

Health technology assessment in South Korea

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Objective: To analyze evolution of the health technology assessment (HTA) at the national level in South Korea.

Methods: Analysis of public documents, personal communication, and literative review.

Results: HTA in South Korea has been developed since 1990s, first introduced by academia and institutionalized within the National Health Insurance (NHI). Rapidly increasing expenditure had been a challenge of the NHI, which considered health technology management as a cost controlling measure. An amendment was made to the NHI Law in 2000, and provision was made to regulate the process of determining new insurance benefits including procedures, drugs, and equipment. This requirement made the NHI agencies to promote HTA approaches in connection with the government and professional organizations. Also the Healthcare Act was revised in October 2006 ruling that HTA focusing on safety and effectiveness be responsible for new health technologies. Currently, the HTA process is governed by a governmental committee comprising twenty members and technically supported by the HTA center created in the NHI structure.

Conclusions: Institutionalized HTA in Korea has been driven mainly by the requirements of the NHI and manifested strengths as well as weaknesses. The government is establishing a new organization for HTA, independent from the NHI.

Keywords: Health insurance, Pharmaceutical economics, South Korea, Technology Assessment

HEALTH TECHNOLOGY ASSESSMENT IN SOUTH KOREA

The Healthcare System

The healthcare system of South Korea (hereafter Korea) has traditionally been dominated by the private sector, with more than 80 percent of hospital beds being privately owned. This is attributable to the low investment in the health sector by the Korean government since the 1970s, when a public health insurance system was set up to lower the economic barriers to healthcare utilization (2).

Compulsory health insurance was first introduced in 1977, and achieved universal coverage in 1989 to form the National Health Insurance (NHI) system. The financial resources of the NHI come primarily from contributions paid by the insured and their employers, but are partially subsidized by the government (currently approximately 20 percent of the total revenue of the NHI). It is self-evident that healthcare utilization and health expenses have increased remarkably over the past 30 years. The annual days of healthcare utilization

per capita have increased from 7.7 in 1990 to 16.0 in 2006, and NHI expenditure has increased ten-fold between 1990 and 2006 (3). However, despite the rapidly increasing healthcare demand with the introduction of the NHI, the government has depended on the mobilization of private resources based on market mechanisms instead of direct investment. Healthcare providers and industry have behaved according to economic incentives by supplying services to be used by consumers. The intensifying dominance of the private sector in healthcare provision has led Korean healthcare to exhibit the characteristics of a free market, even within the NHI system. The provision of beds and major technologies is associated with profits and is operated as in a commercial business, even though the law does not allow for-profit hospitals.

As a result, healthcare resources are unevenly focused on acute care, tertiary care (versus primary care), and new and expensive technologies. In 2006, the number of acute hospital beds was 6.8 per 1,000 of the population, which is far higher than the average and one of the highest among the Organisation for Economic Co-operation and

Development countries (5). There are 13.6 magnetic resonance imaging units and 33.7 computed tomography scanners per million of the population, which is significantly more than in other developed countries. Private-sector dominance is not confined to the provider mix; it is also identified in the composition of healthcare expenditure. In 2006, public health expenditure comprised 55.1 percent of the total expenditure on health (5), a figure that is among the lowest in the developed countries. In addition, total healthcare expenditure has rapidly increased, almost doubling between 2000 and 2006 to reach 6.4 percent of the gross domestic product.

From another perspective, the NHI has suffered from the limitation of benefit coverage, and in particular large copayments from the insured. In addition to the traditionally rather high copayment rates, certain essential services, such as ultrasonography and expensive new drugs, have remained outside the coverage of insurance benefits due to financial considerations. For inpatient care at either a clinic or hospital, patients have to pay approximately 20 percent of the cost formally through copayment, but the total actual copayment is somewhat higher than these rates, because patients also have to pay informally for various services that are excluded from these benefits. The effective total copayment rates in 2007 were estimated to be approximately 33.5 percent for inpatients (4).

