Executive Summary

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

Sungkyu Lee[1], Chaemin Shin[1], Eunjung Park[1], Jooyeon Park[1],
Youngjoo Cha[1], Seonghee Park[1], Songhee Cho[1], Minjoo Kang[1]

[1] National Evidence-based Healthcare Collaborating Agency

▢ Background

The cost of healthcare research and development is expected to continue to increase in the areas of science and technology as the demand for new health technology rises along with an aging population, improved citizen health, and enhanced quality of life. Accordingly, strategies should be established to systematically investigate new health technologies to facilitate their entry into the healthcare market and to minimize the range of error caused by future uncertainty.

To improve the health of Korean citizens, the National Evidence-based Healthcare Collaborating Agency (NECA) has conducted a strategic planning study investigating new health technologies poised to enter the healthcare market. The study preemptively analysed the penetration effect including safety and efficacy in healthcare, the potential impact on society, and plans to widely diffuse the technologies.

The introduction of the Early Awareness and Alert (EAA) system to domestic healthcare provides the opportunity to discover high potential, new health technologies and contributes to an efficient distribution of resources

in the development of medical services, clinical research, and the prevention of the indiscriminate spread of technologies with the potential for misuse or abuse.

To conduct an effective investigation of health technologies in a manner appropriate for the domestic context in Korea, the consideration of specific support and strategies to reinforce the proper processes are urgently required. That is, a business foundation must be established for the Korean investigation system for new technologies.

▢ Objectives

The objectives of this study were to explore the technological information of health technologies under development and analyse the safety, efficacy, potential impact of each technology, and to preemptively provide information to consumers including patients, healthcare service providers, clinical research professionals, industries, government policy decision makers, insurers, and licensors.

Additional objectives were to stimulate the industry through healthcare-related information exchange by coordinating with pertinent domestic institutions and create international information networks. This study aimed to contribute to the inauguration of a system managing the health technology lifecycle and the solid establishment of a health technology assessment system in Korea by building a business foundation for an investigation system of high potential, newly developed health technologies.

▢ Methods

In the first generation phase, we investigated pharmaceutical products, diagnostic and medical devices, and medical practices as targets following

the procedures of discernment, filtering, prioritization, impact analysis, diffusion, monitoring, seeking feedback, and using an investigative tool (NECA H-SIGHT Toolkit) more than once a year. Additionally, attempts were made to internationalize the NECA H-SIGHT activity of EuroScan members and Registrar activities to contribute to organization management by participating in academic conferences and working groups and to participate in external activities and information exchange. Additionally, we operated a web-based system for suggestions on high potential health technologies that targeted consortiums, associations, and individuals using the H-SIGHT homepage developed in 2014. Finally, continuous efforts were made, such as the provision of information relevant to high potential health technologies on the homepage, the introduction of the investigation and EuroScan-related activity, periodic revision and addition of content, and the securing of web accessibility to maintain a high traffic web-site.

In the Second generation phase, efforts were made to strengthen the role of H-SIGHT in establishing and operating a system to manage the health technology life-cycle by seeking coordinated working relationships with the research team and the main office of New Health Technology Assessment (nHTA). This activity justified the need for the project to develop a systematic investigation and define the team roles. To successfully establish the system, the foundational schemes were outlined to strengthen the support for clinical research and generate data on high potential health technologies and to build the R&D support system in the domestic healthcare sector. Efforts were also made to maintain a close collaborative working system for the future discovery of health technologies, which represents the basis of the investigation system, interconnected job functions with the R&D support project, and support to reinforce the linkage between the R&D execution offices.

▢ Results

Ⅰ. First Generation Phase: Investigation of High Potential, Newly Developed Health Technologies and Impact Analysis

1. Investigation of high potential, newly developed health technologies using an investigative tool

A pilot study was conducted early in the year on 305 health technologies, and nine were selected in the filtering stage. Of those nine, selective retina therapy (SRT), multi-channel atomic magnetometer for magnetoencephalography, PNEUMOSTEM®, which is a therapy for bronchopulmonary dysplasia in premature infants, and SOVALDI®, which is a therapy for chronic hepatitis C (a total of four) were finally chosen as high potential, newly developed health technologies.

