Abstract

Comparative study on the health technology assessment systems of major countries

Sukyeong Kim, Sang-Jin Shin, Jeong-Su Park, Jun-Ho Kim, Young-Ji Baek, Eun-Bi Ko,
Chae-Min Shin, Min-Jeong Kim, Jang-Mi Yang
National Evidence-Based Healthcare Collaborating Agency

▢ Introduction

Ⅰ. Background and objectives

It has been believed that new health technologies have been one of the major driving forces that are bringing increase in the healthcare expenditure over the past several decades. Many researchers have reported that as much as 50% of the increase in healthcare expenditure can be traced to changes in health technology. It has also been reported that the rates of adoption or diffusion of new health technology differ greatly across countries. Meanwhile, health technology assessment field has been experiencing a speedy growth because it plays a major role in political and clinical decision making pertaining to the adoption and diffusion of new health technology. Health technology assessment is a multidisciplinary field that addresses the clinical, economic, organizational, social, legal, and ethical impacts, which provide the information required to make decisions. Therefore, discussions and exchanges regarding the methodologies and processes are currently robust. In the 2000s, Korea's national health insurance finance consolidation culminated into a single payer system. Later, in 2006, the Positive List System was introduced to pharmaceutical benefit based on the economic evaluation data and cost effectiveness. Subsequently, in 2007, the New Health Technology Assessment System was introduced for the systematic review and guarantee safety and effectiveness of medical procedures and diagnosis.

Although Korea's health technology assessment system has been developed while taking into account the nation's unique circumstances and history, it is necessary to refine it based on a continuous review of its universality and rationality. In this regard, an international comparison of health technology assessment systems will provide a valid foundation for our system.

The current study aimed to compare and analyze the health technology assessment systems in major nations around the world. The specific objectives of the study were as follows;

- investigate and analyze each country's socioeconomic characteristics and healthcare system
- analyze each country's health technology assessment system focusing on the procedures and roles of relevant agencies
- analyze and compare the specific health technology assessment results available

Ⅱ. Study method

In order to achieve the study objectives, we established a framework for the comparative analysis of the health technology assessment systems. The decision making consisted of market entering, health technology assessment, appraisal for benefit coverage, and reassessment, all of which were classified in terms of decision details, evidence produced, operational characteristics, and other environmental factors for comparison. We checked the performance of the health technology assessment if available.

The nations included in the comparative analysis were selected considering the national health care system, health technology assessment activities, and their regional location. The countries selected for the study included the UK, Sweden, Canada, Australia, Thailand, France, Germany, the Netherlands, the U.S., and Korea. A literature review, visitations, expert consultation, and

discussions were conducted for the analysis of the current health technology assessment status in these countries.

For case studies pertaining to specific health technologies, the most representative health technologies were selected list and then relevant reports on websites or other sources that were made available to the public, were reviewed.

▢ Study results

Ⅰ. Comparison of health technology assessment systems by country

○ Market approval

Market approval is done at a national level. In the case of Europe, however, the EU provides approval, too. Further, the parallel assessment for approval and benefit is currently introduced.

Table S-2. Current market approval practices by country

Characteristics	UK	Sweden	Canada	Australia	France	Germany	Netherlands	US	Thailand	Korea
Licensing agency	EMA, MHRA, MCA/ MDA	EMA,MPA	Health Canada	TGA	LNE/G-MED, EMA/ANSM	EMA, BfArM/PEI	EMA, CBG-MEB	FDA/ CDER	Thai FDA	MFDS
Period	150-210 days			12 months 180 days				180 days		120 days

Characteristics	MHRI device guidance	NOC PMPRB price control	ARTG	FDA-CMS parallel review	NLEM ministry of trade

○ Summary of health technology assessment systems by country

If a single organization is to be in charge of a nation's health technology assessment, the organization is typically broken down into agencies which are responsible for medical practice, pharmaceutical practice, and miscellaneous. The CADTH in Canada, HAS in France, ZINL in the Netherlands, and HITAP in Thailand, are examples of the single organization system. In the UK, decisions are made based on the review results of the health technology assessment performed by the NETSCC, rather than a direct assessment by the NICE. The role of the AHRQ in the U.S. is more pronounced in the areas of research project planning and resource allocation for the projects.

In Sweden, Australia, and Korea, assessment is categorized based on the health technology type. For instance, the SBU practice and comprehensive health technologies, the Swedish health technology assessment council is focusing on medical, while the TLV is responsible for the assessment of pharmaceutical and dental benefits. In Australia, the MSAC, PBAC and PLAC conduct the assessments of medical services, pharmaceuticals and medical devices, each. In Germany, the IQWiG performs the assessments commissioned by the G-BA, which is an appraisal and decision making council. In particular, the IQWiG evaluates pharmaceutical products in accordance with the AMNOG regulations, as commissioned by the G-BA, and submits the results to the G-BA.

