HTA ISPOR Health Technology Assessment Roundtables

ISPOR 30th HTA Roundtable [Asia-Pacific]
Saturday, 3 September 2016 & Sunday, 4 September 2016
Suntec Singapore Convention & Exhibition Center, Singapore

INTRODUCTION

The mission of ISPOR is to advance the science of health economics and health outcomes research (clinical, economic, and patient reported), and to foster and develop the use of this science in health care decisions. ISPOR holds annual roundtables to provide a forum for health care stakeholders to discuss, debate, and share information on health technology issues, as well as bridge the gap between health care decision makers and outcomes researchers to optimize health care decisions. The discussions of the ISPOR 30th HTA Roundtable focused on the role of HTA in health technologies and its impact on patient access to innovative health technologies.

SUMMARY

The ISPOR 30th HTA Roundtable themed "*HTA, Innovative Health Technologies and Patient Access in Asia-Pacific*" was held 3-4 September, 2016 in Singapore during the ISPOR 7th Asia-Pacific Conference. Lou Garrison, ISPOR President and Nancy Berg, ISPOR CEO and Executive Director delivered warm welcome addresses. The Roundtable featured 23 participants representing 14 countries, including 4 HTA agencies, 7 Ministries of Health, and some other public health institutes from across the region. The presentations covered the following topics: 1) HTA and patient access in Asia-Pacific, 2) Economic evaluation of complementary and alternative medicine (CAM). Delegates provided updates on current HTA efforts and achievements in their own countries/regions. They shared their unique experiences, views and perspectives on HTA in health care decision-making, and they also engaged in robust discussions focusing on impacts of HTA on patient access to innovative medical technology, improving HTA processes to accelerate and maximize patient access; different perspectives on innovation value, and patient access policy issues.

HIGHLIGHTS OF PRESENTATIONS

HTA Updates from ISPOR HTA Council

- HTA in ISPOR
  - Briefly overviewed the historical background and role of the ISPOR HTA Council. Emphasized the importance of developing collaborative relationships with WHO regions in order to expand ISPOR's role in regional HEOR communities
  - HTA Roundtable meetings currently held in North America, Europe, Asia-Pacific, and Latin America, and the Roundtable meetings in the Middle East and Africa are under consideration
- Initiatives of ISPOR HTA Council
  - ISPOR HTA training program launched in 2015
    - Featuring regional HTA experiences and varying perspectives from international HTA organizations, academia, and industry
    - Program tailored to the demands of different levels, regional and other settings
    - Upcoming training: Bogotá, Colombia, February 2017
  - HTA Council Working Groups
    - Good practices for synthesizing and using evidence in health care decision making
    - HTA initiatives on medical device
- HTA updates in Europe - EUnetHTA perspectives
  - EUnetHTA: the European network for HTA, developed HTA Core Model, close cooperation with European Medicines Agency, currently over 70 organizations participating in EUnetHTA Joint Action 3
  - EU Council: actively promote and strength EU cooperation on HTA

HTA in China

- New initiative - Healthy China 2030 Plan
  - Primary goal: to enhance people's health by health care reform and innovation
  - 5 radical health reforms: health coverage, primary health care, public hospitals, essential drug, and public health
  - Efforts focusing: promoting healthy lifestyle, optimizing health services, improving health security, building a healthy environment, and developing health industries
- HTA developments
  - The role of HTA for technologies in MOH perspectives: support evidence-based decision making in technology availability, accessibility, affordability, and sustainability across the lifespan of a technology
  - Current HTA used for drug, medical device and procedure, vaccine
  - HTA system development under China Health Act (in progress)
  - National documents/policies on HTA development (coming soon)
  - Building HTA hubs: HTA centers at national and provincial levels - ever-increasing demands for HTA

HTA in South Korea

- HTA required for national health insurance decision making since 2006
  - The Positive List System for National Health Insurance Pharmaceutical Benefit
  - New Health Technology Assessment (nHTA) for medical devices and procedures
  - Drugs exempt from HTA
    - New drugs used for a small number of patients
    - Conditionally approved with only phase II clinical trial data
- Patient access delays
  - Systematic review after regulatory approval (required for medical devices)
  - Insufficient safety and effectiveness evidence - medical devices and orphan drugs, etc
  - Increasing need for evidence generation and synthesis
  - Limited finance for the National Health Insurance
- Policies for improving patient access
  - Introducing Risk Sharing Scheme in 2014
  - One-Stop System for medical devices in 2016: a parallel process of approval, nHTA, and review for NHI coverage, shorten 6 months at least
  - Implementing supporting programs on evidence generation in 2013: for special medical devices and procedures that are failed during the new HTA
  - National Clinical Research and Development Fund (government) in 2015: support the comparative effectiveness research in the clinical phase

