REVIEW ARTICLE

JKMS

https://doi.org/10.3346/jkms.2016.31.S2.S108 • J Korean Med Sci 2016; 31: S108-113

Burden of Disease Study and Priority Setting in Korea: An Ethical Perspective

So-Youn Park,[1] Ivo Kwon,[2] and In-Hwan Oh[3]

[1]Department of Medical Education and Humanities, School of Medicine, Kyung Hee University, Seoul, Korea; [2]Department of Medical Education, School of Medicine, Ewha Womans University, Seoul, Korea; [3]Department of Preventive Medicine, School of Medicine, Kyung Hee University, Seoul, Korea

Received: 16 December 2015
Accepted: 19 May 2016

Address for Correspondence:
In-Hwan Oh, MD
Department of Preventive Medicine, School of Medicine, Kyung Hee University, 26 Kyungheedae-ro, Dongdaemun-gu, Seoul 02447, Korea
E-mail: parenchyme@gmail.com

Funding: This study was supported by a grant from the Korean Health Technology R&D Project, Ministry of Health and Welfare, Republic of Korea (Grant No. HI13C0729).

When thinking about priority setting in access to healthcare resources, decision-making requires that cost-effectiveness is balanced against medical ethics. The burden of disease has emerged as an important approach to the assessment of health needs for political decision-making. However, the disability adjusted life years approach hides conceptual and methodological issues regarding the claims and value of disabled people. In this article, we discuss ethical issues that are raised as a consequence of the introduction of evidence-based health policy, such as economic evidence, in establishing resource allocation priorities. In terms of ethical values in health priority setting in Korea, there is no reliable rationale for the judgment used in decision-making as well as for setting separate and distinct priorities for different government bodies. An important question, therefore, is which ethical values guiding the practice of decision-making should be reconciled with the economic evidence found in Korean healthcare. The health technology assessment core model from the European network for Health Technology Assessment (EUnetHTA) project is a good example of incorporating ethical values into decision-making. We suggest that a fair distribution of scarce healthcare resources in South Korea can be achieved by considering the ethical aspects of healthcare.

Keywords: Cost of Illness; Ethical Analysis; Korea; Health Policy; Burden of Disease

ETHICAL CONSIDERATIONS FOR PRIORITY-SETTING IN HEALTH CARE

Fair distribution is an increasingly important issue in healthcare due to factors such as the scarcity of resources associated with "high tech" medicine, longer life expectancies, and the increasing prevalence of chronic diseases. One way to cope with the scarcity of healthcare resources is to apply cost-effective analysis (CEA) in priority setting. Disability adjusted life years (DALYs) have been used to measure the global burden of disease since they were first launched by the World Bank (1). It is a specific version of the person trade-off technique that uses "disability weights" to reflect the burden of the same health state (2). However, even though the DALY concept enables one to compare different interventions and individuals on a single quantitative scale, it has been criticized for some drawbacks (3). For example, the method implicitly presupposes that the lives of disabled people have less value than the lives of people without disabilities (4). Moreover, the DALY approach discriminates against disabled or older individuals by assuming that they are less entitled to health benefits that would extend their lives (3). Even though this tool is necessary in priority setting, it is still insufficient in assisting decision makers (5).

According to the Institute of Medical Panels on Cost-Effectiveness in Health and Medicine (6), a CEA should be used to aid a decision maker who must weigh the information in the context of other values. Without a consensus on the ethical values that underlie health policies, priority setting in healthcare is insufficient to handle "what *should* be done" (5). This paper aims to provide a discussion on the ethical considerations involved in priority setting for the fair allocation of resources. We present a health technology assessment (HTA) of European network for Health Technology Assessment (EUnetHTA) project as an example of an ethical approach to health policy, and we discuss the necessity for a consensus on a fair procedure to reach an agreement regarding healthy policy in South Korea.

