National Evidence-based Healthcare Collaborating Agency

NECA - 협력연구

Social Values and Health Priority Setting: An International Comparative Analysis

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주 의

1. 이 보고서는 한국보건의료연구원에서 수행한 연구사업의 결과보고서입니다.

2. 이 보고서 내용을 인용할 때에는 반드시 한국보건의료연구원에서 시행한 연구사업의 결과임을 밝혀야 합니다.

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목 차

표 차례

그림 차례

Executive Summary

1. Objectives

1) To present social values and the settings of healthcare priorities in Korea.
2) To explore which factors have influenced decision making of new health technology assessment on approval in Korea.
3) To explore which factors have associated with pharmaceutical reimbursement decision in Korea.

2. Methods

1) To present Korean healthcare priority settings comparable to other countries, two sets of common values configured by Clark and Weale (2011) applied: process values and content values. The process values include transparency, accountability, and participation while the content values include clinical effectiveness, cost effectiveness, justice/equity, solidarity, and autonomy.
2) To analyze decision making results of the Committee for New Health Technology Assessment (CnHTA) on 53 non-drug new health technologies in Korea from July, 2007 to Dec, 2010. The scope of committee is mainly focused on safety and efficacy/effectiveness. Every decision making was based on a systematic review of literature. The committee is composed of health care professionals, policy makers, lawyers and representatives from Non-Government Organizations. Decision makings on therapeutic interventions were included, while ones on diagnostic procedures were excluded.
3) To analyze pharmaceutical reimbursement decision making results of new drug-listing data from 2007 and 2010 from the databases of the Health Insurance Review Agency (HIRA). Decision-making criteria includes clinical benefit, cost-effectiveness, budget impact, reimbursement status in other countries, whether a product is

related with rare disease, medical necessity, drug formulation conveniency, etc.

3. Results

1) In Korean health priority settings, multiple factors are influencing in the decision making process. Among others, effectiveness and safety are two most important values frequently mentioned in the process. Costeffectiveness is also considered in reimbursement decisions for new drugs since 2007. Recently, Health Technology Assessment (HTA) is changing the social value system traditionally used in Korean healthcare priority setting.
2) The factors that have positively influenced on the approval decisions of new health technology are the lower complication rate than existing technology, similarly or more effective than existing technology, ability to save critical organ, absence of alternative intervention, less invasiveness, expansion of patient"s choice set and similar to mechanism of existing technology. The factors that have negatively influenced on the decisions are higher complication rate than existing technology, less effective than comparable technology, low level of evidence, unintelligible mechanism of the intervention, inconsistency, absence of long term outcome, no comparative data, non-standardized technology, heterogeneity between control and treatment, excessively diverse indications, and nongeneralizability.
3) Decision-making criteria includes clinical benefit, cost-effectiveness, budget impact, reimbursement status in other countries, whether a product is related with rare disease, medical necessity, drug formulation conveniency, etc. Among these criteria, we found that clinical benefit and cost-effectiveness were the main influential factors of reimbursement decisions. Unfortunately, we were not able to have an access to cost-effectiveness data such as the type of analysis (i.e., cost utility analysis, cost effectiveness analysis)

and the final outcome measures (i.e., incremental cost effectiveness ratio (ICER)), which became the limitation of this study. It is worthy to notice almost 21% of submissions underwent through a changed decision from rejected for reimbursement to recommended for reimbursement. The main reason for this decision change was because manufacturers agreed to lower the price. We are at the moment to contemplate whether factors related to patient centered elements or social values are sufficiently considered in the decision making process.

4. Discussion and conclusion

This study is a part of international comparative analysis of social values and healthcare priority settings providing fundamental understanding of the Korean healthcare system. An international comparative study like this one can enlighten the decision makers in Korea and results in an improvement in the decision making process.

요 약 문

1. 배경

세계 여러 나라들이 다양한 보건의료체계를 가지고 있지만 몇몇 공통적인 문제점들과 난제들을 가지고 있다. 그중 하나로써 특히 공적 체계에서 의료 자원에 대한 모든 요구를 충족시킬 수 있는 나라는 전 세계적으로 없으며 따라서 우선순위를 위한 의사결정은 불가피한 일이 된다. 이러한 의사결정체계에 있어서 장차 그 과정을 보다 명료하고 합리적으로 만들기 위하여 각 나라들이 근거와 가치를 어떻게 해석하며 의사결정하는지, 의사결정에 어떤 요인들이 영향을 끼쳤는지 그리고 이러한 요인들이 나라별로 어떻게 다르고 유사한지 알아보는 것은 유익하다. 이러한 국제비교 연구는 영국의 NICE와 UCL (University College London) 연구진에 의해 시작되었고 여러 나라들이 참여하여 진행하였다 (부록 참조). 본 보고서는 이러한 국제 비교연구의 일환으로 이루어진 것이며 이를 준비하는 과정에서 우리나라의 의사결정 과정에 어떠한 요인들이 작용하는지에 대해 분석한 것을 포함한다.

2. 목적

본 연구를 통하여 1) 국제적 비교와 함께 우리나라에서의 보건의료 우선순위설정에 있어서 사회적 가치를 제시하고, 2) 우리나라에서 신의료기술의 인정 과정에 어떤 요인들이 의사결정에 영향을 끼치며, 3) 우리나라에서 신약 급여결정과정에 어떤 요인들이 의사결정에 영향을 끼치는지 살펴본다.

3. 방법

1) '과정 가치 (process values) 와 내용 가치 (content values)' (Clark and Weale)로 구성된 국제적 비교를 통해 우리나라의 우선순위선정을 제시하였다. 과정 가치에는 투명성, 책무, 참여가 포함되며 내용 가치에는 임상적 효과, 비용 효과, 정의/형평, 연대책임, 자율성이 포함된다.

2) 신의료기술 인정과정의 의사결정에 작용한 요인을 분석하기 위해 2007년 7월부터 2010년 12월까지 신의료기술평가위원회에서 결정한 53개의 비약물치료 신의료기술에 대하여 분석하였다. 동위원회가 판단하는 범주는 안전성과 효능·효과성에 국한된다. 모든 의사결정은 체계적 문헌고찰연구를 토대로 이루어졌다. 위원회는 보건의료 전문가, 정책결정자, 법조인, 비정부기관대표로 구성되었다.

3) 신약의 급여 결정과정에 작용한 요인을 분석하기 위해 2007년부터 2010년까지 건강보험심사평가원의 148개 신약 데이터에 대하여 임상적 편익, 비용효과성, 재정영향, 제외국 급여현황, 적응증에 있어서 희귀질환 여부, 의학적 필요성, 약제의 제형편리성 등을 고려하여 분석하였다.