HTA in India

- Innovative technology and HTA
  - HTA problem statements from 4 sources: requisitions directly from MOH, submissions from National Health Innovation Portal, themes selected from HTA fellowship program, and requests from Technology Development Board (TBD), and National Pharmaceutical Pricing Authority (NPPA)
  - Submissions must meet the innovation criteria posted on the portal
  - HTA reports submitted to the national HTA committee
  - Approved innovations will be listed in the innovation database of MOH
  - State governments & the union territories receive money from the federal government to purchase innovations and scale them up
- Utilization of HTA in India
  - Approving a technology (mobile health technology for diagnosis of snakebites)
  - Change in a clinical practice (HbA1C)
  - Design improvement of technology
  - Increasing patient access through price control (drug-eluting stents)

HTA in Japan

- Health system
  - Public health insurance scheme covers the entire population
  - Ministry of Health, Labor & Welfare (MHLW): decision maker for health insurance coverage & pricing policies but has to consult with Central Social Insurance Medical Council (Chuikyo)
  - Chuikyo
    - 20 representatives from health insurers, health care providers, and public academia
    - Recommend prices to MHLW on medical procedures & prescription drugs, prices revised every 2 years
    - A huge influence on health care policy
- HTA developments
  - A new committee on cost-effectiveness evaluation was established in 2012 under Chuikyo
  - New pilot program in April 2016: trial introduction of cost-effectiveness evaluation for pharmaceuticals and medical devices
    - Program implemented with a new economic evaluation guideline containing 15 items
    - Targeting existing products (7 drugs & 6 medical devices) but not new products
    - Evaluation results only used for price adjustment decision but not for insurance coverage decision
    - Implementation of re-pricing expected in April 2018
  - Full-scale implementation of cost-effectiveness evaluation in the future
- HTA in pediatric health care in Japan
  - Child health financing and patient access to health care
    - Public subsidies for children: including rare diseases and chronic diseases
    - 0%-30% co-pay, copay caps for expensive medical costs, full or partly covered by local subsidy
    - Significant difference in subsidized coverage depending on different local authorities
    - Unmet needs of long-term healthcare among pediatric patients with chronic diseases and disabilities
  - HTA in pediatric care
    - Economic evaluation in pediatric health care is very rare
    - Limitations of current standard methodologies to evaluate cost-effectiveness, particularly health utilities in child health care
    - Technical limitations to exactly calculate QALYs among young children
    - Limited cognitive abilities to report their health by using abstract concepts in adult-specific methods
    - Need child-friendly tools to measure children's health outcomes - for priority setting and providing high quality and cost-effective health care to children

HTA in Australia

- Australian HTA values: improved health outcomes, efficient use of health care resources, confidence in the best available evidence, transparency, and timeliness
- Systematic consideration of cost-effectiveness is required for all new drugs of the Pharmaceutical Benefit Scheme (PBS, a government program providing subsidized prescription drugs)
- Key factors for decision making:
  - Five quantifiable:
    - Comparative health gain
    - Comparative cost-effectiveness
    - Patient affordability in absence of PBS subsidy
    - Predicted budget implications for PBS
    - Predicted budget implications for the Australia government health budget
  - Less readily quantifiable: confidence in the evidence, presence of effective alternatives, severity of the medical condition treated, ability to target therapy to patients likely to benefit most development of resistance (antimicrobials only)

HTA in New Zealand - NHC Perspectives

- National Health Committee (NHC): Independent, evidence-based advice to the Minister of Health on the management of non-drug technologies with a focus on models of care
- Models of care:
  - Safe, quality, measurable outcomes, value for money and affordability, sustainability
  - Two components of a model of care:
    - Pathway of care for 80% of target patient population
    - Business model that supports and manages the resource critical nodes in the pathway of care
  - Approach with emphasis on business and finances
  - View a technology from four angles
    - Clinical safety and effectiveness
    - Societal and ethical
    - Economic and affordability
    - Feasibility of adoption
  - Leverage existing and new technologies for high benefit and high value
    - Use existing technologies in new creative ways
    - Add disruptive new technologies
    - Find the best mix of new and existing technologies

Introduction on EXCITE International (**Ex**cellence in **C**linical **I**nnovation and **T**echnology **E**valuation)

- A new model of market entry for health technology innovation
  - Technologies engage the health system at a pre-market stage
  - Pre-market collaborative approach: link industry, payers, regulators, academic methodologists, clinicians, and patients in clinical development pathway
  - Accelerate the adoption of disruptive health care technologies
  - Greater certainty at reduced cost
  - Current 3 main markets: Canada, UK, USA
- EXCITE Core Evidentiary Bundle -a robust evidence package includes:
  - Clinical evaluation
  - Systematic review
  - Economic analysis
  - Human factors and usability assessments
  - Analysis of barriers to adoption

HTA in Singapore

- Health care system
  - Primary care: 20% public, 80% private
  - Secondary & tertiary care: 80% public, 20% private
  - Health care coverage: Government subsidies, MediShield Life, Medisave, Medifund
  - No national formulary, but has various hospital formularies with different prices
- HTA developments
  - HTA branch of MOH formally established in 1995
  - HTA for medical devices performed by HTA branch - for subsidy decision on high cost implants, development of clinical practice guidelines (CPG)
  - HTA for drugs performed by PEDU of Health Sciences Authority (HAS) - for subsidy decision on drugs, MOH Standard Drug List
  - Agency for Care Effectiveness (ACE) established in 2015
    - Provide recommendations on the appropriate use of health technologies
    - Support stakeholders in making more informed decisions on health policies and clinical practice
    - Recruited HTA talents from overseas due to lack of local talents

