Executive Summary

2018 Horizon Scanning Service for Emerging Health Technologies in NECA H-SIGHT

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▢ Background

Investment in R&D of the healthcare field has become a core part of the country's competitiveness, and national investment has been accelerating. However, the investment distribution system is maintained as a custom and is distributed to many departments, causing insufficiency in terms of efficiency. Due to the inconsistency and lack of connectivity in government policy of introducing a emerging health technology into the domestic medical market, severance of promising medical technologies is frequently found. To solve similar problems, North America and European countries are seeking to establish a system that preemptively explore promising medical technologies and improve the investment efficiency and connectivity of R&D. Korea conducted a exploration activities for emerging health technology until 2016, but from 2017, it suspended the activities and disbanded the department to solve the budget problem.

▢ Objectives

The purpose of this study is to resume the suspended exploration activities of emerging health technology and rebuild the foundations for the activities. In addition, through the search for direction of the activities, we intend to develop a stable system and activities that is safe from a threat of suspension as a full-time management system of health technology. To this end, we will look into the results of the emerging

health technology exploration activities conducted from 2014 to 2016 and look for directions for further development. In addition, we will perform continuous and focused horizontal exploration activities using the developed navigation tool (NECA H-Sight toolkit) by selecting major search fields that reflect social needs. We aim to contribute to the spread of the results of the future project through organization of exploration information sources, rearrangement of weighting by prioritized items, restoration of closed websites, etc. for establishment of foundations for spread of information.

▢ Methods

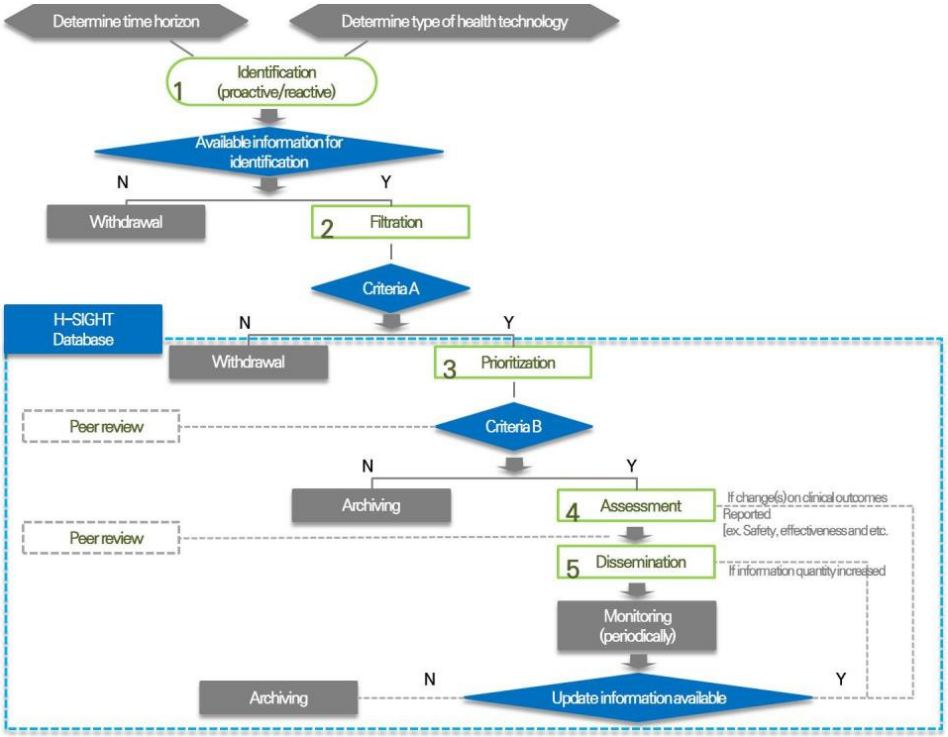
1. Analysis of activity results during 2014 -2016

To analyze the results of the emerging health technology exploration activities, we identified the number of cases performed following the study method from 2014 to 2016 and compared to the number of personnel in charge to calculate the average annual workload.