3. 결과

1) 한국에서 보건의료 우선순위 설정에 있어서는 의사결정 과정에 있어서 다양한 요인들이 영향을 주어왔다. 여러 요인들 중에 효과와 안전성이 가장 중요하게 언급되는 가치이다. 비용경제성은 2007년 이후 신약의 보험 등재 결정 과정에서 고려되기 시작하였다. 최근 의료기술평가가 한국의 보건의료우선순위 결정에 전통적으로 사용되던 사회적 가치 판단에 변화를 주고 있다.
2) 신의료기술의 심의 과정에서 긍정적으로 작용한 요인들은 기존 의료기술에 비해 부작용이 적거나, 효과 면에서 동등하거나 더 개선을 한 경우, 긴요한 장기를 보전할 수 있는 경우, 대체 기술이 없는 경우, 덜 비침습적인 경우, 환자의 선택폭을 넓히기 위한 경우, 기존의 기술과 유사한 메카니즘인 경우였다. 부정적으로 작용한 요인들은 기존 기술보다 부작용률이 더 높거나 효과가 더 떨어지는 경우, 근거의 수준이 낮은 경우, 시술의 기전이 불확실 한 경우, 연구 결과들간에 일관성이 없는 경우, 장기 추적결과가 없는 경우, 비교연구의 결과가 없는 경우, 표준화 되어 있지 않은 경우, 대조군과 치료군이 이질적인 경우, 너무 광범위한 적응증을 갖고 있는 경우, 일반화시키기에 무리한 경우였다.
3) 신약의 급여 결정에 비치는 영향에 대해서는 임상적 편익, 비용효과성, 재정영향, 다른 나라들의 급여 여부, 적응증에 있어서 희귀질환 여부, 의학적 필요성, 약제의 제형 편의성 등이 고려되었다. 본 연구의 분석 결과 이러한 기준들 중에 임상적 효과성과 비용효과성이 급여 의사결정에 가장 큰 영향을 준다는 것을 발견하였다. 비급여에서 급여로 의사결정이 바뀐 것은 30건이었고 이는 전체 의사결정의 21%였고 이의 주된 사유가 비용 절감 등을 통한 비용효과성의 판단이 바뀐 것이었다. 화자 중심의 의사결정과 관련된 요소들이나 사회적 가치와 연관된 요인들이 충분히 고려되었는지에 대해서는 보다 면밀한 분석과 관찰이 필요하다.

4. 결론

본 연구는 국제적 비교연구로서 외국들과 비교하여 우리나라의 우선순위선정과 사회적 가치를 비교하였다. 이러한 국제 비교 연구는 우리나라에서의 의사결정 과정의 개

선에 대해 정책결정자들에게 새로운 조망을 줄 것이다.

I. Social Values and Healthcare Priority Setting in Korea

1.1. Introduction

The Republic of Korea (ROK) is located between China and Japan. According to the 2010 OECD economic survey, ROK has a population of 48.7 million (in 2009), per capita GDP of $28,196 (Purchasing Power Parity base), the third lowest healthcare spending as a share of GDP among the OECD countries in 2007 (6.5%), and the share of public health spending was 55.5% in 2008. In ROK, universal coverage has been achieved in 1989 after 12 years of gradual efforts. The National Health Insurance (NHI) system started in 1989 definitely increased accessibility to health care, however, with a cost of "heavy financial burden" to the system (Yang et al, 2008). To reduce the burden, Korean government tried various efforts including an introduction of positive listing system (PLS) for new drugs applying for NHI reimbursement enlisting in 2006. Prior to PLS, all the drugs approved by the Korean Food and Drug Administration (KFDA) were almost automatically put on the NHI drug list, so called negative listing. In applying PLS, cost effectiveness review was introduced for the first time into the system just like many other countries already did. One issue with PLS introduction was already listed drugs prior to December 2006, since NHI had a huge list of reimbursed drugs more than 21,000 in 2006 (Yang et al, 2008), which is reduced to 14,883 in 2010 mainly by reviewing the status of products whether still in market and actively submitting NHI claims. For these already listed drugs, an ambitious plan of reviewing all of them in 5 years was announced by the Ministry of Health and Welfare (MOHW) in 2007, however, it prematurely stopped in 2010 and changed to a plan to cut the unit price of already listed drugs up to 20% by 2014. Currently, NHI covers 96.7% of ROK population and the remaining 3.3% is covered by a medical aid plan which is directly funded by mostly the national government and local governments budget (patient's out of pocket payment for medical aid

plan is free or minimal). Also there exist public worker's compensation plan and private indemnity type health plans for specific disease such as cancer.

The sharply increasing healthcare spending and aging population are two big challenges in the Korean healthcare system. Both are at the top level among the OECD countries: the annual average real growth in per capita health expenditures between 1997 and 2007 was 8.7% (ranked number one) and the population aging from 2009 to 2050 is projected at the fastest level (population over 65 as a percentage of population aged 20-64: 16.2% in 2009 to 77.4% in 2050). To summarize, ROK is facing an increasing trend of healthcare expenditures and fast growth of elderly population. In 2011, expanding the current national health insurance coverage (about 62% in 2010) is a hot issue in the political arena. In addition, there are growing concerns over irrational uses of high cost technologies which are not covered by the national insurance. Health technology assessment (HTA) becomes more important than ever in Korea to answer all the aforementioned challenges.

1.2. Methods

Two sets of social values suggested by Clark and Weale (2011) were used as common comparators with other countries to compare social values in healthcare priority settings. Table 1 summarizes these two sets.

Table 1. Social values for healthcare priority setting (Clark et al, 2011)

Values	Context
Process Values	
Transparency	Decision making in healthcare priority is inevitably controversial, since it means privileging some needs over others. Making decisions based on explicit pre-set criteria and as transparent as possible can avoid unnecessary controversies.
Accountability	Being accountable in health priority setting means having the obligation to answer questions regarding decisions about which interventions are prioritized and providing public justification for the decisions.
Participation	Healthcare priority setting decisions are fundamentally value judgments - and value judgments will inevitably vary between individuals and groups within society. As such, it has been suggested, the decision making process is more likely to be legitimate if it enables different interests to contribute via participation (Saltmanand Figueras,1997).
Content Values	
Clinical effectiveness	The value of clinical effectiveness is a fundamental one in priority setting decisions, given that it is clearly undesirable to waste limited resources on procedures that are ineffective or, worse still, that may actually do harm. The positive aim of the principle, then, is to ensure that health benefits are achieved
Cost effectiveness	The aim of the principle of cost effectiveness is to ensure that the most health benefits are obtained from the available resources. Cost-effectiveness seeks to establish whether differences in costs between alternative interventions can be justified in terms of the health benefits they respectively produce.
Justice / Equity	The term 'justice' is often used by political theorists and

	philosophers for the value that economists call 'equity'. The difference in terminology is confusing because 'equity' is also used in jurisprudence to refer to the principle that like cases should be treated as like. In what follows we refer to 'justice' but start from the principle that like cases should be treated as like.
Solidarity	Solidarity can take different forms: it can take a contractual form, such as membership of a welfare state or of a basic health care package, where it is primarily expressed through a willingness to share the financial risks of ill-health, or a more generalized humanitarian form which is expressed in decisions which give priority to those who are worst-off in health terms (Hoedemaekers and Dekkers, 2003).
Autonomy	The concept of autonomy has a varied set of meanings (see Feinberg, 1986) but it is often used to refer to the ability of individuals to be self-directing and to make decisions for themselves about important matters. The notion of autonomy goes hand in hand with that of responsibility: if one is to be self-directing and make important choices, those choices will be one's own and thus also one's own responsibility.

