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Correct Evaluation of Evidence

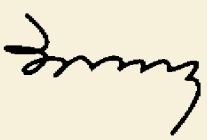
A new anti-cancer drug called 'A', has been approved by the Food and Drug Administration both in the United States and in Korea. The drug is licensed for use in the treatment of pancreatic cancer. No patient has had his or her disease completely cured yet by this drug, but the survival period has been extended by a statically significant value (p=0.025) of 0.46 month (control group 5.91 months, treatment group 6.37 months), which served as the most critical factor for this drug to obtain the approval of the regulatory authorities. However, patients are forced to endure a considerable burden of side effect and out-of-pocket treatment cost just to earn a two-week life extension.

Meanwhile, it is not reasonable to equate that penicillin that can completely cure most patients with pneumonia due to Streptococcus pneumonia but that it may bring critical results if not used with the anti-cancer drug A. Two of these drugs have been approved and available for sale based on reasonable individual grounds however, there is a big difference in interpreting the implications of the use of these drugs. Penicillin has turned out to be effective, backed up by clinical testingalong with statistical significance. The anti-cancer drug A also boasts statistically significant efficacy, but lacks assurance of actual clinical effectiveness. Our society tends to take a dichotomous approach about ground base, that is, a black and white judgment that determines something is well-grounded or groundless, and the criteria used to determine the groundedness of drugs varies widely. Notwithstanding, our society is likely to make a decision based on a simple result regarding the value of something like a drug.

Recently, H1N1 has dominated the headlines. Many believe that development of a vaccine will be the ultimate solution to this problem. Unfortunately, we have the legacy of the Swine flu vaccination campaign in the US in 1976, where more people died of side effects of the vaccine than died of the influenza.

It is still unknown how significant a vaccine to the current H1N1 strain will be. There is an ongoing controversy over the effect of the vaccines against H1N1 and no ground base equivalent to that of penicillin has been presented yet. Now is the right time to establish objective ground base and criteria on a national level to properly respond to diseases such as the New Influenza A.

Oct. 2009
Dae-Seog Heo



History of Pandemic Influenza

Hee-Jin Jung, Professor,
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Influenza is an unwelcome guest that visits our global household every year. This respiratory disease has produced the largest loss of life in the history of humankind. Influenza, which, in otherwise healthy individuals can produce a serious cold that is more of an inconvenience than a health threat, is in reality a dreadful pandemic that can devastate the elderly or those with underlying diseases. Although the influenza vaccine has been in use for the some decades, a variety of problems regarding influenza in the context of increasingly elderly populations globally and the increasing numbers of those afflicted with chronic disease have yet to be resolved in our society. Korea mobilized a nationwide influenza surveillance system in 1997 and designated influenza as aThird-Degree pandemic that was subject to national-level management. Despite these systematic efforts, however, countries around the world suffered through an influenza pandemic, 42 years after the Russian influenza outbreak of 1977. The continuing misery emphasizes the continued need to clearly elucidate that nature and characteristics of influenza. With this in mind, this paper examines recent pertinent clinical and epidemiological studies.

Influenza Virus

The influenza virus is a resistant spiral-shaped RNA virus that belongs to the Orthomyxovirus family. The virus is classified into three types (A, B or C)depending on the structure of nucleic acid. Type A influenza can be further subtypes based on its surface antigen hemmaglutinin (H) and neuraminidase (N). H enables the virus to attach to somatic cells and has 15 different subtypes (H1-H15). N helps the virus to infiltrate into the cell and has nine different subtypes (N1-N9). Three subtypes of H (H1, H2, H3) and two subtypes of N(N1, N2) trigger contagious or sometimes pandemic influenza on a massive scale. Type A influenza spreads not only to humans but also pigs and birds, causing the most serious illness,while type B influenza infects only humans and features more stability from an immunological perspective. The latter brings about relatively lighter influenza symptoms among children and is related to the occurrence of Reye's syndrome.

The influenza virus has the unique characteristic of creating antigen mutants to a small or large degree on an annual basis, which has lead to periodicwidespread influenza outbreaks. These antigenic mutants, which arise mainly due to antigenic shift and drift, have been driven by changes in H and N. H is particularly important as its antibody is neutralizing and defends against infection. Antigenic shift refers to the change of an antigen into a H or N that is totally new and different from existing ones. For example, H3 can shift to H2 or N1 can shift to N2. This kind of dramatic shift has a lot to with pandemic spread. The antigenic shift is most likely to occur in type A influenza, in which different types of viruses may, through gene reshuffling resulting from double infection, create a new type of

virus, which triggers a massive-scale pandemic contagion, especially among those without proper immunity. The antigenic drift mostly occurs in type A and B influenzas as the subtype of a certain influenza causes a slight change in antigen specifically, a point mutation occurs in the RNA controlling H or N, which leads to one or more changes in an amino acid of the proteins. Antigenic drift occurs almost every year, and is a primary cause of epidemic influenza.

Characteristics of Contagious Influenza

Influenza is a highly contagious acute respiratory disease, which has been a threat to humans for millenia. Antigenic shift has caused influenza pandemics about every 10 to 40 years that are coincident with relatively smaller-scale epidemics every 2 to 3 years that are caused by antigen drift every two to three years. Influenza epidemics in the northern hemisphere are prevalent from late autumn of one year until the early spring the following year, while in the southern hemisphere epidemics tends to precede or follow those in the northern hemisphere by about 6 months. Sporadic local epidemics can occur in the family, school and isolated local community. Regional epidemics are distinctive in that they appear suddenly and reaching a climax in 2 to 3 weeks during a 5 to 6 week window of the effective epidemic period. This explosiveness is also characterized by high contagiousness, short latent period and a massive discharge of virus among nasopharynx secretions during the period of virus secretion.

In general, the increase in the number of patients with acute respiratory illness among children is the first signal of an outbreak, although there might be an increase earlier in the number of acute febrile respiratory illness cases among institutionalized patients. Subsequently, there tends to be a gradual rise in the number of adults who develop influenza-like illness, followed by deterioration in patients with pneumonia or chronic pulmonary heart disease, and increased number f hospitalizations. The importance of influenza on pulmonary disease and death rate among the elderly has been recognized. Approximately 10%to 20% of disease occurrence rate is shown in manifest period with up to 40%to 50% rate among certain age groups and those who are more vulnerable.

The Russian outbreak of H1N1 influenza that first occurred in 1977 has continued to the present dayin three different forms of type A H3N2, H1N1 and type B simultaneously on an annual basis with one particular subtype dominating the others. Type A influenza occurs seasonally every year, particularly in the winter for northern hemispheric regions. Subtype H3N2 has more serious clinical characteristics than type A subtype H1N1, while type B influenza demonstrates an intermediate level of virulence.

Closer scrutiny of the phenomenon of influenza pandemics reveals several requirements. Firstly, a new virus, against which humans do not have a corresponding immunity, appears. Secondly, this new virus may cause illness among humans. Thirdly, it occurs at the time when it is easy to transfer from one person to another. The currently prevalent H1N1 meets these three requirements. It started in northern hemisphere in the spring of 2009, spread throughout the southern hemisphere, and returned to the northern hemisphere. What is fortunate about H1N1 is that it does not have a very high virulence, although this reassurance may not extend to the second and third phases of the outbreak. Ultimately, the outcome may be a level of illness and death that is comparable to past pandemics. Industrial countries have just commenced vaccine injection and Korea is also expected to begin vaccine injection beginning at the end of October. It is the right time for us to make multilateral efforts to minimize the damages and losses due to the pandemic with a proactive vaccination campaign and patient management. NEC

Preventive effect and safety of inoculation vaccine

Seung-Soo Sheen,
Associate Professor, Department of Pulmonary and Critical Care Medicine,
Ajou University School of Medicine

⊙ The concern that the current H1N1 influenza outbreak may become pandemic is real and prominent here in Korea, drawing nationwide attention and massive media coverage. As one of the medical practitioners examining and treating patients mostly with respiratory disease, the well-wishing remark that is exchanged among patients every fall that says "Don't forget the flu shot" has never sounded more sincere than today. It is the government's policy to have all Koreans including vulnerable groups such as the elderly get a flu shot before winter comes. On the other hand, however, there is concern about the safety of the vaccine produced within a short period of time. As a medical practitioner, I am not even sure what to tell the patients and their legal guardians who ask if they have to get a preventive inoculation against the new influenza.

