Health Technology Assessment in Korea: what can we and can't we achieve?

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by

Yang, Bong-Min, PhD
Seoul National University
Seoul, South Korea

Outline

- Korean HCS
- Policy background
- New policy on drug
- Implications
- Issues

Health Care System

- Social health insurance (SHI)
  - covers 96% of population-premium financed
  - rest 4% by Medicaid –tax financed
  - Single payer system: NHIC
  - Financing by premiums (partially by government general revenue)
  - Limited coverage of services: MRI, Ultrasono, some expensive therapies not covered by NHI
- Dominant method of payment/reimbursement
  - fee-for-service

Mounting Pressure on Financial Sustainability of KNHI

- Demand and supply factors
  - Continuous expansion of coverage
  - Population aging
  - New technologies
  - Growing demand for and expectation of quality health care by consumers
- Structural factor: Fee-for-service

NHI Reforms Considered

source: Health Insurance Reform Committee (2004)

- Triggered by financial instability of NHI system, the following changes were suggested
- Change in reimbursement method
  - FFS ⟶ DRG ⟶ Global Budgeting
- Design a separate elderly care system
- Introduction of economic evaluation into health care delivery on
  - device
  - ***pharmaceuticals***
  - procedures

Introduction of Economic Evaluation into Pharmaceutical Reimbursement Decisions: HTA Policy (January 2007)

Background(1)

Share of drug expenditure out of total K-NHI expenditure (2001~2006)

(unit : 100 million KRW, %)

	2001	2002	2003	2004	2005	2006
Total exp.	178,195	190,606 (7.0%↑)	205,336 (7.7%↑)	223,559 (8.9%↑)	247,968 (10.9%↑)	285,580 (15.2%↑)
Drug exp.	41,804	48,014 (14.9%↑)	55,831 (16.3%↑)	63,535 (13.8%↑)	72,289 (13.8%↑)	84,041 (16.3%↑)
Drug share	23.5	25.2	27.2	28.4	29.2	29.4

Note 1: share of drug expenditure out of total KNHI expenditure has been increasing from 23.5% (2001) to 29.4% (2006)

Note 2: nominal drug expenditure increased from 4.2 billion KRW to 8.4 billion KRW in 5 years

Note 3: annual increasing rate of 15.0% is compared to 10.6% of KNHI other medical expenditure

Background(2)

Fast Introduction of New Drugs into K-NHI Reimbursement List: 2003-2005

No. of Countries Adopted		0	1	2	3	4	5	6
164 New Drugs to Korea	Number	7	67	32	20	17	12	9
	%	4.3	40.8	19.5	12.2	10.4	7.3	5.5

Note 1: Annually, about 50 new drugs are introduced into Korean NHI
Note 2: There were 7 Korean new drugs during 2003-2005 period
Note 3: Korean NHI introduced 67 (out of 164, 40.8%) new drugs as 2nd country in the world; 32 products (19.5%) 3rd in the world