Based on the social values listed above, Korean healthcare priority setting is examined and described in the following sections.

1.3. Korean Healthcare Decision Making Process

As mentioned earlier, the reimbursement of new drugs is subject to a positive listing system (new regime) under which each is undergoing a cost effectiveness value judgement. The listed drugs prior to December 2006 are covered by a negative listing system (old regime); but there is a plan to review these drugs using a set of similar principles. Non-drug health technologies are covered by a negative system; once they are approved for safety and submitted for reimbursement decision, they are automatically listed.

Table 2. Korean healthcare Decision Making System

	Drugs	Medical Devices	Diagnostics and Procedures
HTA research	National Evidence-based healthcare Collaborating Agency (NECA)	National Evidence-based healthcare Collaborating Agency (NECA)	National Evidence-based healthcare Collaborating Agency (NECA)
nHTA	Korean Food and Drug Administration (KFDA)	Korean Food and Drug Administration (KFDA)	Committee for New Health Technology Assessment (CNHTA)
Review and Recommendation	Health Insurance Review and Assessment Services (HIRA) / National Health Insurance Corporation (NHIC)	Health Insurance Review and Assessment Services (HIRA)	Health Insurance Review and Assessment Services (HIRA)
Decision Making	Ministry Of Health and Welfare (MOHW)	Ministry Of Health and Welfare (MOHW)	Ministry Of Health and Welfare (MOHW)

Table 2 illustrates regulatory and reimbursement decision making process in Korean healthcare system. Decision making for drugs, medical devices, diagnostics and procedures is handled by a number of

bodies including the National Evidence-based healthcare Collaborating Agency (a health technology assessment agency in Korea), Korean Food and Drug Administration (a Korean equivalent of the US FDA), Committee for New Health Technology Assessment (an expert committee approving introduction of new procedures and diagnostic methods), Health Insurance Review and Assessment Services (a Korean agency processing NHI claims and assessing appropriateness in volume of health services), National Health Insurance Corporation (Korean payer of NHI), and Ministry of Health and Welfare (Korean government). Each body may have different priorities in its decision making. For example, for a new drug approval, KFDA looks for safety and efficacy, HIRA reviews cost-effectiveness, NHIC negotiates the drug price with manufacturer while budget impact in mind. In the government's final decision, other social values such as equity, solidarity or autonomy may be also considered though the government accepts most of the recommendations passed to it by HIRA or NHIC. For the case of new procedures and diagnostic methods, CNHTA approves their use in the field based on efficacy and safety reviews performed by the Centre for New Health Technology in NECA. Once approved by the CNHTA, new procedures and diagnostic methods is under review of Medical Technology Review Committee or Medical Device Review Committee in HIRA for reimbursement decision. In these HIRA committees' decision, budget impact and appropriateness are two important values reviewed.

In terms of process values, transparency is often aspired by industry side even though the aforementioned content values in each body of decision making are explicitly given. The transparency gap between Korean decision makers' view and the industry side view is centred on "how the decision is made." The industry side is complaining there is lack of information to judge whether the decision is based on appropriate and relevant reasons. In other words, it is not always clear for the manufacturers why a drug is or is not accepted for reimbursement and how the conclusion was derived. This gap is also

somehow related to accountability issue. Since the HIRA committees' decisions are released through HIRA staffs not committee chair nor any of the committee member, sometimes the background of decision cannot be explained enough by an observer. Participation is a less issue in Korean healthcare decision making since the final decision committee called Health Insurance Policy Review Committee in the ministry includes various professional society representatives and consumer organization representatives including labour union.

In terms of other content values not explicitly used in Korean healthcare decision making, historically autonomy has been valued higher than solidarity in Korean system probably related to the strong presence of private sector in healthcare system. The strength of private sector sometimes change the government priorities radically such as the plan for reviewing already listed drugs. The relative effectiveness assessment of already listed drugs prior to positive listing system has started in 2008. Back then, the government began to evaluate the drugs already listed with the intention of stopping reimbursement for less effective ones. However, this precipitated a political debate, and relative effectiveness / cost-effective analyses of already listed drugs was abandoned in 2010.

1.4. Health Technology Assessment (HTA) in Korea

Recently, Health Technology Assessment (HTA) is changing the social value system traditionally used in Korean healthcare priority setting. Health Insurance Review and Assessment Services (HIRA), which is a reimbursement claims reviewing agency for the National Health Insurance, started HTA activities in Korea: Evidence Based Medicine (EBM) Team and the Center for New Health Technology Assessment. In

December 2008, National Evidence-based healthcare Collaborating Agency (NECA) was established to specialize on HTA research and the Center for New Health Technology Assessment was transferred to NECA in 2010.

For the first time in Korean healthcare research, NECA introduced a topic solicitation system which annually accepts topic suggestions from the general public, academia, decision makers, and so on. The external review committee composed of specialists in each disease area shortlist priority topics in each disease area in the first step and the expert review committee composed of methodological experts ranks the research topics in the pool of shortlists. In the selection process, both committees use criteria such as public needs including burden of disease and policy makers' needs, feasibility of study, and so on. After considering the annual research budget, research topics are selected from the highest rank. This new system opened, for the first time in Korean healthcare history, a door for the general public to participate directly into the priority seeking process. Also more HTA research results produced by NECA increases public awareness of social value principles, such as cost-effectiveness, clinical effectiveness (safety and relative effectiveness), applied in healthcare priority setting in Korea.

Systematic literature reviews and economic modelling are typical forms of HTA in NECA. Outcomes research using patient registries and national health insurance claims database are also frequently used. In collaboration with the government supported clinical research centers, NECA can perform clinical trials if necessary. Currently, NECA hosts the National Strategic Coordinating Center for Clinical Research (NSCR). The Center for New Health Technology Assessment in NECA reviews applications of new health technology to be used in Korean medical fields (by the current medical law, any new health technology should prove its efficacy and safety through the Committee for New Health Technology Assessment which makes decisions based on the Center reviews).

Even though there is no formal legislation to support NECA HTA research results to be used in decision makings, the results are often used in the HIRA and the government committee decisions. As a result, transparency is increasing since NECA research results are open to the public. The Center for New Health Technology Assessment review results are officially used in the committee decisions.

