Executive Summary

□ Introduction

Even though it is easy to access medical services in Korea, health insurance coverage rate is relatively lower than the average of the OECD countries. In addition, the portion of out of pocket payments for healthcare to the household expenses well exceeds the OECD average. This is ascribed to the fact that there are too many non-covered items and the statutory copayment rates for covered items are high. Despite the government's efforts to expand the health insurance coverage over the past few years, the coverage rate remains stagnant due to an increase in the number of non-covered items mainly from new health technologies become available. Such increased non-covered items can add up to the burden of the people and deteriorate the quality of medical services (Ministry of Health and Welfare: 2012).

Most of non-covered items in the diagnostics and examinations category are 'procedure' items. Given an increasing trend of test-related items, there is an ongoing concern that this can increase people's financial burden. Recently the Korean government announced a national health insurance policy to extend medical coverage to 4 major diseases such as all types of cancer, heart conditions, cerebrovascular diseases, and rare and incurable illnesses (Ministry of Health and Welfare: June 26, 2013). As several diagnostics and examinations related items were designated as essential medical services, the ultrasound test switched from a non-covered item to a covered one, and the MRI test is expected to extend to heart diseases, along with the existing coverage of cancers, brain and spinal diseases, starting from the concerned year. As the selective benefit items include the capsule endoscopy with a built-in camera, it is expected to switch to a covered item in the essential genetic test category starting from 2016.

As of now, there is a need to establish the grounds for a comprehensive evaluation to assess a new medical technology whose safety and effectiveness are already proven by the New Health Technology Assessment System or other medical technologies which have a strong social demand to switch from an non-covered item to a covered item, or to review the existing medical

technologies which have not been introduced (J Ahn et al, 2012). Therefore, this study aimed to provide data on policy grounds for the evaluation and management of non-covered examination items.

Deliberation on Criteria for Non-covered Items

As Korea's insurance benefit system differs from those of advanced countries, it was difficult to directly compare it with them. Despite that, the study was able to review the outlines of health insurance benefit system in the diagnosis and examination category, the current status of copayment, types of financing, etc. In the U.K. a comprehensive medical service is provided on a national level and is financed from taxes. Although the General Practitioners (GP) consortium has an authority to decide which diagnosis and examination items to be covered, any concept similar to a non-covered item in the Korean health insurance system does not exist. In Canada, about 15% of the total health expenses were financed from the pockets of patients, but because they consist of alternative and supplementary therapies, eye treatment and over-the-counter drug purchases, it is difficult to identify these items' diagnosis and examination domain within the system, and some types of MRI and CT diagnoses were financed from copayments or by private insurance. In the U.S, there is nothing in the diagnosis and examination similar to the concept of non-covered items, but it has a separate formal process for promising drugs, medical devices and diagnostic methods and procedures, which are difficult to enter the domain of health insurance coverage. The state-run Medicare is limited only to reasonable and essential treatments and diagnostic methods, and is characterized by the National Coverage Determination (NCD), which ensures public participation in the process of deciding whether Medicare will pay for an item or service through a ground-based procedure. Australia has a system where Medicare, the state-financed public health insurance program, and the private health insurance coexist. And the country's medical technology evaluation institute under the umbrella of a governmental organization is divided into several fields including medical service, medical drug coverage, medical devices, which mutually cooperate for each other. The evaluation scope of the Medical Services Advisory committee (MSAC) responsible for the medical service field includes diagnostic tests, while the medical technology evaluation items include safety, clinical benefits and cost-effectiveness. The institute is provided with information about the influence of a diagnosis method on patients (such as increased survival rates

and improved quality of life), and is responsible for evaluating it.

Basically, Canada, Australia, and the U.K. even consider the aspect of cost-effectiveness through a comprehensive medical technology evaluation system. Although Korea has stably operated the New Health Technology Assessment System, there is much room for improvement in terms of economic feasibility analysis. If we break the influence of a change in the non-covered diagnostic items into the expansion and shrinkage of the national health insurance coverage, an increase in the CT and MRI coverage generated a growth in patients' demand, but the providers had to increase or decrease their supply or decrease in order to prevent a decrease in their income-to-expense ratio, while the insurer sought a policy measure to suppress a growth in the demand caused by the inclusion into health insurance coverage (M Shin, 2009).

Starting from this year, most of the uncovered items of 4 major diseases are expected to switch to covered items depending on the results of the evaluation, in accordance with the governmental policy. Therefore, the country needs to develop a policy to reduce the ratio of uncovered items in the diagnosis and examination category and a comprehensive evaluation system to evaluate not only safety and effectiveness but also economic feasibility. To this end, this study developed an economic feasibility analysis model which can be used to decide which items are to be covered by the national health insurance, through consultation with the Korean Societies of Radiology and Laboratory Medicine.