Regulations

The Ministry of Health, Welfare, and Family Affairs (MIH-WAF) is the cornerstone of healthcare regulation, including technology. The basic regulatory scheme for healthcare is divided into two interrelated but separate structures: healthcare regulation and NHI requirement. The Healthcare Act is a platform for controlling healthcare supply and provision in general, by putting in place standards and criteria for healthcare facilities and the workforce. However, the Act only provides minimum requirements and cannot control the healthcare providers in the market. For example, new construction of hospitals or hospital beds should be approved by the local government, but they are not regulated at all in reality. Capital investment in, for example, high-cost technology is determined by each hospital, including public hospitals, investment in which also depends on its own revenue generated from the healthcare market.

NHI regulations are more influential in terms of controlling provider behavior, because they are more directly related to the financial incentives. The NHI is a single payer with a monopsony, and can regulate the providers in several ways. First, the determination of benefit, although eventually under the control of the government, is a strong factor in provider decision making as to whether or not a technology is adopted. For example, the use of positron-emission tomography has proliferated since the NHI included this tech-

nology in its insurance benefit list. Another mechanism by which technology adoption and diffusion are affected is how well a technology is paid by the NHI. The payment policy is an effective way of controlling the technology market, if indirectly.

INTRODUCTION OF HEALTH TECHNOLOGY ASSESSMENT

Traditionally, the driving forces of health technology assessment (HTA) in Korea have been closely connected to the twofold challenges of health technologies: the source of healthcare expenditure and inefficient use of technologies. These challenges are undoubtedly the outcomes of the overall performance of the healthcare system.

HTA initially attracted the interest of researchers, and the area of health services research in particular; as might be expected, healthcare quality issues were the reasons underlying this interest. In 1990, some researchers based in a university department (Department of Health Policy and Management, Seoul National University College of Medicine, Korea) initiated government-funded research on the current quality problems and policy measures. The results of this research aroused noteworthy responses from policy makers as well as other researchers, and subsequent research and policy development has thus been performed by a bigger pool of researchers. In addition to the institution-based approach, they also covered policy framework at the national level. Their interest in national-level policy led to the expansion of academic interest to cover HTA for the cost-effective use of technology. For them, the rational adoption and utilization of technologies, which had been very much *laissez-faire*, became one of the main challenges to improving quality in healthcare. However, no policy makers at that time were aware of the potential implications of health technologies in health care and health insurance.

The ever-expanding interests of researchers resulted in government-funded research into the national HTA policy in 1995. This research, which was on a relatively large scale by Korean standards at that time, was led by the author and covered the basic theory and methodologies of HTA, the current status of health technologies and problems, and the national policy proposal. Although the rather ambitious aim of that research was to provide a comprehensive national policy, the impact was not very influential, partly because the government was not prepared to consider HTA in the management of health technologies. However, the need for a new approach to health technology was now being recognized by stakeholders, even if this interest was sporadic and rarely systematic. In addition, one of the other driving forces was diffusion of the global approaches to HTA into Korea. For example, more Korean researchers have participated in international HTA meetings, and influential scholars, such as Dr. David Banta (in 1999), have visited Korea and communicated with stakeholders.

INSTITUTIONALIZATION OF HTA

An amendment was made to the NHI Law in 2000, and provision was made to regulate the process of determining new insurance benefits including procedures, drugs, and equipment. With this change, an agency of the NHI, the Health Insurance Review and Assessment Service (HIRA, formerly the Health Insurance Review Agency), which is responsible for working-level benefit determination, produced new measures for dealing with the emerging need for more rational decision making. The HIRA is a semigovernmental organization that was set up to review insurance claims and assess the quality of health care. In addition to its core functions, the HIRA has supported governmental policy making on benefit determination and fixing the fee schedule at a working level, which has led to requirement to enhance rationality in the decision-making process. As one of such measures, HTA has strongly attracted attentions of the HIRA as well as the government. First, the HIRA developed a more explicit evaluation process, which required the applicants to provide all available evidence to be approved by the formal committees within the HIRA. Second, human resource development was promoted to meet with the need for more expertise. A new section was instituted within the HIRA and several professional staffs were trained both at home and abroad. Third, the HIRA has been an advocate for HTA by sponsoring academic meetings and disseminating relevant information among stakeholders.