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Despite the fact that there has never been a previous case where a nation-wide vaccination campaign was conducted within such a short period of time since we started vaccination publically, I do not see any evidence of serious contemplation on the possible effects that this short-term massive preventive inoculation may bring. In fact, the vaccination campaign against the swine flu in the United States in 1976, which triggered a nationwide controversy over the effectiveness and probable problems involving vaccination along with case reports of adverse effects and criticism against the government policies, may have contributedto the re-election failure of President Gerald Ford, and has colored debate about vaccination campaigns. According to Gina Kolata, author of the book 'Flu', the swine flu vaccination debacle is an apt demonstration of how the lack of knowledge can expand and distort the truth on the political stage and how powerful sensational journalism can be.

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The resulting suspicions over the effectiveness and safety of the flu vaccine can be broadly classified into the problem of the germ itself and another problem with the vaccine additives. First, let's take a look at the effectiveness. Most of today's vaccines are manufactured in a way to weaken part of the virus and are delivered into the body through injection instead of through respiratory system, which is the infiltration path of flu virus. However, there is a rampant speculation that this method not only does not fulfill the original intent of preventing the occurrence of flu prior to the activation of immune mechanism but also obstructs the natural immunization process acquired after infection, facilitating the future occurrence of illness. Those who raise this suspicion often quote some cases where the

vaccination of infantile paralysis and smallpox rather triggered the occurrence of corresponding diseases. What is potentially a more serious concern focusses on the safety of the vaccine as it uses potentially harmful substances such as organic mercury, formaldehyde and aluminum as preservatives. Anti-vaccine advocates claim that exposure to these harmful substances leads to the occurrence of diseases that used to be uncommon in the past. They also correlate vaccination with the increase in a variety of modern diseases including cancer, leukemia, Lou Gehrig's disease, Guillian-Barre syndrome, Alzheimer's disease and autism.

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Of course, the mainstream medical world maintains consistent position that no evidence has been found torefute the safety of vaccine, calling the previously mentioned allegations groundless. However, it is not easy to make a precise evaluation on the effectiveness and safety of the activity intended for preventive measures unlike that of generic medicine for treatment. In particular, we cannot deny the suspicion that the rigorous safety standards set by the US Food & Drug Administration to evaluate several major medicines, which were withdrawn from the market within a few years of their introduction, have been applied differently to vaccine products. The suspicion will remain, even among professionals much less laymen,unless the suspicion regarding inconsistent evaluation criteria on vaccinesis cleared up. Against this backdrop, sincere efforts of relevant authorities that can provide a credible explanation on the effectiveness and safety of vaccines are urgently required. NECA

New Influenza A and evidence-based decision-making

Sang-Il Lee,
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⊙ Three major factors that need to be taken into consideration with respect decision-making regarding patients or public health and medical service for population are evidence, value and resources used. The latter two have served as the basis for 'opinion-based decision making' in the past. Opinion-based decision making has gained more significance recently with increasing worldwide pressure regarding the use of resources, and is surpassing evidence-based decision making. This trend is disturbing, and has increased efforts to find evidence on which to base an evaluation. However, evidence can be difficult to find and/or can be of questionable quality.

Diffusion of Fear of the New Influenza A

Whether we are actually implementing evidence-based decision making in view of the recent responses of various groups to the 2009 H1N1 influenza outbreak is a legitimate question to ponder. Press coverage that conducts near-live broadcasts of the mounting death toll, while mentioning the 1918 Spanish Flu pandemic that claimed some 30 million lives fosters fear and panic among people with regard to ongoing H1N1 outbreak. People are overwhelmed with fear that they and their family members might become victims of the latest outbreak. As it is known that deteriorating health upon influenza infection can prelude second-phase bacterial diseases such as pneumonia, the demand for vaccines pneumococcal pneumonia vaccines has exceeded supply in some regions. It is no exaggeration to call this phenomenon a new influenza phobia.

Chance of getting infected with the latest influenza A strain

The current H1N1 influenza A is highly contagious but the disease occurrence rate is low. Proper daily hygiene practices dramatically reduce the chance of getting infected with the flu and, even if a person is infected, he or she is most likely to recover completely over time without taking any specific action including use of anti-virus medication. In addition, adults develop antibodies against the flu with a single shot of vaccine. Current data indicates that the death rate from the 2009 H1N1 strain is around 0.07%, similar to that of seasonal influenza. Considering the fact that the average number of people who die of seasonal influenza is about 300,000 worldwide, the fear of a hugely lethal pandemic may be unfounded. Experts in Korea and elsewhere, including the World Health Organization (WHO) have pointed out that too much weight has been given to the dire consequences of the latest influenza strain, and that this more rational message has not been adequately delivered to the public through the mainstream media. It certainly is prudent to be alert, but we should

remember that excessive responses incur unnecessary social costs.

Recently, it has been reported that WHO is undetaking measures to control the level of response to the current H1N1 outbreak. In view of the intensity of recent press reports, this recent change in approach seems to have been overlooked. An old saying is that "A dog biting a human is not news but a human biting another human is". It is true that things are better seen after they happened but the responses to the current H1N1 outbreak so far may be 'making a mountain out of a molehill'.

Prudent Responese Required

Now is the time to calmly rethink and work out proper responses to the new influenza A. There should not be an impetuous approval on the vaccine as a way of jumping on the bandwagon without a sufficient prior review of its safety, while paying extra attention to the abuse or misuse of Tamiflu. There is no denying the necessity of coming up with proper responsive measures against the new influenza A, but there is also some concern that too much emphasis on taking measures might shrink the size of budget allocated for overall public health.

I would like to share the following excerpt from the article called 'Flu Phobia, Ugly Truth' written by Denis Declaw, a chief researcher of French National Science Research Center, for September edition of (Le Monde Deplomatique) in Korean version.

"Come to think of it, the real big danger doesn't seem to lie in what people think. Lameness of our society obsessed with safety can be a good example except its present status is more serious than what it's supposed to be. First of all, a comprehensive range of reasonable public health policies are obstructed because of that. Distrust for health policies makes it difficult to have information on present status and treatment of epidemics and on health surveillance campaign delivered to the publicas it is without a grain of salt, which also encourages uncontrolled distribution of a variety of groundless rumors. It is important to understand fear and uncertainty that ordinary people feel and help them establish their opinions based on reasonable data and evidence.

In order to foster evidence-based decision-making, the media should be discouraged from selectively covering what may lead public opinion towards a specific direction. The new flu pandemic is still ongoing and decision-making is not easy due to underlying uncertainties but we should make efforts to share 'reasonable data'regarding social costs and benefits in planning and implementing responsive measures against the flu and pave the way for solidifying the basis for evidence-backed decision-making." NECA

Donggwoldo (Painting of Eastern Palace) : This astonishing 16-piece long bird-eye-view painting of Changdeok-gung (palace) and Changgyeong-gung-(palace) painted by the members of Dohwaseo in the late Joseon dynasty era. Coincidentally, this is the exact view from the National Evidence-based Healthcare Collaborating Agency (NECA), situated in Wonnam-dong. National treasure No. 249. Collection of Korea University Museum.

