The Advance-HTA partnership: From Concept to Delivery

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Key Trends

- Uptake and use of HTA principles across geographies: strengthening & implementation
- Discussion on whether HTA captures all important dimensions of value
- New technologies may require different approaches in assessment
- Heterogeneity in HTA recommendations across settings – opportunity costs?
- Moving beyond HTA to address affordability issues: MEAs, ‘special’ purchasing, ‘special’ funding
- Quality of life measures and preference elicitation
- Challenges to sustainable financing
  - Budget impact
  - Uncertainty when making coverage decisions
  - Incomplete access
  - Broader socio-economic impact
  - Incentives for innovation
  - Meaningful improvement in health outcomes
- Suggestions that current HTA systems need to change to an iterative process involving real-world evidence with greater scope for negotiations
- Regulatory developments back the above trend
Taxonomy of options for the sustainable financing of innovative therapies - 1

Healthcare Programmes

Financial Support Programmes
- AbbVie Patient Assistance Foundation (USA)
- Gilead U.S. Advancing Access (USA)
- NORD medication specific financial support programs (USA)
- ACCU-Chek Patient Assistance programme (USA)

Patient Education/Integrated Care
- Expert Patients Programme (UK)
- Care Transition Programme (USA)
- Transitional Care Model (USA)

Special Population Programmes
- WHO Health in Prison Population Programme
- Fraser Health Aboriginal Health Programme (BC, Canada)

National & Regional Plans
- Hepatitis C Action plan (Scotland)
- National Action Plan for Combating Antibiotic-Resistant Bacteria (USA)

Disease Management Programmes
- Congestive Heart Failure Program (USA)
- Diabetes Management Program (USA)
- Chiesi Asthma Management Support Programme (UK)
Taxonomy of options for the sustainable financing of innovative therapies - 2

Pricing and Funding Models

Managed Entry Agreements (MEAs)
- Finance-based MEAs
  - Discounts
  - Price-volume agreements
  - Price/dose cap
  - Price match
- Health Outcome-based MEAs
  - Pay-for-performance
  - Conditional treatment continuation
  - Eligible patient only
  - Coverage with evidence development

Special Funding Arrangement
- Earmarked Drug Funds
  - UK Cancer Drugs Fund
  - Scotland Rare Orphan Medicines Fund
- Individual Patient Treatment Requests
  - Scotland & Czech Republic
- Early Access Schemes
  - ATU - France
- Special Treatment Pathways
  - Highly Innovative Medicines Treatment Pathway – Czech Republic
- Priority Funds
  - Belgian Fund for RDs & Ods
- Central Purchasing
  - Strategic Fund (LatAm)
  - Revolving Fund (LatAm)
  - Joint procurement (EU)

Social Financing
- Social Impact Bonds
  - Peterborough Prison SIB - UK
  - New South Wales Foster Care Social Benefit Bond - Australia
- Health Impact Bonds
  - Fresno, CA – Pediatric Asthma HIB – USA

High-Cost Drug Mortgage
- Proposed model only
Taxonomy of options for the sustainable financing of innovative therapies - 3

Financing Mechanisms Linked to IP

- Prizes
  - Examples
    - Patent buy-out
      - Medical Innovation Prize Fund Act - USA (Proposed Model only)
    - Innovation Reward
      - Prize4Life $1 Million prize for ALS biomarker
      - Welcome Trust Pathfinder Award

- Health Impact Fund
  - Examples
    - Proposed models only:
      - Global Health Impact Fund
      - Antibiotic Health Impact Fund
      - Mini-Health Impact Fund

- Payor licenses
  - Examples
    - Proposed model only.

- Open Source Initiatives
  - Examples
    - The Synaptic Leap
    - The Open Source Drug Discovery Initiative - India

- Medicines Patent Pools
  - Examples
Taxonomy of options for the sustainable financing of innovative therapies - 4

Financing Mechanisms Linked to IP

- PPPs in Research and Development
  - Examples: Recent partnership between BARDA, IMI & AstraZeneca for antibiotics

- Corporate Bonds
  - Examples: Similar instruments are seen with the Green Bond, which provides capital for environmental projects and the Vaccines Bond, run by GAVI

- Priority Review Vouchers (PRV)
  - Examples: Coartem – Novartis 2009 PRV Used
    - Vimizim – BioMarin 2014 PRV sold to Sanofi/Regeneron for $67.5 million
    - Impavido – Knight 2014 PRV sold to Gilead for $125 million
    - Unituxin – United Therapeutics 2015 PRV sold to AbbVie for $350 million

- Market Exclusivity Extensions
  - Examples: Supplementary Protection Certificate (SPC)
    - Patent Term Extension
    - Data Exclusivity
    - Pediatric Indication extensions
    - Orphan Drug Market Exclusivity
What is this project trying to answer?

- What factors influence value for money decisions and how does HTA link with regulatory practices?
- Can we develop decision-support frameworks that improve the quality of the evidence required for different medical technologies?
- How can we incorporate other dimensions of value beyond economic evaluation? What would then be the impact on resource allocation?
- Is the process of and evidence on preference elicitation robust and is there scope for improvement?
- Are current HTA tools suitable across different categories of medical devices?
- How can we improve the implementation of and capacity-building in HTA in different settings?
Overall objective

- To contribute to the advancement of methods and practices for HTA in European and other settings by involving the wider stakeholder community in areas actively and heavily debated given their implications for decision-making and resource allocation
WP7 - Potential implications: lessons learnt, policy recommendations and advances in HTA

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Advance-HTA Consortium

Consortium Partners
1. London School of Economics and Political Science, UK (Coordinator);
2. London School of Hygiene and Tropical Medicine, UK;
3. University Castilla- La Mancha, Faculty of Health Science, Spain;
4. Institute for Economic Research, Slovenia;
5. Technische Universität Berlin, Germany;
6. Andalusian School of Public Health, Spain;
7. Istituto Superiore di Sanita, Rome, Italy
8. Pan-American Health Organisation, USA;
9. European Brain Council, (EBC), Belgium;
10. University Paris Est Créteil, France;
11. NICE International, UK;
12. Health Technology Assessment Agency, Poland (AOTMiT);
13. Dental and Pharmaceutical Benefits Board (TLV), Sweden

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