Executive Summary

Study of Horizon Scanning and Potential Health Impact Assessment of Emerging Health Technology and Development of Operation System of H-SIGHT

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▢ Background

The increasing investment of research development expenditure in healthcare is predicted to continue in response to increased demand for new health technologies aimed at assisting aging populations, promoting public health, and improving quality of life. However, in 2012, the National Science and Technology Council (NSTC) has pointed out overlapping investments in research development expenditure on healthcare, and new problems are arising due to the spread of new health technologies. It is, therefore, necessary to establish a strategy to promote introduction of new, useful, and effective health technologies to the healthcare sector and to minimize the range of error due to uncertainty about the future. This may be achieved by systematic implementation of scanning activities for newly developed health technologies, making use of methodologies based on existing health technologies as well as future forecasting techniques.

In order to address these types of issues, developed countries have implemented an early awareness and alert (EAA) system. The National Evidence-Based Healthcare Collaborating Agency (NECA) performs horizon scanning activities relating to new health technologies just before their entry into markets and preemptively analyzes their safety and effectiveness in

healthcare as well the potential impact of these technologies on society.

The horizon scanning activities, that provide opportunities to discover new and emerging healthcare technology at the natural level, were introduced in the domestic healthcare sector to contribute to an efficient allocation of health services and clinical research resources, and to prevent indiscriminate spread of health technologies with latent potential for harm or abuse. Supports and planning are urgently needed to strengthen the practical functioning of horizon scanning activities that identify new and emerging health technology by implementing in a manner appropriate to domestic conditions. Establishment of this horizon scanning system requires a pilot project and horizon scanning activities to build the groundwork for its safe use as an independent system in the future.

▢ Objectives

The purpose of this study was to develop an optimized horizon scanning system appropriate for Korea by implementing a pilot horizon scanning activities' operating system for new and emerging health technology developed in 2013.

In order to achieve this purpose, the first part of the study built collaboration with domestic agencies and an international network related to horizon scanning activities for new health technologies, constructing a system for dissemination of information to support activities of the domestic healthcare industry, and creating the basis of diverse domestic and international cooperation.

The second part of the study made continuous modifications to and took complementary measures for step-by-step procedures for the pilot study for horizon scanning activities of new and emerging health technology. This optimized horizon scanning procedure produced a customized report analyzing the potential impact of new and emerging health technology,

which was disseminated to policy decision makers in healthcare, health service providers, the healthcare industry, and the public.

▢ Methods

As part of the first part study, a basic format was created for development of a fact sheet for the advanced consultation system at the Center for New Health Technology Assessment (nHTA) that would explore the current support and development plans for new domestic health technology by summarizing and making visual representations of its direction and procedures. The consensus of research staff, experts, the person leading the nHTA team, etc. was determined in an open discussion. In order to build the foundations of interagency cooperation, domestic health technology at the development stage was discovered and support measures were derived through meetings with the Korean Health Technology Portal Service (KHIDI), the Korean Institute of Science and Technology Information (KISTI), and the EuroScan, an international network, identifies key issues with its member countries via a consensus approach based on participation in official face-to-face meetings three times annually, which involve discussions about strengthening horizon scanning activities as well as the network's internal and external activities. Development of a homepage for measures to build a dissemination system was based on task instructions developed during more than four face-to-face meetings with enterprises about project plans and progress.

In the method of the second part study, the H-SIGHT Toolkit was reviewed for scanning activities of new and emerging health technology. For review, international case studies were examined and an investigation of related literature was conducted based on the operating plans developed in 2013. Particularly, the detailed contents of the EuroScan Toolkit and the Agency for Healthcare Research and Quality (AHRQ) Protocol were

considered and, based on domestic conditions, criteria were prepared for collection and selection of sources used to identify and filter information.

In addition, surveys of relevant experts allowed development of priority information and scoring forms. In order to set prioritization criteria and weighted values for each criterion, prioritization was examined using a Delphi approach that targeted 54 experts from every field (healthcare, government/insurer, academia/researcher, law, related institute, industry, patient/consumer organization, etc.); a weighted value for each criterion was set according to the results. With advice from healthcare experts collected through in-depth interviews, criteria for information gathering were prepared to select scanning resources for new and emerging health technology as well as items for assessing their potential impact. Expert committees were organized with consideration of the specialties pertaining to each technology. Members of nHTA and expert committee members in each field at NECA were targeted for these committees. Members participated in advisory meetings as part of the evaluation process, prioritizing and examining potential impact of each health technology.