▼ THIS Page is aimed to draw out agreement of the experts in various groups on pending social issue

Research result on the reuse of single use medical device

Yoon-Jae Lee,
Researcher of National Evidence-based Healthcare Collaborating Agency

⊙ National Evidence-based Healthcare Collaborating Agency (NECA) of Korea has released the research results on the reuse of use medical device and is scheduled to hold a forum where experts from the industrial, legal, and medical sectors, as well as policy makers will discuss the issue.

Korea has reprocessed and reused single use medical device at the hospital level, but there are no written recommendations or guidelines from relevant health authorities, as exists in the United States, Germany and Australia. There is an ongoing controversy over the reuse of single use medical device from multiple perspectives, including not only ethical and legal aspects but also on the reuse of expensive single use medical device and even on the environmental pollution problems associated with single use device. In 2009, the Anti-Corruption & Civil Rights Commission prohibited the reuse of single use medical device disposal medical equipment and recommended establishment of relevant disciplinal regulations. However, a large difference in perspectives among experts remains, even in medical field. With the issue of reusing medical device surfacing as a social, legal and environmental issue, there is a need to a social consensus and agreement among relevant interest parties by establishing objective evidence for reasonable decision-making.

(Refer to proposal Ga of the result presentation and forum)

Result presentation speech and forum (to be scheduled)

The result presentation speech will present the results of research into national policies on the reuse of single use medical device in major countries, whether it is clinically safe and effective to reuse single use medical device and considerations to be made on device equipmentthe reuse from social and ethical perspectives. The results wereis largely classified into two categories as will be described below. Before this, however, several questions can be posed. First, has it been proven that the reuse of single use medical device is clinically safe and effective compared to the designed one- time use? Second, is there a reporting system on adverse effects incurred by the reuse of single use medical device anywhere in the world, and, if so, have there been reports of long-term follow-up problems?

To conduct research to address the question of safety of reused device, we assessed the relevance and quality of four systematic reviews identified in the literature. We chose a recently published and well-conducted systematic review as best available evidence and additionally investigated the primary articles published in Korean. Finally, we adopted the conclusion of AETMIS (Agence d'evaluation des technolgoies et des modes d'intervention en sante) Health Technology Assessment (HTA) report as the best available evidence; pertaining to, haemodialysis membranes, the findings of studies published in Korean

language were consistent with the results of the AETMIS HTAealth Technology Assessment. Our review can be considered could be called as a comprehensive review using existing systematic reviews in methodology. The following table, which summarizes the (evidence of single use medical device by type) describes the evidence of clinical safety and effectiveness in 13 critical and 3 semi-critical medical devices designed for single use that were reused after reprocessing.

Concerning the question of whether an adverse events reporting system exists elsewhere, let us take the United States as an example. The US FDA (Food and Drug Administration) GAO (Government Accountabilit Office) administer the reuse of single use medical device through a rigorous reprocessing guideline. Both agencies have concluded that there is no harmful effect on patients based on the regulated report system regarding safety after reuse. Different countries have different policies regarding the reuse of single use medical device. France does not allow the reuse while the United Kingdom does not, while countries like Japan and Finland no current policy.

(Refer to the classification table by country)

A Research into the ethical and social issues surrounding single use medical device reuse have been conducted through analysis of existing documents and consultation with relevant experts. (refer to ethical issue table regarding the reuse of single use medical device)

Reference of classification by country

With a clear decision yet to be made on the reuse of single use medical device disposable medical equipment due to the gap in opinions among different stakeholders, the research results can serve as a reference to set the compass. It is expected that the forum will collect a variety of opinions from various sectors and incorporate them into an improved decision-making process. NECA

❖ Presentation of research result on the reuse of disposable medical equipment (scheduled)

Theme	Participants
Presentation and discussion on the reuse of disposable medical equipment	**Presenter :** Sang-Moo Lee, Chief Researcher (NECA) **Modultor :** Jong-Myon Bae, Chief Researcher (NECA) **Panel Members :** One representative each from the Ministry of Health and Welfare, Health Insurance Review & Assessment Service, National Health Insurance Corporation, Food & Drug Administration, Legal Expert, Consumer's Association, Press, Korea Medical Devices Industry Association

❖ Forum(scheduled)

Date & Time : 2:00~5:00 PM, Thursday Nov. 52009 / **Venue :** Lee Geon Hee Hall, Cancer Research Center, Seoul National University

❖ Measures on Reuse of Single use medical device Disposal Medical Equipment by Country

Prohibited	Not Recommended	Allowed under qualitative management	No official announcement
France, Spain, Austria, Portugal, Switzerland, Canada (Manitoba, Northwest Territories)	UK, Hungary, Canada (New Brunswick, Ontario, Alberta, British Columbia), Italy	Germany, US, Australia, Denmark, Sweden, Belgium, Norway, Netherlands, Canada (Quebec)	Singapore, Japan, Taiwan, Greece, New Zealand, Poland, Finland, South Africa

❖ Summary of evidence of single use medical device by type

Type of medical device		Evidence Summary
Critical	PTCA catheter	B
	Balloon catheter	C
Critical	Electro-physiology catheter	B
	Central venous catheter	C
	Angioscopes	C
	Argon plasma coagulation probes	C
	Perfusion cannulas	C
	Disposable trocars	B
	Hemodialysers	A
	Sphincterotomes	B
	needle tip (Phacomulsification needle tips)	C
	Biopsy forceps	D
	Microkeratome blade	C
	Ultrasound Catheter(AcuNav [TM])	C
	Arthroscopic shaver blade	C
Semi-Critical	components of orthopedic external fixator	B
	Breathing circuit filter	C
	stopcocks (Bronchoscopic stopcocks) /airway devices	C
	Sterile polymer sheaths	C

A : Strong evidence sufficient enough to make conclusions on safety and effectiveness

B: Reuse appears to be safe if it conforms to the rigorous reprocessing standards within experiment lab but further well-designed clinical tests are required.

C : Insufficient data to reach conclusions, due to insufficient experimental research infrastructure.

D: Safety after reprocessing needs more research.

❖ Ethical issues related to reuse of reprocessed SUD

Principle	Concerning points	Questions	Resources for Decision
Beneficence/ non-maleficence	Potential risk	Does the probability of failure in infection and treatment increase?	Clinical evidence, gao report
Autonomy, contractarianism	Informed consent	Is there a change of increase in harm?	Overseas policies and relevant cases
Justice	System for reprocessing SUD	• Which single use medical device will be allowed to be reprocessed? • What is the proper reprocessing of each medical device? • What is an appropriate compensation for the reprocessing cost of medical device? • Is there a monitoring system that can reduce the potential harm?	Medical basis, overseas policies, and domestic practices
Utilitarianism	Net social benefit	Does our country have social benefits greater than potential harm to individuals if reuse is allowed?	Cost effectiveness of reprocessing, Necessity of reducing medical wastes
Land ethic perspective	Environmental pollution	What is the environmental impact of not performing reprocessing of single use device as opposed to performing it?	How much medical wastes can be reduced?

Announcement of the principles of suspending meaningless life sustaining treatment based on social consensus

Ho-Geol Ryu, Associate Researcher of National Evidence-based Healthcare Collaborating Agency

⊙ National Evidence-based Healthcare Collaborating Agency (NECA) held three forums and a panel discussion among representatives of academic, religious, legal, ethical, and social organizations for the past three months on suspension of meaningless life sustaining treatment. NECA also conducted a national survey on controversial issues surrounding meaningless life sustaining treatments. In addition, in collaboration with the Ministry of Health and Welfare and the Health Insurance Review and Assessment Service, NECA investigated the use of medical services prior to death and the current practice of meaningless life sustaining treatments. Combining all of the above, NECA developed the following priniciples and unsettled issues that require further discussion.