In the second part of the year, eight health technologies were selected out of 83 through investigative activity. After the prioritization stage, gastrointestinal bleeding control using endoscopically sprayed haemostatic powder and 'VM202-DPN' to treat diabetic neuropathy (a total of two) were selected as high potential, newly developed health technologies.

(1) Selective retina therapy

Selective retina therapy is a treatment for diabetic macular edema and central serous chorioretinopathy based on the principle of targeting the area of macula lutea responsible for visual acuity and selectively damaging the retinal pigment epithelium. There has been no report of complications during surgery and, thus, safety is not an issue. However, currently, more evidence for clinical efficacy is required on the main efficacy outcome measures (retina thickness, regeneration of retinal pigment epithelium, and the extent of damage to peripheral tissues). To verify more precisely the effect of this health technology, substantial clinical research that involves the optoacoustic system is required.

(2) Multi-channel atomic magnetometer for magnetoencephalography

Magnetoencephalography is a diagnostic health technology that measures brain function with high accuracy by projecting and measuring the magnetic fields generated around neuronal activity in the human body. Recently, magnetoencephalography has been used to measure higher level cognitive function, to map brain function prior to surgery, and to predict the region of the brain in which a seizure occurs. However, the signals of a magnetic field generated with neuronal activity are extremely small, and it is only possible to measure them using superconducting magnetic sensors. Research and development is continuously being conducted to commercialise the technology by improving precision levels using atomic magnetometers. This technology is expected to have greater economic value compared to the SQUID technology around which developmental efforts have been concentrated so far, and clinical research is needed to support the idea. Health and biomaterial magnetic measurement using atomic magnetometers shows excellent levels of effectiveness as an alternative to SQUID and, therefore, it is expected to contribute to the diffusion of diagnostic tools based on biomagnetic measurement.

(3) Therapy for bronchopulmonary dysplasia in premature infants, PNEUMOSTEM®

PNEUMOSTEM® is a pharmaceutical product manufactured with mesenchymal stem cells as its raw material, which is extracted from a full-term infant's umbilical cord blood. It was developed to prevent and treat bronchopulmonary dysplasia in premature infants and is expected to lower the likelihood of progression to a chronic disease and decrease various complications. The treatment method is not difficult and no great risk is expected during the treatment process. However, there is a need to accumulate more evidence with regard to its efficacy, the safety of the health technology, and to assess cost-effectiveness on the basis of the evidence.

(4) Therapy for chronic hepatitis C, SOVALD®

SOVALDI®, an NS5B polymerase inhibitor, is a drug that terminates HCV RNA replication by binding to NS5B polymerase competitively with nucleotides after being phosphorylated in the liver. Various clinical studies have demonstrated that it has a superb level of virus removal efficiency in comparison to existing treatments. It is indicated for hepatitis C patients and can also be used for HIV-infected patients with hepatitis C who are on the waiting list for a liver transplant. The drug is expensive. Therefore, price should be the priority and the insurance fee should be considered in the calculation in the future.

(5) Gastrointestinal bleeding control using endoscopically sprayed haemostatic powder

This technology is differentiated from the existing methods of endoscopic haemostasis in such functional aspects as the material and delivery mechanism because it uses a new haemostatic agent that can be absorbed by the body. It can be used even in cases where endoscopic bleeding control in vessels like capillaries is ineffective or impossible and to resolve large areas of bleeding by spraying haemostatic powder. However, currently, clinical data are insufficient to confirm the safety and efficacy of the technology.

(6) Therapy for diabetic neuropathy, 'VM202-DPN'

Aiming at new blood vessel generation, this is a hepatocyte growth factor gene therapy that facilitates the formation of collateral vessels to assume the function of closed or stenotic vessels. Treatment is possible with intramuscular injection in the affected area and unlike the conventional method of drug therapy, this technology can be an option for patients who are in a condition requiring improved vascular function but who cannot undergo surgery or patients with no other alternative. Additionally, clinical research on VM202 is being conducted to study a variety of vascular diseases (such as ischemic peripheral vascular disease, coronary artery diseases, and

amyotrophic lateral sclerosis). Therefore, there is a possibility for indications to expand.

