Executive Summary

Establishment of administration system by developing a process and methodology for the health technology reassessment program

Dong Ah Park[1], Min Lee[1], Yunjung Kim[1], Jimin Kim[1], Eunjung Park[1], Ji Jeong Park[1], Ji Eun Yun[1], NaRae Lee[1], YuRim Kim[1], Wolsook Lee[1], Junghub Lee[1], Insoon Choi[1], Jayun Lee[1], Aejung Cho[1], Jessie Lee[1], Kyunghee Han[1]

[1] National Evidence-based Healthcare Collaborating Agency

▢ Background

With the announcement of the health insurance coverage reinforcement policy in August 2017, the Ministry of Health and Welfare suggested the policy direction of using health technology reassessment to promote the widespread use of safe, valid, and cost-effective health technologies by the public.

A preliminary benefits policy, in which benefits for health technologies that have a medical necessity but are not cost-effective are determined by health technology reassessment after 3-5 years of use, was suggested. This proposal also underscores the need to prepare additional management mechanisms for conducting reassessments of existing health technologies that are covered but may have safety or efficacy issues.

Korea has no management mechanism for health technologies after they enter the healthcare market and are in use. Therefore, it is urgent to prepare a health technology reassessment system to manage the whole cycle of health technologies within the framework of the Medical Service Act, to support decision-making regarding the suitability of health insurance benefits according to the newly reorganized health technology reassessment system, and to develop measures to build accompanying infrastructure for health technology reassessment.

▢ Objective

The purpose of this research is to establish a system for managing the whole cycle of health technologies and to prepare operational measures to promote the efficient use of healthcare resources. Specifically, this study aims to propose a detailed implementation process and practical operational methods for health technology reassessment implemented by the National Evidence-based Healthcare Collaborating Agency (NECA), and to suggest measures for constructing an information system and legal framework for health technology reassessment in order to provide support for policy decision-making within the healthcare system.

Section 1: Implementation of Health Technology Reassessment

▢ Methods

Foreign health technology reassessment systems were analyzed through a literature search of domestic and international databases, and implications for a health technology reassessment system suitable for Korea were deduced.

Related international laws and standards, reports, and papers were examined, from which data were collected and confirmed through interviews with experts in each field of health technology, experts in healthcare policy, experts in methodology, and persons in charge of the operation of the pertinent systems.

The status of policies regarding the introduction and operation of health technology reassessment systems in major countries was examined. Implications were deduced for the establishment of health technology reassessment in Korea, and some points of view were confirmed. To that end, in-person and written consultations regarding health technology reassessment were held with domestic and international experts. In particular, we visited Health Quality Ontario (HQO) in Canada and the

Medical Services Advisory Committee (MSAC) in Australia (organizations that assess health technologies), directly collected information about their activities, and attended meetings where health technology assessment was conducted to evaluate their assessment methods and the methods used to reach agreement for determining recommendations.

We planned detailed measures for implementing health technology reassessment through a literature search of domestic and international policy-related literature and through in-person meetings with international experts during visits to organizations in major countries, based on data and evidence from pilot studies on existing selective benefits reassessment research. The consultations with experts in related fields were regularly held according to the draft plan, and a multidisciplinary advisory panel (containing over 18 persons) was organized. Through deliberative procedures at over six in-person meetings of the panel, we modified and supplemented plans for the overall health technology reassessment system.

A trial recommendation decision was carried out to confirm that the goals for the recommendation processes were achieved and that the process worked as intended. Another purpose of this trial was to identify revision and improvement measures through a virtual application of the draft plan and the decision-making process for recommendations.

Eighteen persons on the advisory panel for health technology reassessment virtually played the roles of the health technology reassessment committee and other agents involved in the trial application of the recommendation process. The health technology used for the trial application was robot surgery for prostate cancer. We conducted the trial application of health technology reassessment based on research reports conducted by NECA in 2013 and 2014. For the trial recommendation decision, a preliminary meeting was held and the final meeting for making a recommendation was held at the plenary meeting on November 21, 2018. The procedure for reaching agreement on the final recommendation decision was applied, and after the trial procedure was

concluded, we discussed possible ways of revising and complementing the draft plan and the process of making a recommendation.