1. Subject	• In patients with incurable terminal disease, life sustaining treatments that only prolong the process of dying can be withheld or withdrawn. • It is inappropriate to continue life sustaining treatments in brain-dead patients and the related legislature should be amended to this end.
2. Procedure	• The judgement of the termial state should be done by 2 physicians including the attending physician and a specialist of the corresponding field. • The physician bears the responsibility to explain and counsel the terminally ill patient about the advance directive and the option of hospice care. • It is inappropriate to require notarization of the advance directives in terminally ill patients. • In order to minimize the risk implied by the uncertanties in medical and value judgement, the role of the ethics committee as a safegard is important. Each hospital should have an ethics committee that includes external medical ethics experts and the ethics committee should be supported in every way so that it can play the intended role.
3. Content	• Basic care such as fluids, nutritional support, and pain control should be maintained. • When a terminally ill patient expresses his or her wishes to refuse cardiopulmonary resuscitation or ventilatory support, they can be stopped. • The patient can express wishes regarding life sustaining treatments other than cardiopulmonary resuscitation or ventilatory support. The physician should take this into consideration when making a medical decision. • Euthanasia and physician assisted suicide are unacceptable.
4. Policy	• Legal grounds for withholding or withdrawing meaningless life sustaining treatments must be provided. • Socioeconomic support such as a stronger social safety net and better access to hospice care is prerequisite for the successful embedding of these principles into our society.

The following issues require further discussion.

❶ The following opinions have been presented regarding meaningless life sustaining treatment in unconscious terminally ill patients and consensus is yet to be reached.

1 · Joint decision between the patient's family and medical staff.
2 · Involving the Hospital Ethics Committee or court of justice.

❷ The persistent vegetative state patient includes a spectrum of medical status. Explicit approval or prohibition through general regulations carries a high risk of causing confusion. Therefore, social consensus is required on this issue.

❸ Ethically and legally, withholding and withdrawing meaningless life sustaining treatment is equivalent. However, consensus considering the current social acceptance of this concept is required.

The final report, ¡°Societal consensus formation regarding the withdrawl of meaningless life sustaining treatment¡± can be downloaded in a PDF format from the NECA website. Contact neca@neca.re.kr for more details.

Cost-effectiveness analysis used for B/C analysis and CEA policy-making

Jeong-Hoon Ahn, Chief Researcher of National Evidence-based Healthcare Collaborating Agency

With the introduction of a positive listing system of new pharmaceuticalproducts on the National Health Insurance (NHI) in 2006, the term, Cost-Effectiveness Analysis (CEA) become a more familiar term to those in the publichealth sector. This methodology is related to the Cost Benefit Analysis (CBA) in public policy sector, which is widely used and better known as Benefit Cost(B/C) analysis and has been often misunderstood, due to the term "cost", as being equated with a simple cost analysis for currency value calculation (mostly by researchers from clinical background) or benefit cost(B/C) analysis (policy makers familiar with B/C analysis). This manuscript aims to summarize CEA within the framework of economic analysis and introduces the difference between CEA and B/C analysis as well as their use in public policy sector of US.

Traditional Cost Benefit Analysis

The traditional cost benefit analysisis used to assess the worth of a project such as building a dam or constructing a railroad, which summarizes the expected benefits and the expected costs of the project by a number. This number can be calculated by 1) B/C analysis where the aggregated sum of benefits (in the present value) and aggregated costs (in the present value) are placed on numerator and denominator, respectively or 2) NPV(Net Present Value) estimation which is an aggregated sum of benefits (in the present value) minus the aggregated costs (in the present value). The method of selecting an alternative with the least cost among the ones with the same amount of benefits is called Cost Minimization Analysis (CMA). Many countries around the world, including Korea require a procedure ofverifying economic justification for most national projects funded by taxes and CBA is also used in evaluating the feasibility of a new project among private companies as well.

Cost-effectiveness analysis of health technology

The traditional cost benefit analysis is convenient since it can express not only costs but also benefits in a currency term, however, it is problematic to convert the typical benefits of the health technology such as the Life Years Gained (LYG), or the Number of Events Avoided into a pecuniary values. Hence, CEA which directly uses health outcomes as the denominator is more frequently used in medical economics, particularly in pharmaceutical economics. An economic analysis in the health sector encompasses all four methodologies of CBA, CMA, CEA and Cost Utility Analysis (CUA) which uses health utility as a means of representing health outcomes. The CEA, which is most frequently used among them, is often used as a term that represents these four methodologies.

Therefore, an economic analysis in health sector is commonly referred asCEA and the meaning of CEA should be judged according to the context, whether the one out of four methodologies or the common name for all four.

The following table summarizes four different methodologies.

▼ Comparison of cost effectiveness analysis methodologies in health sector

Methodology	Benefits	Example of Benefits	Result
Cost Minimization Analysis (CMA)	Equivalent	–	Cost by alternative
Cost Benefit Analysis (CBA)	Benefits expressed in a currency term	One hundred million won	Net Benefit by alternative or Benefit/Cost Ratio or Cost/Benefit Ratio
Cost Effectiveness Analysis (CEA)	Health Outcomes	Life Years Gained : LYG, (Number of Events Avoided and so on.	Cost/Effectiveness Ratio by alternative or Incremental Cost Effectiveness Ratio (ICER) between two alternatives
Cost Utility Analysis (CUA)	Health Utility	Quality Adjusted Life Years : QALY	Cost/Utility Ratio by alternative or Incremental Cost Effectiveness Ratio (ICER) between two alternatives termed in QALY)

Difference between CEA and B/C Analysis

Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. Methods for the economic evaluation of health care programms, 3rd ed. Oxford: Oxford University Press : 2005summarized the cost effectiveness analysis in health care has a narrower scope and does not usually capture externalities of economics such as spill-over effect, while traditional B/C analysis employs Willingness To Pay(WTP) measurementsbroadly to incorporate various externalities into the calculation. Another important consideration to be made along with these comparisons is the objective of cost effectiveness analysis. Since CEA has started from the problem of converting a value of life in a monetary value, the traditionalB/C analysis is not appropriate for the analyses comparing values of life or values of health. However, if the objective of analysis is to compare among different national projects most of whose outcomes are not health related, there is little reason to insist CEA. In addition, even if an objective is to compare projects in health care sector, a traditional B/C analysis might be more appropriate if the comparison is made on a non-health outcome nothing to do with the value of life such as which region is more appropriate location to allow a new medical school.

CEA and B/C analysis that are used in public policies of US

Cost Effectiveness Analysis (CEA) is widely used in the economic evaluation stage of US public policy making process though B/C analysis is more popular. In addition, it seems their usages are not clearly differentiable. For example, "the Clean Air Act forbids use of CBA to make certain types of decisions whereas the Safe Drinking Water Act mandates its use." In addition, the Environmental Protection Agency typically performs CBA and adds CEA as a supplementary analysis. In contrast, "the Occupational Safety arid Health Administration (OSHA) generally applies CEA and does not convert either morbidity or mortality benefits" (Krupnick AJ. Comments on OMB draft guidelines for the conduct of regulatory analysis and the format of accounting statements. May 30, 2003).

Since the differences in applied methodologies for economic evaluations among government agencies make it difficult for policy makers such as the Congress or the President, who need to make comparisons across the government agencies, the Office of Management and Budgetunder the direction of the President tried to cut difficulties by preparing a guideline on economic evaluations. In particular, the 2003 revised guideline recommends a CEA if the majority of benefits are improvements in health andsafety, whereas a use of CBA can be justified only if valid monetary values can be assigned to the expected benefits. On the other hand, for the regulations not focused on health and safety, the agencies must use CBA except some part of benefits cannot be expressed in monetary values where CEA should be performed. In addition, two noticeable values of CBA is mentioned as "a) provides some indication of what the public is willing to pay for improvements in health and safety and b) offers additional information on preferences for health using a different research design than is used in CEA." One more important message from Krupnick (2003) is refining "valid monetary values." First, in CBA, there are differences between calculations based on WTP and ones based on Cost of Illness (COI), hence COI based calculations are not necessarily lower than WTP based calculations except for the cases in food safety or air quality where a reasonable consensus exists. If so, converting a COI based calculation to WTP based calculation by multiplying a factor greater than one should be avoided. Second, converting QALYs to monetary measures by applying a conversion factor (for example, $50,000 per QALY) is not valid because there is no social agreement on the conversion factor.

