Executive Summary

New health technology assessment guideline development

Seon-Heui Lee[1], Moo Yeol Lee[1], Min Lee[1], Ah-Ram Sul[1], Won-Jung Choi[1], Dong-Ah Park[1], Sungkyu Lee[1], Sung-Hee Oh[1], Ja Young Kim[1], Sungwon Lim[1], Soo Young Kim[2], Juneyoung Lee[3], You-Kyoung Lee[4], Sollip Kim[5]

[1] National Evidence-based Healthcare Collaborating Agency

[2] Hallym University, College of Medicine

[3] Korea University, College of Medicine

[4] Soonchunhyang University, College of Medicine

[5] Inje University, College of Medicine

☐ Introduction

Although the importance and role of new health technology assessment (nHTA) is growing every day, there is no clear guideline for the standard of judgment whether a case requires new health technology assessment, which has caused much confusion in the business and medical world. In order to solve such a problem, the National Evidence-based Healthcare Collaborating Agency (NECA) developed a guideline that clarifies the standard of judgment for nHTA as well as the standard for assessing safety and effectiveness to promote the predictability, consistency, and transparency of the new health technology assessment.

☐ Methodology

For development of a nHTA guideline, a case analysis was conducted. Based on 1,122 cases of applications for nHTA from Apr. 28, 2007 to Dec. 31, 2012, interventional cases, cases of in vitro examination, and cases of gene tests were analyzed by dividing them into cases for deliberating the target of assessment and cases for deliberating the assessment of safety and effectiveness. With the case analysis, in order to collect various opinions from professionals in each field relevant

to intervention, in vitro examination, and gene test, the advisory committee was held by professionals and a subcommittee for diagnostic test of nHTA(Apr. 24, 2013). Also, a deliberation committee for nHTA(Apr. 26, 2013 and Dec. 27, 2013) introduced the contents and shared opinions on the standard for judging the target of assessment (plan) and the standard for assessing safety and effectiveness. Finally, a task force consultative group, including representatives in relevant works of the Ministry of Health & Welfare, the industry, NECA, and the Health Insurance Review & Assessment Service (HIRA) prepared the standard for judging the target of nHTA.

□ Results

<Guideline for interventional new health technology assessment>

Targets of the nHTA include new technology, existing technology whose purpose of use, targets and methods are to be changed, and it is because it may require being considered as a separate medical practice. However, we tried to make a little change to the existing guideline for assessment. Of course, in cases where the operation route is changed, surgical operation is changed into interventional technique or there may be a change in the pattern of medical practice. Also, the level of invasion of the medical procedure by changing the operation procedure, which may cause changes in safety and effectiveness, should be maintained as the target of assessment. However, cases in which types of laser is changed with the same principle means the medical procedure is newly added to the existing technology or in which a manual therapy is changed into one using an automation device are considered as an existing technology, which will be excluded from the target of assessment. when the energy source or materials for treatment are changed, it is difficult to deliberate the technology as an existing technology because it includes both cases where changes in the type of medical practice and the level of invasion are large or small, so we tried to consult applicants' convenience by newly establishing a fast track for quick evaluation.

Table 1. Classification of target of assessment in the interventional method (plan)

Type of health technology	Whether it is a target of assessment in the future

Type of health technology	Whether it is a target of assessment in the future
1. New technology	Target of assessment
2. Technology whose purpose of use and targets are changed	Target of assessment
3. Technology whose way of use is changed	Target of assessment
3-1. Technology whose operation route is changed	Target of assessment
3-2. Technology where surgical operation is changed into interventional technique	Target of assessment
3-3. Technology whose operational procedure is changed	Target of assessment
3-4. Technology whose energy source is changed	Review to newly establish a fast track
3-5. Technology whose type of laser is changed	Existing technology
3-6. Technology where means of medical procedure is newly added to existing procedure	Existing technology
3-7. Technology whose manual therapy is changed into automation one	Existing technology
3-8. Technology whose materials for treatment are changed	Review to newly establish a fast track

As for safety and effectiveness of the Interventional cases, In order to be recognized as a new health technology, an interventional technology should not only be as effective as, or more effective than the existing technology, but it should also be safe. Once the technology is successfully accepted as safe and effective, the nHTA then evaluates the technology based on the following criteria: proper comparator, sample size, consistence of study findings, sample selection, equivalence between case and control groups, relevant outcome, adoption of blinded method, control confounding factors, enough follow-up period, confirmation of dropped samples, relevant statistical analysis, and conflict of interests.