By implementing the in-house-developed H-SIGHT Toolkit, horizon scanning activities of health technology were performed twice consecutively with a total of six cases. These results were disseminated to related institutions and healthcare personnel through internal research staff meetings, peer review, prioritization information forms, expert committees, and advisory meetings; expert advisory meetings, reviews of the associated industries, publication of reports, and distribution of press releases were used to assess the potential impact of the health technologies finally selected by this process.

With recommendations from related institutes, a total of 10 industrial experts comprised an advisory committee that prepared plans for improvement of horizon scanning activities for new and emerging health technology in February 2014. After sending requests via post newsletters, horizon scanning activities reports, and the results of the pilot project, an

industry advisory meeting was held on November 17, 2014. Industry experts and experts from each field performed assessments and provided opinions, and a consensus on the H-SIGHT Toolkit, the horizon scanning system, and plans for future development was reached through open discussions based on surveys and face-to-face meetings.

▢ Results

Ⅰ. Development of an operating system for search new and emerging health technology

Currently, searching for health and medical technology development is very vulnerable in both public and private areas. Although predicting future emerging science technology has emphasized wide horizon scanning of technology-related issues, trends, and signals, it is difficult to collect information on new health technology to file beforehand, because early assessment of newly developed health technology in Korean health system is conducted only when new health technologies apply for assessment.

In the United States, Canada, Australia, New Zealand, and 20 European countries including the UK, dedicated horizon scanning organizations for searching new and emerging health technology have been operating for at least 10 years, and independent horizon scanning system have also been built. Particularly, countries in Europe are devoting their efforts towards developing methodologies for sharing and analyzing information of new and emerging health technology.

1. Support and development of new domestic health technology

Construction of systems for information exchange and cooperation among organizations are necessary for understanding the new health technology certification system from the Korea Health Industry Development Institute. In

addition, promotional materials from a previous consultation have been produced and distributed to relevant organizations. The goal was to develop a methodology to support the industry by establishing definite criteria for its role of seeking new and emerging health technology and reinforcing its differential characters. However, there were some difficulties in establishing a support system for seeking methods to support entry of new health technology into the new health technology assessment step. Therefore, an advisory committee of relevant organizations was created to collect opinions on methods to support the industry for system settlement in NECA and to shorten the assessment period of new health technology. It was also intended to prepare methods to allow the system to settle in the future.

Internal modifications and conferences were also used to develop an internal system for cooperating within NECA.

2. EuroScan activity

EuroScan is an international network organization designed to assess health technology by performing horizon scanning activities for new and emerging health technologies centering on countries in Europe. Member countries include major the EU countries, such as the UK, Germany, and France, as well as Australia and Canada; NECA obtained EuroScan membership approval in October 2013 and qualified for formal membership. EuroScan holds regular physical meetings 3 times annually, in spring, autumn, and the international Health Technology Assessment (HTAi) conference. NECA has participated as a member since spring, 2014.

The activities of EuroScan member countries are classified into internal activities (organization operation, research, information and knowledge sharing, and strategizing external activities) and external activities (i.e., communication with other organizations such as the International Network of Agencies for Health Technology [INHATA] and the World Health Organization [WHO]). These activities include updating the EuroScan Toolkit, comparative analysis of mutual activities, cooperation case reports, and

discussions on use and modification of the EuroScan homepage. In addition, to its other external activities, EuroScan has actively solicited opinions about and participated in activities with related and consultative organization (WHO, INHATA, HTAi) and is seeking to establish a strategy to lead Asian countries and expand the EAA system on the basis of development and EAA activity experiences. In order to share activity strategies between EuroScan members, its secretariat investigated future organization activity strategies in March, 2014 and shared information, such as the subjects and people in charge of the EuroScan DB and its homepage, as well as the current subjects of horizon scanning activities in order to prevent exchange or overlap between members.

The Executive Committee elected the representative of NECA H-SIGHT as a Registrar in October 2014 in acknowledgement of its activities after its member subscription in EuroScan; the Registrar will conduct activities of the Executive Committee for two years from 2015.

3. Development of H-SIGHT homepage

H-SIGHT homepage was developed with the main purpose of introducing activities of new and emerging health technology search (H-SIGHT) and to share information, such as potential impact assessment reports on newly developed health technology through domestic EAA system and products, such as various newsletters to policy decision makers of health and medical service, medical professionals, and national people preemptively. Therefore, the homepage was developed to provide and disseminate information. It was written in Korean to optimize information access and comprehension. It was also developed as English versions for external dissemination.

Through several modifications and complementary procedures, the Korean homepage of new and emerging health technology search (H-SIGHT) was officially opened on July 29, 2014. In addition, the English homepage (http://neca.re.kr/hsight/eng/) was released in September, 2014.