Proposal

Most people will agree that it is not easy to monetize a value of life or a value of health. If so, it is time to connect this agreement to policy-making and there should be some tries to adopt QALYs in the traditional B/C analysis as a supplemental outcome (i.e. CUA) at least for the cases whose main benefits are related to health or safety. NECA

This article has nothing to do with the opinion of
the National Evidence-based Healthcare Collaborating Agency.

▸▸ Personal Vitae of Jeong-Hoon Ahn, Chief Researcher

· 1992 B.A. from the Seoul National University (International Economics)
· 1994 M.A. from the Seoul National University (Econometrics)
· 2000 Ph.D. from the University of Southern California (Health Econometrics)
· 2000~2002 Post Doctoral Fellow in the University of Maryland School of Pharmacy (Pharmacoeconomics and Outcomes Research)
· 2002~2009 Assistant Professor in the University of Southern California Department of Pharmaceutical Economics and Policy
· 2009.4 Chief Researcher and Director of Economic Evaluations in the National Evidence-based Healthcare Collaborating Agency

The First NECA Evidence-Based Healthcare International Workshop

⊙ The Evidence-Based Healthcare International Workshop was held for four days with the topics including 'Indirect Comparison', 'Mixed Treatment Comparison', and 'Understanding Diagnostic Tests, Systematic Review of Diagnostic Tests.'

The workshop dealt with practical research methodologies in depth based on social recognition of the need for evidence-based decision-making, which has developed through a series of international symposiums here in Korea. 'Multiple-treatments meta-analysis' by Dr. Georgia Salanti is one of the most recent research methodologies to find out the best treatment alternative out of various treatment options. Particularly, in times of the need for comparative effectiveness research and the reality that there are not many head to head trials and a lot of medicines are used for the same purpose, it draws global attention. Dr. Patrick Bossuyt is one of the most internationally renowned professors and leads Cochran's research on diagnostic tests and the STARD group that presents global standards on reporting of studies of diagnostic accuracy. He gave passionate lectures taking into account on various perspectives including the architecture of medical test evaluation, and prognosis and prediction tests.

<table>
<tr><th>October 5th</th><th>6th</th><th>7th</th><th>8th</th></tr>
<tr><td>Registration</td><td></td><td></td><td></td></tr>
<tr><td>Special Issues in Systematic Literature Search : Advanced Course
· Hee-Young Lee : the director of Healthcare Assessment Team, NECA</td><td>Weighing Risk Versus Benefit in Therapeutic Decision Making
· Soo-Young Kim : Prof. Department of family medicine, Hallym university medical college</td><td rowspan="2">The Architecture of Medical Test Evaluation</td><td rowspan="2">Systematic Reviews of Test Accuracy Studies</td></tr>
<tr><td>Effect size and Outcome
· Seung-Soo Sheen : Prof. Internal Medicine, Ajou University Medical Center</td><td>Introduction of Appraisal in Therapeutic Intervention
· Sang-Moo Lee : the executive director of HTA research division of NECA</td></tr>
<tr><td>Meta–analysis : Exploring heterogeneity and meta–regression
· Byeong-Ho Nam : the head of Office of Clinical Reaserch Coordination, National Cancer Center</td><td rowspan="2">Indirect and mixed treatment Comparison
· Dr. Georgia Salanti
(University of Ioannina School of Medicine)</td><td rowspan="2">Diagnostic Test Accuracy Studies</td><td rowspan="2">Tests for Prognosis, Prediction, and Monitoring</td></tr>
<tr><td>An introduction of Bayesian method
· Jeong-Hoon Ahn : the director of Economic Evaluations, NECA</td></tr>
<tr><td colspan="2"></td><td colspan="2">· Dr. Patrick Bossuyt : University of Amsterdam
(Small group discussion)</td></tr>
</table>

INTERVIEW

Eun-Hee Shin_National Evidence-based Healthcare Collaborating Agency

The First NECA Evidence-Based Healthcare International Workshop organized and prepared from spring this year was held from October 5th to 8th, 2009 at the main conference room (11thfl.) of NECA. Looking back, we started making phone calls in preparation of the workshop from May this year and it seemed October was far away back then. However, in July, when domestic participants and lecturers were determined and we made a full-fledged preparation for the event as we collected and published necessary materials, the time started to fly so quickly. Chuseok, Korean Thanksgiving Day, came before I knew it and finally the four-day workshop began with a number of outside participants as well as NECA researchers with deep interests.

For the first two days, lectures were given by domestic experts on methodologies of evaluating the scientific evidence of various treatments. Then Dr. Georgia Salanti from the School of Medicine of the University of Ioannina delivered a lecture on the latest meta-analysis to select the best alterative among available treatment options, while Dr. Patrick Bossuyt from the University of Amsterdam introduced the basic concept of diagnostics and the effects that research results have on diagnostic test accuracy. It was a significantly meaningful time to obtain the latest knowledge and information on various research methodologies for qualitative improvement of healthcare and to share various opinions among participants through lectures and heated small group debates.

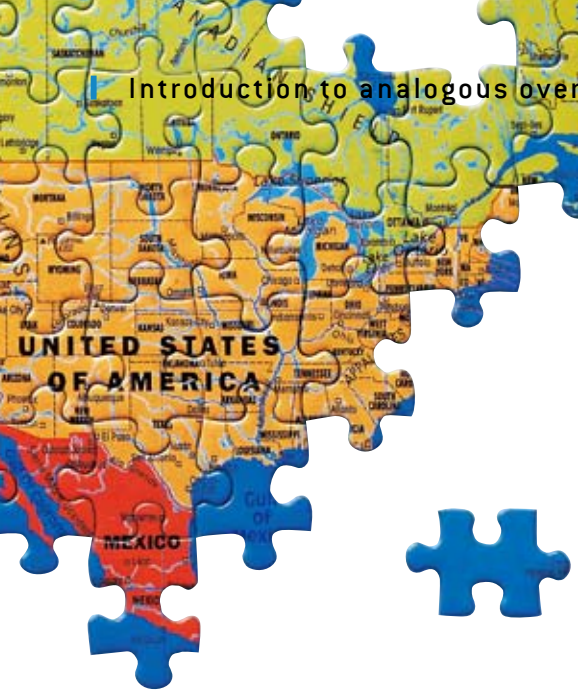
I expect that the active exchange of knowledge and information through the workshop will pave the way for having the evidence-based healthcare take root in Korea and further develop into sophisticated level of quality medical services. I would like to propose we collaborate to build up competitiveness of NECA through deeper and more advanced quality workshops for years to come.

Seon-Hee Lee, Health Insurance Review Agency

As one of the researchers that evaluate diagnostic tests through systematic review, I was so delighted about the international workshop where I was able to share ideas and thoughts with Dr. Bossuyt and to listen to his lectures. I managed to participate in the four day workshop everyday on a tight schedule of having to prepare for parliamentary inspection of the administrationas well as tons of reports. The first and second day discussed major strategies in systematic review, effect size, meta analysis and Bayesian method and I was able to systematicallyobtain the knowledge I was thirsty for. There were lectures of Dr. Bossuytand small-group discussions for the remaining two days. It was not easy to digest everything because there were lots of new things to learn, including not only systematic review and meta analysis on diagnostic tests but also new concepts such as Calibration. It was informative and useful as I obtained the information applicable to practice through lectures, Q&As and discussions. In addition to gaining quality knowledge, I was able to socialize with good people through small group discussion and break time. I would like to express my gratitude to NECA for this wonderful opportunity to learn and discuss new and interesting knowledge.

