Executive Summary

A Pilot study on the System and Execution Model for Health Technology Reassessment

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▢ Background

The market coverage of new health-related technologies is expanding, while the current health technology is deteriorating with regard to its life cycle. However, there is no mechanism available to assess and manage the suitability of the existing health technology after its introduction into the healthcare market. Therefore, a health technology reassessment (HTR) is essential in terms of overall life cycle management, and a systemic mechanism based on scientific health technology assessment approaches is in demand. Meanwhile, NECA has developed a system and execution model for health technology reassessment suited for a local healthcare system by reviewing and mirroring ideas from foreign health technology systems. In order to apply the execution model for health technology reassessment developed in the previous study (NECA, 2014) into the actual process of health technology reassessment, a transitional mechanism is required. This mechanism will identify and complement the strengths and weaknesses through a pilot project, which will lead to improvement in its suitability and acceptability within the local healthcare system.

▢ Objectives

The objective of this study is to establish a system for health technology reassessment suited for a local healthcare system through pilot appraisals of health technology reassessment. The prime objectives are to first perform pilot assessments based on the execution model for health technology developed in the previous study, and secondly to propose a system for health technology reassessment suited for a local healthcare system.

▢ Methods

Ⅰ. Identification and prioritization

The health technology reassessment subjects for the year 2015 were identified according to NECA's survey on topic suggestion and the study topic selection process. The selection process is carried out largely on the basis of the survey on topic suggestion, the primary and secondary topic reviews, and the tertiary final study plan reviews.

The prioritization was limited to the preeminent topics from the primary assessment and was conducted through the review of the NECA planning and management committee, in which the results of Quick Review for each study topic were provided and evaluated for prioritization based on four criteria: feasibility, the extent of disease concern, social needs, and the utilization of study results. Eventually, health technologies for reassessment were selected through internal meeting and peer review.

Ⅱ. Implementation of reassessment

The researchers performed reassessments for two health technologies selected for pilot appraisals. Based on a systematic review, a situation analysis was performed according to the characteristics of the corresponding health technology.

1. [Scenario 1] Safety and efficiency analysis of a small bowel capsule

endoscopy in patients with a suspected small bowel disease

A systematic review was conducted to develop key questions and search three foreign databases and seven local databases. The texts were finally selected according to the literature selection and exclusion criteria, data extraction, as well as quality assessment. Where quantitative approach was possible, a meta-analysis was performed; else, a qualitative review was performed.

2. [Scenario 2] Safety and efficiency analysis of steroid intra discal therapy (SIDT)

A systematic review was conducted to develop key questions and search three foreign databases and seven local databases. The texts were finally selected according to the literature selection and exclusion criteria, data extraction, as well as quality assessment. Where quantitative analysis was possible, a meta-analysis was performed; else, a qualitative review was performed. Health insurance claims-related data analysis was conducted using relevant data for a total of five years between January 1, 2009 and December 31, 2013. The situation analysis was conducted with patients suffering from low back pain and new patients with low back pain for whom the steroid intradiscal therapy had been applied.

Ⅲ. Decision on the grading of recommendation

A literature review of the grading of recommendation systems used in the healthcare sector in foreign countries has been conducted. The advantages and disadvantages of each grading of recommendation were taken into consideration based on the review, and a decision was reached that the grading of recommendation systems should be suited for reassessment. The approved grading of recommendation systems was revised and elaborated through an internal review with regard to its suitability for local healthcare environment and health technology reassessment, and was suggested as the final grading of recommendation for reassessment (proposal).

HTR's specialized committee derived the grading of recommendation for

pilot reassessments of two health technologies via face-to-face meetings. Based on the grading of recommendation scheme prepared by the researchers, the HTR form was evaluated to derive the grading of recommendation.

Ⅳ. Revision and elaboration of reassessment system (proposal)

Expert opinions on the reassessment system (proposal) were collected in various ways such as peer reviews, research presentations, panel discussions, and written advice. Experts (stakeholder) expressed their thoughts in oral and written form depending on the specific agenda for the different locations. The feedback was collected and organized by the researchers. Collected expert opinions were sequentially categorized according to reassessment procedures and analyzed for valuable expert opinion.

▢ Results

- **Identification**: Demand for periodic monitoring systems established by NECA and related organizations
- **Prioritization**: Clarification and independence of the main body engaged in identification of reassessment subjects
- **Execution of reassessment**: Application of various health technology approaches and transparency of the main body engaged in determining the grading of recommendation
- **Determination of grading of recommendation**: Necessity for measures accounting for the increase of information utilization when reaching grading of recommendation decision for reassessment

Ⅰ. Identification and prioritization

1. Identification of 2015 health technology reassessment

A total of 10 cases of health technology related to health technology reassessment were proposed in accordance with the 2015 NECA survey of

topic suggestion and identification procedures.