Ⅱ. The second detailed study: Analytical research on potential impact of new and emerging health technology

In order to build a horizon scanning system for new and emerging health technology, case studies were performed in the United States, the UK, and other developed countries. Experts in relevant fields were invited to Korea, workshops were held, and in-depth discussions were conducted relating to horizon scanning activities and procedures. Additionally, for the development of horizon scanning system for new and emerging health technology, in order to reflect consumer demands in advance and provide customized information, the H-SIGHT Toolkit, developed using the 2013 study results, was piloted to demonstrate horizon scanning activities for new and emerging health technology during the 2014 study period. In this way, through an iterative process of amendments and additions, the detailed contents were finalized for each stage.

In the present study, after identifying new health technology using a version of the H-SIGHT Toolkit optimized for domestic conditions, subjects for analysis were selected through filtering. After filtering, priorities were determined and an analysis on the potential impact of the technology was disseminated, based on related clinical evidence and expert opinions. An expert assessment of these procedures was carried out to prepare plans for improvement.

1. Preparing the H-SIGHT Toolkit

In order to build a horizon scanning system for new and emerging health technology, case studies were performed in the United States, the UK, and other developed countries. Experts in relevant fields were invited to Korea to participate in workshops and in-depth discussions relating to horizon scanning activities and procedures. A scanning system suited to the domestic healthcare environment was thus constructed through amendments and additions; finally, the H-SIGHT Toolkit necessary for horizon scanning

activities was prepared.

(1) Identification

Based on a combination of cases in developed countries and domestic conditions, continued and widespread monitoring is performed based on various scanning sources selected in advance as well as identification of data collected through applications for new health technology assessment and external suggestions. Their expected timeline for entry into the domestic medical market and innovativeness are considered to identify targets for scanning; information that does not meet the selection criteria are removed from further consideration.

(2) Filtration

In this filtration step, an internal expert filters out health technologies other than new and emerging health technology. At this time, the selection criteria include relevance, innovativeness, and potential to enter the domestic market. Expert consultation is available if necessary, and agreement of at least three relevant investigators is required. Health technologies eliminated at this stage may go through this filtration step again after further development.

(3) Prioritization

The person in charge prepares an information form for the filtered health technology. Its priority is determined during an expert advisory meeting. Consideration items for prioritization include disease burden, clinical effect, innovativeness, economic effect, acceptability, social impact, and alternatives as necessary. The priority is ultimately determined by considering the total score of the weighted values of the assessment items.