You-Kyeong Lee, Department of Laboratory Medicine, Bucheon Hospital, Soonchunhyang University

I participated in the international workshop hosted by the NECA while wondering why I study the evidence-based healthcare at 15 years after I obtained board specialty certification. I listened to all lectures for four days. I was hopping between hope and despair while listening to all available lectures without skipping any. Mathematical formulas popped up all of a sudden and I have never seemed to deal with since I graduated from high school. I naturally didn't understand them properly (I apologized to Dr. Salantifor not following what she explained, but I wasn't sure whether she understood what I meant). I looked around and found people nodding, which taught me that I still have a lot of things to learn and understand. I was so glad when Dr. Bossuyt mentioned something about diagnostic tests and Dr. Bossuyt's lecture for the last two days was simply overwhelming. The concept of being able to perform RCT in the field of diagnostic tests and having to measure outcomes that can be obtained from patients was rather exceptional and made me think of a lot of things. I was pretty convinced that I have done a lot of contemplations on accuracy, reliability and clinical effectiveness of diagnostic tests, but now I think I need to think over calmly. Alas, I've got another assignment to do. I was so lucky though that I was able to listen to such prestigious scholars that I could meet only in books in a small group discussion. Furthermore, their lectures left me an assignment to do. Some say world is wide and there are lots of works yet to be done. I felt deep into my bones that I still have a long way to go with a lot more to be done and learned yet. My brain was full of concepts such as fixed effect model, heterogeneity, hierarchy, study design after the four day lectures. I'm so thankful to NECA for this excellent opportunity and I expect something like this from time to time. NECA



Introduction to AHRQ

(Agency for Healthcare Research and Quality)

Sang -Moo Lee,
Chief Researcher of National Evidence-based Healthcare Collaborating Agency

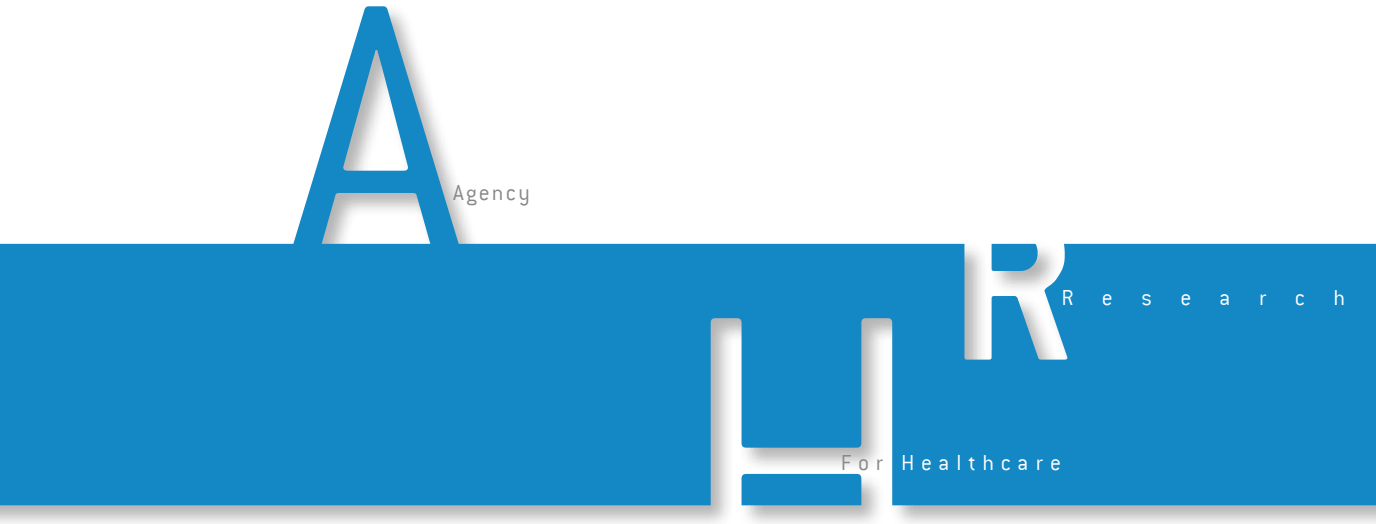
⊙ Many governments have conducted evaluations ofhealth technologies in an attempt to provide quality medical services and relevant information to those who use the health system, and to Medicare service providers in terms of public health assurance. [1] The United States established the Office of Technology Assessment (OTA) in 1972 as an independent government institution with the intention of providing proper information on medical technologies through scientific analysis. However, OTA withered in the face of opposition from the medical and industrial sectors. In the aftermath of OTA, a number of initiatives designed to evaluate health technologies have been established and disappeared. A success story is the Agency for Health Care Policy and Research (AHCPR). AHCPR was founded in 1989 under the umbrella of Public Health Service. The US Congress passed the bill in 1999 that allowed the organization to expand its authority and perform health service research with the Department of Health and Human Services (HHS) as one of the official government institutions. In the US, the National Institutes of Health (NIH) is tasked with conducting biomedical research, while AHRQ has sought ways to provide quality medical services and to reduce medical errors as an axis of medical service research. The aim is to promote and improve the safety of patients.

Existence Value and Role of AHRQ

AHRQ is comprised of four offices and five centers; among these, the Center for Outcomes and Evidence (COE) functions similar to the National Evidence-based Healthcare Collaborating Agency, and engages in several primary works including evaluation on the safety, quality, effectiveness and cost effectiveness of health technologies, collection and analysis of relevant data, provision of evidence-based information for medical practitioners and policy makers, fostering evidence-based decision-making, and promotion of partnering relationship with medical service providers, insurers and subscribers.

Recently, high-cost medicines and treatments have been introduced and widely used in medical the US health service market, but the necessity of conducting comparative research into effectiveness of high-cost health technologies as opposed to traditional ones has been raised. The Obama administration has acknowledged the significance of Medicare restructuring and increased the allotted funds by $1.1 billion, while AHRQ is playing a pivotal role in operating relevant researches.

Questions remain. Why do we need this comparative effectiveness research? What will be the optimal treatment for mentally depressed patients accompanied with different diseases? What kind of medical approach will be optimal to prevent a child patient who suffers psychological impediment from being re-hospitalized? We do not actually know the answer to these patient-oriented questions regarding comparative effectiveness of medical technologies. 2) The primary purpose of the comparative effectiveness research is to provide medical practitioners, patients and policy makers with the most appropriate patient-relevant information. The outcome of this research should hopefully be the provision of the right treatment applied to the patient. Comparative effectiveness research is the intermediary process of releasing a new medicine into the market. This differs from clinical research, which aims to prove



the efficacy of the medicine by showing the efficacy of treatment in ideal circumstance such as patients with specific limiting conditions and by comparing the groups with or without the medicine. [2]

The definition of the comparative effectiveness research, according to a press release of the Federal Coordinating Council, is: "Comparative effectiveness research refers to several different arbitrations that prevent, diagnose, treat and trace a certain health status in realistic environment and the comparison of strategic gains and losses as well as comprehensive research."

Prior to this full-fledged investment, AHRQ has operated an effective health and medical program intended to enhance the quality, effectiveness and efficiency of health delivery for all Americans.

Two proposal procedures must be followed to confirm that the research theme originates from the interested parties and to promote transparency. The first step is topic solicitation, where a research theme is proposed through a website. The second step is topic generation, where the research theme is recognized by establishing contact with interest groups. A research theme is drawn out through these two different paths and a successful research theme is selected with appropriateness, significance, redundancy, feasibility and potential value taken into account by theme selection group comprised of in-house people whose expertise is relevant to the program.

If the amount of information is sufficient and comparative effectiveness research is implementable, Effectiveness Review or Comparative Effectiveness Review (CER) is conducted. When it comes to emerging technology, the research horizon is scanned by the preparation of a technical brief, which augments a systematic review of the pertinent literature. If the amount of information is not enough to necessitate the first-phase of research, the research theme shifts toward evidence creation.