HTA in Malaysia

- Health care in Malaysia
  - Public and private sectors, dominated by public sector that owned by MOH
  - No national health insurance - no reimbursement
- HTA in MOH drug formulary
  - Evaluations performed by Evaluation Unit (EBM & PE), Technical and Drug Working Committee (TDWC), and Medicines Evaluation Review Committee
  - Drug selection/listing process: explicit and transparent process, evidence-based approach, comparative evaluation, economic evidence
  - Formulary includes some affordable essential drug list
  - Decision maker - MOH Drug List Review Panel, reviewed 3 times per year
  - New submission guideline in January 2016 - single channel submission only by pharmaceutical industry
  - Non-formulary drugs are allowed to use in some specific cases under special approval
  - Limited capacity to conduct HTA

HTA in Kazakhstan

- Health care
  - Kazakh national formulary system created in 2015
  - Forming national drug list by MHSD still slowly ongoing due to political factor - the ISPOR Kazakhstan Chapter, Kazakhstan Agency of HTA & Republican Center for Health Development currently involved
  - Joint Commission on Quality Health Services established in 2015 under MHSD - patient representatives have been included (patient organizations gaining attention from government)
- 3 types of HTA conducted:
  - HTA with national significance: focus on invasive procedures for informing national policy decisions
  - Rapid/mini HTA: for new drugs to support development of CPG for decision-making at local level
  - Full HTA: full range of HTA methods used
- Challenges: lack of national HTA policy framework & HTA guidelines, limited ability and capacity, etc

HTA in Taiwan

- Steps for introducing a new drug to the healthcare system
  - Marketing approval
    - Technical Review: CDE (Center for Drug Evaluation, 1998)
    - Appraisal: DAC (Drug Advisory Committee in Taiwan FDA)
    - Decision: Taiwan FDA
  - Reimbursed by the National Health Insurance Scheme since 1995
    - Assessment: HTA division in CDE since 2008: HTA report required within 42 days
    - Recommendation: Expert Group Meeting
    - Appraisal: Pharmaceutical Benefit and Reimbursement Standard (PBRS) Joint Meeting
    - Decision: National Health Insurance Administration (NHIA) in MHW
- Patient Access to health technology covered by NHIA or out of pocket
  - Comprehensive coverage
  - Easy access
  - Incentive for visiting primary care physician first
  - Free choice of health care providers
  - Low copay
- Increase in patient involvement: forming alliance of patient organizations, patient group educational activities

HTA in Philippines

- Philippine Health Insurance Corporation (PhilHealth)
  - Government-owned, attached agency of Department of Health
  - Manage National Health Insurance Program
  - Cover 92% population, fragmented service coverage, out-of-pocket expenses is 57%
- HTA developments
  - HTA was introduced to Philippines by PhilHealth in 1993, and a HTA committee was established but it became inactive in 2011 due to leadership changes and lack of support
  - Gained attention in recent years - the HTA Committee included in the National Health Insurance Act of 2013
  - Institutionalization of HTA in Philippines: in progress with supports from PhilHealth, WHO, Department of Health, FDA, and the ISPOR Philippine Chapter
- Resent HTA activities in PhilHealth: for maximizing coverage and providing financial protection
  - Developing a Guaranteed Health Benefit Package addressing the most disease burdens through the most cost-effective interventions
  - Using HTA to prioritize coverage for those new interventions that are not covered by the Guaranteed Health Benefits Package

Complementary and Alternative Medicine (CAM) in South Korea

- Current status of CAM (TKM: Traditional Korean Medicine)
  - Growing needs for CAM in Korea
  - Vigorous government efforts for promoting collaboration between Korean medicine & Western medicine
    - Institutional change since 2010 - unique medical model
      - Added Korean medicine departments in general hospitals
      - Established Western medicine departments in Korean medicine hospitals
    - Formed Monitoring Center for Korean Medicine & Western Medicine Collaboration (MCMC) in 2015
  - 5-year comprehensive plan to foster and develop traditional Korean medicine (2016-2020)
    - CPG development for TKM
    - Economic evaluation required for CPG development
  - Reinforcement of national health insurance coverage for TKM is the major issue of the government's health and welfare policy.
- 1st pilot project of **K**orean medicine and **W**estern medicine **C**ollaboration (KWC) in MCMC
  - Project objectives
    - Establish KWC patients registration system
    - Monitor patients treated with KWC
    - Monitor patients with the 4 major diseases treated with KWC
    - Comparative effectiveness research & economic evaluation for KWC
  - Recent accomplishments
    - Established a strong research organizational structure with 38 researchers from 4 medical institutions
    - Established web-based clinical study support system approved by Korean CDC for electronic data capture & clinical data management
    - Established big data analyzing system enabling directly access to the claim data of HIRA for cost effectiveness analysis
  - Future works
    - Patient registration study on KWC
    - Current status survey on KWC participating hospitals
    - Health insurance cost study on KWC practice