Executive Summary

A Study On the Introduction Of the New Assessment Method For Innovative Health Technologies

Joo Youn Kim[1], Eui-Kyung Lee[2],..

[1] National Evidence-based Healthcare Collaborating Agency

[2] Department of Pharmacy, Sung Kyun Kwan University

▢ Background

In 2016, the main theme of the World Economic Forum was 'Mastering the Fourth Industrial Revolution' which made a huge wave of the fourth industrial revolution, world widely. Fourth industrial revolution is defined as combination of different fields including 'Digital', 'Bio', 'Physics' and etc.. Advanced countries developed national strategy for the new innovation, at the same time, Korea also established a response system for the new industrial innovation. Korea launched 'Presidential Committee on the 4th Industrial Revolution' to deliberate upon and coordinate important policy matters pertaining to the development and acquisition of new science and technology and also new industries and services necessary for Korean society's adaptation to the 4th industrial revolution. In healthcare field, a special sub-committee to suggest the vision and to discuss action plans for the vision was organized. The special sub-committee decides main agendas and six major projects in healthcare field, and also makes and push forward a response plan for the 4th Industrial Revolution. One of the six major projects is 'Development and regulatory system improvement regarding smart complex medical devices'. In that project, regulatory system of MFDS (Ministry of Food and Drug Safety), nHTA system and health insurance

system of MOHW (Ministry of Health and Welfare) became targets of the system improvement.

The nHTA system uses the evidence-based literature review method in which scientifically and objectively search, analyze and synthesize evidences from the clinical literatures. The main assessment method of nHTA is systematic reviews. Reviewing textbooks or guidelines are also conducted and even expert opinions based on the objective evidence are also reviewed in nHTA. Review system of objective evidences has been pointed out as an inadequate assessment methodology in a situation of rapid and massive development of healthcare technologies with a new concept, such as emerging or complex technologies. NECA conducted a research to develop value-based HTA methodology to the emerging medical technology in 2017. In the study, we investigated the current state of value-based assessment in HTA system and selected value items that could be considered in nHTA system.

▢ Objective

The present study was conducted to develop the new assessment method on innovative or emerging health technology (innovative emerging technology) which has difficulties to applicate evidence-based literature review method. The present study also aimed to present the items to be considered essentially in the nHTA.

▢ Methods

Organizing and operating a subcommittee of nHTA committee for emerging technology

In the previous study, we suggested the state and role of a subcommittee (subcommittee for value assessment) in nHTA system. In the present study, we suggested concrete composition of the subcommittee (subcommittee for emerging technology) to assess innovative emerging technology and also operated the subcommittee to confirm the possibility of introduction of new methodology.

Development of assessment items and tool

We developed items and tool to assess value of innovative emerging technology, to apply various social demands beside evidences. Total 8 assessment items were developed, including rarity of disease, severity of disease, physical burden on the patient, economic burden on the patient, possibility of abuse, affects on the quality of life, state of alternative technology and innovation level of technology. Medical experts, healthcare-policy specialists, patient-civil group member and health industry stakeholders conducted consultation regarding the relevance of item definition, form of assessment tool and method of conclusion suggestion. We collected their opinions and apply to reconfigurate contents and assessment tool.

Pilot assessment for innovative emerging technology

We conducted total 4 pilot assessments in the present study. Suitability of assessment items and tool was examined through the pilot assessment. In the pilot assessment, we tried to find out and correct errors and increase utilization of new assessment system.

‘24 hour continuous IOP monitoring using contact lens sensor’, ‘surgery simulation for repair of congenital heart disease using patient-specific three-dimensional heart model’, ‘Percutaneous left ventricular partitioning in patients with chronic heart failure’ and ‘personalized surgical simulation of

renal cancer' were selected in the pilot assessments. Sub-committee was composed for the pilot assessments and assessments were conducted in the same manner as the real assessment system.

▢ Results

Compsition of sub-committee

The composition of sub-committee for innovative emerging technology result from the consultation of experts and stakeholder are as follows. Members are composed as the chairperson, four medical experts(two fixed and two changeable), a patient-civil group member and a industrial technology expert. The chairman was selected one of the nHTA committee member. Two fixed medical expert members were recommended from the medical society and two changeable members were as members of evidence assessment sub-committee of the technology. The patient-civil group member was recommended from the group on public involvement in NECA.

After the sub-committee composed, researchers make materials by reviewing submitted materials and searching related evidences and submit to the sub-committee. We suggest that members discuss with deliberation about the technology since the assessment is not based on objective evidence. Thus the assessment result should be presented in the recommendation form.