Integrating expert advice for each step and discussions of the advisory panel, we suggested policy directions for a whole-cycle health technology assessment system that can promote the appropriate use of future health technologies and the efficient use of healthcare resources.

▢ Results

1. Status and Implications of the Health Technology Reassessment System

Health technology reassessment systems have been established worldwide since the mid-2000s. Although Spain and the US operate separate health technology reassessment programs, most countries (such as the UK and Canada) operate a reassessment system within the health technology assessment process.

Although some countries utilize health technology reassessment only to promote market exit of health technologies, most countries, including Korea, aim to optimize the use of existing health technologies and to promote disinvestment as appropriate.

Healthcare technologies are selected for reassessment based on suggestions from a variety of stakeholders and by prioritizing the applied health technologies.

Furthermore, for health technology reassessment, social, ethical, and economic factors should be assessed more broadly, in addition to clinical parameters. Generally, health technology assessment institutions conduct reassessment, and the process and methods of reassessment are not significantly different from those of health technology assessment. The relevant institutions examine clinical safety, effectiveness, and economic feasibility based on systematic literature reviews and use other research methods as appropriate, such as analyses of economic feasibility and

investigations of medical use amount and preferences by using data from patients in their country.

The results of health technology reassessment are presented as recommendations or used as a basis for supporting decision-making by the policy-making authority (regarding issues such as decisions about public resource investments and benefits) and by stakeholders, such as healthcare providers and users.

2. Health Technology Reassessment System

Health technology reassessment is a structured multidisciplinary method of analyzing health technologies currently used in the medical system based on the most up-to-date information on parameters such as clinical safety, comparative effectiveness, social and ethical problems, and the economic feasibility of promoting the efficient use of healthcare resources and optimizing health technology. The purpose of health technology reassessment is to promote the proper use of health technologies and to provide a basis for policy decisions regarding the management of existing health technologies.

The framework of this project suggests NECA's operation of health technology reassessment. The scope of health technology reassessment includes all existing covered benefits, selective benefits, and uncovered benefits. The core items evaluated in health technology reassessment include clinical safety, effectiveness, and cost-effectiveness. Additionally, social value in various domains and the feasibility of reassessment are considered as items to assess in the recommendation decision.

The basic areas to be considered in health technology reassessment include disease burden (priority, importance), evidence level (degree of confidence about the effect of health technology), equity, and acceptance. Recommendations, along with their rationales, are proposed based on the various items that are evaluated in the reassessment process.

The procedure of health technology reassessment involves 3 stages: selecting a technology for reassessment, carrying out the reassessment, and determining the recommendation. The total required duration can be between 7 month and 24 months due to differences in assessment methods according to the characteristics of health technologies. In all stages, opinions should be collected from experts and stakeholders, such as patients, and all decision-making stages of the reassessment procedure should be managed transparently.

Major decisions of health technology reassessment are made by the health technology reassessment committee, while details related to the reassessment process are discussed and decided at the subcommittee level. The final report of health technology reassessment is submitted to the drug reimbursement evaluation committee and to the healthcare review and assessment committee to support decision-making about drug reimbursement and policy.

3. Selecting Candidates for Health Technology Reassessment

Technologies are selected for reassessment by collecting data about candidate technologies for reassessment, and then listing, screening, and prioritizing the candidates. The process also includes a needs assessment survey to reflect external viewpoints and internal monitoring activities to identify candidate technologies.

The procedure of selecting technologies should include a preliminary examination of the candidate technologies, and the NECA reassessment operation team will create an information sheet to support the selection of candidates for reassessment and operate the health technology reassessment committee. In the process of selecting technologies, the information sheet can be examined to identify advice from clinical experts, and the final prioritization of candidates is determined by the health technology reassessment committee.