2. Exploration of emerging health technologies of 2018 and analysis of potential impact

In order to carry out horizontal exploration activities in accordance with social needs, we selected exploration fields by taking social issues into consideration. By focusing on ICT-based health technology, which is in the spotlight in the field of future healthcare, we selected exploration fields and made a list of technologies and selected exploration fields in reference to Gartner 2018 Top 10 Strategic Technology and books on 4th Industrial Revolution. We confined the exploration fields to medical technologies that use Virtual Reality(VR), Augmented Reality(AR), Robotics, 3D Printing, Block Chain, Artificial Intelligence(AI), Mobile Application / Device. After identifying trends of relevant domestic and foreign fields related to the exploration field and analyzing status of studies, we performed identification, filtration, prioritization, potential impact assessment, and dissemination of drugs, diagnostic and medical

devices, and medical practices that are likely to be introduced into Korea within about one to five years according to the procedure.



3. Establishment of the foundation for information dissemination

In order to perform efficient exploration activities, we reorganization the conventional exploration sources and reduced them from 24 to 8 sources. The criterion for reorganization primarily included the connectivity to the related field, accuracy of information, efficiency of exploration, and accessibility. We prioritized the items and differentiated the weight before prioritizing 7 items of “burden of disease," "clinical effect," "innovation," "economic item," "acceptability," "social effect," and “evidence,” which are taken into consideration during prioritization in the exploration phase. However, since the number of homepages per researcher is limited, the homepage restoration was changed to creation of a new one upon agreement. We created exploratory reports that

include literature reviews and potential impact analysis for each health technology and spread the final publication to a variety of consumers. We conducted in-depth interviews and consultations with Policy Advisory Board experts on research purpose and direction, identification activities, consultation on the results of filtration activities, detailed indicators of research outcome and academic achievements.

▢ Results

1. Analysis of activity results during 2014-2016

1) Analysis of researcher's workload

We identified 921 health technologies through identification activities for three years from 2014 to 2016 and conducted 16 prioritization assignments and potential impact assessments through 41 filtration activities. An average of 5.67 personnel was employed over three years and for 1 case of potential impact analysis, one personnel was in charge of 54 cases of identification activity and 2.4 cases of filtration activity, wrote an information form, and conducted 0.9 case of prioritization and 0.9 case of potential impact assessment procedures.

2) Analysis of potential impact evaluation result

The classification of 16 cases for which potential impact evaluation has been performed through the emerging health technology exploration activities by health technology showed the result in the order of 9 cases of medical devices(56.25%), 6 cases of medicines(37.5%), and 1 case of treatment materials(6.25%), and classification by medical practice showed the result of 1 case of diagnosis(6.25%) and 15 cases of treatment(93.75%). The classification by the subject disease showed that circulatory system, endocrine, nutritional and metabolic diseases showed the most potential, each accounting for 3 cases(18.75%), followed by nervous system and eye and eye appendix diseases, each accounting for 2 cases(12.5%).

Specific infectious and parasitic diseases, blood and hematopoietic diseases, and specific disorders invading immune mechanisms, respiratory system diseases, digestive system diseases, musculoskeletal system and connective tissue diseases, congenital anomalies, deformation and chromosomal abnormalities each accounted for 1 case(6.25%).

2. Exploration of emerging health technologies of 2018 and analysis of potential impact

1) Identification

4 internal researchers conducted a search of medical technologies that fit each topic through 8 exploration sources and found a total of 137 technologies, including 22 cases of Virtual Reality(VR), Augmented Reality(AR), and Mixed Reality(MR), 9 cases of Robotics, 30 cases of 3D Printing, 2 cases of Block Chain, 27 cases of Artificial Intelligence(AI), and 47 cases of Mobile application/device.

2) Filtration

The identified medical technologies were further filtrated through internal research team discussion and peer review, and a total of 15 technologies were selected, including 1 case of VR/AR, 4 cases of Robotics, 3 cases of 3D Printing, 3 cases of AI, and 4 cases of Mobile application/device.