<Guideline for nHTA in in-vitro diagnostic tests>

As for diagnostic examination, cases where target substances are changed or where the reporting system and clinical specimen is changed are the target of nHTA as usual. However, we are to considerably simplify the range of targets of nHTA by changing a paradigm where all changes in detailed techniques were to be the target of assessment and by bringing techniques with similar principles for examination together. To do this, we prepared a plan for the standard of judgment of targets of nHTA in the field of examination, which found an agreement of views from the

industry, the medical profession, the Korean Society for Laboratory Medicine (KSLM), and the HIRA through the TF activity of the Ministry of Health & Welfare that detailed examples will be added and regular reclassification will be reviewed, arranged, and decided by the Center for New Health Technology Assessment.

The biggest improvement in the field of diagnostic examination is the reduction of targets of assessment in multiple tests. Contents of the improvement is that the test items whose safety and effectiveness is already verified will not go through the new health technology assessment, while test items whose safety and effectiveness is not verified and which are included to items of multiple tests will be the target of assessment. The Ministry of Food and Drug Safety (MFDS) shall review whether performance of the multiple tests is worse than that of individual test when admitting items.

The standard for assessing the clinical usefulness of the handy tests is also changed. In the past, cases where the necessity of rapid diagnosis is recognized because of the characteristics of diseases, such as a heart disease are only recognized with the usefulness of a handy test, but we are to prepare a plan for acknowledging diseases with less necessity of rapid diagnosis, such as thyroid cancer and colorectal cancer, considering the convenience of 1st health care institutions. It is judged that the standard for assessing clinical usefulness of a handy test will be eased, but it will be necessary to review the standard for test abuse or target of use at the level of reimbursement policy. From an aspect of the usefulness of the handy test, the guideline is decided to evaluate the range of harms and abuses caused by the test as well as the urgency and convenience. In addition, as for in Diagnostic test, it is necessary to strengthen the effort to verify the necessity to produce reference through domestic clinical tests in the country when introducing the health technology in the country.

When it is recognized as an effective diagnostic test, the nHTA evaluates analytical performance, diagnostic performance, and clinical utility of the test. The main reasons why the tests are rejected are because: the targeted agent is not a key factor for a disease; there is no additional clinical benefit for diagnosis; there is no local data due to different ethnicity and lower disease prevalence; and diagnostic accuracy is lower than existing tests.

<Guideline for nHTA in genetic tests>

Genetic tests are divided into "a genetic test for congenital rare diseases" and "a genetic test for tumor, pharmacogenetics, etc." based on the target of the test, and the assessment system and available procedure depends on the type. Genetic test is basically assessed by rapid system, and have the assessment procedure of rapid review, rapid assessment, and systematic review. As for a genetic test for congenital rare diseases, decision on whether it is the target of assessment, and the assessment of safety and effectiveness are done in one process. Also, it can be assessed through rapid review procedure that had the review through a subcommittee for genetic test followed by deliberation in nHTA committee. When a test having the same target, test purpose, and only different test method compared to the applied genetic test for congenital rare diseases is already listed, and when it is judged that the applied test method is already established, it will follow the rapid review procedure. And review about effectiveness of test is performed according to three core criteria through relevant reference and search of GeneTests. "Clinical validity" is reviewed by considering: whether it is listed in GeneTests; whether there is a study for Korean and the detection rate, and review on "clinical utillity" is performed based on the number of clinical institutions confirmed in GeneTests, the effect of the test result on treatment, clarification of health risk when treating a patient; and whether it uses epidemiologic data. Also, the assessment reviews "the ethical and social implications" relevant to banned tests, risk of abuse, and branding caused by the test result or social disadvantages. As a genetic test is conducted in vitro by collecting a patient' s tissues, it does not harm the patient directly, and it may be judged as to be a certain level of safety similar to existing biopsy, so safety will not be additionally assessed. Finally, the specialized subcommittee for genetic test reviews the applied test based on the three standards for assessment, and when the genetic test meet all criteria, it is rapidly approved as a new health technology acknowledged for its safety and effectiveness. For examples, a genetic test could be assessed as an emerging technology or a experimental technology as follows; there is no study for Korean people about a genetic test, or it is the test of gene has low detection rate with locus heterogeneity. Meanwhile, whether single gene satisfies the standard for assessment, a gene has high detection rate in diseases with locus