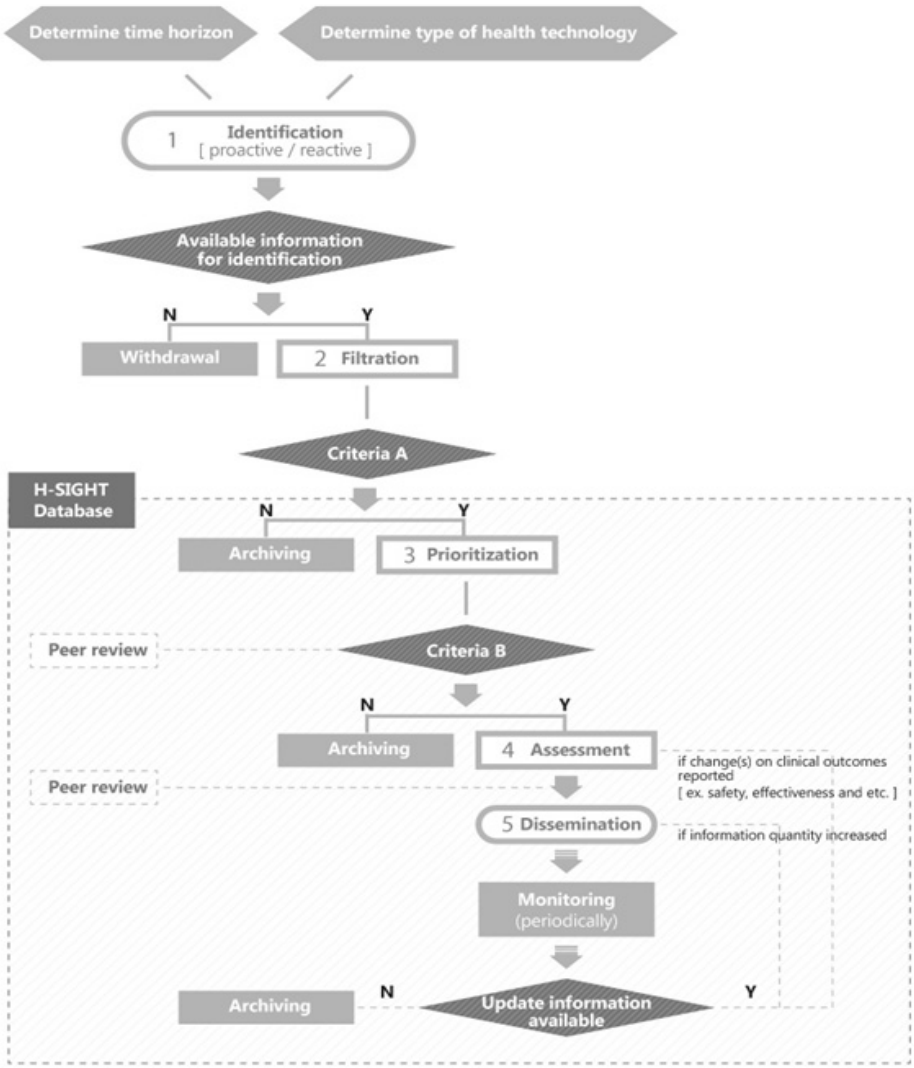

Figure 1. Scanning process of new and emerging health technology

(4) Assessment

The potential positive and negative impacts expected by introduction of the selected technology into the domestic market are assessed by reflecting grounds to date and the opinions of relevant experts. Unsatisfied medical demands; improved patient health; health equity aspects; changed medical behaviors; acceptability in the aspect of patient and clinical condition,

changes of medical cost; and social, ethical, political, and cultural impacts are considered systematically.

(5) Dissemination

After assessing the potential impact of the health technology, its report is revised via discussion with relevant entities. Based on the results of these analyses, information tailored to the customer needs is provided as a leaflet, report (brief or in-depth), or newsletter disseminated through e-mail and the homepage. It is possible to update related information via regular monitoring and feedback even after dissemination.

2. Publication of an assessment report on the application of the H-SIGHT Toolkit

Their therapeutic effects and clinical basis information are as follows. In addition, the second scanning in the second half of the year resulted in eight of 128 health technologies selected: proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor, an anti-hyperlipidemia, and a drug-eluting punctum plug, an ophthalmic medical device, were selected via prioritization.

The first pilot project, conducted during the first half of the year on 144 health technologies, identified eight health technologies via two filtration steps. Of these, four technologies–bronchial thermoplasty, renal denervation, cardiovascular therapy using extracorporeal shockwave, and meniscal partial transplantation using polyurethane support–were selected as new and emerging health technologies.

(1) Bronchial thermoplasty

This procedure involves administering high-frequency thermal energy to reduce the contractile force of thickened airway walls of patients with severe continuous asthma whose symptoms have not improved despite medication. Studies have reported improved quality of life, reduced progression of

symptoms, and reduced hospitalization rates. A recent long-term follow up study reported that respiratory adverse events were maintained at a similar level for 5 years after operation and there was no deterioration in the pulmonary functions.

(2) Renal denervation

An alternative procedure for patients with resistant hypertension that has received international attention recently, recent reports have suggested that there is no difference in blood pressure reduction between the renal denervation group and the control group, after 6 months of treatment, but there were some difference in subgroup analysis results according to age, renal function, and race. Long-term follow-up studies are necessary for impact assessment of result parameters including cardiovascular disease prevalence and mortality.

(3) Cardiovascular therapy using extracorporeal shock wave

This technique was developed to mitigate symptoms by administering extracorporeal shock waves to patients with intractable cardiovascular disease. Although it is expected to have large potential impact on patient therapy and disease improvement after its effects are verified, long-term follow-up studies will be necessary with larger patient study populations to test for potential biases in the current literature with small sample populations.

(4) Meniscal partial transplantation using polyurethane support

This technology was developed to treat broken or damaged articular meniscuses; although it is expected to eliminate pain in patients with damaged cartilage, additional global studies to support its safety and effectiveness are needed.