1.5. A Glucosamine Example

The Korean case study features glucosamine, often used for osteoarthritis. This comes in two forms: the sulphate, available in Korea as a prescription drug and a health supplement; and the hydrochloride, categorised as a health supplement.

As mentioned earlier, several agencies are involved in decisions: KFDA approves the drug in a regulatory sense, while HIRA makes recommendations to the ministry of health about which drugs should be covered for insurance purposes in the formulary. Through a topic suggestion from the public, the effectiveness of glucosamine came to NECA, which is responsible for collecting evidence, assessing it and making policy recommendations for the suggested topics. After a systematic review study, NECA held a couple of closed meetings with policymakers and other bodies, and also open meeting for public hearings. The main stakeholder is the manufacturing sector, because the health supplement market is so large in Korea.

Effectiveness and safety are the main determinants of decisions. Cost effectiveness is not yet a consideration. In the case of glucosamine there was relatively little concern about safety whereas a big debate about its effectiveness. The debate drew peoples' attention because glucosamine is a frequent gift to mothers or mothers-in-law, especially if they are suffering from bad knees. Participation included patient surveys of patient

views, and also open hearings.

In the case of the sulphate there was a little evidence to suggest a beneficial effect of using it; for the hydrochloride there was no evidence at all. The only immediate outcome was a minor modification by KFDA to the package insert. In the end there was some reduction in the use of the glucosamine on account of a greater public awareness of the paucity of evidence. After almost 20 months after the release of NECA glucosamine study results, there was a news report saying HIRA informed the manufacturers of glucosamine sulphate for delisting from the NHI formulary. Then, an appealing process will be open for the manufacturers before the final decision.

1.6. Conclusions

In Korean healthcare priority setting, more content values such as clinical effectiveness (efficacy and safety) and cost-effectiveness are considered (to some extent) while there is a considerable lack in process values such as transparency and accountability. In reality, these social values are somewhat complementary each other, however, an international comparative study like this one can enlighten the decision makers in Korea and results in an improvement in the decision making process.

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II. Factors Influencing Decision-Making on Therapeutic Intervention in Terms of Safety and Efficacy

2.1. Introduction

Acceptance of new technology differs from person to person. The Institute of Medicine (IOM) report mentioned that patients prefer technology that helps them better meet their personal goals, live lives that are nearly normal where the value of time is concerned, and ensure the out-of-pocket expenses will be covered. Clinicians attached importance to confidence in the effectiveness of services offered. Health insurers considered effectiveness and efficiency and sought high levels of evidence.

There are two stages in the evidence-based decision-making process: assessment and appraisal. Assessment is finding evidence of synthesis through critical appraisal of the quality of existing studies and economic evaluation. Appraisal is the process of determining the quality of value judgments. Goetghebeur's group suggests mathematical models like MCDA, which may be helpful for a value estimate. The group discussed a value matrix using the limitations of current interventions, improvement of efficacy/effectiveness, improvement of safety and tolerability, improvement of patient-reported outcomes, convenience and adherence with regard to the type of medical service for health-care intervention.

Medical necessity has been an important principle in decision making for reimbursement in the USA. The definition of medical necessity is important to consumers, policy makers, and stakeholders; however, the definitions have been so various that many efforts have been made to decrease the number of variations. Sarah's group mentions that judgment on the effectiveness of new health technology was determined by scientific evidence, demonstrating a causal relationship between intervention and health outcomes.

The Blue Cross and Blue Shield Association (BCBSA) has five criteria, including conclusive scientific evidence of the health effects of technology, evidence that the technology's benefits are comparable to

any established alternatives, and generalizability regarding technology as a medical necessity.

Since July 2007, the evidence-based decision-making system has been used in the decision-making process to adopt new non-pharmacologic health technology in terms of safety and efficacy/effectiveness. However, we do not have any distinct criteria for decision-making concerning the social adoption of technology. We wish to explore which factors have influenced decision-making results in new health technology assessment, specifically in terms of safety and effectiveness, and to analyze which factors positively supported a decision and which had negative effects. It will be helpful to develop a guideline and promote greater objectivity in the decision-making process in Korea.

2.2. Methods

The Committee for New Health Technology Assessment (CnHTA) has reviewed new non-pharmacologic health technology using the HTA reports undertaken by the Center for New Health Technology Assessment at NECA, which addresses safety and efficacy/effectiveness: factors relevant to the KFDA for drug approval (Figure 1).

Figure 1. Korean Accommodating System for Accommodating New Health Technologies

Cost and cost effectiveness were not considered in the review. The new health technologies recommended by CnHTA were accepted as submissions to the Expert Committee, which decides how to reimburse the HIRA.

We analyzed the decision-making results of CnHTA for 53 new non-drug health technologies in Korea from July 2007 to December 2010 (Table 3).

Every decision made was based on a systematic review of literature. The committee was composed of health-care professionals, policy makers, lawyers, and representatives from non-government organizations. Decisions made on therapeutic interventions were included, while diagnostic procedures were excluded for this analysis.

First, we located the sentences in each assessment report that addressed the reasons recommendations were or were not adopted. Second, we categorized the sentences until there was nothing further to categorize. We regard the reasons as factors influencing decision making. After that, we classified each study according to these factors. We allowed a double count if two or more factors influenced a decision. The factors were analyzed separately according to whether the recommendation direction was positive or negative. We also analyzed the factors according to the recommendation grade. The committee uses the evidence levels and recommendation grades of SIGN.

Table 3. Characteristics and Results of Decisions for 53 Therapeutic Technologies

Classification of technologies	Noninvasive or minimally invasive procedures: 17	
	Surgical intervention: 4	
	Interventions related to the nervous system, spine and pain: 7	
	Interventions in the field of ENT: 5	
	Ophthalmic intervention: 5	
	Interventions using cells (bone marrow, stem cell, cultured cells): 4	
	Radiation therapy: 1	
	Intervention using autologous blood components: 3	
	Others: 7	
Decision	Recommended to be adopted	36
		Grade of recommendation
		A: 4
		B: 11
		C: 3
		D: 18
	Judged as investigational technology	17

ENT = Ear, nose and throat

2.3. Results

The factors that have positively influenced decisions have lower complication rates than existing technology and transient complications in the context of safety issues (Table 4). Having similar or greater effectiveness than existing technology, ability to save critical organs, an absence of alternative interventions, less invasiveness, expansiveness of patients' choices, and mechanisms similar to existing technology are the positive factors in the context of efficacy and other values. The most common factor to support recommendation of adoption is comparable effectiveness with existing technology. No alternative technology follows it in the perspective of effectiveness.

Table 4. Positive Factors Influencing Decision Making

Positive factors	Number
Lower complication rate than existing technology	12
Transient complication	2
Similar or more effective than existing technology	23
Saving critical organ	1
Absence of intervention/overcome the limit of existing technology	10
Less invasive	3
Patient diverse choice (patient centric decision)	1
Similar Mechanism of technology similar to with existing one	3

Although there are factors with high-grade recommendations, if there is no alternative intervention or it overcomes the limitations of existing technology, it is regarded as having a remarkable influence on the adoption of a new technology, even given the low levels of evidence (Figure 2).