Table S-3. Summary of health technology assessment systems by country

Characteristics	UK	Sweden	Canada	Australia	France	Germany	Netherlands	US	Thailand	Korea
HTA-organization	NETSCC (university) (NICE)	Health technology SBU/ pharmaceutical products TLV	CADTH regional RHAs, hospital	MSAC PBAC PLAC	HAS	DAHTA IQWiG (G-BA)	ZIN	AHRQ private insurance company	HITAP	Pharmaceutical products : HPA, Medical practice: NECA
Operation characteristics	National	National /County	Federal /Provincial	National	National	National	National	Federal	National	National
HTA-finance	Central government	Central government	Central /local governments	Central government	Publicly financed and agency revenue[a)]	Hospitalization/additional cost per outpatient visit[b)]	Central government/health insurance	Insurer /federal /state government	Central government	Insurer /central government

○ Items for the assessments

All the countries assess the clinical effectiveness. Cost-effectiveness, although typically recommended, is not specified in the case of Germany; however, the Positive List System is available for some medical devices. The ICER is commonly used to determine the cost-effectiveness. However, few countries indicate the specific ICER threshold.

Table S-4. Assessment items by country

Category	UK	Sweden	Canada	Australia	France	Germany	Netherlands	US	Thailand	Korea
Assessment item	Clinical effect, cost effectiveness	Clinical effect, cost effectiveness	Clinical effect, cost effectiveness	Clinical comparison effect, cost effectiveness	Clinical benefit SMR /clinical benefit improvement ASMR/cost effectiveness	Additional benefit/economic feasibility(efficiency)	Necessity, cost effectiveness, level of financial burden on ,individual	Safety, cost effectiveness, appropriateness, etc.	Safety, effectiveness, cost effectiveness, effects on budget	Safety, effectiveness/substitution, cost effectiveness, effects on budget
Economic feasibility, assessment trend	ICER	ICER	ICER	ICER	ICER	Efficiency frontier	ICER	CER; Effectiveness only	ICER	ICER
	NETSCC: direct assessment, NICE: dossier + academia	TLV: dossier, SBU: direct assessment	CADTH CDR: dossier, SR: direct assessment	Dossier + academia (contract)	Dossier + direct assessment	Direct assessment + dossier	Direct assessment + dossier	AHRQ direct assessment + academia + dossier	Direct assessment + dossier	NECA: direct assessment, HIRA: dossier
Coverage recommendation	NICE Peview committee	TLV SBU	CADTH-CDR	PBAC PLAC MSAC	CEPS/ UNCAM CEPS UNCAM	G-BA	ZIN.	CMS	Committee for Benefit Package Development	Benefit assessment-pharmaceuticals, treatment material
Determined coverage	National -NHS	Local-county (DTC)	Local-province (Minister)	National MoH	National MoH UNCAM	National G-BA	National (ZIN./ NZa)	National (CMS/ NCD)	National /AWS	National/ MoHW HIPDC

(HIPDC: Health Insurance Policy Deliberation Committee)

○ Assessment process and transparency

Health technology assessment is typically led by experts who can also review the methodologies and results submitted. However, the social value needs to be evaluated by various interest groups even citizens. In fact, information sharing is becoming more commonplace in health technology assessments.

Table S-5. Assessment process and participation

Country	UK	Sweden	Canada	Australia	Thailand	France	Korea	Germany	Netherlands	US
Composition	Party of interest	Party of interest	Expert+ non-expert	MSAC: expert	HITAP: party of interest	CT expert+ non-expert (-)	Expert	Expert + party of interest (-)	ZINL expert	Expert council expert+ patient representative
Participation	o	o	O	o	o	o	△	o	△	o
Assessment period (publicly announced)	18-24 Mo	TLV:? SBU:1-3 Yrs		PBAC/MSAC: 12-18 Mo PLAC: 5 Mo	Average 6-7 Mo (+meta analysis)	CEESP:180 days	NECA: 270 days HIRA: approx. 150 days	Pharmaceutical product: 180 days/1 Yr.; new health technology : 90 days	180 days outpatient, prescription drugs:90 days	9 Mo; MEDICAC max. 9 Mo
classify reports	o	o	△	o	o	o	o/△	o	o	o

○ Reassessment and performance

Most countries examined in the current study had a system in place for the reassessment of pharmaceuticals. In the cases of Korea and Germany, an attempt to adopt a pharmaceuticals reassessment system was quashed due to

opposition. In France, all pharmaceutical products on the benefit list are reassessed every five years, to update AMR and reimbursement rates based on evidence. In Sweden and Australia, the health technologies that require reassessment are publicly selected by agency and government. In the US, insurance benefits are up for reassessment every 10 years. In the Netherlands, highly expensive drugs and orphan drugs are assessed separately. After the initial assessment, new clinical trial results and dosages are typically reviewed to reevaluate the clinical effectiveness, safety, and economic feasibility. The assessment results are used to determine if the benefit registration is to be retained.