3) Prioritization

For the selected medical technologies, the internal personnel in charge prepared the technical information sheet for prioritization, which was conducted through the expert committee based on the written information. For prioritization, the total score was calculated by taking the weight of each item into consideration, and after combining the review results, researchers evaluated newly developed promising medical technologies that have a total score of 60 or more

and are innovative and finalized the potential impact analysis. In the prioritization meeting, 11 researchers(one radiologist, one pediatric surgeon, one electrical and electronics engineer, one preventive medicine expert, one cardiologist, 3 biomedical engineers, one ophthalmologist, one mechanical engineer, and one rehabilitation doctor) participated in consultation. Based on the results of the consultation, the total score was calculated by taking the weight of each prioritization item into account, and the following techniques were finally selected.

- Automated insulin delivery system, MiniMed 670G
- Continuous blood glucose measurement system, Freestyle Libre Pro flash glucose monitoring system
- 3D printing-based artificial cartilage
- AI-based mammography assistive detection for early diagnosis of breast cancer
- Watson for Oncology
- Renal transplantation using robotic surgery

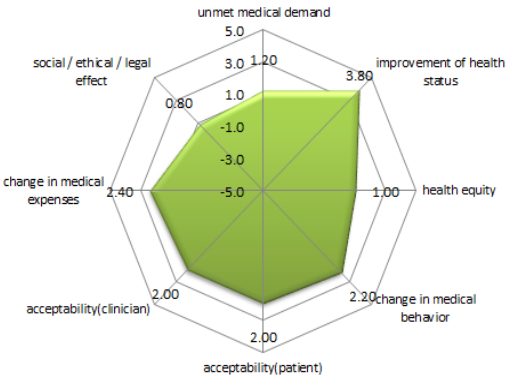
4) Assessment

Assessment result of potential impact for each technology is as follows.

(1) Automated Insulin MiniMed 670G

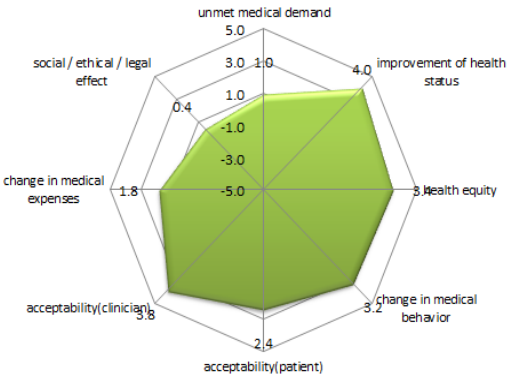
This is a medical device that combines Continuous glucose Monitors(CGM) and insulin pump in one device. It automatically measures blood sugar without the need of a patient to measure blood sugar separately and administers or stops insulin depending on the measured blood sugar level. This allows the patient to maintain a stable blood glucose level during sleep or exercise. Because no manual operation is required, the device is expected to reduce the burden on patients and caregivers and help improve the quality of life. However, there was an opinion that it costs excessive more than the conventional technology and that there is a risk of infection

caused by the sensor chip inserted into the body(Overall score: 2.6 / 5.0 points).



(2) Professional continuous blood glucose measurement device: FreeStyle Libre Pro flash glucose Monitoring System

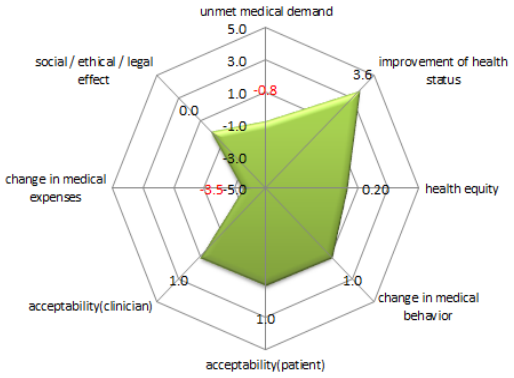
This health technique is a continuous blood glucose measurement device that measures blood glucose through subcutaneous interstitial fluid by attaching a sensor to the back of the upper arm without invasive blood collection. It consists of a sensor that measures blood glucose and a mobile reader that displays the measured blood sugar when shaken near the attached sensor. It is expected to relieve pressure of blood collection from diabetic patients who had difficulty in managing blood sugar and help them better manage the blood sugar level. However, there is risk of infection or dermatitis occurring at the site of sensor insertion, and instability close to 50% becomes a burden to long-term use since it is a wearable-type of product. In addition, because the sensor needs to be replaced every 10 days, it costs about 1900 dollars per year, and the cost is higher if the repair expenses due to breakage or breakdown are included. There was an opinion that it is highly costly for a medical aid and that it is necessary to prepare the domestic bioengineering service for the measures to cope with the damage and repair(Overall score: 3.8 / 5.0 points).



