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Assessment of Pharmacoeconomic Evaluations Submitted for Reimbursement in Korea

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ABSTRACT

Objective: To assess the quality of pharmacoeconomic evaluations (PEs) submitted with new drug applications for reimbursement and to investigate the role of PEs for coverage decisions in Korea. **Methods:** Forty-seven PEs that were submitted by pharmaceutical companies for coverage decisions between June 2005 and December 2009 were included in this study. To assess their appropriateness with regard to the PE guidelines, we used the Health Insurance Review and Assessment services (HIRA) checklist consisting of 20 items based on the PE guidelines. We also evaluated the results for coverage decisions, as "recommended," "recommended with restricted use," or "not recommended," based on the incremental cost-effectiveness ratio and the range of uncertainty. **Results:** On average, 14 of the 20 items on the HIRA checklist were fulfilled (70.9%, range 35.0%–100%). The compliance rate for the following items was above 70%: presentation of perspectives and evaluation methods, a sufficient time horizon, and appropriateness of comparators and health outcomes. The compliance rate for the following items was below 70%: omission of objectives for the study, inappropriate target population, unclear selection process for effectiveness and cost, inappropriate cost estimation, insufficient justification of generalizability, and description of study limitations. The range of incremental cost-effectiveness ratios per quality-adjusted life-years of PEs from a societal perspective varied from dominant to 59K USD (n = 13): it consisted of dominant to 28K USD for "recommended" submissions (n = 6), 8K to 20K USD for "recommended with restricted use" submissions (n = 4), and 13K to 59K for "not recommended" ones (n = 3). **Conclusions:** Our study showed that most PEs in this study have reached an adequate level for coverage decisions. Overall barriers associated with a lack of relevant evidence could account for the low compliance rate with specific items in the PE guidelines. PEs with good quality submitted for coverage decisions have played an important role for selecting cost-effective drugs.

Keywords: drug reimbursement, Korea, pharmacoeconomic evaluations, quality assessment.

Introduction

Recently, expenditures on pharmaceuticals are the fastest growing sector within health care. In an attempt to control expenditures and to assess the value of new drugs, economic evaluations are increasingly used by several bodies such as government agencies and managed care groups that determine whether new pharmaceutical treatments should be listed in public formularies [1–6].

Although total spending on health as a share of the gross domestic product (GDP) in Korea is low (6.4% of the GDP in 2006), real health expenditures per capita have increased rapidly over the past decade. The rise in pharmaceutical spending has been one of the factors behind the increase in total health-care spending in Korea [7]. In 2006, spending on pharmaceuticals accounted for 25.4% of total health-care spending, one of the highest proportions in the Organization for Economic Co-Operation and Development area and well above its average of 17.3% [8]. In addition, compared with other countries such as Switzerland, Canada, and Sweden, which are in a positive list system, our previous pharmaceutical benefit schedule in the negative list system consisted of approximately 20,000 drugs, which was huge [9–11]. Under the negative list system, almost all the drugs that were approved by the Korean Food and Drug Administration were automatically listed for reimbursement, and the cost-effectiveness of new drugs was rarely taken into account in coverage decisions. Therefore, it was hard to manage the National Health Insurance reimbursement list efficiently, and nobody knew the monetary value of the listed drugs.

With growing attention to pharmaceutical spending, the Korean government implemented the Health Care System Reform Act effective December 29, 2006. The goal was to convert the pharmaceutical benefit schedule to a positive list system that selects drugs that are both therapeutically effective and cost-effective. This was done in accordance with a rationalization plan for the sustainability of the National Health Insurance. To ensure credibility and objectivity in pharmaceutical reimbursement decision making, the government delegated authority to the HIRA, an independent and specialized agency for reviewing and evaluating health-care technologies. HIRA is responsible for the assessment

Conflicts of interest: All authors have no conflicts of interest with regard to the content of this article.

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Table 1 – The HIRA checklist for quality assessment of pharmacoeconomic evaluations submitted for coverage decisions.