Development of assessment items and tool

In order to construct the contents, the concept and definition, explanation and examination of the assessment items were reviewed by various kinds of experts. We categorized items as clinical value (severity of disease, rarity of disease, affects on the quality of life, physical burden on the patient and

state of alternative technology), social value (economic burden on the patient, innovation level of technology and possibility of abuse) and we developed assessment tool draft as followed: 1) quantitative assessment by applying points and weights 2) qualitative assessment by presenting assessment opinions and suggestions 3) mixed form assessment of quantitative and qualitative assessmet.

Assessment tool was revied for 3 times. The first review was carried out by medical experts, health policy expert andmedical industry stakeholder and the second review was by nHTA committee members and patinet-civil group member. For last review, we conducted in-depth interview of medical experts and nHTA committee members.

Results of pilot-assessments

We conducted total four pilot assessments of innovative emerging technologies with sub-committee members.

- 24 hour continuous IOP monitoring using contact lens sensor

This technology was deliberated as a research state technology since lack of effectiveness evidence and the technology does not crucially influence on the treatment of glaucoma. In the pilot assessment, however, experts gave their opinion that the technology can influence on the diagnosis or treatment way decision of glaucoma in a specific patient group such as presenting clinical symptoms of IOP elevation with normal IOP. Although patient's IOP can be monitored everytime, IOP measurement is one of many methods to diagnose the glaucoma. Thus the sub-committee made a decision that this technology is useful only in a limited condition with the recommendation level is moderately recommendation.

- Surgery simulation for repair of congenital heart disease using patient-specific three-dimensional(3D) heart model

The disease is rare and the influence on the patient is large. Also, it is hard to find the alternative technology and the technology has potential value to increase the safety by assisting to determine the surgery plan and the treatment way decision. On the other hand, because of the possibility of abuse is high on the acquired heart disease, the sub-committee made a decision to limit the patient to congenital heart disease with the recommendation level is moderately recommendation. The sub-committee decided that although the technology can be very helpful for the treatment way decision, it is inappropriate to make a recommendation as 'strong' because it is performed outside of the patient's body. As a minority opinion, a member of sub-committee mentioned that 3D printing technology is useful for student education and not necessary for the medical field.

- Percutaneous left ventricular partitioning in patients with chronic heart failure

The disease is not rare, but the influence on the patient is large and physical burden on the patient is low. Economic burden on the patient is expected high and alternative technology is already exist. The safety risk of the technology on the patient is high. Thus the sub-committee decided that clinical value of the technology is very poor with low recommendation level.

- Personalized surgical simulation of renal cancer

Clinical utility of the technology on the patient with severe partial resection of the kidney is expected high. In sub-committee there was a argue about the application to all kidney surgery including total resection. Recimmendation level was not suggested because the sub-committee failed to agree between members. In such a case, it is recommended that the nHTA committee make the final decisoin.

▢ Conclusions

We confirmed composition of subcommittee members, assessment items and tools used in assessment in the present study. And through four pilot assessments, we try to confirm the feasibility of new assessment system. We selected 8 assessment items, that are rarity of disease, severity of disease, physical burden on the patient, economic burden on the patient, possibility of abuse, affects on the quality of life, state of alternative technology and innovation level of technology. In terms of assessment tool, quantitative assessment tool for the innovative emerging technology was planned in the first place. However during the pilot assessment, we found quantitative assessment is not an appropriate method since the way of making conclusion is gathering consensus opinions of committee members. Instead, using qualitative assessment tool with consensus opinion is more appropriate in the innovative emerging technology assessment. We developed two or three points scale standard of each assessment items to minimize diversity of opinions and make easier to achieve a consensus of committee members.

New health technologies(which are permitted to be implemented in nHTA) through the new assessment method might have less clinical evidences than those using usual assessment method. Thus those technologies should be permitted with condition and adapted to patients under some managements. First, evidence creation should be tried while applying to patients. Thus, protocol submission from hospital and verification by NECA are essential processes. Second, hospitals applying innovative emerging technologies should satisfy some capacity, such as creating clinical evidences and running expensive equipments. Monitoring of evidence creation process for successful evidence acquisition is also needed. We believe that the process of creating evidence should be established and managed and appropriate reassessment of implemented technologies makes it possible the new assessment system established in the health insurance system.

Results from the present study will be used practically when we introduce

new assessment methodology of health technology. Although considering values of patients in HTA is tried in some cases as a research, new assessment methodology other than evidence-based HTA is not introduced in any HTA system until the present. It is the first attempt of nHTA in the world to derive value items and establish value-based assessment as a system for the registration of public insurance coverage list.

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Key words

new health technology assessment, innovative emerging technology, value assessment