(3) 3D Printing-based artificial cartilage

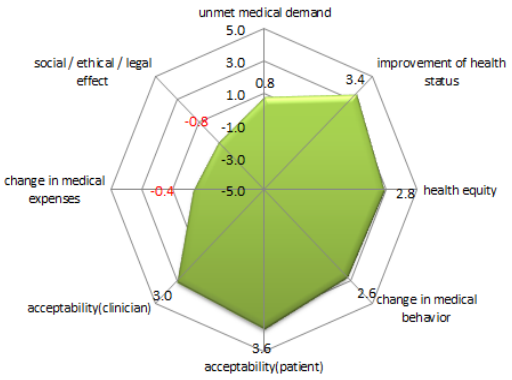
This health technology is a technique that transplants an artificial cartilage into a patient after making artificial cartilage using the 3D printing by utilizing the cartilage cells directly taken from a patient to be treated. Bio-ink, which is made by differentiating chondrocytes collected directly from the patient, not only showed a structure similar to natural cartilage but also showed a stronger density. However, it is necessary to study more about the problem of biocompatibility, and it is expected to take more time to enter the market since it is currently studied in the laboratory. The result of the potential impact analysis revealed that the 3D printing artificial cartilage technology can be more widely used than the conventional chondrocyte transplantation by using the patient-customized bio ink, and it has a high possibility of succeeding in technology development. Furthermore, it was positively evaluated because it can restore activity of a patient unlike the conventional artificial cartilage, exhibits great tissue adhesiveness and can reduce the burden on the patient through one-time operation. On the other hand, if the cellulose used in the artificial cartilage production causes rejection inside the human body, there is a risk of removing the entire cartilage. In addition, negative opinions stated that there is a lack of clinical evidence of safety / efficacy, long cell culture and

3D-printing production period puts burden on the patient, and there is a lack of ethics / legal system, etc.(Overall score: 0.8 / 5.0 points).



(4) AI-based mammography assistive detection for early diagnosis of breast cancer

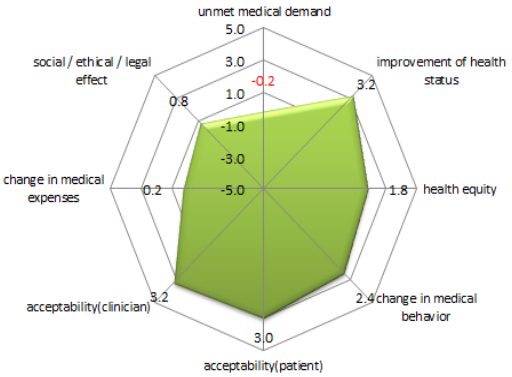
This technology is an AI-based mammography assistive detection for early diagnosis of breast cancer(Data-driven Imaging Biomarker in Mammograpy(DIB-MG)), which is used for detection of abnormal region suspected of nodule by using AI-based diagnosis supportive software. The AI-based DIB-MG algorithm was developed from the previous computer-aided detection(CAD) to improve the accuracy of breast cancer diagnosis. In the analysis of the potential impact, the AI-based mammography assistive detection for early diagnosis of breast cancer was positively evaluated for improving the diagnosis rate and reducing misdiagnosis rate through application of the deep-learning technology to help with the early treatment, for applicability in primary screening test of breast cancer in health check-up and for saving time and manpower. On the other hand, it was negatively evaluated because it is not known whether it will be actually cost effective, additional sensitivity analysis according to tumor size is needed, sensitivity / specificity at present is not satisfactory, and more data is needed for deep-learning(Overall score: 3.2 / 5.0 points).