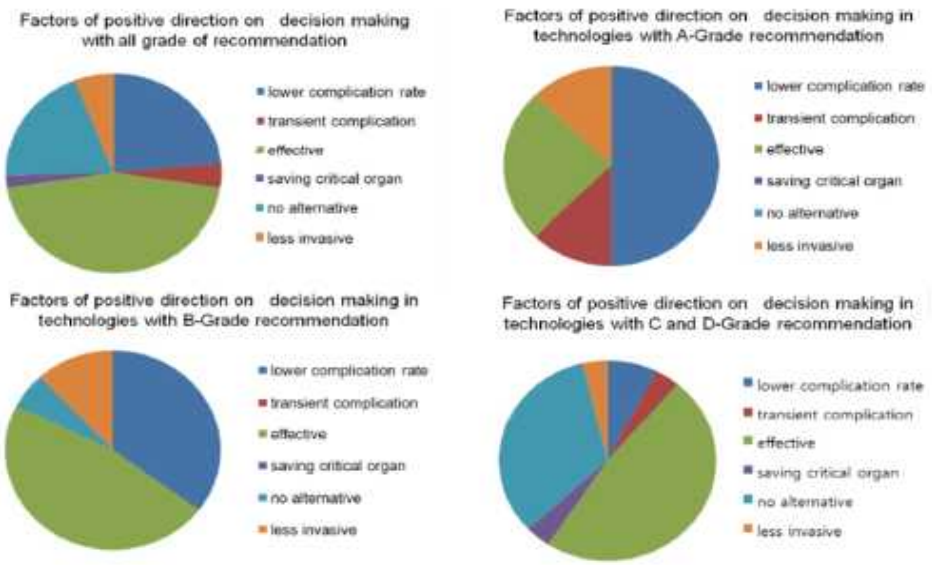

Figure 2. Positive Factors Influencing Decisions According to The Recommendation Grade

The factors that influence decisions negatively have a higher complication rate than existing technology, less effectiveness than comparable technology, lower level of evidence, unintelligibility of the mechanism of intervention, inconsistency, absence of long-term outcomes, no comparative data, non-standardized technology, heterogeneity between control and treatment, excessively diverse indications, and non-generalizability (Table5).

Table 5. Negative Factors Influencing Decision Making

Negative factors	Number
Higher complication rate than existing technology	1
Less effective than comparable technology	1
Low level of evidence (ex; case series only) or small amount of relevant studies	12
No explainable mechanism of the intervention	1
Inconsistency	2
No long term outcome	2
No comparative data	3
No standardization of the technology	1
Different characteristics of index and control treatment groups	2
Too diverse indication	1
Not generalizable	1

2.4. Discussion

Scientifically, a new technology may be adopted if evidence shows that benefits outweigh harms, especially in the cases of technology with effectiveness equal to or exceeding that of existing technology. CnHTA does not consider the cost or cost-effectiveness in the decision-making process, but the committee assesses whether or not our society should adopt a new technology in terms of safety and efficacy/effectiveness. These principles are similar to medical necessity, which is the general principle behind the reimbursement policy in the USA.

Even though the principle has been used for a long time and has been widely adopted by policy makers in the USA, there is no explicit definition of it at the federal-government level. Because there have been some conflicts around the interpretation of the principle, several efforts have been made to decrease the variation in the interpretation of "medical necessity." The results of Singer et al.'s report exemplify such efforts and the concept their research proposes was adopted as the definition for "medical necessity" in the Hawaiian state. Their definition emphasizes that scientific evidence should demonstrate a causal relationship between the intervention and health outcomes for new health technology. They argue that low-quality clinical studies are not adequate for explaining causal relationships. If the new interventions are not feasible for high quality clinical trials owing to rare or new diseases, decisions may be made on the basis of professional standards of care or expert opinions.

The Technology Evaluation center of the BCBSA uses five evaluation criteria, including quality of the body of studies, consistency of the results, benefits as strong as any established alternatives, and generalizability.

These factors have been used by CnHTA to decide whether to adopt a new health technology or not and are seen as similar to the factors that define medical necessity in the USA. Besides comparable effectiveness

and safety of alternative interventions, consistency, generalizability, and quality of the evidence, we could identify some other factors, such as saving critical organs, no alternative interventions, the deficiencies in existing technology, lesser invasiveness, and chances for diverse patient choices.

Implantation of the intrathecal drug infusion pump was recommended for reducing drug amounts due to its lower complication rate. In the case of continuous femoral nerve blockage for patients with total knee replacement or total knee arthroplasty, the committee agreed that it is more effective than comparators, including intravenous pain killers or epidural PCA patient-controlled analgesia (PCA). Eyeball brachytherapy was recommended owing to the potential of saving eyeballs and limiting existing external radiotherapy with high-complication rates. Gastric banding for obesity was favored for its lesser invasiveness and lower complication rate. Although the outcomes for weight reduction were not superior to gastric bypass surgery, the committee decided to adopt the technology for the patients who prefer less invasiveness. Even though the level of supporting evidence was low, thrombectomy using an aspiration device in an intracranial vessel was adopted because potential benefits were observed and no alternative intervention was available from three to eight hours after the onset of symptoms of ischemic stroke. Femtosecond laser keratectomy for corneal transplantation was adopted as a mechanism similar to existing technology for penetrating keratoplasty despite little direct evidence regarding its effects.

The factors that have been considered in CnHTA for determining whether new technology is investigational are higher complication rate than existing technology, lesser effectiveness than comparable technology, lower levels of evidence, unintelligibility of the mechanism of intervention, inconsistency, absence of long-term outcomes, no comparative data, non-standardized technology, heterogeneity between control and treatment, excessively diverse indications, and non-generalizability.

Posterior lumbar dynamic stabilization using DIAM, Wallis system,

X-stop, and interspinous U/Coflex was determined to be investigational technology owing to the lack of explainable mechanisms of intervention, inconsistent results, and low levels of evidence. Autologous non-cultured epidermal cellular transplantation was also regarded as an investigational technology because of inconsistency in the results and low quality of the evidence. In the case of therapeutic use of autologous bone marrow cells in patients with peripheral arterial disease, since studies have shown heterogeneity between control and treatment, there is limitationin generalizability. Descemet-stripping automated endothelial keratoplasty has a higher complication rate than the comparator of penetrating keratoplasty, which was counted negatively; however, it was recommended to be adopted owing to its transient nature and controllability.