The health technologies that are reassessed should be in current use,

with alternative treatments that have safety issues, require evaluation for effectiveness, impose excessive or inappropriate medical costs, or show noticeable changes (increases/decreases) in frequency of use

Anyone, including various stakeholders, healthcare experts, and patients, can suggest health technologies for reassessment and propose topics for discussion by collecting opinions from related organizations and clinical associations or by participating in regular discussions at the reassessment working group conferences held by relevant organizations such as Ministry of Health and Welfare and the Health Insurance Review and Assessment Service (HIRA). The candidates are selected from suggestions or based on internal monitoring. Candidates for reassessment are prioritized logically, according to priority selection criteria that have been prepared to maintain the appropriateness, efficiency, and objectiveness of technology selection. Scores are calculated using an objective index derived from the information sheet to ensure that candidates are selected for reassessment in a valid, applicable, and transparent manner.

The final stage of selecting technologies for reassessment is to hold a pre-discussion with the Ministry of Health and Welfare about the possibility of executing reassessments of the list of prioritized candidate technologies and to finally confirm the subject of reassessment at a meeting of the health technology reassessment committee.

To ensure procedural transparency in the selection of technologies for reassessment, the relevant information will be disclosed on the homepage to solicit the opinions of various stakeholders, such as clinical associations, patient/consumers, citizen groups, and industry.

4. Performing Health Technology Reassessments

The process of carrying out the reassessment includes a planning stage where the scope of reassessment is decided and a stage where the reassessment is actually carried out, generating a report.

To specify the scope of the reassessment, the assessors, stakeholders, and expert assessment committees by field are gathered, the reassessment scope is summarized, and the opinions of stakeholders are collected. Through these steps, the health technology reassessment committee determines the final scope and methodology of the reassessment.

The items that are assessed are mainly divided into 1) disease and medical use status, 2) safety and effectiveness, 3) economic feasibility, and 4) social value. Medical use status, safety, and effectiveness are basic items that are evaluated for all technologies being reassessed. For health technologies whose safety and effectiveness have not been ensured, safety and effectiveness are investigated through a systematic literature review, performance analysis, and construction of prospective clinical data. Furthermore, when the scope of the reassessment is confirmed, additional evaluations of economic feasibility and social value can be conducted when appropriate based on treatment effectiveness, disease burden, and social need.

An economic feasibility assessment, including a cost-effectiveness analysis, is conducted when the clinical effectiveness of a technology is confirmed to be to higher than that of alternative treatment methods.

A financial influence analysis is conducted when it is necessary to predict the influence of a technology on health insurance finances in the future, and such an analysis considers the application of new health insurance benefits or changes in current benefit criteria (benefit rate or increases/decreases in indications).

Prospective clinical data are constructed when technologies relate to the specific characteristics of domestic diseases and disease burden (e.g., technologies that require the creation of domestic databases on diseases such as gastric cancer or liver cancer), when database creation is difficult in real-world circumstances (e.g., technologies with for which clinical and industrial researchers have a low motivation to create databases, or technologies for rare incurable diseases), and when

long-term results must be gathered due to specific characteristics of the health technology in question (e.g., technologies with controversial long-term results in the opinion of experts).

Detailed assessment methods and assessment plans are made based on a summary of the scope of the assessment, and assessors and subcommittee members are assembled as appropriate based on the scope, items, and methodology of the assessment. The final assessment plan is then approved by the health technology reassessment committee.

The reassessment execution team carries out the reassessment according to the approved protocol, and subcommittee and expert meetings are held for each stage.

The assessment report is developed by integrating information about clinical safety, effectiveness, economic feasibility, financial influence, and social value, and a draft of the assessment report is submitted to the health technology reassessment committee after collecting opinions from the subcommittee.