(5) Watson for Oncology (WFO)

This technology is a system that assists doctors in treatment of cancer patients by using the AI-based clinical decision support system(CDSS) software. The advanced AI technology applied to the clinical decision support system recommends a faster and more accurate treatment to doctors. When patient data is entered into the system, it recommends appropriate treatment methods based on past clinical cases, literatures written by medical institutions, medical journals, and expert data, and when the doctor is making a decision on treatment method, it gives literature evidences. Although recent studies reported improvement of the recommendation concordance rate by cancer type compared to the earlier studies, no official studies have been conducted on randomized clinical trials yet. The potential impact analysis positively evaluated Watson for Oncology for it can increase doctors' diagnostic accuracy and broaden choice of treatment, can alleviate problems of medical delivery system, which is concentrated in tertiary hospitals, by improving accessibility to high-quality medical care when used by relatively inexperienced doctors, and may be satisfactory to both doctors and patients when used after input of a large amount of data. However, there were negative opinions, stating that it is unrealistic to use the uniform system of WFO at present considering the differences between

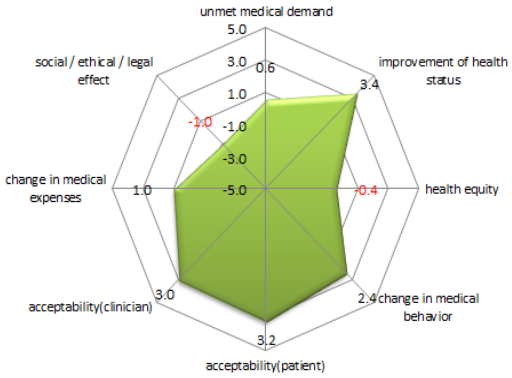
countries and institutions and requires reevaluation and verification in the future, it can only play the role of information provision if domestic data is not accumulated enough to operate and the diagnosis of acute patients may be divergent depending on the doctor, reliance on data-based treatment can affect doctors' own treatment standards, legal disputes in the decision of wrong treatment may occur, and who will make final decisions on RCT research results and correct algorithm must be carefully decided(Overall score: 3.0/5.0 points).



(6) Renal transplantation using robotic surgery

This is a health technology that can perform minimally invasive renal transplantation for patients with chronic renal failure using conventional surgical robots. It can shorten the recovery time of the patients, reduce complications, and minimize surgical scars and in particular, great medical results on obese patients have been reported. The medical devices used in the surgery have already been domestically and internationally approved, and eight clinical studies at the case study level have been conducted. The potential impact analysis positively evaluated the renal transplantation using robotic surgery because it can improve the accuracy of surgery and minimize the surgical scars caused by to side effects or complications through minimal invasion, can secure safety for obese patients with high BMI

and kidney donors, patient satisfaction is high, and surgical data can be obtained. However, negative opinions stated that legal disputes may arise in the case of side effects and complications from surgery, this technology has no significant meaning except for increasing the efficacy of the conventional robotic surgery, training and time for the medical staff to acquire the surgical technique are necessary, and further measures need to be taken to resolve more economic burden put on patients than the open surgery(Overall score: 2.0/ 5.0 points).



3. Establishment of foundations for spread of information

1) Reorganization of exploration sources related to horizontal exploration activity

In order to perform efficient exploration activities, we reorganized the conventional exploration sources and reduced them from 24 to 8 data sources. For the criterion of reorganization, we primarily considered relevance of the related fields, accuracy of information, efficiency of search, and accessibility.

2) Rearrangement of weight by prioritized item

For the weight of prioritized items, priority was given to seven items, including “burden by disease,” “clinical effect,” “innovation,” “economic item,” “acceptability,” “evidence,” and “social effect.” The rearranged priority of items was in the order of “innovation,” “clinical

effect," "burden by disease," "economic effect," "acceptability," "evidence," and "social effect."

3) Operation of information dissemination system(homepage, etc.)

We tried to restore the homepage that was closed in 2017 due to project suspension, but the number of homepages per researcher was limited. In accordance with the consultation with the computer information team, the contents of the project were added to the healthcare evidence research project within the main project. We briefly described the purpose and result of the exploration research for the emerging health technology as follows and completed the update.