2. EuroScan activity

EuroScan is an international health technology assessment network organised among European countries to investigate high potential newly developed health technologies. EuroScan holds a total of three regular in-person meetings per year including meetings in the spring and the autumn and an annual academic conference. NECA contributes to a variety of activities since it became qualified as a regular member in October 2013. The main activities include internal activities (organizational operations, conducting research, sharing information and knowledge, and establishing strategies for external activities) and external activities (exchanges with collaborating institutions such as INHATA and WHO). For activities at a detailed level, NECA updated investigative tools, conducted a comparative analysis of member countries' interactions, reported case studies on collaboration among member organizations, and discussed ways to revise the web-site homepage and promote Internet traffic. With respect to external activities, diverse collaborative activities are under way through a memorandum of understanding with the international organizations and councils (for example, WHO, INAHTA, HTAi, and HTAsiaLink). In addition to the activities performed as a member country, NECA is attempting to internationally spread and expand investigative activity to discover high potential newly developed health technologies.

3. Information diffusion using a website and a homepage

A homepage was created in July 2014 to introduce the investigative activity of high potential, newly developed health technologies that may be unfamiliar to citizens and to preemptively provide policy decision-makers in the healthcare sector, medical staff, and citizens with impact analysis reports

and various newsletters.

In 2015, a system for suggested information operated on the homepage to create an environment where citizens could voluntarily suggest information and improve the effectiveness of search processes. Efforts were made to increase homepage use by updating relevant information, revising and adding content, identifying current status, and to continuously monitor the health technology sector. Additionally, web accessibility certification was acquired from a specialist to secure easy access by diverse users including the disabled and the elderly.

Ⅱ. Second Generation Phase: Establishment of the Investigation System Foundation for High Potential Newly Developed Health Technologies

Collaboration involves multiple organizations or local branches working together on a task to solve a shared problem or provide administrative services. Recently, collaboration between local branches or between organizations has increased and is conserving human and material resources and providing client (customer) -centered holistic public service. Additionally, a task can be performed collaboratively by multiple organizations, each providing different types of service and collaborating from a macro perspective to raise the level of task effectiveness.

To investigate high potential, newly developed health technologies, collaborative activities were considered both inside and outside Korea so that constant investigation can be conducted by building a database of new health technologies in Korea, and early entry to the market may be supported for high potential technologies as a result of active networking.

1. Securing the Justification for Investigation of High Potential, Newly Developed Health Technologies and Defining Roles

(1) Facilitation of Task Collaboration with nHTA

There are cases where a health technology developed through R&D research

without considering clinical demand and clinical usefulness entered the healthcare market late or faced difficulty entering the market. Additionally, because of overlapping investment and selection criteria that differ according to the stage in the life-cycle of a health technology, awareness of the demand conditions in the clinical field is lacking. To augment such disconnection, the connections must be strengthened between business and various activities so that clinical evidence of high potential health technologies can be sufficiently accumulated to pass nHTA. Additionally, new criteria must be applied to reinforce the R&D support system for the health technologies under study following the nHTA outcome including prioritization according to the investigation system and reinforcement of R&D support considering the classification criteria for the study phase following the nHTA.

For task collaboration between the investigation activity of new technologies and nHTA, above all, clinical research support is necessary so that a health technology with insufficient evidence to evaluate clinical safety and efficacy can enter the healthcare market through nHTA. Specific actionable strategies are as follows:

First, when a newly developed health technology approved by the Ministry of Food and Drug Safety (MFDS) is discovered before the nHTA stage through the investigation activity of new technologies, it should be proposed as a candidate in the announcement of the R&D support business even before nHTA is conducted if it is a high priority health technology.

Second, the mission and goals of the business must be met by inspecting the proposals in relation to nHTA-KHIDI's (Korea Health Industry Development Institute) R&D collaborative support and by selecting the optimal tasks using the investigative tool.

Third, engage with working councils, who are the best complementary source of information that is timely and appropriate for the domestic context and survey the current status and trends in the health technology sector through continuous monitoring even when specific applications are not received.

Fourth, promote the preliminary counselling procedure for task selection targeting companies that require R&D support to enter the health technology market and provide customized counselling so that companies can generate the data required for evaluation.