The research is conducted in 14 Evidence-based Practices Centers in the US and Canada in the cases of CER, CE, and Technical Brief, and goes through a research mechanism such as DEcIDE to create the new first phase evidence. Research that utilizes electronic medical record (EMR) is conducted; an example is the Distributed Network for Ambulatory Research in Therapeutics (DARTNet), which is comprised of about 500 clinical treatments and 400,000 patients. Another example is the or DEcIDE consortium connected to HMO research network (HMORN) of 15 HMOs.

AHRQ operates the National Guideline Clearing House (NGC) that pertains to clinical treatment guideline, and operates an informationized database on clinical treatment guidelines that are evaluated by a qualitative screening process. In order for a guideline to be included in NGC, it must be systematically

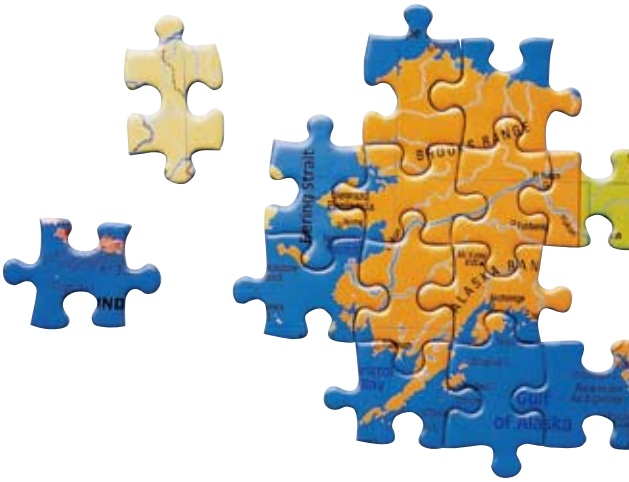
and Quality

developed; published under the sponsor of medical academic society, government or health and medical institution; created based on evidence drawn out through a systematic literature-based and written in English. Its primary purpose is to inhibit the redundancy of clinical treatment guidelines, promote distribution and stimulate updating. A total of 7200 guidelines from 335 institutions have been submitted as of March 2009. Among these, about 10% have been rejected for failing to meet the predetermined requirements. The 2,400 guidelines from 200 institutions that have been published are used by approximately 700,000 people on a monthly basis.

In addition to the generic research through theme extraction, CMS requests AHRQ for evidence-based research for analysis of medical evidence used to set codes for new health technology within the US and national coverage decisions (NCD) during the process of determining Medicare pay, and pay standards are set on the basis of it. AHRQ conducts research on the corresponding technology based on the analysis of scientific evidence independently or jointly with the Evidence-based Practices Center, while performing a systematic review for the agreement extraction program of NIH.

In conclusion, AHRQ is one of the core health and medical institutions that have contributed to promoting health for people by conducting analysis and research into medical evidences required on a national level as one of the public institutions of the US federal government. NECA

1) John M. Eisenberg, Deborah Zarin. Health technology assessment in the United States. International Journal of Technology Assessment in Health Care, 2002;18(2):192-8.
2) Federal Coordinating Council for Comparative Effectiveness Research Report to the President and the Congress June 30, 2009



Report on AHRQ Annual Meeting

Hee-Young Lee,
Associate Researcher of National Evidence-based Healthcare Collaborating Agency

⊙ 2009 Annual Conference of AHRQ(Agency for Healthcare Research and Quality) was held in Washington for four days from September 13 through 16 with the theme of Research to Reform : Achieving Health System Change'. It was interesting that the conference was held in Washington where there were mass demonstrations for and against the Healthcare reform of Obama administration. While congress and crowds of people were debating about reform, those engaged in research seemed to prepare for the change and update of the health and medical system incurred by reform.

The annual conference is intended to discuss the annual business performance of the institution as well as planning for next year, unlike presentation of academic research result, and is open to everyone for free. In particular, $1.1 billion research fund was allocated this year in accordance with American Recovery and Reinvestment Act, out of which AHRQ operated $400,000,000. A lot of changes are expected as Comparative Effectiveness Research(CER) is scheduled to perform a full-fledged take-off. I believe the AHRQ has a lot more to do with dramatically increased budget.

The conference is largely comprised of six themes with the entire plenary session held for two days. Six themes include ❶ Health Care Infrastructure ❷ Organization of How services are delivered ❸ Health Care Quality and Safety ❹ Improving Americans Health Status ❺ Provider Performance and Payment reform and ❻ Increasing Patient and Consumer involvement in their care. In addition, there were Exhibit Tables with more heated debates conducted in sectors that were determined to be granted with research funds in accordance with American Recovery and Reinvestment Act, including Effective Health Care Program, Health Information Technology Activities, and General Patient Safety Activities.

Lively Discussion by Theme

In the Plenary Session on the first day, Sibelius, Secretary of Department of Health and Human Services and new maker with respect to recent Healthcare reform hosted a panel discussion with the theme of medical service restructuring and system change - for affordable quality medical services. The issue of 'High Quality' and 'Affordable' is the subject matter that not only US but many other countries around the world are dealing with and the evaluation on comparative effectiveness and IT technology as well as recovery of public medical system have been presented for more efficient medical system.

In the Plenary Sessionon the second day, the panel discussion was conducted with the host of Clancy, the president of AHRQ as in the first day with the subtitle of 'For emphasis of Health Disparities'added to the title on the first day. Disparityhas long been an issue in US and has served as a primary reason for the recent Medicare restructuring. The discussion between audiences who shared on-site real life stories and researchers who were seeking solution to the problems was both serious and lively.

AHRQ retains a variety of infrastructures including DB and Clearing House with Evidence Synthesis, Evidence Generation and Evidence Dissemination as major axes. Healthcare Infrastructure deals with various issues regarding Data Link, in particular

while the role of Health IT and concrete CER methodologies were mentioned. A concrete discussion was conducted regarding use of GRADE in CPG development, the importance of Conditional coverage with Evidence Development, and Patient Reported Outcome Measurement in Medicare and Conflict of Interest problems in Recommendation. What was particularly noticeable to us was the methodological, ethical and legal approach to integrate the relevant IT data. Efficient data integration seems to draw keen attention in medical industry with Medicare restructuring neat at hand as it not only facilitates effective research into health outcomes of patients but also reduces overall medical costs as the basic data for comparative effectiveness research.

The major issues of Medical Delivery System, the second topic, include community, resource distribution and human resources in primary care, the importance of health promotionand excessive use of preventive services and redesigning of hospital services. There was a heated debate on preventive and health promotion services with respect to costs issue of health insurance coverage of entire people. With respect to this issue, a variety of experiences were discussed regarding how Clinical and Community of USPSTF(US Preventive Service Task Force) can be applied to local communities and hospitals. Particularly the excessive use was pointed out as a problem to be resolved so 'Provision of appropriate services in accordance with optimal guide' was the main subject of discussion.

2,000 participants for three days

The quality and safety of medical services, the third topic, was one of the most significant topics and particularly there were a number of presentations regarding the improvement proposals through an efficient use of IT and infection problemin hospital and community. When it comes to the use IT in medical decision-making, the approach by disease and circumstance was especially noticeable and the assertion that a steady training and education of doctors about the safety is important drew out attention as well. The AHRQ Quality Indicator with Ver 4.0 was announced in June as a tool to monitor the quality of medical services as a part of the process of evaluating the quality of medical services on a national level while creating National Report every year. The major issues addressed in discussion include the considerations to make in developingthis tool and how to implement them into policy-making.

A number of topics regarding promotion of health status including preventive service, drug abuse or misuse, psychological health, health complaints were also discussed along with the impact of MIPPA bill that expands the preventive service of Medicare based on USPSTF guideline in 2009. What was also included in discussion topics was how to improvehealth status through participation of patients and local communities and relevant actual cases were also introduced along with the importance of media and utilization of IT.