Topic	Questions*
Objectives	Is the object of the study presented in a clear and specific manner?
Perspective	Are the perspective of the analysis and reasons for its selection stated?
Type of evaluation	Is the evaluating method presented and appropriate?
Target population	Is there consistency between evaluated and reimbursed patients?
Time horizon	Does the analytic horizon allow time for all relevant and important outcomes?
Comparator	Are the reasons for the selection of comparator(s) mentioned?
	Is the choice of comparator(s) appropriate?
Data source	Is the methodology for searching and abstracting data clearly stated?
Clinical benefit estimation	Is the clinical evidence unbiased and obtained from the target patients expected to be reimbursed?
Cost estimation	Is the methodology for estimating quantities and unit costs described in a clear and disaggregate way?
	Is the measurement of relative costs appropriate?
Health outcomes	Are the health outcome measures and scales valid and reliable?
Discounting	Has the discount rate been used for both costs and effects?
Model analysis	Are the choice of economic model, main assumptions, and limitations of the study stated and justified?
Uncertainty evaluation	Is sensitivity analysis performed for uncertainty of all assumptions and variables incurring uncertainty?
	Is uncertainty fully handled to cover the range of assumptions?
Generalizability	Are the included data sources proper to generalize the applicable population?
Results	Has an incremental analysis been made?
Budget impact	Has the financial impact been analyzed?
Others	Do the authors explicitly discuss the direction and magnitude of potential biases?

HIRA, Health Insurance Review and Assessment Services.

* Questions, which consisted of 20 items, were developed for assessing appropriateness according to the pharmacoeconomic evaluation guidelines that were developed in Korea for assisting in preparing pharmacoeconomic evaluations for coverage decisions.

on the appropriateness of reimbursement, and the reimbursement restrictions of all submitted drugs by considering the efficiency of drugs and the severity of the disease. In the process of decision making, internal HIRA staff members carefully review submitted dossiers as well as additional data obtained from a comprehensive search, claims data, and experts' opinion. Finally, HIRA is advised by the Drug Benefit Coverage Assessment Committee, which is composed of 18 multidisciplinary members with expertise in medical practice, clinical pharmacology, health economics, pharmacoepidemiology, and other disciplines. According to the Act, pharmaceutical companies that want their new drugs to be listed on the National Health Insurance reimbursement list can, to justify their value for reimbursement, voluntarily submit dossiers following a prespecified form. Pharmacoeconomic evaluations (PEs) were mandatorily requested for drugs, especially ones superior to the comparator drug in terms of clinical benefits but costing more, to justify the higher cost corresponding to the improved effectiveness of drugs. HIRA published the draft guideline in 2005 and the official guidelines in 2006 for PEs. The guidelines assist companies in preparing documents to justify the cost-effectiveness of drugs that can be listed in the national drug formulary [12,13].

Although several countries, such as Canada and Australia, have implemented their own PE guidelines over the past decade, divergence from the guidelines was frequently reported [14–19]. Items for which they were incompliant with the guidelines in the other countries were uncertainty about clinical effectiveness [1], cost estimation [16], and transparency of the methods [14,15,20]. Before HIRA published the PE guidelines, there have also been similar issues for PEs that were published in Korean journals [2]. This study was conducted to evaluate the current state of the PEs that were submitted for coverage decisions by assessing the quality level of the PEs since the development of the PE guidelines. In addition, we investigated the role of the PEs by evaluating the results for coverage decisions in Korea.

Methods

We assessed PEs that were submitted by pharmaceutical companies for coverage decisions and completed for decision making by HIRA between June 2005, when the first PE was evaluated, and December 2009. We analyzed the completed HIRA checklists and HIRA decision documents for submitted PEs and confidential dossiers that were finalized by the pharmaceutical companies according to HIRA's review process. All data extracted for this study were verified retrospectively by independent internal reviewers.

To assess the quality and identify the general features of the PEs, HIRA used the HIRA quality assessment checklist (Table 1) based on the PE guidelines developed in Korea. The checklist was composed of 15 topics and 20 subordinate items that allowed a choice of three responses: "yes," "no," or "not applicable." The compliance rate of each submission was calculated by dividing the number of "yes" responses by the total number of items on the HIRA checklist. The compliance rate of the individual items was calculated by dividing the number of submissions with "yes" responses by the total number of applicable submissions. We also evaluated the quality of the PEs by using the Quality of Health Economic Studies (QHES) instrument to make comparisons with other sites. The QHES checklist contains 16 items and scores each as 0 (lowest quality) to 100 (highest quality) with weighted point values [21]. Mean compliance rates of both checklists and the QHES score were calculated by giving default points on inapplicable topics.

We assessed the compliance rates of all submissions according to coverage decisions, as "recommended," "recommended