Although business threats and limitations may not be completely resolved by collaborative actions, we consider synergistic expansion of the research activity to be possible. Additionally, the collaborative actions will provide a systematic and continual process for the health technologies developed with R&D support at the country level to be established in the domestic healthcare market and offer efficient task performance by collaborating along similar lines of work. Moreover, the domestic health industry will advance with investment and management concentrated inn high potential health technologies, and the healthcare market will contribute to the expansion of the health sector from greater industry competitiveness. In practice, in 2015, when the 'support for new health technologies to enter the market' within the KHIDI Healthcare R&D Project was first launched, 'selective retina therapy' was selected. This technology was discovered through investigation activity of health technologies as an outcome of work completed in the first six months of the year. The technology is currently under clinical trials with research funding from the KHIDI Healthcare R&D project.

(2) Convergence of Industry Opinion on the Establishment of a Business Foundation

To establish a business foundation for investigation activity of high potential, newly developed health technologies, identifying and merging the demands and opinions of the relevant industry and forming an organic relationship are the most important steps. Accordingly, this study used a phase to collect and merge the opinions of industry representatives, recommended by Korea Medical Devices Industry Association (KMDIA), on investigative activity.

New health technology products already developed or currently under development in other countries must be included in the investigation. However, industry representatives considered it more desirable to focus on investigating high potential health technologies under development in Korea, acquire information on the technologies currently at an early developmental stage in collaboration with other organizations, exchange ideas with the companies or R&D organizations, advise on how to ultimately commercialize the technology as a product, and provide services to supply necessary resources. Additionally, the industry representatives raised the question of how to collaborate with the industry. They mentioned that from an industry standpoint, the most urgent task is the commercialization of a developed product, and nHTA is perceived to be the greatest hurdle in commercialization. Therefore, the representatives claim that information consumers benefit the most when specific ways are suggested to overcome this hurdle. Moreover, the representatives stressed that specific planning as a result of investigation activity should be reflected by healthcare policy decision makers later and, ultimately, should galvanise investigation activity. It should meet the demand of the companies developing health technologies among various stakeholders.

2. Seeking Multi-dimensional Strategies for Successful System Implementation

(1) Korea Institute of Science and Technology Information (KISTI)

To prevent a health technology from disappearing before it enters the market because of barriers to entry and to diffuse the benefits of technology development to the healthcare industry in Korea, analysis of scientific technological information is required. Additionally, there is increased demand for preemptive, customized, practical information as a result of convergence studies that combine diverse methodologies. To meet current needs, the research team for the investigation of newly developed health technologies began working with KISTI as the first collaborative work activity.

As a specific collaboration plan, we aimed to provide client-customized

information and establish a pre-consulting system for high potential health technologies by conducting an impact analysis of health technologies expected to enter the market within one to five years. Additionally, we planned to create a collaborative research network of NECA and KISTI and to operate an information linking service to facilitate information search and analysis of newly developed health technologies.

As a component of collaboration, we planned to conduct collaborative research on the investigation activity of newly developed health technologies and to create an expert consulting system to review technologies for a future technology knowledge base and to form a collaborative research council for information search and analysis. The following activities were suggested:

- Operation of a consulting system for the clinical effectiveness of future technologies and planning for the diffusion of review outcomes.
- Methodological application of each of the review steps in the investigative tool (NECA H-SIGHT Toolkit).
- Expansion of the collaborative research scope on the basis of the healthcare expert human resource pool.
- Discovery of future technologies in the healthcare sector and applied research on analytical techniques.
- Impact analysis of future technologies in the healthcare sector and the creation of a peer evaluation project.

The activities above are expected to contribute to the accelerated entry of health technologies to the market and the expansion of new areas with additional value by providing customized information based on an efficient information search and analysis that fully utilizes the unique capabilities of each organization. However, the collaborative activities did not steadily progress because we were not selected in the final round for the Ministry of Strategy and Finance Government 3.0 Collaboration Task to form an investigation council and to build an information service system between NECA (managing organization) and KISTI (assisting organization).