5. Determining Recommendations

For determining recommendations of health technology reassessment in a way that promotes the efficient use of healthcare resources, a scientifically-reasonable and practical system must be established for reaching agreement among the sub-processes of health technology reassessment carried out by the NECA. Thus, we have planned the recommendation system, including specifications of the form of the final recommendation, the method for reaching agreement, and related data, as well as detailed procedures for the process between the execution of a reassessment and the announcement of a recommendation.

Plans for a recommendation system, agreement method, recommendation form, and process were drafted based on the practices of domestic and foreign health technology assessment organizations and clinical treatment guidelines, and they were finalized based on expert

advice and a trial application of the recommendation system. The recommendation system consists of two grades: "Ⅰ. Recommended," and "Ⅱ. Not recommended", with subgrades of "I-a" (Strong recommendation strength) and "I-b" (Weak recommendation strength) prepared.

The form of the recommendation for a given technology consists of the recommendation itself and its rationale. The recommendation is written in a way that refers to the decision-making agent (the health technology reassessment committee), candidates, indications, related conditions, and recommendation grade. Opinions on the recommendation decision and additional necessary matters (accumulation of evidences, limit of use) are presented in the rationale.

The decision-making agent for recommendations is the health technology reassessment committee, and the method for reaching agreement is discussions at in-person meetings. Specifically, the established agreement process involves discussion of the items being reassessed (with no need to agree on the individual items) and subsequent agreement on the final recommendation grade. Committee meetings for deciding a recommendation will only be held when the majority of members participate and the decision on the recommendation grade must be based on the agreement of at least two-thirds of the present members.

However, when agreement is not reached, a second round of discussions is held. If members do not reach agreement (with a threshold of at least two-thirds of the present members) in the second round, the agreement criteria will be lowered for the third round of discussions. In the third round, the decision about the recommendation grade only requires a simple majority. In the event of a tie in the third round of voting or in further rounds, the chairman will have the tie-breaking vote.

The final recommendation and rationale will be announced by the Ministry of Health and Welfare, after which opinions will be collected from the public for about one month (20 work days), and the content of

the reassessment report and recommendation decision will be posted on the NECA homepage and forwarded to related organizations.

Section 2: Infrastructure for Health Technology Reassessment

▢ Methods

First, the domestic and international literature, legal materials, and the status of reassessment-related committee construction procedures were investigated. Regarding construction of a platform for health technology reassessment, the platforms of organizations such as Clinical Practice Research Datalink (CPRD), Medical Research Council (MRC), National Cancer Registration and Analysis Service (NCRAS), and National Health Service (NHS) digital were benchmarked through in-person overseas visits.

Second, experts' opinions on the content and aims of laws related to reassessment and the construction and procedures of the health technology reassessment committee were collected, and input was solicited on plans for a health technology reassessment platform.

▢ Results

1. Examination of Laws for the Introduction of the Health Technology Reassessment Institution

It was suggested that the relevant content for a health technology reassessment institution should be incorporated through amendments of the Medical Service Act, which provides the legal basis for new health technology assessment. Although the subject of the law is stipulated to only include new medical technology (in Article 53 of the Medical Service Act), an amendment was prepared to expand the subject of the

law by including health technology reassessment, with a newly established provision recommending prohibition of use or limitation of use as measures to be taken based on health technology reassessments in Article 52 (2). A plan for establishing the health technology reassessment committee was prepared in Article 54 (2), and an amendment including health technology reassessment into the entrustment of affairs for new health technology assessment was suggested in Article 55. In Article 55 (2), a provision for authorizing data collection from government agencies, public organizations, and medical institutions was established. In the Penal Provisions of Article 88, a provision penalizing those who use prohibited health technologies was newly established, and in Article 56, a provision for prohibiting medical advertisement of the prohibited health technologies was inserted.