STATUS OF PRIORITY SETTING IN KOREA

A remarkable aspect of healthcare in South Korea is the universal coverage of its population. After the introduction of social health insurance in 1977, the National Health Insurance (NHI) system was extended to the "entire population" in only 12 years (7,8). Because South Korea only spends approximately 6% of its gross domestic product on healthcare, which is the third lowest level for health care expenditures in the Organisation for Eco-

pISSN 1011-8934
eISSN 1598-6357

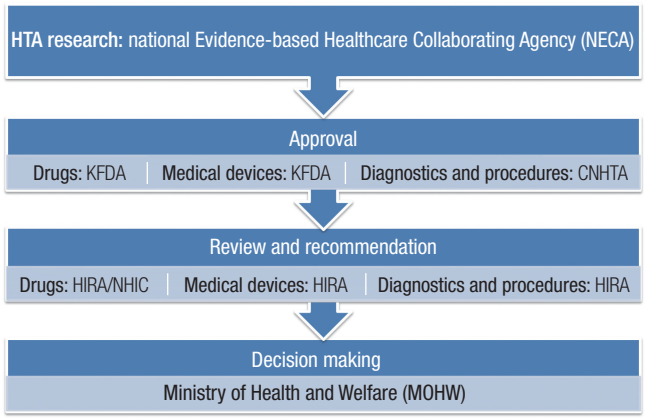

Fig. 1. The decision-making system for healthcare in Korea.

Table 1. Assessment elements in discretionary benefits by Health Insurance Review and Assessment Services

Rating categories	Assessment elements
Clinical effectiveness	Improvement of a patient's outcomes Improvement of the procedure Improvement of the subjective symptoms: decrease pain and increase QOL General guidelines and recommendations Necessity for quality control in medical care
Cost-effectiveness	Improvement effect vs. extra costs for the procedure
Social demands for coverage	Prevalence of the disease or usage frequency Availability of the vulnerable Economic burden of diseases Direct relation to the sequelae Emergency situation Impact on other diseases or society

QOL, quality of life.

nomic Co-operation and Development (OECD) area (8), expanding access to healthcare puts a "heavy financial burden" on the system (9). Furthermore, South Korea has been facing the largest increase in life expectancy among OECD countries (8). Thus, there have been multiple efforts by the Korean government to reduce the financial burden. In 2006, the government introduced the positive listing system (PLS) to slow the growth of expenditures on pharmaceuticals (8). Rules addressing generic drugs were also adjusted by the government. Testing the cost-effectiveness of healthcare was introduced into the system at that time (9).

Currently, inconsistent processes for priority setting in healthcare may be the biggest challenge in Korea. Several government bodies participate in the decision-making system in Korea (Fig. 1). First, the National Evidence-based Healthcare Collaborating Agency (NECA) specializes in health technology assessments (HTAs) in Korea (9). Decision-making for the approval of drugs, medical devices, and diagnostic procedures is handled by separate bodies such as the Korean Food and Drug Administration (KFDA) and the Committee for New Health Technology Assessment (CNHTA). After approval by the KFDA or the CNHTA, the Health Insurance Review and Assessment Service (HIRA) assesses the appropriateness of the budget impact of drugs, medical devices, and diagnostic procedures. The Ministry of Health and Welfare (MOHW) has the authority to approve final decision-making. In the case of approval of a new drug for tuberculosis treatment, for instance, the KFDA investigates safety as well as the efficacy of the drug, and HIRA evaluates the cost-effectiveness. Then, the National Health Insurance Corporation (NHIC) negotiates the price of the drug with the manufacturer (9,10). The out-of-pocket payments are determined according to economic efficiency and health insurance benefits, in a broad sense, but specific standards for assessment are different between "diagnostics and procedures" and "drugs." In terms of ethical values in healthcare priority setting in Korea, there is no reliable rationale for the judgment used in decision-making. This challenge introduced essential or discretionary benefits to cover most of the previously non-covered medical services. HIRA's website states the evaluation criteria for discretionary benefits are as follows: 1) clinical efficacy, 2) cost-effectiveness, and 3) social demands for coverage (11). The term "social demands" includes social value judgments. Social value judgments are defined as "judgments made on the basis of the moral or ethical values of a particular society" (12). The particular form of social values might be made from purely moral values and be refined by the cultural, social, and institutional features of a given society (12). However, in HIRA's statement, there is no clear moral vision that underpins these social values. For social demands, they only include the vulnerable, emergent diseases, or direct correlations between a disease and a disability (Table 1). Even though some ethical considerations and value judgments such as "vulnerability" are embedded in these criteria, there is no information available to pass judgment on these values in decision-making. Another problem is that each body in the Korean healthcare decision-making system may have different priorities in its policy making (9). An important question, therefore, is which ethical values guiding the practice of decision-making should be reconciled with the economic evidence found in Korean healthcare.