The factors determining whether a new technology may be adopted or not in terms of safety are severity of complication from an intervention and whether or not it is transient and controllable. In terms of efficacy/effectiveness, besides considering whether the benefits are the same or greater than those in existing comparable technologies, consistency of the results, and generalizability, it is necessary to take into account that lesser invasiveness, deficiencies of existing technology, and room for patients' choice may outweigh the uncertainty of effectiveness when the supporting evidence is of a low quality. We need an explicit guideline for incorporating these factors into decision-making practices, especially in the case of existing uncertainty due to low levels of evidence.

2.5. Conclusions

Four years ago, the evidence-based decision-making system was introduced to the process of decision making on adoption of new non-pharmacologic health technology in terms of safety and efficacy/effectiveness. However, we do not have any distinct criteria for decision making on the social adoption of technology. This qualitative analysis of past decision-making results

provides us with insight regarding which values decision makers in the Korean CnHTA considered in terms of safety and effectiveness. Thus far, no explicit guideline exists for making decisions regarding the kinds of new technology to be adopted for daily practice in Korea. To make the process more transparent and decisions more consistent, we need to document and clearly define a guideline for the whole process. These findings will help us develop such a guideline for appraisal and enhance the objectivity of the decision-making process in Korea.

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III. Factors Associated with Pharmaceutical Reimbursement in Korea

3.1. Introduction

In Korea, we have a social insurance system and South Korean citizens are covered by health insurance by law. During the half century, we underwent and still undergoing through medical breakthroughs and significant health-care advances which improve the quality of healthcare. Alongside, we are enfacing a steep increase in healthcare costs which are exceeding Korea's economic growth rate. Prioritization of reimbursement has become a major issue within the national health insurance system in Korea (Park et al, 2008).

For pharmaceuticals (medications), Korean Food and Drug Administration makes the approval decision based on safety and efficacy. To control the markedly increasing pharmaceutical spending, the government announced a drug expenditure rationalization plan which has the major component of the plan named the positive list system introduced in December 29, 2006. The pharmaceutical benefit schedule changed from a negative list to positive list that considers drugs effective in both therapeutic and economic aspects for health insurance benefits. Under this system, the Health Insurance and Review and Assessment service (HIRA) assesses the appropriateness of reimbursement of a new drug. If the drug is appropriate based on the dossier submitted voluntarily by manufacturers, the National Health Insurance Corporation and the manufacturer negotiate the price and expected usage volumes. HIRA reviews the dossier and gets advise from the Drug Benefit Coverage Assessment Committee, which is consisted of multidisciplinary members from areas of medicine, clinical pharmacology, health economics, etc (Bae et al, 2009).

Two literatures have been published while we were doing this research. One is a comparative analysis of the impact of a positive list system on new chemical entity drugs and incrementally modified drugs in South Korea (Ha et al, 2011). They performed descriptive analyses on the reimbursement rate and logistic regression analysis to examine

significant factors affecting the listing of new chemical entities and incrementally modified drugs using new drug-listing data between 2007 and 2008. A total of 150 reimbursement applications were examined and the overall drug-listing rate was lower than before the inception of the positive list system. They found that the drug reimbursement rates for new chemical entities were significantly lower than those for incrementally modified drugs (50.6% and 74.6%, respectively; p = 0.0025). Significant factors influencing the listing of new chemical entities were cost-effectiveness and budget impact, while no significant factors were found for incrementally modified drugs.

Another study evaluated the first two years of the positive list system in South Korea analyzing 91 submissions with reimbursement decision completed by December 31, 2008 (Park et al, 2012). They found out that the HIRA recommended 64 submissions for reimbursement and rejected 27 submission. The main reason for rejection was unacceptable cost-effectiveness. Three factors were found to be significantly associated with the recommendation decision for reimbursement: (1) whether a drug was superior to its comparator, (2) whether treatment cost was not greater than costs of its comparator, and (3) whether the number of recommended decision made by other committees increased. Other committees included Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, the Canadian Expert Drug Advisory Committee (CEDAC), and the Technical Appraisal Committee (TAC) of the National Institute for Clinical Excellence (NICE) in the United Kingdom.

In this study, we intend to examine what kind of values (factors) were associated with pharmaceutical reimbursement decision in Korea from the beginning of positive list system (2007) through August 2010.

3.2. Methods

We obtained the new drug-listing data from 2007 and 2010 from the

databases of the Health Insurance Review Agency (HIRA). Four reviewers analyzed and extracted the data which were considered to make reimbursement decisions. We categorized the data by three categories: (1) general information including drug components, product name, company, indication, and the number of evaluation; (2) evaluation result including the final decision and reason of such decision; and (3) evaluation contents including medical necessity, clinical benefits, cost-effectiveness, budget impact, and the number of other listed countries.

After retrieving the necessary information and categorizing the data, tour reviewers generated variables related to decision criteria based on HIRA data, and cross-checked the data validity of each other. The coding of variables with associated values are shown in Table 6. For drug formulation conveniency, we regarded a drug with sustained-release formulation or with lesser dosing frequency as having this trait although the drug formulation conveniency was not mentioned in the data.

In our descriptive analyses, we have regarded three products with different data as distinguished observation resulting in 148 cases. These three products were dasatinib, sildenafil, and medroxyprogesterone. Dasatinib had different data in terms of medical necessity and substitutibility which were different for two indications - chronic and acute myeloid leukemia. Two products had different cost-effectiveness and clinical benefit results based on the indication. One was sildenafil which had category 1 (<cost and ≥clinical benefit) result for WHO class III and category 3 (>cost and ≤clinical benefit) result for WHO class II. The budget impact of Sildenafil reported to be decreased for WHO class III and increased for WHO class II. The other product was medroxyprogesterone which had category 1 (<cost and ≥ clinical benefit) result for endometriosis and category 2 (>cost and >clinical benefit) result for malignant breast tumor. We have conducted descriptive analyses by using Chi-square test and Student's t-test comparing between drugs recommended for reimbursement and drugs rejected for reimbursement.

A multivariate logistic regression analysis was developed to examine the significant factors associated with the reimbursement decision. In this analysis, we used 145 cases instead of 148 cases because treating the same product as separate observation might affect standard errors of beta coefficients. As for dasatinib, we used the data for chronic myeloid leukemia indication because this information seemed to influence the decision making process dominantly. Same reasoning applied for sildenafil and medroxyprogesterone when we used the data for WHO class III and malignant breast tumor, respectively. To check the model performance, c-statistics and the Hosmer-Lemeshow test (an omnibus diagnostic test) were examined (Hosmer et al, 2000).

We used a 5% significance level to consider whether the differences were significant or not. Analyses were performed by using SAS statistical software version 9.2 (SAS Institute, Cary) and STATA software release 10.0 (StataCorp LP, College Station).