Source: MOHW, Government of Korea

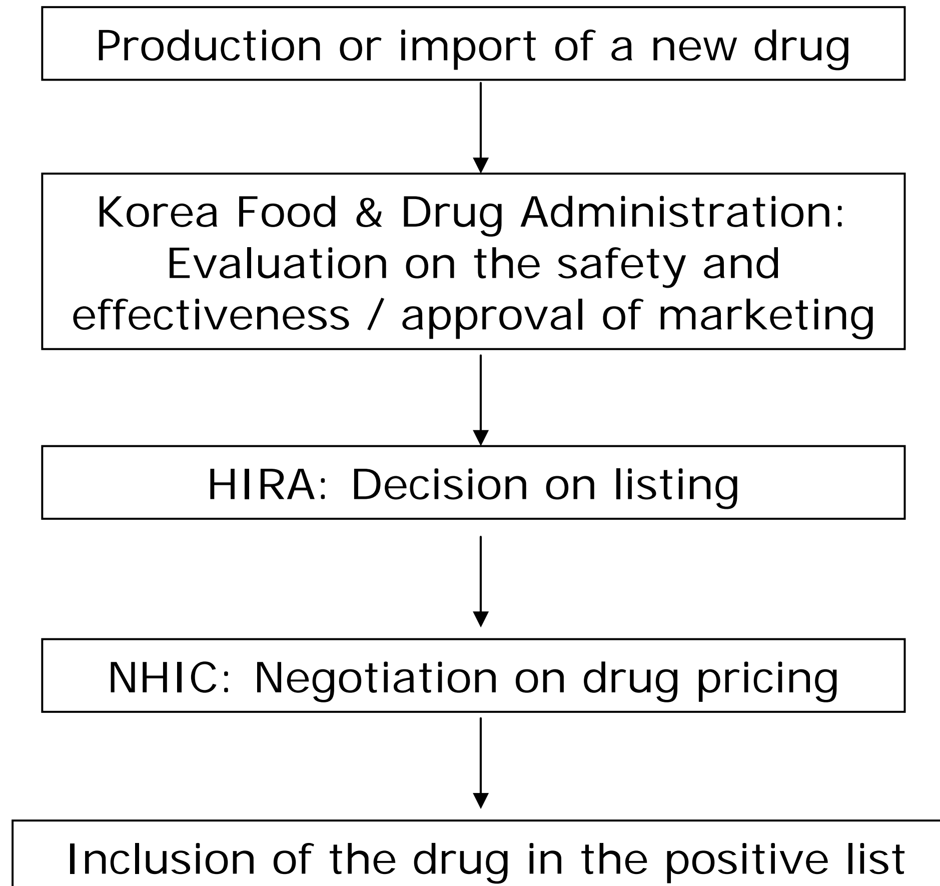
Other Concerns

- The number of drugs reimbursed in the NHI amounted to over 21,000 in 2006. There were large variations in prices among drugs with same effectiveness
- Drugs had been enlisted in the reimbursement list with little consideration of budget impacts and cost-effectiveness
- Value for money in drug expenditure necessary to be examined at the system level

Policy changes

- As a measure of getting value for money in drug expenditures, the government introduced a “Positive List System” in December 2006, which was characterized as
  - Selective listing of drugs
    - Enhanced importance of cost effectiveness in addition to clinical effectiveness
  - Separation of decision on listing from pricing
    - New procedure for price negotiation

Procedure for reimbursement decision



Listing new drugs

- For new drugs to be reimbursed under the NHI, submission of pharmaco-economic evidence became mandatory from 2007
- Decisions to reimburse new drugs decreased while decisions not to reimburse increased
  - Between Jan 2007 and June 2009, a total of 169 drugs applied for reimbursement in the NHI
  - About 25% were denied reimbursement
  - About 80% of those denied drugs were due to lack of evidence on cost-effectiveness

Pricing new drugs

- Pricing process was separate from decision making on listing from 2007
  - Once HIRA decides to reimburse a new drug in the NHI, the manufacturer has to negotiate its price with the National Health Insurance Corporation (NHIC)

- A price-volume arrangement was introduced to control drug expenditures
  - Considering budget impact, NHIC negotiates price based on the expected sales of new drugs as well as their substitution effect. If actual sales exceed the expected ones during a specified period, the price of the drug should be reduced proportionately

Re-assessment of listed drugs

- Drugs reimbursed under the previous "Negative List" system were allowed to remain in the new "Positive List"

- Starting from 2007, 5-year-long re-assessment of the listed drugs was planned. In 2007, two therapeutic groups of drugs, migraine and hyperlipidemia, were re-assessed. In 2009-2010, all hypertension drugs currently in the list are under re-assessment

- The main criterion for decision on whether to keep them in the list or out of the list is cost-effectiveness in addition to clinical effectiveness