When it comes to the payment reimbursement policy, the method of measurement and evaluation was raised as the most critical issue as expected and the application of method of payment compensation based on the health result and performance of medical staff was among the major issues addressed. Last but not least, the participation of patients and consumers has been consistently emphasized throughout all topics while concrete methods of participating in decision-making including Shared decision making and Informing Care decision were discussed along with how we can incorporate the result of CAHPS(The Consumer Assessment of Healthcare Providers and Systems) into policy-making decisions.

The event that lasted for three days was participated by some 2000 relevant participants from a number of institutions, including not onlygovernment institutions such as Department of Health and Human Services, AHRQ, CDC, and FDA but also universities, clinical academic societies, Private Research Center, insurance companies and pharmaceutical companies. How nice it would be if an annual conference like this were held in Korea. I mean the conference where the officials of Ministry of Health and Welfare, Government Research Organization and relevant researchers come together to discuss the research performance of the year and to talk about agendas of next year. It would be nice to have interactive discussion on concrete alternatives with sufficient amount of time for debate and discussion instead of one-way presentation meeting. Wouldn't it be so exciting just to talk about Healthcare Reform for four days and three nights? NECA

Evidence-Based Healthcare

Introduction to authors

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⊙ It is an introduction that will serve as a guide that facilitates the understanding of evidence-based healthcare as well as the reasonable decision-making applicable to actual cases. It briefly and plainly describes a wide range of topics including basics, clinical application, application to healthcare practice and policy-making decision. The informationon the major literature and websites is provided for those who want to study further. It is comprised of three sections of general outline, particulars and application. The general outline (background and necessity) describesthe definition and development background of evidence-based healthcare, the evaluation of evidence, and decision-making regarding healthcare. The particulars (methodologies) deals with a number of topics intended to obtain evidences, including designs of clinical research, critical evaluation of clinical research and understanding of the results, systematic review, economic evaluation, clinical practice guideline, and outcome research. Finally, the evidence-based decision-making systems in foreign countries were introduced along with proposals for establishment of effective evidence-based healthcare suitable to our country. NECA

NECA NEWS

Work collaboration agreement with Health Insurance Review Agency

NECA held an agreement ceremony to establish mutual work collaboration system with Health Insurance Review Agency (president Jai-Seong Song) in the conference room of Health Insurance Review Agencyon August 20, 2009.

Two institutions have presented the principle of exchanging information and research materials as well as human and materialistic exchange and collaboration during the process of conducting research within the range required in implementing functions and works while conforming to the background of establishment with detailed agreements to be conducted through consultations among working-level managers.

The Agreement is expected to create synergy effects as it enables researchers to lay the groundwork for utilizing treatment information and know-how retained by Health Insurance Review Agency in research intended to establish the evidence of health and medical service while the Health Insurance Review Agencywill be able to utilize the research results.

Presentation of final report, "Societal consensus formation regarding the withdrawal of meaningless life sustaining treatment"

The research institution announced 12 basic principlesregarding institutionalizing the suspension of meaningless treatment based on the opinions of experts and relevant groups and public survey of people's perception.

Jong-Myon Bae, the director of health and medical analysis division, presented the present status of domestic meaningless life sustaining treatment, followed by the presentation of Ho-Geol Ryu, the team leader of Health and Medical Performance Analysis Team regarding the survey result of general public and expert groups. And then, Hee-Young Lee, the team leader of Medical Technology Analysis Team presented the final report along with Q&A, which concluded the session related to 'The withdrawal of meaningless life sustaining treatment' that has continued since July.

The final report included additional agreements on necessity of legal restructuring, preparation of legal basis for suspension of meaningless treatment, objection to mandating notarization of advance directive in addition to nine agreements announced in the first round.

Mandating ethical research review for the first time among public research institutions

The research institution is the first public research institution under government control that mandated its research projects reviewed and inspected by Institutional Review Board(IRB)

The Board comprised of experts from various fields, including clinical medicine, medical statistics, legal affairs and clinical research prepared standard operating guidelines and appointed professor Chang-Han Kim(Department of Human Medicine, Wulsan Medical School) as the first board chairman.

The Board has completed review and inspection on 24 research projects that are conducted in 2009 with focus on finding out if a research project does not involve ethical or scientific problems, which is expected to elevate the research ethics among public institutions in health and medical sector by serving as a guide to protect rights and safety of the examinees.

Indirect Comparison Methods for Economic Decision Modeling

National Evidence-based Healthcare Collaborating Agency will host a workshop (with practice sessions) on indirect comparison methods. The topics of the workshop are as follows:

- » An Introduction to Indirect Comparison Methods
- » An Introduction to Bayesian Methods and WinBUGS Program
- » Bayesian Meta Regression: fixed effect vs. random effect
- » Mixed treatment comparisons
- » Bayesian Evidence Synthesis and Economic Decision Model
- » Matching and Indirect Comparison

• Workshop Schedule and Inquiry

Date : 9AM ~ 5PM, Sat., October 31

Location : Conference room, 11th floor, NECA

Preparation : Personal laptop computer installed with WinBUGS freeware (downloadable free of charge from http://www.mrc-bsu.cam.ac.uk/bugs/winbugs/contents.shtml)

Registration : 50people (by order of receipt)

Registration fee(lunch included) : 200,000 won(general)

Contact : Jeonghoon Ahn (jahn@neca.re.kr), Chief Researcher, National Evidence-based Healthcare Collaborating Agency

Conditional Coverage with Evidence Development Workshop

● Overview: It is designed to seek a right direction of establishing the conditional coverage system to implement top-down based Pragmatic Clinical Trial (PCT). The system can create publically beneficial evidences for health technologies with insufficient evidences regarding clinical effectiveness and/or safety in spite of high social values with cost effectiveness and quality of life taken into account.

● Date and Location

Date: 1:30~5:30 PM, Friday, November 27th, 2009

Location: International Remote Conference Room, the first basement of the Centennial Memorial Hall, Korea University

● Registration and Inquiry

Registration: No registration fee (The registration schedule will be announced soon.)

Inquiry: Person in charge of the workshop (sunvia@neca.re.kr, 02-2174-2743)

● Program

Schedule	Content	Lecturer	The senior Person present
13 : 30~ 14 : 00	Domestic Pragmatic Clinical Trial (PCT) and insurance coverage	Eun-Gyeong Shin, Administrator in the Office for Insurance Coverage, the Ministry for Health, Welfare and Family Affairs	Jong-Myon Bae, Chief Reseacher (NECA)
14 : 00 ~ 14 : 30	Conditional coverage of new technologies	Jae-Taeck Hwang, Central Review Committee Member(Healthcare Review and AssessmentCommittee, Health Insurance Review Agency)	
14 : 50 ~ 15 : 20	Research fund support plan for the evaluation of clinical effectiveness and safety of new technologies	Young-Sun Choi, Vice Researcher (National Health Insurance Corporation)	
15 : 20 ~ 16 : 00	Relative value score of new health technologies	Hun-Sik Yang, Insurance Director (Korean Medical Association)	
16 : 20 ~ 16 : 50	Presentation of overseas cases	Sang-Moo Lee, Chief Researcher (NECA)	
16 : 50 ~ 17 : 10	Presentation of the progress of NECA	Eun-Hee Shin, Principle Researcher (NECA)	
17 : 10 ~ 17 : 30	Discussion and Closure		

National Evidence-based Healthcare Collaborating Agency (NECA) provides scientific evidences to the policy makers and the general public, by analyzing economical efficiency of pharmaceuticals, medical devices and health technology ultimately contributing to the enhancement of public health. 〈Evidence and Value〉 is a journal of NECA to develop the necessary evidences in healthcare sector for rational decision making and efficient resource utilization.