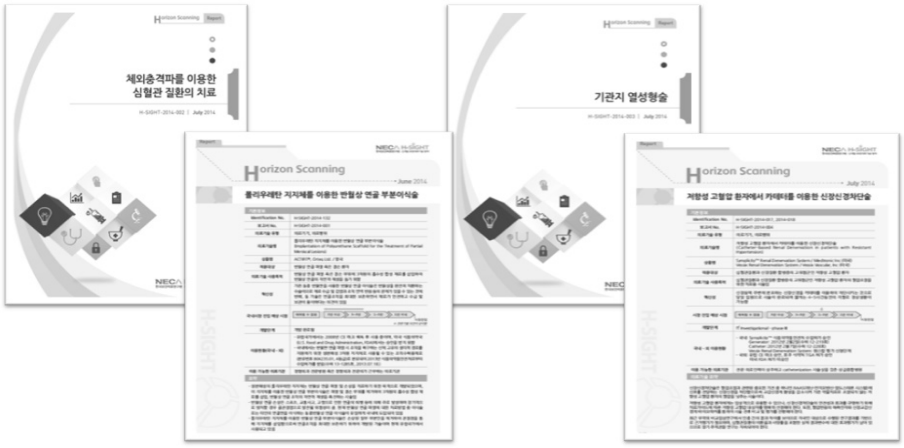

Figure 2. Report for dissemination of new and emerging health technology

(5) PCSK9 inhibitor

A human monoclonal antibody drug that inhibits PCSK9(Proprotein Convertase Subtilisin/Kexin type 9) promotes digestion of LDL cholesterol (LDL-C) and blocks its absorption by binding to an LDL receptor may be a new alternative therapy for patients whose cholesterol cannot be controlled, despite medication combined with other lipid lowering agents, those who are unable to take statin-related drugs, and those with lipoprotein metabolic diseases such as familial hypercholesterolemia.

(6) Drug-eluting punctum plugs

This medical device is inserted into an opening site over the lacrimal papilla of the eyelid that mitigates inflammation and pain after ophthalmic surgery by releasing a drug through the punctum plug. Medical professionals can insert it easily; it contracts and expands its length and width to fill the available space, and is absorbed by the human body without need for removal, making it a relatively noninvasive solution. Although it can be distinguished from other similar technologies, additional study is required on its safety and effectiveness associated with specific available drug types.

3. Opinions of Industry Experts on Preparing Plans for Improving Scanning Activities

Combining the opinions of the industry advisory committee on horizon scanning activities for new and emerging health technology resulted in a recommendation that advances should be made in helping, rather than regulating, the industry through periodic management of health technology by building a domestic health and medical support system. There were also opinions that, although horizon scanning activities for new and emerging health technology were conducted in the pilot project using limited data sets, future research must consider various data sets in the identification step, and fairness and objectivity could be secured in all steps by using objective criteria and experts from diverse fields including the clinic; the results gained through horizon scanning activities could then be used as a reference for policy makers in healthcare as well as insurers.

▢ Conclusions

In order to provide accurate and timely information to the health industry, medical service providers, policy decision makers, and patients through regular monitoring and assessment of the potential impact on the health industry, pilot projects of new and emerging health technology scanning system were carried out, and a study to establish methods for design and performance of concrete methodologies for the horizon scanning activity was performed.

Based on the actual condition of domestic and foreign health technology scanning and results of preference survey on horizon scanning activity against customers, which was attempted through advanced researches in 2013 to continue the scanning activity of new and emerging health technology, a scanning tool optimized for domestic medical circumstance was developed in this study in 2014. A scan was attempted using the tool kit developed in this pilot project, and potential impact and social effect of

health technologies developed for introduction to the Korean medical market within 1-5 years were analyzed. The results of this analysis were prepared as a universally accessible prospective report provided as a customized information service to medical service providers and related industries, including consumer groups.

While scanning for new and emerging health technology as a pilot project in 2014, several limitations were encountered. Due to insufficient understanding by various stakeholders on the purpose and methods for horizon scanning for new and emerging health technology in health and medical fields, there was some lack of cooperation and collaboration. In addition, there were some limitations in anticipative information collection for sensitive information including general technical information because the climate and environment for information release were not constructed for domestic medical circumstances.

There were some limitations in performing regular monitoring and horizon scanning due to the lack of a database and insufficient research personnel specialized in performing scans for new and emerging health technology. Thus, the horizon scanning process was fragmented and timely dissemination of information was frequently difficult. Continuous updates should be done by adding validation of detailed contents and criteria for each step (e.g., potential impact assessment items, prioritization criteria) included in the horizon scanning method resulting from this pilot project.

Promoting the cooperation of businesses with relevant organizations will help establish the horizon scanning system of new and emerging health technology prepared based on this pilot study project. In addition, in order to present a direction for the health and medical R&D support system to support the previous health technology assessment and management system in actuality, and to drive an efficient project creating tangible output through this newly attempted horizon scanning activity of new and emerging health technology, it is necessary to establish a long-term strategy and seek an overall method to construct a foreign base. This system is expected to

explore safe and cost-effective emerging health technology, promote their introduction into domestic and foreign medical markets, and contribute to development of the health and medical industry by rapidly assessing international health technologies and new health technologies supported by domestic research and development investment, by raising their prediction potential.

Key words

New and emerging health technology, R&D in healthcare, Assessment of potential impact, EuroScan