Another driving force pushing HTA forward was the NHI financial crisis during 2001–02; as a direct result of the separation of prescribing and dispensing, and the doctors' strike in 2000, payments to doctors and pharmacist were greatly increased. The government and the NHI were very eager to contain NHI expenditure and paid attention to the potential effect of more prudent use of health technologies. The first initiative was from the area of healthcare policy, not NHI policy directly related to the financial crisis. However, it was only reactive to general hostility of healthcare providers to the widespread cost-containment measures by the NHI. Officially, the government had noticed on several occasions that the aim of managing technology was to rationalize overall health technology management, which is not related to NHI cost-containment measures. In fact, they had long been criticized for not fulfilling their responsibility of managing health technologies. Until that time, there had been no formal process for assessing the safety and efficacy of health technologies, and instead the NHI had assessed safety and efficacy, and sometimes efficiency, for their own purposes.

The aim of the healthcare policy section of the government was, at least officially, to construct a formal structure for HTA that was separate from the NHI. However, despite the formal notice, nobody could deny that the implicit goal of the government was to regulate new technologies from the perspective of cost containment. This is why almost all health technologies have been used within the realm of the

NHI. Until recently, health technologies outside of the NHI have been very rare, and HTA solely for healthcare policy area is not plausible. In addition, the government was unable to locate an appropriate agent for HTA except for the HIRA, only the professional staff of which had some experiences with HTA. As a consequence, in 2003, the government requested that the HIRA organize a preparatory team to establish an independent HTA organization. That HIRA team, with a staff of four to seven, operated until June 2007 when a formal organization having been launched based on the Healthcare Act revised in October 2006 ruling that HTA be responsible for new health technologies.

Between 2003 and 2007, the main goal of the HIRA (preparatory) team was to establish the basics for a government-led HTA. Activities included staff training, education of professionals (physicians and nurses), collection and dissemination of information, creation of a clearing house, and pilot assessment. They also cooperated with the government to revise the Healthcare Act to include HTA. One of their more highly prioritized activities was to build a consensus for HTA within the academic community, mainly in medical professional organizations. Perhaps not surprisingly, many academic organizations had already an interest in evidence-based medicine (EBM), and HTA was strategically combined with the "move" toward EBM. For example, in 2005, the HIRA team hosted an international conference on evidence-based decision making and attracted an audience of more than 700. Invited speakers came from various countries, including the United Kingdom, United States, Canada, and Australia. Although the meeting was held under the title of EBM, its actual aim was to disseminate the rationales and principles of HTA. In the meantime, two pilot assessments were performed for radiofrequency ablation in liver cancer (2003) and the real-time polymerase chain reaction (2005). Staff training took place intramurally until 2007 when the HIRA team opened training sessions for hospitals and professional organizations and attracted surprisingly large numbers of applicants. The widespread concerns of hospitals and health professionals reflected the governmental HTA policy, but more importantly the expected requirement for an explicit process for the approval of new technologies by the NHI.

Another track related to HTA was the evaluation of pharmaceuticals. Traditionally, the proportion of pharmaceutical expenditure of the total health expenditure has been fairly high compared with other developed countries. In 2006, drug expenses comprised 25.8 percent of the total health expenditure (5), and approximately 30 percent of the NHI expenditure. As a result, the government and NHI have been concerned about the utilization and reimbursement of drugs. In May 2006, the MIHWAF proposed a pharmaceutical policy reform to include conversion of a negative to a positive list system. Until then, as many as 28,000 drugs were listed, and the reimbursement method was criticized as being unreasonable and cost pushing. The main pitfall of pricing was believed to be the absolute lack of evidence of