(2) Commercialisation Promotion Agency for R&D Outcomes (COMPA)

COMPA is an organization specializing in the facilitation of technology transfer and business that bridges scientific research outcomes of the Ministry of Science, ICT, and Future Planning (MSIP) with economic achievement. To support the business of domestic health technologies by providing preemptive, customised information for clinical commercialization, a need for collaboration with relevant organizations arose. Thus, the NECA research team for the investigation of high potential newly developed health technologies planned to hold an advisory meeting with clinical specialists to support a technology transfer project and consolidate the preliminary review process for clinical safety, efficacy, and acceptability of the health technology. The advisory meeting was required to facilitate health technologies developed with domestic R&D support entering the healthcare market. The areas addressed in the technologies survey administered to clinical specialists are summarized as technology (the level of innovation in comparison to existing technologies, similar technologies, clinical adoptability, and safety or risk potential) and marketability (clinical acceptability, areas in the clinical field in which it can be adopted, and considerations and limitations within the healthcare system). The survey consisted of both closed-ended and open-ended questions and was individually filled out on paper.

At the opening of the advisory meeting, each organization, the investigation activity, and the status of business support were introduced and the mission of the clinical specialist advisory meeting was explained, but time was limited for detailed explanations. Several times, some attendees who did not fully grasp the mission of the advisory meeting voiced their opinion, which impeded other specialists from completing the survey because they were providing advice on different health technologies. Additionally, they often needed a preliminary review of the health technologies or requested study outcomes or references with which to evaluate clinical efficacy and safety.

Therefore, an agreement was reached between the two organizations that at a future advisory meeting discussion subjects would be determined that

consider health technologies for high-burden diseases, rare diseases, incurable diseases, health technologies with a clear treatment goal, and the government's policy direction or the use of a weighting method. Additionally, we decided to move toward the following items for future collaboration:

① Review of the possibility of collaboration to facilitate the entry of health technologies to the clinical field in 2016.
② Creation of a consulting system with clinical specialists to support the health technology life-cycle for technology transfer and business.
③ Development of a database of newly developed health technologies and the discovery of domestic, high potential convergence health technologies.

Improving the prediction of health technologies by identifying the most recent movement and performing trend analysis.

▢ Conclusions

The 2015 investigation activity of high potential, newly developed health technologies was conducted using the investigative tool developed in 2014 (H-SIGHT Toolkit). We believe that the investigation results will be reliable and that the productivity of investigations will increase as a result of efficient system operation if the following points are complemented and reinforced.

First, during overall investigation activity, information sharing and communication between the industry and researchers are necessary and, thus, communication methods and procedures should be developed and recorded. Second, for accurate evaluation of innovativeness and the prediction of the timing of a health technology's market entry, in addition to internal researchers, licensing or nHTA specialists who are fair and objective should be added to bolster the system. Third, if a process to utilize already accumulated information on details of health technologies is in place and current developmental and clinical basic information is available on a regular

basis to R&D researchers, industries, and policy decision makers, this will help the development of related products as well as policy planning. Fourth, standards to revise impact analysis reports distributed periodically and re-analysis should be planned and executed and the methods of information diffusion and weaknesses in content should be explored and pursued by surveying the level of information utilization by consumers.

Vigorous and active member activities at EuroScan provided opportunities to internationally promote domestic technologies and we were able to receive advice from other member countries when a problem arose during the investigation activity. This reinforced the importance of establishing meaningful relationships with EuroScan. Additionally, to establish the business foundation of the investigation system, internally, an organic collaborative task system was outlined between nHTA and the research team. Thus, a support system for research phases and technologies at an early developmental stage was created. Externally, through collaboration with COMPA, an organization under government R&D, we identified the entire range of domestic health technologies supported by government R&D and designed a framework within which discussions could be performed to design a standardized support system and increase the level of future support.

The collaboration with COMPA should not stop but should continue and be strengthened in the future. This will form the basis on which to construct a collaborative system with other organizations and related research institutions, such as MSIP and MOTIE (Ministry of Trade, Industry and Energy). The outcome of our efforts is to realize the national keynote, Government 3.0, and we expect that, ultimately, it will trigger the steady development and early clinical application of new high potential health technologies.

Key words

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