Implications of recent policy

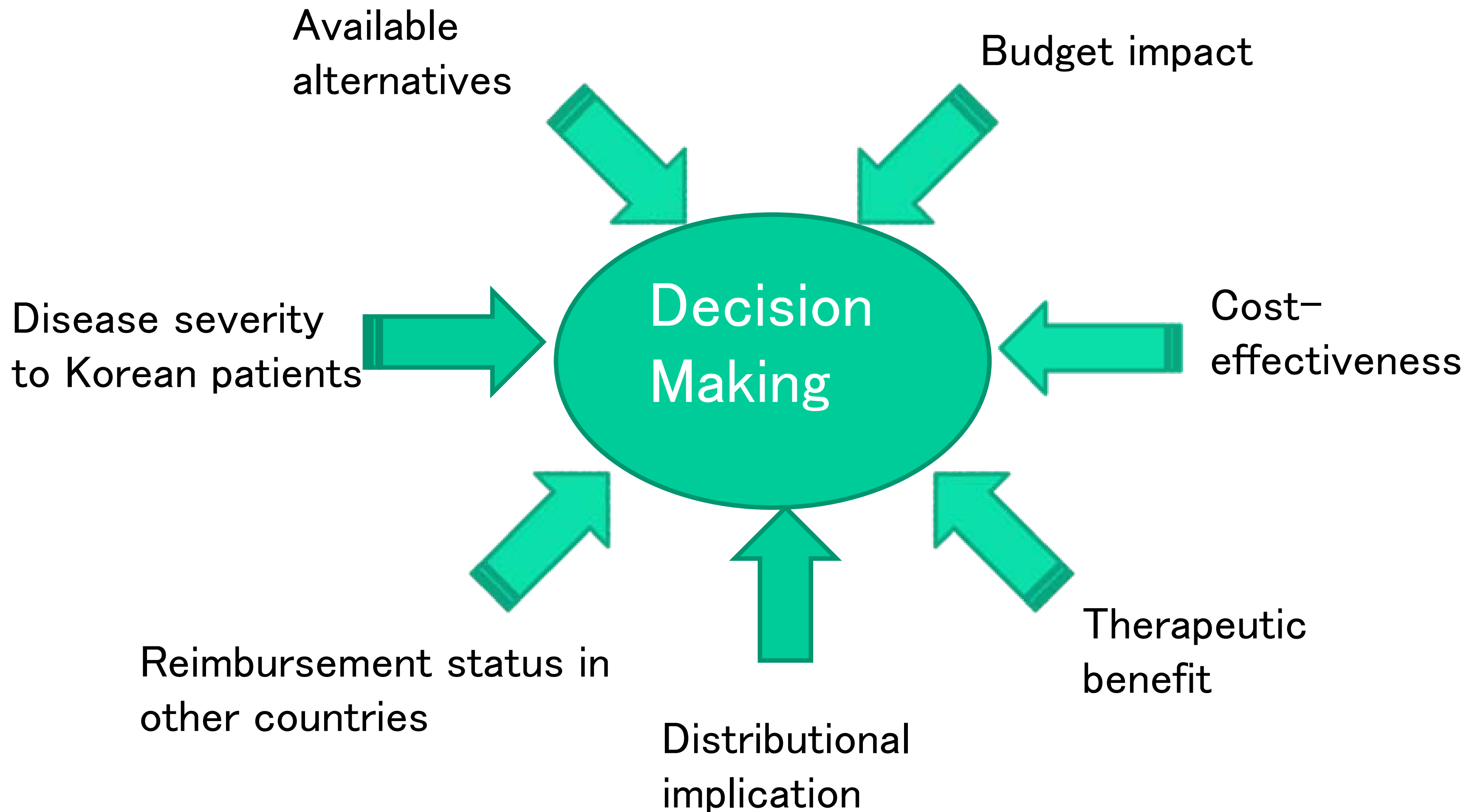
- Health system effect
  - Value for money sought at the system level
- Economic effects
  - Possible to utilize drugs with similar therapeutic effects at lower costs
  - Price cut as a byproduct of re-assessment of the listed drugs
- Access to new drugs
  - Delayed due to the fourth hurdle and two-tier process for listing and pricing
  - Enhanced access to cost-effective quality drugs
- Dynamic efficiency
  - Industry R & D may be affected, both positively and negatively
  - Need to look at incentive compatible pricing

"Value" alone is not enough

- HTA → (when cost-effective) value for money proven →

  need to check our affordability
- Just because HTA demonstrates cost-effectiveness of an intervention does not mean we can afford it
- Other factors need to be considered
- At the same time, what is NEW is wonderful, but we also look at the disinvestment

Factors Considered in Appraisal



Pervasive Misunderstanding on HTA(EE)

- HTA(EE) is an economic tool to cut prices, costs, and expenditures
  - Which is not true (think about the concept of ICER and threshold)
- But the truth is
  - Through EE, we only check the ***value for money*** of a new or an existing intervention
  - That is, we obtain a nice piece of information for decision making, which is not the same as decision itself
- If price cut is our primary concern, we may use other policy tool

Some limitations/issues involved with pharmaco-economic data preparation: case of Korea

Defects and Uncertainties with EE Data

- EE data (comparing the intervention with the comparator) in principle is embedded with defects and uncertainties
- Outcome data: (to be provided)

Uncertainty(2)

- Utility weights (for QALY): most likely from Western world
- Cost/utilization data: (to be provided)

Uncertainty(3)

- In real analyses, all the above are supposedly overcome by ***assumptions and sensitivity analyses***
- Okay? Or not?
- No matter what, it is always better to reduce the level of uncertainties involved
- Therefore, EE itself in a health care system setting has to be a continuous evolving process

Uncertainty(4)

- Then, how about decision w/o EE data?
- Can we safely claim that the results from decisions for our society is better w/o using EE at all?
- When one asks how our limited insurance revenues are used for our population health, how can you answer such questions?
- Despite all sorts of defects and uncertainties, there are reasons for using EE in health care system's decisions for resource use

What can’t we achieve through HTA?

- Value for money, for sure
- But all other things, such as
  - Price cut
  - Expenditure cut
  - Financial sustainability of HTA related sector
  - Restructuring health care system

are beyond its capacity, though not impossible

Concluding Comments

- Evident that role of HTA/EE in the allocation of scarce health resource is important, but its role is somewhat limited by nature of decision process
- We need it, but we shouldn't expect too much from it
- HTA in a country is a continuously evolving process, trying to improve the quality of evidence being produced
- International agencies such as WHO, World Bank, ADB suggests to use it for efficient allocation of health budget

Comments(2)

- Global private aiding agencies including Gates Foundation, Rockefeller Foundation, UK-DFID, GTZ,,, also take similar stance
- With Korean EE, added constraint is the high level of uncertainty with available data – a long way to go for reliable data base
- However, no system can be perfect from the beginning
- Under many constraints, Korea′s HTA policy started
- We expect refinements and improvements of the system over the years as it goes