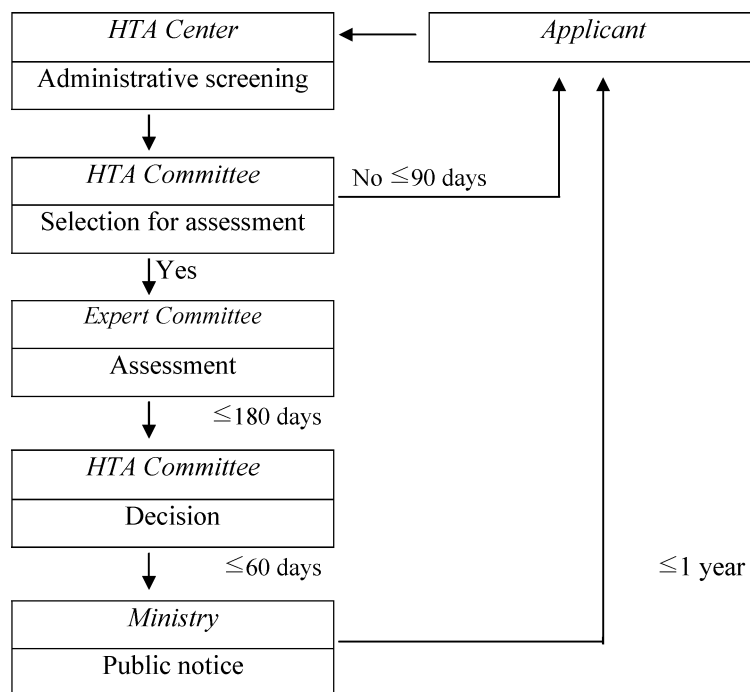


Figure 1. Flow diagram of health technology assessment (HTA).

cost-effectiveness, for both brand-name and generic drugs, in the decision-making process. For example, in some cases drug companies produced more than fifty different generic drugs for a chemical entity and prices varied to a large extent. This was an inevitable consequence of the preexisting pricing system, which was not based on reasonable principle(s). To address this issue, the government planned to adopt an economic evaluation for new drugs as well as prelisted drugs in selecting drugs to be listed. Although the application of the new policy was noticed as to be implemented in an incremental manner, this evaluation of drugs has emerged as one of the most debated topics in both academia and industry. Again the HIRA, already responsible for the price setting of drugs, had to design a new system for the economic evaluation of drugs that was separate from the building HTA scheme. The drug-evaluation program is not connected to the HTA process and is linked to the preexisting drug-benefit determination process.

HTA NOW

The revised Healthcare Act including provisions on HTA was passed by the National Assembly in October 2006, ruling that every new technology should be assessed in terms of its safety and efficacy. However, technology is rather narrowly interpreted and does not cover drugs and systems. In addition, because this legislation is not part of the NHI Act, new technology is not obliged to apply to be approved as insurance benefit. The Healthcare Act stipulates the new HTA process be governed by an HTA committee comprising twenty members appointed by the Minister of MIHWAF.

Current members comprise nine from the field of medicine, two dentists, two Korean traditional medics, two consumer organizations, one lawyer, three from health policy and management, and one from the government. The committee also comprises five expert subcommittees: internal medicine, surgery, other medicine, dental medicine, and Korean traditional medicine. Each expert committee must comprise more than 30 members; there are currently 248 members appointed. Ad-hoc expert subcommittees are responsible for systematic literature reviews and draft reports.

In June 2007, the government contracted with an expanded HIRA team to perform HTA on behalf of the government, and the HTA Center was created within the HIRA according to the rulings of the Act. Although the center was to be managed administratively by the HIRA, its function is actually independent, but under government supervision. A flow diagram of HTA is shown in Figure 1. The time limit for a decision on selection for full assessment is 90 days, and that for total assessment is 1 year. After the launch of the HTA Center in 2007, fifty-five applications were submitted and twenty-two were accepted for full assessment (1). A mean of 74.9 days were required to make a decision as to whether to put a technology forward for full assessment. In 2008, thirty-four full assessments are being performed for including skin allograft, small-intestine transplantation, stimulation of the motor cortex, extracorporeal photopheresis, autologous bone-marrow stem-cell transplantation, and high-frequency chest-wall oscillation. Currently, at the end of 2008, committee activities are supported at the HTA Center by twenty-three staff, including eighteen researchers, and a revenue of approximately €1,000,000 (1).