MORE ROOM FOR ETHICS

Previous studies agree that value judgments must be made "somewhere in the process" of creating guidelines for decision-making, but it is difficult to clearly state "how these judgments should be made" (13-16). In this article, we take the EUnetHTA project to put forth a model for incorporating ethical values into decision-making (16). Implementing health technologies can lead to moral consequences and technology itself carries values that justify integrating an ethical analysis into the "traditional assessment" of cost-effectiveness (17). The key contents of the model are presented below.

The EUnetHTA project

In 2006, the EUnetHTA project was launched as a response to the need for a practical transnational collaboration between the European Commission (EC) and European Union (EU) Member States (16). The objective of the EUnetHTA is to provide reliable, timely, transferable, and transparent information and to support policy decisions (17). Fig. 2 shows the relation between the HTA and policy processes. Fifty-nine partner organizations from 31 countries joined this project and 10 international teams developed a generic "HTA core model" to guide the assessment. The basic idea of the HTA core model is to divide information contained in an HTA into standardized pieces of information, the "assessment elements" (18). The assessment elements are described in detail in element cards and formulated as several questions (e.g., Do drug-eluting stents decrease symptoms such as chest pain in patients with angina pectoris?). This process establishes a methodological framework for an HTA, allowing users to obtain relevant and high quality information (16).

Ethical analysis in the EUnetHTA

The ethics model is one part of nine domains in the core model (Fig. 3). The ethical analysis aims to "provide a thorough understanding of norms and values that need to be taken into account during the HTA and in the decision-makin(9n)4is presc

the EUnetHTA, the ethical domain contains six different topics: 1) beneficence/nonmaleficence, 2) autonomy, 3) respect for persons involved, 4) justice and equity, 5) legislation, and 6) ethical consequences of the HTA. Table 2 presents ethical domains and 19 issues that are covered by these domains.

Description of the methodology for ethical analysis: an example of a core HTA on drug-eluting stents for coronary artery disease

An example of the model on drug eluting stents (DES), which was developed as a pilot assessment by Work Package 4 of the EUnetHTA project in 2008, is presented below (20). To conduct a successful ethical analysis, it is important to identify all stakeholder perspectives. In this analysis, a literature search (regarding existing HTA reports, articles on ethical topics relating to DES, etc.) was performed and 88 references from journals were examined. The principle questions of the analysis are as follows:

1) "Is the utilization of DES intended to be an innovative mode of care, an 'add on' to a standard mode of care, or a replacement of a standard?", 2) "Can DES challenge religious, cultural, or moral convictions, the beliefs of some groups, or can they change current social arrangements?", and 3) "What are the hidden or unintended consequences of DES and their application to different stakeholders?" (20). MC /Span /Lang (en-US)/MCI4 330 BDC BT/T1

The ethical domain was developed and the model had 14 other questions addressing the core issues regarding DES (Table 3). To integrate an ethical analysis into an HTA, it is important to consider the technology in the context of the given healthcare system, and there are several methods for users to conduct a discrete analysis (17). Table 4 presents several meth-

https://doi.org/10.3346/jkms.2016.31.S2.S108

Table 2. The structure of the ethical domain and the assessment elements of EUnetHTA

Topics	Issues*
Beneficence/nonmaleficence	What are the symptoms and the burden of disease or health condition for the patient? What are the known and estimated benefits and harms for patients when implementing or not implementing the technology? What are the benefits and harms of the technology for relatives, other patients, organizations, commercial entities, society, etc.? Are there any other hidden or unintended consequences of the technology and its applications for patients/users, relatives, other patients, organizations, commercial entities, society etc.?
Autonomy	Is the technology used for patients/people that are especially vulnerable? Does the implementation or use of the technology affect the patient´s capability and possibility to exercise autonomy? Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used? Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles?
Respect for persons	Does the implementation or use of the technology affect human dignity? Does the implementation or use of the technology affect the user´s moral, religious or cultural integrity? Does the technology invade the sphere of privacy of the patient/user?
Justice and equity	How does implementation or withdrawal of the technology affect the distribution of health care resources? How are technologies with similar ethical issues treated in the health care system? Are there factors that could prevent a group or person from gaining access to the technology?
Legislation	Does the implementation or use of the technology affect the realization of basic human rights? Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?
Ethical consequences of the HTA	What are the ethical consequences of the choice of end-points, cut-off values and comparators/controls in the assessment? Does the economic evaluation of the technology contain any ethical problems? What are the ethical consequences of the assessment of the technology?