Of these, the study subject of radiation hyperthermia earned high marks at the primary review. In addition, three cases with similar topics were received, for which the secondary review was consequently carried out and resulted in bringing in the planning and management committee for reexamining the feasibility, the extent of disease burden, social needs, and utilization of related study results. However, the study subject of "health technology reassessment of radiation hyperthermia and hyperthermia therapy planning" was finally discarded as a potential subject for future studies because reclassification of the reimbursement action names might be required due to a variety of cancer types, whereas the evidence level of literature on cancer types was deemed insufficient.

2. Reprioritization

In the previous study (NECA, 2014), two health technologies (Steroid Intra Discal Therapy and radiofrequency myolysis) were prioritized for this year's pilot assessment studies of health technology reassessments. However, while going through relevant documentation for pilot assessments, it was discovered that there was a limit to the pilot assessment topic of radiofrequency myolysis for reassessments due to lack of related evidence. As a result of the reprioritization assessments, the study subject of small bowel capsule endoscopy was selected for a two-way pilot assessment with a reimbursement purpose.

Ⅱ. Execution of reassessment

1. [Scenario 1] Safety and efficiency analysis of capsule endoscopy in patients with suspected small bowel disease

Capsule endoscopy is a non-invasive and simple procedure in gastrointestinal bleeding cases of unknown origin, and can be utilized as a primary diagnostic test. When considering treatment procedures such as extinction of bleeding causes, a double balloon endoscopy is recommended.

The capsule endoscopy in patients with small intestine-related Crohn's disease is useful in the diagnosis of lesions in patients without extralumina and transmural lesions. However, caution has to be exercised in case of patients with small intestine obstructions or occlusions. The capsule endoscopy is more useful in identifying intestine polyps than MR enteroclysis. When considering removal and treatment of polyps, a small bowel endoscopy is recommended. However, there is insufficient evidence for the efficiency of capsule endoscopy in other diseases excluding gastrointestinal bleeding of unknown causes, Crohn's disease, small intestine polyps, and tumors; hence, a conclusion in this regard is difficult to reach. In terms of safety, a capsule endoscopy is a diagnostic test with a relatively high safety level, but it is recommendable for an endoscopy to be conducted after examining the presence of occlusions in relevant diseases such as Crohn's disease, and tumors with frequent strictures.

2. [Scenario 2] Safety and efficiency analysis of steroid intradiscal therapy (SIDT)

With regard to the safety and efficacy assessment of the steroid intradiscal therapy, the systematic review and health insurance reimbursement claims data analysis conducted in this study showed that it is difficult to make a definite conclusion on the safety and efficacy of such a therapy. According to the systematic review results, the total number of comparative study texts on this therapy was insufficient and it was difficult to perform a quantitative analysis because of the varying interventions designated as the comparison group. More than half of the selected texts that studied patient groups were found to be published before 2004, which limited the relevant information obtained from this literature in terms of quality and contemporary impact. It was difficult to formulate an operational definition of patient groups for the health insurance claims data analysis due to the fact that the health insurance fee code of steroid intradiscal therapy was set as an applicable fee. Also, if a post-operative side effect was associated but not treated in a hospital for such a complication, such a case cannot be included in this

analysis.

Although the results of this study, through medical literature evidence and analysis of secondary sources, do not provide sufficient evidence to make a definite conclusion on the safety and efficiency of the concerned therapy, it is judged necessary to establish a management measure for performing the therapy, considering the fact that the therapy is a health technology that has raised safety issues in the past.

Ⅲ. Determination of grading of recommendation

1. Provision of grading of recommendation for reassessment (proposal)

The grading of recommendation for health technology reassessment was established on the basis of the GRADE approach. In particular, EtD Frameworks presented in the GRADE approach were used as a decision-making tool on the grading of recommendation for health technology reassessment, named HTR form. The HTR form was to be flexibly and selectively applied depending on the nature and reassessment purposes of the health technology.