In addition to HTA, the pharmaceutical benefit section of the HIRA has been performing independent economic evaluations of drugs since early 2007. However, the HTA for drugs are a combination of traditional assessment for pricing and new paradigm of more systematic evaluation. For the new economic evaluation, the HIRA initially targeted new drugs, and subsequently two groups of old drugs, those for migraine and cholesterol-lowering agents, as pilot evaluation. Despite policy drive, main feature of evaluation for new drug is still traditional, only reviewing submitted data on economic evaluation by manufacturers. From January 2007 to June 2008, seventy-eight new drugs have been evaluated (1).

DISCUSSION

Institutionalized HTA in Korea has been driven mainly by the requirements of the NHI. As a consequence, the structure of HTA has become embedded within the NHI. It has both strengths and weaknesses. First, providers cannot escape the HTA framework if they wish to be reimbursed by the NHI. Although current HTA structure and function are theoretically independent of the NHI, actual implementation is not free of NHI influence. It provides a strong incentive for new technologies to be assessed. However, HTA is vulnerable to the influences of the NHI, particularly its financial status. This relationship between HTA and NHI has aroused some critics from academia as well as healthcare providers. As a result, the government has proposed the establishment of a new national independent organization for HTA and related research, based on the model of the National Institute for Health and Clinical Excellence of the UK. This new institute is under design and will be complete in 2009. Tentatively, the institute will take over the function of the HTA Center based on the HIRA, but not drug evaluation. It means that HTA function could be separated between the new institute and the preexisting HIRA. In this case, the NHI could perform a portion of HTA for its own purpose, evaluation of technologies for the determination of benefit focusing on cost-effectiveness. Even in this case, of course, the NHI could contract out HTA activities to the new institute. However, it is very probable that national HTA scheme will be divided and a new challenge for functional integration will be issued.

Separation of drug evaluation from the HTA reflects the division of healthcare policy and drug policy at the policy-making level in the Ministry. Although there could be several special issues for drug evaluation, a fragmented HTA structure seems to be inefficient. However, the integration will not be achieved easily, even after the establishment of the new HTA organization, because drug evaluation is currently very deeply embedded in the NHI scheme. More fundamental change of drug policy in the NHI, such as a complete change to positive listing, could facilitate the integration of HTA functions with different historical paths.

The strategic approach of the HTA to professional organizations has been to emphasize the implications of EBM

in healthcare practice through joint academic activities. The government and HIRA have also supported professional organizations, specialized in their discipline but not strong in the HTA-related areas, by providing expertise and information. These cooperative approaches have minimized resistance from health professionals and the main stakeholders of professional organizations. The negative side of these approaches is the rather weak involvement of citizens and consumer groups in the process. Although the NHI Act requires the participation of representatives from citizens or consumer groups, they are actually other professions only representing groups. From very early stages there has been no systematic effort to involve lay persons in the process; it is important socially to make a more concerted effort to include such people in the formal decision-making process.

Technically, one of the biggest challenges has been, and still is, how to develop human resources. From the very early stage of development, the HIRA has concentrated on the recruitment and development of professional staff. However, the number of well-trained staff has been insufficient, and this shortage has had a pivotal influence on the progress of the overall HTA. It will take a long time to meet the fast-increasing demand for HTA inside as well as outside of the current HTA system.

HTA in Korea is still evolving to formulate a nationwide system. Until recently, the system has been heavily dependent on the NHI system. However, with the establishment of the new institute, the HTA system will be more independent from the NHI and faced with new challenges including how to efficiently manage technologies rapidly introduced into marketized healthcare system. Stewardship of the government, with effective utilization of the NHI mechanism, will play a pivotal role in rationalizing HTA system.

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