : Mr. Renaudin

3 to x (7) months

MA application

SEMA/AFSSAPS

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What is the process for access to reimbursement ?

What are the criteria considered by the Transparency Committee ?

Should the product be reimbursed ?
For which patients ? At which rate ?

Service médical rendu (SMR *)

Risk/benefit ratio

Severity of disease

Number of alternatives, if any

Position in therapeutic strategy (first/second line, sub group of patients)

Restricted reimbursement

Benefit for the public health

Rating

Major or « Important »
Moderate »
weak ou « Insufficient »

* medical service rendered

Prices for pharmaceuticals have been regulated since 1945
OTC/non reimbursable market share is limited to 8 %
Reimbursement is submitted to enlisting on positive lists (4)

What is the process for access to reimbursement ?

What are the data considered by the Transparency Committee ?

Epidemiology
Programs, registries, databases
Prospective of papers & htas assessment

CT opinion

Clinical data

Data supporting MA : EPAB/CHMP opinion
Other clinical data : on-going clinical trials, post-marketing surveillance
Risk management plan

National (HAS, Scientific societies) Other HTAs assessment

BNF (NICE in UK)

Drug database

Epidemiology & Public Health

Clinical data

CT opinion

Medical Guidelines

3 to 6 months

MAMA

HAute Autorité de Santé
Chairman : Pr. Bouvenot

Transparency Committee (CT)

Mission

Health, Finance and industry Ministries
Payers (mandatory & complementary)

Members

Health, Finance and industry Ministries
Payers (mandatory & complementary)

Members

Epidemiology & Public Health

Co-payments

Ad hoc studies

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MA application

SEMA/AFSSAPS
Should the product be priced at a premium price?

- « Amélioration du Service médical rendu » (ASMR *)

Clinical studies versus reference product:
- Cheapest, most prescribed, most recently enlisted
- Usual therapy eventually

Direct or indirect comparisons (meta-analysis, lit review, experts opinions)

Determined for each indication / sub-group of population

Rating versus comparator

Grade I: Major
Grade II: Important
Grade III: Moderate
Grade IV: Minor
Grade V: no ASMR

* Improvement of medical service rendered

What are the criteria considered by the Transparency Committee?

The CT assessment is determinant for price negotiation

Technical assessment by CT

- SMR rate
- ASMR rate
- Target population, position in therapeutic strategy, duration of treatment
- Utilisation profile, real life effectiveness, new clinical evidence

Economic negotiation with CEPS

- Reimbursement rate (100%, 65%, 35%)
- EU price corridor
- Premium price versus competitor (I to III)
- Sales / volumes price agreement

Re-assessment of ASMR with price/volume agreement consequences

No pharmacoeconomics are required, although they can be taken into consideration

Who pays for prescription drugs in Canada?

Canadian Health Care System

- Federal Canada Health Act defines Canadian “Medicare”
  - Universal access – all Canadians covered
  - Publicly administered
  - Coverage is portable across provinces
  - Comprehensive – most medical necessary services are covered
  - (But not prescription drugs dispensed outside hospitals)
  - Publicly funded (funding shared between federal/provincial governments)
- All provinces have established prescription drug benefit programs (no federal funding)
- Significant differences in coverage, eligibility between provinces
- Federal government has established drug benefit plans for:
  - Veterans, Native Peoples, Federal Prisons, etc.

Who pays for prescription drugs in Canada?

- Public (government funded) schemes
  - Over 65 years of age
  - Social assistance (welfare)
  - High drug costs to income
  - Targeted diseases (e.g., HIV/AIDS, MS)
  - Hospital in-patients (covered by hospital “global” budget)
- Private insurers provide coverage to working populations
  - part of “extended health care benefits” offered by employers, employee groups or associations (and more recently to individuals)
- No coverage
  - Uninsured (e.g., unemployed, self-employed, small employers)
  - Non-reimbursed drugs (e.g., lifestyle drugs)
- Total “out of pocket”
  - Individuals contribute 22% of total expenditures
    - no coverage + deductibles / co-payments

SMR 2006:
- 87 % rated major / important
- 3 % rated unsufficient

ASMR 2006:
- 11 % rated I to III
- 4 % rated IV
- 87 % rated V

Source HAS – report 2006

Canada

- Government 45%
- Private Insurers 33%
- Out of Pocket 22%

ISPOR Global Health care Systems Road Map

ISPOR Global Health care Systems Road Map

ISPOR Global Health care Systems Road Map

ISPOR Global Health care Systems Road Map
Canada Price Controls

Patented Medicine Prices Review Board (PMPRB)
- Federal quasi-judicial agency with a mandate to ensure prices of patented medicines are not excessive can order price reductions, repayment of excess revenues
- PMPRB limits prices of most new medicines to the range of prices in the same therapeutic class
  - Breakthrough / Substantial Improvement drugs may be allowed higher prices (international median price)
  - PMPRB limits price increases to increases in CPI
  - Prices of patented medicines can never exceed the range of international prices (among PMPRB reference countries)
- France, Germany, Italy, Sweden, Switzerland, UK, US
- PMPRB decisions have no direct role in reimbursement or decisions of drug plans to list (or not list) new drugs as benefits

PMPRB Price Review Tests

<table>
<thead>
<tr>
<th>New Medicine Category</th>
<th>Primary Test</th>
<th>Secondary Test*</th>
<th>All Patented Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Line Extension</td>
<td>Reasonable Relationship Test</td>
<td>Therapeutic Class Comparison</td>
<td>Prices of patented medicines cannot exceed international Maximum Price</td>
</tr>
<tr>
<td>2. Breakthrough / Substantial Improvement</td>
<td>Higher of Therapeutic Class &amp; Intl. Median</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>3. Moderate / No Improvement</td>
<td>Therapeutic Class Comparison</td>
<td>International Overview</td>
<td>(if primary test is not possible or not appropriate)</td>
</tr>
</tbody>
</table>

Existing Medicines: CPI Test: 3 year cumulative change in CPI
1 year "cap" (1.5 x CPI)
Prices of patented medicines cannot exceed International Maximum Price

PMPRB Guidelines do not consider "cost-effectiveness" in determining whether prices are excessive

*if primary test is not possible or not appropriate

Common Drug Review (CDR)

- The CDR is a program of the Canadian Agency for Drugs and Technology in Health (CADTH)
- The CDR reviews new drugs (and new indications) provides formulary listing recommendations to all publicly-funded drug benefit plans in Canada (except Quebec)
- The CDR conducts clinical and health economic reviews but not budget impact
  - Budget impact analyses need to be submitted to each of the drug plans and must be specific to each plan
- Each drug plan independently advises manufacturer of its listing decision and coverage status of the drug.
  - Affordability / budget impact are often the key factors for the plans

Common Drug Review Process

- The majority of new drugs are refused by CDR
- Those with a positive recommendation usually have restrictions

Common Drug Review Process: CDR Recommendations

- List: 4%
- List with Conditions: 28%
- Do not List: 54%
- List as Similar: 14%

Navigating Health Technology Assessment Processes Around the World

Thank you
Merci