Table 6. Data Dictionary for Analyzing Data of Reimbursement Decision

Variables	Values	Definition
Medical necessity	0	Yes
	1	No
Rare disease	0	Yes
	1	No
	2	Not mentioned
Substitutibility	0	Yes
	1	No
	2	Not mentioned
Cost-effectiveness*	1	〈cost and ≥clinical benefit
	2	〉cost and 〉clinical benefit
	3	〉cost and ≤clinical benefit
	4	〈cost and no efficacy
	5	Similar to comparator
	6	Uncertain
	7	Suitable to economic evaluation criteria for incrementally modified drugs
	8	Unsuitable to economic evaluation criteria for incrementally modified drugs
	9	Not mentioned
Budget impact	1	Decrease
	2	No change
	3	Increase
	4	Uncertain
	9	Not mentioned
Number of other listed countries	number	
Clinical study type	0	Not a non-inferiority trial
	1	Non-inferiority trial
Drug formulation conveniency	0	No
	1	Yes
	2	Not mentioned
Clinical benefits	0	No
	1	Yes (including non-inferior)
Number of evaluation	number	
Indication	First 3 codes of the International Classification of Diseases, 10th Revision (ICD-10) code	Primary diagnosis

* We have merged group 4 and 7 as one group, and group 3 and 8 as other group in the regression analysis.

3.3. Results

We had 145 submissions for analysis. We had 29, 53, 45, and 18 submissions in 2007, 2008, 2009, and 2010. Among 148 cases (note: we have treated three submissions with different data for each indication as separate cases, thus the total number of cases are 148), 105 cases (70.9%) had decisions with reimbursement and 43 cases (29.1%) were not able to be reimbursed (Table 7).

Table 7. Distribution of Reimbursement Decisions by Year

Year	Number of submissions recommended for reimbursement	Number of submissions not recommended for reimbursement	Total
2007	18 (62%)	11 (38%)	29
2008	38 (72%)	15 (28%)	53
2009	34 (76%)	11 (24%)	45
2010	13 (72%)	5 (28%)	18
Total	103 (71%)	42 (29%)	145

The number of drugs with changed decision from rejected for reimbursement to recommended for reimbursement was 30 (20.7%). Majority of reasons were manufacturers agreed to lower the price and drugs became cost-effective (12 submissions (40.0%) mentioned this explicitly and 16 submissions (53.3%) were assumed to be in this case). One submission had a changed decision due to updated meta-analysis and the other one had no mention about the reason.

Table 8 shows the descriptive characteristics between submissions recommended for reimbursement and those rejected for reimbursement. Cost-effectiveness, budget impact, clinical benefits, substitutibility, and the number of other listed countries were significantly different among two submissions ($p < 0.0001$ for first three factors, $p = 0.007$ for substitutibility, and $p = 0.017$ for the last factor). The number of evaluation, drug formulation conveniency, medical necessity, and whether drugs submitted are related

with rare diseases were not significantly different among two submissions (p = 0.416, p = 0.709, p = 0.138, and p = 0.101, respectively). Fisher's exact p are reported if at least one cell has observations less than five.

Table 8. Comparing Characteristics of Submissions Between those Recommended and Rejected for Reimbursement

Factors	Recommended for reimbursement (105 cases)*	Rejected for reimbursement (43 cases)	p
Number of evaluation, no(%)			
1	75 (71.4%)	26 (60.5%)	
2	22 (20.9%)	13 (30.2%)	0.416
3	8 (7.6%)	4 (9.3%)	
Cost-effectiveness, no(%)			
〈cost and ≥clinical benefit	47 (45.6%)	3 (7.3%)	
〉cost and 〉clinical benefit	9 (8.7%)	3 (7.3%)	
〉cost and ≤clinical benefit	17 (16.5%)	11 (26.8%)	
〈cost and no efficacy	0 (0.0%)	2 (4.9%)	
Similar to comparator	4 (3.9%)	1 (2.4%)	
Uncertain	8 (8.7%)	18 (43.9%)	〈 0.0001
Suitable to economic evaluation criteria for incrementally modified drugs	18 (17.5%)	1 (2.4%)	
Unsuitable to economic evaluation criteria for incrementally modified drugs	0 (0.0%)	2 (4.9%)	
Missing information	2	2	
Budget impact			
Decrease	51 (60.0%)	7 (20.0%)	
No change	6 (7.1%)	2 (5.7%)	
Increase	27 (31.8%)	24 (68.6%)	〈 0.0001
Uncertain	1 (1.2%)	2 (5.7%)	
Missing information	20	8	
Clinical benefits			
No	6 (5.7%)	16 (37.2%)	
Yes (including non-inferior)	99 (94.3%)	27 (62.8%)	〈 0.0001
Drug formulation conveniency			
No	1 (0.9%)	0 (0.0%)	
Yes	15 (14.3%)	4 (9.3%)	0.709
Not mentioned	89 (84.8%)	39 (90.7%)	

Factors	Recommended for reimbursement (105 cases)*	Rejected for reimbursement (43 cases)	p
Medical necessity			
Yes	5 (4.8%)	1 (2.3%)	
No	100 (95.2%)	40 (93.0%)	0.138
Not mentioned	0 (0.0%)	2 (4.7%)	
Rare disease			
Yes	9 (8.6%)	2 (4.7%)	
No	94 (89.5%)	37 (86.1%)	0.101
Not mentioned	2 (1.9%)	4 (9.3%)	
Substitutibility			
Yes	101 (96.2%)	39 (90.7%)	
No	4 (3.8%)	0 (0.0%)	0.007
Not mentioned	0 (0.0%)	4 (9.3%)	
Number of other listed countries			
0	4 (11.1%)	31 (30.4%)	
1	11 (30.6%)	17 (16.7%)	
2	5 (13.9%)	8 (7.8%)	
3	6 (16.7%)	9 (8.8%)	
4	1 (2.8%)	11 (10.8%)	0.017
5	4 (11.1%)	8 (7.8%)	
6	2 (5.6%)	16 (15.7%)	
7	1 (2.8%)	1 (0.9%)	
8	2 (5.6%)	1 (0.9%)	
Missing information	3	7	

* The total number of submissions was 145. However, we have regarded three products (dasatinib, sildenafil, and medroxyprogesterone) with different data as distinguished observation in this descriptive analysis. For example, the cost-effectiveness, medical necessity, and substitutibility were different for different indications in one product.

Table 9 shows the factors which influenced the reimbursement decision for drugs as recommended. The clinical benefit data was the most influential factor on making the reimbursement decision. If a product showed clinical benefits, the odds to get reimbursement recommendation was higher comparing with a product showing no clinical benefits (odds ratio 26.44, $p < 0.001$).

The cost-effectiveness data were the second highest significant factor which affected the reimbursement decision. The product with uncertain cost-effectiveness had a significantly lower odds to get reimbursement decision as recommended when compared with the product with

higher cost and lower clinical benefit cost-effectiveness data (odds ratio 0.24, p = 0.047). The number of evaluation and whether the disease related with the product was rare disease were not the significant factor affecting the reimbursement decision.