□ Cases of Evaluation

Ⅰ. Cardiac MRI Examination

To review the clinical effectiveness and cost-effectiveness of the cardiac MRI test, 12 research literatures relevant to the core questions were selected through a systematic review of existing research papers and literatures related to economic feasibility analysis, and another three literatures were added through clinical consultation (1 systematic review and 2 review articles), bringing the total to 15 literatures. To assess the quality of 13 literatures whore research type was classified as a systematic review of existing literature, the AMSTAR was used by this study. As a result, 3 literatures were given 6 points and another two scored 4 points, which were equal to or slightly lower than the mid-level quality.

The cardiac MRI showed an exceptionally high level of sensitivity and

specificity in the diagnosis of Coronary Artery Diseases (CAD). The study by Dejong et al. (2012) carried out a comparative analysis was to evaluate the diagnostic accuracy of MRI, SPECT and Echocardiogram (ECHO), and reported that MRI showed a higher level of diagnostic test accuracy than SPECT and ECHO. Only when compared with PET, MRI failed to show any significant difference (Advisory Secretariat_D, 2010). In addition, when MSCT was compared with MRI, MSCT displayed a higher level of diagnostic accuracy than MRI but failed to indicate any statistically significant differences (Schuijf et al, 2006; Asferg et al, 2012). Although it showed an almost similar level of diagnostic accuracy compared to PET and MSCT, MRI has an advantage over them, because it does not in involve any risks of exposure to radiation.

In addition, the cardiac MRI was a very useful examination in that it can assess not only perfusion but also myocardial function. Although CADs can be detected only by looking at the perfusion, it is possible to make an exact diagnosis on patients with ischemic heart diseases by checking the condition and function of heart muscles as well as the perfusion. Schinkel et al (2007) reported that the MRI showed a high level of diagnostic test accuracy in detecting scar tissues in heart muscles. Especially, it could enable to predict the recovery of heart muscles after undergoing a surgical treatment by measuring the thickness of heart muscles. If the wall thickness at the end-diastole was thinner than 5.5mm, a patient would have a hard time recovering after undergoing artery revascularization. Kaandorp et al. (2005) reported that the myocardial walls could recover to the point of 95% sensitivity and 41% specificity. Tomlinson et al. (2005) reported that the CMR could provide visual images of the structure and perfusion of a heart with an extremely high level of spatial resolution.

Among all types of MRI, the delayed-enhancement magnetic resonance imaging (DE MRI) is widely carried out in diagnosis of heart diseases, while the dobutamin stress MRI can be conducted as a complementary test for elderly patients or when the results of the DE MRI are uncertain. Because the specificity of the dobutamine stress MRI is extremely high, the test is useful when assessing the viability of heat muscles in patients with high risks.

In terms of the cost-effectiveness, the heart MRI test is usually more cost-effective than SPECT in diagnosis of patients with suspected coronary artery diseases (CAD), but it was found to be not as cost-effective as echocardiogram.

Ⅱ. MRSA Genetic Test [Real-time Polymerase Chain Reaction]: Systematic Literature Review

For the systematic review of literatures on the MRSA genetic test [real-time polymerase chain reaction] of ICU patients, a total of 15 research literatures (3 domestic and 12 overseas research papers) were selected. According to their research type, 10 studies were classified as the diagnostic test evaluation research, while the remaining five papers were categorized as the comparative observation research. Major research questions consisted of diagnostic accuracy of an interventional examination and clinical effectiveness of an active surveillance for MRSA infections using an interventional examination. The microbial culture and screening test (enrichment culture) was defined as the reference standard test.

First of all, in regard to diagnostic accuracy, a qualitative synthesis was carried out on 10 cases of diagnostic accuracy reports from 9 diagnostic test evaluation research papers which allowed meta-analysis. According to the results, the pooled sensitivity and specificity were estimated at 0.95 (95%CI: 0.90-0.97) and 0.96 (95% CI: 0.89-0.98) respectively, whereas the pooled positive likelihood ratio (LR+) and negative likelihood ratio (LR-) were measured at 21.87 (95%CI: 8.56-55.89) and 0.53 (95%CI: 0.03-0.10) respectively. According to the results of an additional analysis on the heterogeneity caused by the distribution of the MRSA positive rates (the number of MRSA positive cases/the total number of tests), this study divided the literatures into two groups; one with 0% or higher MRSA positive rates and the other with less than 30% MRSA positive rates. Although this study observed significant differences in the sensitivity and specificity, it was impossible to conduct an additional statistical analysis because there were only 2 research papers that had higher than 30% MRSA positive rates. Although Korea does not have the exact national statistics on MRSA infections, it is widely known to have a high MRSA carriage rate in hospital settings by several research papers, which should be considered when comparing with overseas research literatures.