Table S-6. Reassessment and performance

Country	UK	Sweden	Canada	Australia	France	Germany	Netherlands	US	Thailand	Korea
Reassessment	In effect	TLV reassessment of pharmaceutical products, SBU reassessment selection	Therapeutic review (comparison with new drugs)	Post-MarketReview	Differentiate repayment rate based on evidence/reassessment every 5 years	None. 2013/attempted regarding DM-gliptine	Out-of-budget drugs/assessment after 4 years of data collection	Regular reassessment 10 years after coverage decision	-	None. 2009 drug trial/research in progress
Performance	Expansion of NICE leads HTA worldwide	Slow decision making/ globally recognized in the field of medicine	When recommended by CADTH Regional circumstances not taken into account	Coverage decision making process by the Minister of Health	HAS role enhanced	Autonomy, professionalism, efficiency, economic Feasibility. Insufficient assessment	Needs to develop assessment methodology	HTA reform system inefficiency	Government led	Disjointed assessment decision making/ A surge in healthcare cost

The NICE in the UK has established itself as an internationally recognized health technology assessment organization. Similarly, the CADTH of Canada,

and HAS in France, have also been expanding their roles. Germany puts an emphasis on efficiency rather than on cost effectiveness. The IQWiG, in particular, continues to expand the organization with focus on the added values in accordance with the AMNOG regulations. Sweden's SBU has been criticized for the long assessment period. In Korea, activities and policies pertaining to health technology assessment have continued to expand. However, the assessment of medical practices, pharmaceuticals, and medical equipment are segmented. This insufficient lack of health technology management, coupled with the fee-for-service payment expansion of services and paid out-of-pocket pay development, hinders effective response to the increasing healthcare expenses.

Ⅱ. Comparison of health technology assessment cases

○ Selecting subjects

Potential study subjects were reviewed with a focus on genetic testing and relevant pharmaceutical products, the demand for which has been increasing steadily over the recent years in the name of 'personalized medicine'. Initially, assessment reports pertaining to genetic testing were filtered out of all health technology assessment reports that were made available by relevant agencies. Out of these, the reports that concerned common health technologies, in terms of nature and scope, were selected for the analysis. Subsequently, for the genetic testing, the EGFR genetic test for non-small cell lung cancer was selected, and Iressa and Tarceva were selected as relevant drugs. Ultimately, the UK, Canada, and Australia were chosen for the comparison of the final coverage decisions with Korea.

○ Comparison results

In 2003, Korea decided to list on national health insurance Iressa for lung cancer patients in whom chemotherapy had failed. France and the UK also

recommended its coverage based on the assessment results, in 2009 and 2010, respectively. Coverage for Tarceva was also approved for patients in whom chemotherapy had failed or for those who needed maintenance therapy.

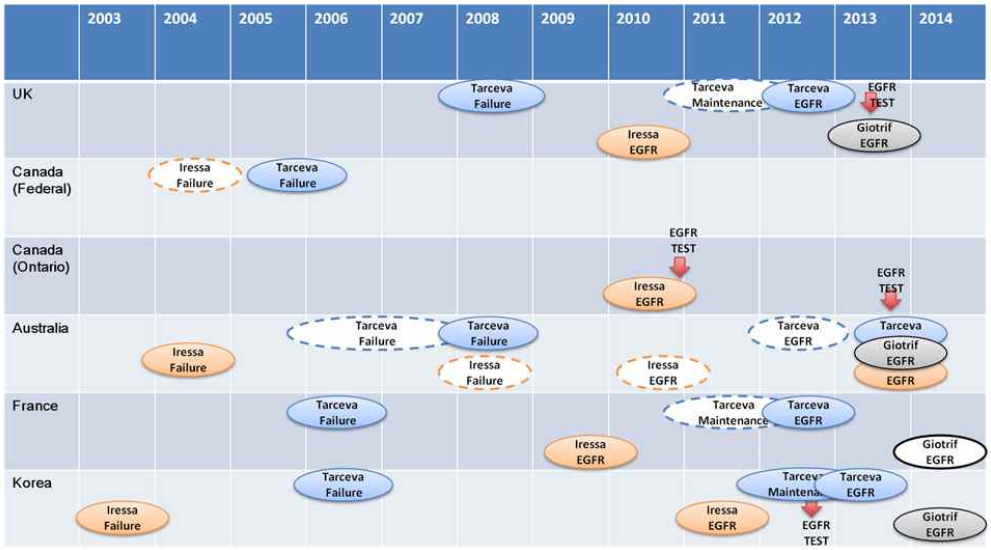

Figure 3.2.12. Coverage decisions for genetic testing and anti-cancer by country

※ Dotted lines indicate coverage denied.

▢ Discussion and conclusion

As a result of this comparison following implication:

First, there is a great need for a more efficient management of financial and health resources by introducing reassessment of the existing technologies. Further efforts to activate the comparative effectiveness researches and institutionalize monitoring the adoption and diffusion of new health technologies will be needed as well.

Second, transparency of health technology assessment needs to be enhanced, specifically in terms of methodologies, results, etc.

Third, the participation of citizens and interest groups in the assessment

process needs to be encouraged. Additionally, citizens' values and preferences must be clearly reflected in the society's decision making process.

Fourth, communication and project connectedness need to be enhanced among health technology assessment program an agency. In other words, rather than individual assessment programs of pharmaceuticals and medical examinations efforts must be made to develop a comprehensive collaborating assessment system.

Keywords: health technology assessment, decision making, market approval, national health care coverage, reassessment