2. Construction and Procedures of the Health Technology Reassessment Organization (Committee)

To construct a health technology reassessment committee, a plan was made to reorganize the health technology assessment committee by expanding and reorganizing it according to the basic plan of health technology assessment of the Ministry of Health and Welfare. However, according to expert advice that a separate committee should be constructed, as the process and content of health technology reassessment differ from those of new health technology assessment, a plan to construct a separate health technology reassessment committee (tentative name) was suggested. It was suggested that the health technology reassessment committee should include representatives of the medical field recommended by the Korean Medical Association, the Korea Dental Association, and the Society of Korean Medicine; lawyers recommended by the Korean Bar Association; experts of evaluating economic feasibility in the healthcare field; experts in evidence-based medicine; the department head in charge of the entrusted organization; persons

recommended by patients, consumers and civic groups; and division managers of the Ministry of Health and Welfare. We first suggested including representatives from industry, because this arrangement was found in some of the international cases studies that we evaluated. However, we ultimately chose to exclude such representatives based on the advice of the advisory panel of experts, who pointed out that the interests of industry are clear and that industrial representatives could put issues regarding competitors on the agenda. Instead, industrial representatives will be given an opportunity to suggest opinions.

3. Construction and Use of the Health Technology Assessment Information System

As a platform for health technology reassessment, we suggested analyzing cumulative real-world data at a secure server administered by NECA and evaluating and analyzing data requiring linkage by connecting that server with those of organizations that maintain public archives.

An online case report form (e-CRF) including a unique identifying key and sensitive information was developed to collect data in clinical settings. Among the collected clinical field data, non-secure data and secure data that include sensitive information are managed separately in general-purpose data storage servers and secure servers. The analysis/storage server of the NECA is used for the analysis and storage of non-connected data, and when linkage with public archives is needed, we suggest conducting a virtual analysis, using the server of the related public organization for analysis and storage.

▢ Conclusions and Policy Suggestion

Although the treatment of diseases and improvements in quality of life

are the ultimate goals of the healthcare system, chronic diseases are gradually becoming more common, aggravating the burden of national medical expenses for health technologies. It is necessary to assess how beneficial health technologies are for patients and the medical field to support policy decision-making for existing health technologies given limited financial resources amid the increasing expense of health technologies as part of initiatives to strengthen health insurance coverage.

Recently, a variety of policy efforts and discussions to strengthen health insurance coverage have been held internationally due to the increased medical expenses caused by an aging population. These considerations are also quite important for domestic health policies. For this reason, in Korea, policy strategies are needed to promote the management and appropriate use of existing health technologies considering value changes across the whole cycle of health technologies.

This research is significant in that it promotes the appropriate use of health technologies by preparing a foundation for the execution of health technology reassessment with the purpose of supporting reasonable healthcare coverage and medical decision-making. Fragmented decisions are currently being made by medical service expert evaluation committees, treatment material expert evaluation committees, and drug benefit evaluation committees regarding benefits for services, treatment materials and drugs, respectively. Generally, those expert committees are operated by the experts recommended by each group, with poor controls in place to manage conflicts of interests. Therefore, a system is needed to supplement existing methods.

The advantage of this plan is that it improves objectivity and consistency in the execution of reassessment, and changing social values can be appropriately reflected by collecting data from patients. It is also necessary to reflect the opinions of stakeholders, such as clinical experts, patients, and industrial representatives in all stages of the procedure of selecting technologies for reassessment, carrying out the reassessment, and

determining the recommendation. These stages comprise the entire process of health technology reassessment, and all decision-making stages should be managed transparently. Additionally, this study presents plans to construct corresponding research panels to carry out the reassessment by suggesting specific practical measures for health technology reassessment.

The short-term plan for managing the whole cycle of health technologies based on this study is to update their evidence level based on the list of technologies for which new health technology assessment has been executed and to carry out reassessments on that basis. It is especially important to stabilize the corresponding institutions in the domestic health system as soon as possible by presenting detailed content about the health technology reassessment system and the construction of its infrastructure.

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Key words

Health technology reassessment, Health insurance coverage reinforcement, the Optimal use of health technologies, Prioritization, Execution of reassessment, Recommendation decision, Infrastructure, Medical Service Act, The health technology reassessment committee, Information system