heterogeneity, the same genetic test is listed in a way with high detection rate in diseases with locus heterogeneity, or gene mutation is detected, which is not detected in existing other test methods, the genetic test can be assessed as a new health technology. As for some genetic tests for congenital rare diseases, when other tests, which have the same target and purpose of use as the applied test but have different methods are already listed, or when there is little reference or it is necessary to judge clinical utility of applied test, an advisory committee composed of clinical professionals can arrange a rapid assessment to evaluate safety and effectiveness. Then, when it requires to conduct verification as there is no listed test with the same target and purpose of use or it is difficult to judge that the test method is established despite there are listed tests with the same target and purpose of use and different test methods, safety and effectiveness is assessed by performing systematic review if there is sufficient quality and quantity of relevant reference.

For a genetic test for tumor, drug susceptibility, and others, the assessment is conducted under the same assessment system and standard as that of the in vitro diagnostic test.

☐ Conclusions

A guideline for nHTA in interventional test, in vitro diagnostic tests, and gene tests through the same study has summarized major results. Suggestions for policies deducted by enacting this guideline are as follows: A plan for using whether the technology is listed in foreign HTA, European DRG additional codes, or USA CPT when excluding it from the target of nHTA or applying the fast track was suggested, and it is necessary to review a more detailed suggestion (plan) on this. That is, it is necessary to review the exemption of nHTA or the application of the fast track by making the applicant submit relevant data on DRG code of relevant technology or supporting evidence, such as foreign sales conditions. Also, as it is difficult to directly apply DRG or CPT codes because of the difference with Korean system, it is necessary to review the validity of detailed application model.

As for simultaneous progress of an approval of product items and the new health technology assessment, we are currently preparing a reasonable plan by coordinating

opinions from the industry and the medical profession. Although we are deducting a detailed execution plan by coordinating various opinions of the interested parties in each field, every party has different opinions so it is necessary to suggest a reasonable policy plan. A guideline for nHTA was first enacted in interventional procedures, in vitro diagnostic tests, and genetic tests through this study, and after reviewing whether it is necessary to expand the application range, it should contribute to the development of new health technology assessment. In addition, it is necessary to efficiently arrange the approval of items, health technology assessment, and registration of medical care expenses through one-stop service implemented from the end of 2013. Besides, there is a request to include in vitro diagnostic devices to the target of this service so it should be reviewed actively.

A plan for differentiating the period of review by each technology field and the intensity of clinical-based reference is a part required to be reviewed additionally after stabilizing the operation of the system applying the guideline for efficiency of the system operation. As there is a definite harm by health technology, it is more appropriate to conduct deliberation considering medical distinctiveness, such as rare occurrence rate when there is a problem on the medical ethics rather than differentiating the intensity of the ground reference on specific fields (e.g., imaging examination, etc.).

A plan for improving the procedure to conduct the nHTA was also deducted during the process of developing this guideline, which is a plan to have an opportunity for applicants to state opinions through a subcommittee in order to expand the acceptability of the assessment result. This should continue to improve problems caused when performing procedures, and it is important to minimize the possibility to have influences on external factors by the exposure of members of the subcommittee.

health technology assessment, safety, efficacy, effectiveness, manual, guideline