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Social values and healthcare priority setting in Korea

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Abstract

Purpose – The purpose of this paper is to present the role of social values in setting healthcare priorities in Korea.

Design/methodology/approach – Using Clark and Weale's draft framework, Korean healthcare priority setting was analysed. The process values used were transparency, accountability, and participation, and the content values used were clinical effectiveness, cost effectiveness, justice/equity, solidarity and autonomy.

Findings – In the Korean health priority setting, it was found that multiple factors influence the decision-making process. Effectiveness and safety are the two most important values mentioned in the process. Cost-effectiveness is also considered in reimbursement decisions for new drugs since 2007. Recently, health technology assessment (HTA) has begun to change the social value system traditionally used in the Korean healthcare priority setting.

Originality/value – The paper extends understanding of health priority setting in Korea, and how the interpretation and use of social values has changed over recent years.

Keywords Korea, Social values, Health care, Health organization and management, Healthcare priority, International comparison, Effectiveness

Paper type Research paper

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Introduction

The Republic of Korea (ROK) is located between China and Japan. According to the 2010 OECD economic survey (OECD, 2010), 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 percent), and the share of public health spending was 55.5 percent 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 five 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 percent by 2014. Currently, NHI covers 96.7 percent of ROK population and the remaining 3.3 percent 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 percent (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 percent in 2009 to 77.4 percent 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 percent 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. Therefore, health technology assessment (HTA) becomes more important than ever in Korea to answer all the aforementioned challenges. However, the challenges to Korean HTA system or the first evidence based decision making system in Korea are lack of principles and consensus on how to prioritize healthcare needs and how to interpret each domain of social values.

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 I summarizes these two sets.

Based on the social values listed above, each value is tested on each Korean healthcare decision making process on drugs, medical devices, and diagnostic methods/procedures, which were identified by interviews with decision makers and searching for public documents available online including decision documents on drug reimbursement reviews and health technology reimbursement reviews. Some values cannot be tested directly since the concept is new to the decision making process. In these cases, they are listed as limitations.

Results

Korean healthcare decision making process

Even though reimbursement process of new drugs in Korea is subject to a positive listing system (new regime) under which each is undergoing a cost effectiveness value judgment, non-drug health technologies are still covered by a negative system (old regime); once they are approved for safety and submitted for reimbursement decision, they are automatically listed. This difference, or apparent inconsistency, clearly reveals the complex profiles of Korean healthcare decision making process.

Table II 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. However, these different decision making process are similar in a sense that they lack considerations on variety of social values. They tend to focus on clinical effectiveness such as safety and efficacy along with occasional consideration of economic values such as cost effectiveness and budget impacts. Transparency and accountability is applied to some extent whereas participation is limited. Justice/equity, solidarity, and autonomy are not clearly employed in the decision making process.

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, which sometimes pressured by patients groups, providers, or politicians. However, there is no transparent accountable information available to judge these values were considered in decision making.

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

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 (Saltman and 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

Table I.
Social values for healthcare priority setting (Clark and Weale, 2011)

	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)
Approval	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 II. Korean healthcare decision making system

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 centered 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 the committee chair nor any of the committee members, 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 labor 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 changes 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.

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 modeling 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.

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, categorized 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 arthritis pain. Participation included patient surveys of patient views, and also open hearings.

In the case of the glucosamine 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. As this example showed, process values such as transparency, accountability, and participation, are better reflected in Korean healthcare decision making process whereas some content values such as justice/equity, solidarity, and autonomy are not clearly defined in the process and rarely observable in the process.

Conclusions

Given that most information on the Korean healthcare decisions is only available in Korean, hence, this study serves as a rare summary of Korean healthcare decision making process for the non-Korean speaking researchers. 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, especially participation. Other process values such as transparency and accountability are employed to some extent but not sufficiently since there are still arguments on these values. In many cases, clear explanations for why the decisions are made are missing in the publicly available documents.

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 their decision making process.

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