The grading of recommendation is decided at the interchangeable face-to-face opinion meetings. The contents of HTR form developed by internal researchers were introduced by the researchers, followed by sufficient discussions and arguments by the HTR special committee for evaluation. It was deemed fair that the briefing on HTR form is made by the representative of the peer review committee, summoned for the preparation of the HTR form. The HTR form goes through the sequential process of exchanging opinions on each of the criteria, individual assessments (voting), and sharing the results. This process is vital as it serves as a pre-step to the overall assessment of the concerned health technology. In addition, the HTR form assessment results are expected to be utilized as evidence for the decision-making process on the grading of recommendation. After the HTR form assessment is finished, overall assessment for the concerned health technology is performed on the basis of HTR form assessment, after which the grading of recommendation is decided by voting. Reassessed health technology is presented in one of the following

four grades of recommendation according to the GRADE approach.

A	It is recommended not to use the concerned intervention (Strong against).
B	It is suggested not to use the concerned intervention (Weak against).
C	It is suggested to use the concerned intervention (Weak for).
D	It is recommended to use the concerned intervention (Strong for)

2. Decision on the grading of recommendation for pilot evaluation of health technology reassessment

The pilot evaluation was conducted in the presence of 6 out of 15 HTR specialized committee quorum which failed to meet the majority. A decision was reached in favor of the use of small bowel endoscopy in gastrointestinal bleeding of unknown causes (Weak for), and against the use of steroid intra distal therapy (Weak against).

Ⅳ. Revision and elaboration of the system for reassessment (proposal)

The final proposed system for reassessment was set up based on the existing 4-staged system for health technology reassessment with the purpose to additionally reflect the grading of recommendation (proposal) as well as the pilot assessment experiences as provided in this study. Based on the existing 4-staged system for local health technology reassessment, the content of the applied pilot assessments, along with all related revisions and elaborations, is summarized below.

stage	2013 Reassessment system (proposal)	2014 Pilot assessment (execution)		2014 Revised reassessment system (proposal)
1. Identification	- Government and related organization survey on topic suggestions - NECA survey on topic suggestions - NECA internal monitoring - Reassessment of essential items	- NECA survey on suggestion topics (reassessment criteria included)	⇨	- Due to a limitation on voluntary application mechanisms such as the survey on topic suggestions, periodic NECA monitoring system (e.g., Quick review) is required. - Related institutions need to establish

			monitoring systems for healthcare utilization.
2. Prioritization	HTR specialized committee's prioritization	- NECA review of prioritization of study topics (Planning and Management Committee) - HTR specialized committee reprioritization	- Selective assessment by committee members according to their specialty areas - Clarity and independence of the main decision body =〉 HTR specialized committee or health technology assessment committee
3. Reassessment	Reassessment execution methods (draft) - Systematic review - Additionally conducted retrospective study - (Economic evaluation)	Reassessment ① Small bowel capsule endoscopy - Systematic review ② SIDT - Systematic review - HIRA data analysis	- Operation of subcommittee during reassessment - Application of various health technology assessment approaches (e.g., awareness survey, economic analysis) - Provision of sufficient study period if patient data collection and economic analysis are required
		Drafted the grading of recommendation - Establishment of decision procedure for grading of recommendation - Grading of recommendation application in pilot projects - HTR specialized committee piloting	- Securing of the representativeness of the main decision body (HTR specialized committee) for grading of recommendation (draft) - Transparency of grading of recommendation
4. Decision	- 'Decision-making determined as 1) Approval withdrawn 2) Grading of assessment		- Terminology updated to grading of recommendation : The reassessment results are presented in grading of recommendation, not in decision-making

▢ Conclusion and policy suggestions

The study's goal was to perform pilot assessment for two health technologies which were determined in the previous Study of system and execution model development for new health technology reassessment (2014) and to revise and elaborate the previously proposed system in order to enhance its acceptability and suitability within the local healthcare system. The study's major revisions and conclusions include the following:

First, it is necessary for NECA and related organizations to establish a monitoring system in the stage of identification.

Second, it is recommendable for NECA and related organizations to provide procedures ensuring the clarity of the main body engaged in selecting reassessment subjects, and objectivity of the selection process in the stage of prioritization.

Third, it is advisable for NECA and related organizations to set up a specialized committee for relevant health technology in the same manner as in the new health technology assessment process. Wherever necessary, various health technology assessment approaches in the stage of reassessment must be utilized. It is mandatory to ensure the professionalism of the main body engaged in deciding on the grading of recommendation and to provide a transparent and fair system for reassessment in the stage of drafting decision on the grading of recommendation.

Last, it is advisable that the grading of recommendation be announced in order to promote an optimal use of the concerned health technology after the reassessment in the stage of the final decision on the grading of recommendation.

Keyword

: health technology reassessment, pilot assessment, small bowel capsule endoscopy, steroid intra discal therapy, grading of recommendation