EUnetHTA, European network for Health Technology Assessment.
*Adapted from EUnetHTA Joint Action 2, Work Package 8. HTA Core Model® version 2.1 (19).

Table 3. The frame of ethical analysis on drug eluting stents

Topics	Issues*
Beneficence/nonmaleficence	What are the benefits and harms for patients and what is the balance between the benefits and harms when implementing and when not implementing DES rather than BMS? Who will balance the risks and benefits of preferring DES over BMS in practice and how? Can the implementation of DES rather than BMS harm any of the stakeholders? What are potential benefits and harms of implementing DES rather than BMS for other stakeholders?
Autonomy	Does the implementation or use of DES challenge patient autonomy? Is DES used for patients that are especially vulnerable? Does DES have special challenges/risks that the patient needs to be informed of? Does the implementation of DES challenge or change professional roles?
Respect for persons	Does the implementation or use of DES rather than BMS affect human dignity? Does the implementation or use of DES rather than BMS affect human integrity?
Justice and equity	What are the consequences of implementing/not implementing DES on justice in the health care system? (Are principles of fairness, justness and solidarity respected?) How are technologies presenting with similar (ethical) problems as DES treated in the health care sector? Are there any third parties involved when implementing DES rather than BMS?
Legislation	Does the implementation of DES rather than BMS affect the realization of basic human rights? Is legislation to use DES rather than BMS fair and adequate?

DES, drug eluting stents; BMS, bare metal stents.
*Adapted from EUnetHTA Work Package 4, Core HTA on drug eluting stents, pilot assessment (20).

Table 4. The methodological approaches used for ethical analysis in health technology assessment

Method*	Description
Casuistry	Solves morally challenging cases by referring to relevant typical cases for which an undisputed solutions existed
Coherence analysis	A reflective process of the consistency of ethical theories or values on different levels to help achieve a logical coherence
Interactive, participatory HTA approach	To improve the validity of the HTA, approach ethically problematic issues with real discourse by different stakeholders
Principlism	Resolve ethical problems through basic ethical principles which are based on a common morality
Social shaping of technology	Consider the interaction between technology and society and emphasize how technology can influence society positively
Wide reflective equilibrium	A process of rational reflective adjustment that draw a coherent conclusion among general arguments and judgments

HTA, health technology assessment.
*Adapted from EUnetHTA Joint Action 2, Work Package 8. HTA Core Model® version 2.1 (17,19).

ods identified by the International Network of Agencies for Health Technology Assessment (INAHTA) working group to conduct an ethical analysis (17,19).

Based on these methods, ethical arguments related to the

topics listed in Table 3 were discussed. For example, regarding the topic beneficence/non-maleficence, the answer to the question "What are the potential benefits and harms of implementing DES rather than bare metal stents (BMS) for other stakeholders?" was recorded in a result card from the perspective of various stakeholders such as care providers, professions, payers, society, and industry (19). For care providers, an attractive goal is to gain the reputation of providing the most advanced care in their facilities. Furthermore, if the system supports a fee for service reimbursement, this technology may provide an opportunity for an additional financial gain for care providers. On the other hand, if a provider lives in a country where a flat rate reimbursement system does not cover the costs of the procedure, DES can bring additional costs to this provider.

From the societal point of view, the working group took notice that guaranteeing equal access to adequate care service is one of the basic principles for the provision of healthcare. They also considered that there are strong beliefs among patients and the public regarding the possibility of obtaining optimal results through advanced technologies (21). Previous studies and media responses concerning DES illustrated the belief that the implementation of DES is the treatment of choice for coronary artery diseases. Thus, a society with a private healthcare market might experience "two class healthcare" when they accept the implementation of DES. The extra costs for the procedure are another adverse consequence of the implementation of DES. Meanwhile, implementing DES can earn that society a reputation for providing the most innovative care. There are several companies manufacturing DES and a number of trials, as well as most of the data, are supported by these companies. Implementing DES provides financial gains to these manufactures, and as a result, the industry is able to support further data collection on the "real life use" of DES. However, ongoing competition for market shares is a predictable adverse consequence when proceeding with implementation.