Although the evaluation of the clinical effectiveness was conducted on one paper in the diagnostic test evaluation category and another five papers in the comparative observation research category, a qualitative synthesis was carried out because the heterogeneity in the intervention methods at the study design phase was too high. Three papers reported a significant drop in the

hospital-acquired MRSA infection rate after an active surveillance for hospital infections by utilizing interventional test methods, whereas another paper indicated a decrease but failed to show any significant change. One study in the retrospective comparative observation research category reported a difference in the sensitivity of the prediction of hospital-acquired MSA infection occurrence. And according to the research, the prediction sensitivity of the interventional examination was reported to be significantly higher than the standard test.
One overseas research literature said that the use of an interventional examination could reduce the isolation period compared to the standard test, and could generate cost-saving effects. According to the paper, a reduced examination time compared to the standard test could enable an early preventive isolation. The isolation could be finished earlier because less time would be required to determine whether to terminate the isolation. However, there were limitations to this study, in that only one and three papers in each category reported clinical effectiveness; that it was difficult to standardize the infection occurrence and the infection rate; that there could be various external variables which can have influence on carriage and incidence. Therefore, further studies need to be conducted to verify the clinical effectiveness of interventional examinations by using a random clinical trial study.

Ⅲ. MRSA Genetic Test [Real-time Polymerase Chain Reaction]: Economic Evaluation

For economic evaluation, this study targeted all patients who stayed for more than 48 hours since being newly admitted to the intensive care unit (ICU); those who left the hospital within the 48 hours or were found to have MRSA infections were excluded from the study. It conducted a comparative analysis on the two MRSA test methods-a PCR-based test and a traditional culture-based test. The cost-effect analysis was carried out in consideration of the accuracy of each test method from the health insurance system perspective. The analysis period was limited to the hospitalization period. The study conducted an analysis using a decision-tree model with decolonization (model 1) and isolation (model2) strategies. It was carried out on the assumption that the medical expenses included examination and treatment fees as well as all kinds of operating expenses necessary to run an isolation facility but excluded transportation and nursing fees.

In term of the reduced MRSA incidence rate in newly admitted ICU patients thanks to the PCR examination, the patients showed a 6% decrease rate in case of decolonization and a 12% decline in event of isolation. The additional costs incurred by the PCR examination were estimated at 873,909 KRW in case of decolonization and 881,982 KRW in event of isolation. In other words, the incremental cost-effectiveness ratio in case of the PCR examination, which indicates the change in costs to incremental benefits of the therapeutic intervention to reduce one MRSA infected patient, was recorded at 7.33 million won/14.24 million KRW. Considering that the Korean cost-effectiveness standard of 20 million/30 million KRW (J Ahn et al., 2010: J Ahn et al., 2013), it was considered to be significantly cost-effective.

□ Conclusion and Suggestion

This study aimed to provide basic data for a future evaluation system of non-covered diagnosis and examination items to assess them from a medical technology evaluation perspective. To this end, the study assessed the domestic status of insurance payment system and the current operation of the system for non-covered diagnosis and examination items, and searched for research papers on the status of similar systems and management practices in major foreign countries. In addition, the study provided examples about the assessment of the cardiac MRI test and the MRSA genetic test (real-time polymerase chain reaction) by motoring domestic policy trends and through consultation on clinical demands with the related academic societies. A systemic review of existing literature and an economic feasibility assessment were used as the study methods.

As the study was conducted using only two evaluation items, it has several limitations. First of all, as these items were not selected by a systematic priority-setting process of each field, the usefulness of the study results could be limited. Despite that, the study has a meaningful significance in that it has set a good example in building the grounds necessary for policy decision-making. Therefore, the value of this study will be more pronounced out, if a procedure to select evaluation items depending on their levels of influence on the future health and medical system is to be established in the future. Another limitation to the study is that it could not conduct a separate feasibility study for each indication

due to time constraints, in case of an examination on which is difficult to develop a feasibility analysis model because of excessive indications like cardiac MRI. In absence of enough literatures required for an economic feasibility analysis, there could be limitations in developing a framework for a successful economic feasibility assessment.

As of now, the two evaluation items used by this study have switched from covered items to non-covered items under the current national health insurance system. If a policy measure to include these items in the insurance benefits is to be formulated, it can be useful for policy decision making to review relevant existing research literatures, to assess their clinical effectiveness and to conduct a cost-effect analysis on a series of options. Recently, there have been some attempts to develop policies to reduce the scope of non-covered items or to switch them to covered items, in order to reinforce the benefits of the national health insurance. To this end, Korea needs to develop a system which can manage a comprehensive medical technology assessment systematically like major foreign countries. Also, in order to establish such a comprehensive assessment system, the country needs to create an environment which encourages methodology experts from each of the relevant fields to participate in the policy decision-making.

Key words:
Health Technology Assessment, Economic Evaluation, Diagnostics and Examinations, Non-covered Items