The model goodness of fit was satisfactory because the Hosmer-Lemeshow test statistic was not significant (p = 0.757) and the *c*-statistic was 0.890. We did not include the information for drug formulation conveniency in the regression because too many missing values existed.

Table 9. Multivariate Logistic Regression Result Presenting Factors Influencing the Decision of Recommending Reimbursement for Drugs

Factors	Coefficient [standard error]	Odds ratio [95% confidence interval]	p
Number of evaluation	-0.23 [0.41]	0.77 [0.35, 1.80]	0.584
Cost-effectiveness			
〉cost and ≤clinical benefit OR Unsuitable to economic evaluation criteria for IMR [reference]			
〈cost and ≥clinical benefit	1.86 [1.00]	6.45 [0.90, 46.07]	0.063
〉cost and 〉clinical benefit	0.61 [0.90]	1.84 [0.32, 10.71]	0.498
〈cost and no efficacy OR Suitable to economic evaluation criteria for IMR	1.61 [1.17]	4.98 [0.51, 48.97]	0.169
Similar to comparator	1.61 [1.58]	4.99 [0.23, 109.39]	0.308
Uncertain	-1.42* [0.72]	0.24* [0.06, 0.98]	0.047
Budget impact			
Decrease [reference]			
No change	-0.95 [1.41]	0.39 [0.02, 6.07]	0.498
Increase	-1.78 [0.98]	0.17 [0.02, 1.16]	0.071
Uncertain	-3.11 [1.70]	0.04 [0.002, 1.25]	0.067
Not mentioned	0.08 [1.12]	1.08 [0.12, 9.73]	0.943

Factors	Coefficient [standard error]	Odds ratio [95% confidence interval]	p
Clinical benefits			
No [reference]			
Yes	3.27*** [0.90]	26.44*** [4.51, 155.14]	〈 0.001
Rare disease			
Yes [reference]			
No	-0.01 [1.04]	1.00 [0.13, 7.66]	0.999

* p〈0.05;**p〈0.01;***p〈0.001;IMR=Incrementally Modified Drugs. N=135 submissions.

3.4. Conclusion

Various aspects are considered in making the decision whether to reimburse a drug or not. Decision-making criteria includes clinical benefit, cost-effectiveness, budget impact, reimbursement status in other countries, whether a product is related with rare disease, medical necessity, drug formulation conveniency, etc. Among these criteria, we found that clinical benefit and cost-effectiveness were the main influential factors of reimbursement decisions. Unfortunately, we were not able to have an access to cost-effectiveness data such as the type of analysis (i.e., cost utility analysis, cost effectiveness analysis) and the final outcome measures (i.e., incremental cost effectiveness ratio (ICER)), which became the limitation of this study. It is worthy to notice almost 21% of submissions underwent through a changed decision from rejected for reimbursement to recommended for reimbursement. The main reason for this decision change was because manufacturers agreed to lower the price. We are at the moment to contemplate whether factors related to patient centered elements or social values are sufficiently considered in the decision making process. This will be our future homework to think about.

3.5. References

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Ⅳ. Conclusion and Suggestion

Since 2007, the evidence-based decision-making system was introduced to the process of decision making on adoption of new non-pharmacologic health technology in terms of safety and efficacy/effectiveness. However, we do not have any distinct criteria for decision making on the social adoption of technology. This qualitative analysis of past decision-making results provides us with insight regarding which values decision makers in the Korean CnHTA considered in terms of safety and effectiveness. Thus far, no explicit guideline exists for making decisions regarding the kinds of new technology to be adopted for daily practice in Korea. To make the process more transparent and decisions more consistent, we need to document and clearly define a guideline for the whole process. These findings will help us develop such a guideline for appraisal and enhance the objectivity of the decision-making process in Korea.

Since 2007, the decision making system for reimbursement of new drug also adopted evidence-based decision making system. their scopes include efficiency. Various aspects are considered in making the decision whether to reimburse a drug or not. Decision-making criteria includes clinical benefit, cost-effectiveness, budget impact and reimbursement status in other countries, whether a product is related with rare disease, medical necessity, drug formulation conveniency, etc. Among these criteria, we found that clinical benefit and cost-effectiveness were the main influential factors of reimbursement decisions. It is worthy to notice almost 21% of submissions underwent through a changed decision from rejected for reimbursement to recommended for reimbursement. The main reason for this decision change was because manufacturers agreed to lower the price. We are at the moment to contemplate whether factors related to patient centered elements or social values are sufficiently considered in the decision making process. This will be our future homework to think about.

In Korean healthcare priority setting, more content values such as clinical effectiveness (efficacy and safety) and cost-effectiveness are considered (to some extent) while there is a considerable lack in process values such as transparency and accountability. In reality, these social

values are somewhat complementary to each other, however, an international comparative study like this one can enlighten the decision makers in Korea and results in an improvement in the decision making process.

V. Appendix

5.1. The network of researchers:

The project is jointly led by Professor Albert Weale and Dr Sarah Clark at UCL School of Public Policy, and Professor Peter Littlejohns at NICE and Kalipso Chalkidou at NICE International.

A network of researchers and policy-makers from around the world are collaborating in the project. Currently, this network includes the following:

Individual	Country	Institution
Professor Peter Littlejohns Dr Kalipso Chalkidou Lucy Connor Kim Jeong Tarang Sharma	UK	National Institute for Health and Clinical Excellence (NICE)
Professor Albert Weale Dr Sarah Clark	UK	University College London (UCL)
Prof. Ruth Faden	USA	Berman Institute, Johns Hopkins University
Danielle Lavallee	USA	Centre for Medical Technology Policy, Baltimore
Sang Moo Lee Jeonghoon Ahn Hae Sun Suh	Korea	NECA, Korea (National Evidence-based Healthcare Collaborating Agency)
Yot Teerawattananon Sripen Tantivess Jomkwan Yothasamut Hatai Limprayoonyong	Thailand	HITAP, Thailand (Health Intervention and Technology Assessment Program
Prof. Hufeng Wang	China	
Prof. Lise Rochaix	France	HAS, France (Haute Autorit□ de Sant□)
Andreas Gerber	Germany	IQWIG, Germany (Institute for Quality and Efficiency in Health Care)
Ole Frith Norheim	Norway	World Health Organisation
Maria Luisa Escobar Leonardo Cubillos	Columbia	World Bank
Lloyd Sansom	Australia	Pharmaceutical Benefits Advisory Committee
Paul Scuffham	Australia	Griffith University Medical School
Manal Bouhaied	Kuwait	Kuwait Medical School
Iestyn Williams Suzanne Robinson	UK	University of Birmingham, Health Services Management Centre
Sian Davies Benedict Rumbold	UK	Nuffield Trust

Individual	Country	Institution
Alexandre Lemgruber	Brazil	ANVISA, Brazil (Agencia Nacional de Vigiliancia Sanitaria)
Flavia Elias	Brazil	Brazilian Ministry of Health

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