4) Conductance of policy consultation

In-depth interviews and consultations were conducted four times with the experts from the Policy Advisory Committee. In-depth interviews and consultations included research purpose and direction, identification activity result, filtration activity result, detailed indicators of research outcome, and academic achievement.

▢ Conclusion

This study was carried out to resume the suspended exploration of newly developed promising medical technologies and reconstruct the foundation necessary for the exploration activity. To do this, we examined the direction in which it can be further developed by reviewing the workload and results of the emerging health technology exploration activities that were carried out from 2014 to 2016 before the suspension. By analyzing the results of the review, we intended to develop it into a whole-cycle management system of health technology as a stable system and project that is safe from threat of suspension. In addition, we selected major exploration areas reflecting social needs and performed continuous and focused horizontal exploration activities using the exploration tools developed in previous researches. Also, we carryied out

additional activities for dissemination of information and establishment of foundation to contribute to the spread of the results of the future project.

The emerging health technology exploration activities performed 16 potential impact assessments over three years from 2014 to 2016. To accomplish this, an average of 5.67 staff members each year performed 54 identification activities, 2.4 filtration activities, 0.9 prioritization procedures, and 0.9 potential impact assessments. In the potential impact assessment, the size of positive and negative influences tended to coincide with each other according to the subjective judgment of the evaluation committee, but large deviations were found in some items. The variation in medical expenditure, unmet medical demand, and changes in the medical form tended to increase, which is interpreted as differences in perspective by specialty area. In addition, 16 cases of emerging health technology exploration results, for which potential impact was assessed, were the medical technologies used for treatment that received high scores in terms of health technology effect and innovation. It was obscure to decide whether medical technologies with the purpose of prevention or functional improvement are included in the conventional health technology, and the medical technologies with a rehabilitation purpose were mostly included in the conventional health technology.

The results of potential impact assessment of the six newly developed promising medical technologies selected in 2018 included many positive opinions in terms of “improvement of health status” and “acceptability of clinicians” with negative opinions on “changes in the medical expenses.” The selected 6 medical technologies were expected have clinical efficacy, but there was a high concern about the increase of medical expenses due to development of new medical technologies. In addition, there were some negative opinions in terms of “social, ethical, and legal effects” because it is often the case that the source of responsibility for the medical accidents caused by the emerging health technology is unclear.

We tried to collect the documented information to assess the progress of suspension of the emerging health technology exploration activity, but we found no related information. The exact dates and details of the suspension were unclear, and we were only able to confirm that the action was taken as a result of the reduction in the government budget. These results can become a major hindrance to operation of projects with a characteristic of continuity. While it important to identify and evaluate newly developed promising medical technologies and spread the results domestically and internationally, if we leave no results in record, there will be no data to spread in the end. Horizontal assessment is filtered by relevance, innovation, and possibility of domestic adoption, and prioritization process is selected based on burden of disease, clinical effect, innovation, economic effect, acceptability, social influence, and evidence. Unselected technologies will continue to be monitored for appropriateness, innovation, and potential for adoption through the archiving process. Since innovation and the possibility of introduction into the country can change with time, the exploration for promising health technology needs to be continuously carried out. When performed in fragmented and segmented studies, there is a risk that the quality of the outcome used for spreading of information is progressively lowered.

In order to continuously carry out the exploration activity for promising medical technologies in the future, it is necessary to allocate appropriate manpower when setting the target number. According to the three-year workload, at least one person should be assigned to explore 1 case of new health technology that has been assessed for potential impact. Also, in order to increase the utilization of the results, a legal and institutional foundation should be established to confirm the policy reflection rate. Newly developed promising medical technologies that have been assessed for potential influences were evaluated based on the criteria of unmet medical demand, improvement of health status, health equity, change in medical behavior, acceptability (patient / clinician), change in medical expenses, social / ethical / legal effect. Therefore, they can be selected

for a R&D project or used as a reference material for evaluation of a new health technology according to Article 55 of the Medical Law. However, there may be a conflict of interest because the results of the exploration activity for emerging health technology were analyzed focused on drugs, medical devices, and therapeutic materials of specific pharmaceutical companies. In order to overcome such problem, evaluation standards and procedures should be operated transparently.

Key words

emerging health technology, horizontal exploration activity, potential impact, innovation