Going through the 14 questions in Table 3, the working group identified related areas that are ethically problematic when using DES. Questions for ethical analysis were answered based on valuation through different types of stakeholder perspectives. For example, for the question "What are the hidden or unintended consequences of DES and their application to different stakeholders?", the working group revealed that at least 50% of the devices were used for "off-label" purposes in patients who suffered from more severe coronary artery diseases, rather than for the "intended purposes" (20). They also expressed doubt regarding the autonomy of patients that are especially vulnerable (who are in an emergency situation such as acute cardiac syndrome) in understanding the differences between the risk/benefit profile of DES and that of BMS. The question-based structure of this model is open to contextual interpretation and has flexibility for broader use (17).

Application of the new selective reimbursement system in Korea

How, then, can the ethical analysis suggested by the EUnetHTA guide decision-making in Korea? Consider the selective reimbursement system that applies to four major conditions. When an item is determined to be a selective reimbursement item, the NHI will cover it with differentiated patient payments (22). As we explained in Table 1, each determination of coverage has three components: clinical efficacy, cost-effectiveness, and social demands for coverage. Even though there are elements for decision-making, there are still issues with the definition and application of "social demands." The elements used to make a final determination should attempt to avoid ambiguities. Furthermore, it is easy to ignore some items that are difficult to quantify. The lack of consistency in the decision-making process might be another issue. If the decision-making committee is to provide judgment about social demands, they should utilize an ethical analysis of the assessment elements. For example, a set of questions can be used for capsule endoscopy, which is included on the 2015 list for selective reimbursement by the HIRA. Some of the questions are as follows. Does the use of capsule endoscopy add a new mode of care or is it intended to replace a standard care mode? What are the potential unintended consequences of capsule endoscopy for different stakeholders? Is capsule endoscopy used for patients who are especially vulnerable? Can capsule endoscopy entail special risks of which the person should be informed? Does the implementation of capsule endoscopy affect other diseases? The information elicited may support the generation of evidence and successful implementation of the policy.

CONCLUSION

In this article, we present ethical issues of priority setting in access to healthcare resources. What is needed for fair distribution is a moral vision underpinning healthcare policy. This vision calls for a reasonable consensus on what is the best for the public good (3). An ethical analysis from the planning stage through the entire decision-making process can provide insight into achieving healthcare goals and resource allocation. As discussed above, the ethical analysis in the EUnetHTA can be a useful tool to provide a balance between values and norms through discussions on several issues including the political, cultural, economic, legal, and other social aspects that are affected by the application of new technologies.

It is true that this model does not represent all the ethical content for decision-making processes in healthcare. Actually, there are some limitations to the model, such as the fact that it highlights an "individualistic perspective" that is suitable for

 https://doi.org/10.3346/jkms.2016.31.S2.S108

only "certain types" of healthcare organizations (17). Establishing a transparent process in collecting and reporting evidence is also a critical prerequisite for maintaining the balanced views of different stakeholders. However, considering the fact that priority setting in healthcare policy requires value-laden judgments and that few policy analyses in Korea have explicitly attempted these assessments, this effort can be a turning point in integrating ethical analyses into decision-making in the Korean healthcare system.

Ethical analyses challenge traditional priority setting methods in Korea. When applying the results of the Korean Burden of Disease Study to healthcare decisions, ethical principles and transparent processes may be essential features of a fair healthcare system. An ethical framework in harmony with a cost-effectiveness analysis is the key to increasing policy relevance.

DISCLOSURE

The authors have no potential conflicts of interest to disclose.

AUTHOR CONTRIBUTION

Conception and design: Park SY, Kwon I. Acquisition of data: Park SY, Oh IH. Writing: Park SY, Kwon I, Oh IH. Approval of final manuscript: all authors.

ORCID

So-Youn Park http://orcid.org/0000-0003-0553-5381
Ivo Kown http://orcid.org/0000-0002-2690-1849
In-Hwan Oh http://orcid.org/0000-0002-5450-9887

REFERENCES

1. World Bank. World Development Report 1993: Investing in Health. New York, NY: Oxford University Press, 1993.
2. Murray CJ. Rethinking DALYs. In: Murray CJ, Lopez AD, editors. The Global Burden of Disease: a Comprehensive Assessment of Mortality and Disability from Diseases, Injuries and Risk Factors in 1990 and Projected to 2020 (Global Burden of Disease and Injury Series Vol. 1). Cambridge, MA: Harvard University Press, 1996, p1¬98.
3. Ruger JP. Ethics in American health 1: ethical approaches to health policy. *Am J Public Health* 2008; 98: 1751-6.
4. Arnesen T, Nord E. The value of DALY life: problems with ethics and validity of disability adjusted life years. *BMJ* 1999; 319: 1423-5.
5. Gibson JL, Martin DK, Singer PA. Priority setting for new technologies in medicine: a transdisciplinary study. *BMC Health Serv Res* 2002; 2: 14.
6. Russell LB, Gold MR, Siegel JE, Daniels N, Weinstein MC; Panel on Cost-Effectiveness in Health and Medicine. The role of cost-effectiveness analysis in health and medicine. *JAMA* 1996; 276: 1172-7.
7. Kwon S. Thirty years of national health insurance in South Korea: lessons for achieving universal health care coverage. *Health Policy Plan* 2009; 24: 63-71.
8. Jones RS. Health-Care Reform in Korea: OECD Economics Department Working Papers No. 797. Paris: OECD Publishing, 2010.
9. Ahn J, Kim G, Suh HS, Lee SM. Social values and healthcare priority setting in Korea. *J Health Organ Manag* 2012; 26: 343-50.
10. Kim Y. Towards universal coverage: an evaluation of the benefit enhancement plan for four major conditions in Korean National Health Insurance. *J Korean Med Assoc* 2014; 57: 198-203.
11. Health Insurance Review and Assessment Service (KR). HIRA information system [Internet]. Available at http://www.hira.or.kr/dummy.do?pgmid=HIRAA070001000510 [accessed on 27 November 2015].
12. Clark S, Weale A. Social values in health priority setting: a conceptual framework. *J Health Organ Manag* 2012; 26: 293-316.
13. Saarni SI, Gylling HA. Evidence based medicine guidelines: a solution to rationing or politics disguised as science? *J Med Ethics* 2004; 30: 171-5.
14. Harbour R, Miller J. A new system for grading recommendations in evidence based guidelines. *BMJ* 2001; 323: 334-6.
15. Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. *BMJ* 1999; 318: 593-6.
16. Kristensen FB, Lampe K, Chase DL, Lee-Robin SH, Wild C, Moharra M, Garrido MV, Nielsen CP, Røttingen JA, Neikter SA, et al. Practical tools and methods for health technology assessment in Europe: structures, methodologies, and tools developed by the European Network for Health Technology Assessment, EUnetHTA. *Int J Technol Assess Health Care* 2009; 25 Suppl 2: 1-8.
17. Saarni SI, Hofmann B, Lampe K, Lühmann D, Mäkelä M, Velasco-Garrido M, Autti-Rämö I. Ethical analysis to improve decision-making on health technologies. *Bull World Health Organ* 2008; 86: 617-23.
18. Lampe K, Mäkelä M, Garrido MV, Anttila H, Autti-Rämö I, Hicks NJ, Hofmann B, Koivisto J, Kunz R, Kärki P, et al. The HTA core model: a novel method for producing and reporting health technology assessments. *Int J Technol Assess Health Care* 2009; 25 Suppl 2: 9-20.
19. EUnetHTA (FI). Joint action 2, work package 8: HTA Core Model® version 2.1 [Internet]. Available at http://meka.thl.fi/htacore/model/HTACoreModel2.1PublicDraft.pdf [accessed on 12 November 2015].
20. EUnetHTA (FI). Work package 4: Core HTA on drug eluting stents, pilot assessment [Internet]. Available at http://www.eunethta.eu/outputs/core-hta-drug-eluting-stents [accessed on 30 November 2015].
21. Deyo RA, Patrick DL. Medical innovations and American culture. In: Deyo RA, Patrick DL, editors. Hope or Hype: the Obsession with Medical Advances and the High Cost of False Promises. New York, NY: AMACOM, 2005, p13-25.
22. Park DA, Ahn J, Yun JE, Rhee J, Lee NR, Son SK, Lim S, Lee MJ, Lee SH, Oh EH. The System Development of Clinical Study for Conditional Coverage with Evidence Generation. Seoul: National Evidence-based Healthcare Collaborating Agency, 2015.