

"New Age" Decision Making in HTA: Is It Applicable in Asia?



HTAi Conference, Tokyo, May 2016

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About HTAi

Health Technology Assessment international (HTAi) is the global scientific and professional society for all those who produce, use or encounter HTA. HTAi has members from over 65 countries and embraces all stakeholders, including researchers, agencies, policy makers, industry, academia, health service providers and patients/consumers. HTAi is a neutral forum for collaboration and the sharing of leading information and expertise. Annual meetings are held once per year, and are key international gatherings for sharing the latest research, advancing discussions in policy and methods, and building global networks. For more information see: <http://www.htai.org/>.

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- Our mission is to promote better health care policies by leading innovative economic and statistical analyses on health and health care issues.
- OHE undertakes research on three key themes: the economics of health care systems, the economics of HTA, and the economics of the life sciences industry.

About this report

The HTAi 2016 annual meeting was held in Tokyo on 10–14 May, with the theme "Informing Health Care Decisions with Values and Evidence". This report summarises a panel session entitled "New Age Decision-Making in HTA: Is It Applicable in Asia?", which took place on Thursday 12 May. The report has been approved by all presenters to be put forward as a public record of the HTAi panel session.

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1. INTRODUCTION

This report provides a detailed summary of a panel session which took place at the HTAi 2016 annual meeting in Tokyo. The panel session was entitled "New Age Decision Making in HTA: Is It Applicable in Asia?". To open the session, David Grainger (Eli Lilly & Company) provided an overview of the session, offering useful background to the topic.

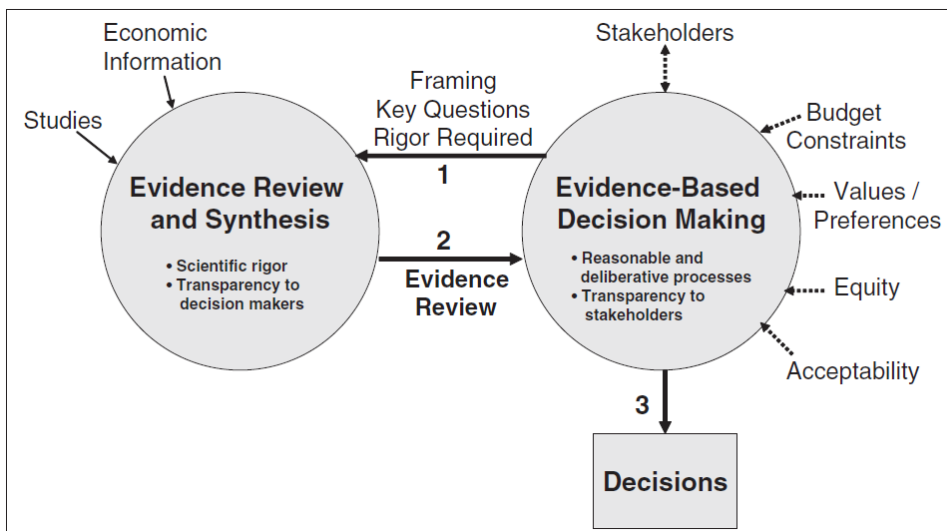
2. BACKGROUND

Existing health technology assessment (HTA) systems have devoted a significant amount of time and effort to the methodologies and evidence requirements of HTA, but less attention to the actual "decision-making" processes and mechanics. This was the focus of the panel session described in this report.

Definitions of HTA vary, but generally indicate that HTA is a multidisciplinary process that summarises and weighs up a variety of issues of relevance. The EUnetHTA definition of HTA is "a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner." (EUnetHTA, 2016). HTA is clearly required to pull together and assess information from various strands, but it is not always clear how this is, or should be, done in practice.

Teutsch and Berger (2005) describe HTA as a combination of technical **evaluation** and broad-based **appraisal**. The dynamic relationship between evidence review and synthesis (the evaluation) and evidence-based decision making (the appraisal) is summarised in Figure 1.

Figure 1. Relationship between evidence review (evaluation) and decision making (appraisal)



Source: Teutsch and Berger (2005), pp. 487

The diagram shows that the appraisal involves decision making which, as well as the evidence review, includes consideration of elements such as affordability, equity and societal values or preferences, which are not necessarily related to the evidence for the product. Thus the way in which these factors are incorporated into decision making is an important matter for discussion. This is the focus of this report.

Decision-making challenges have been discussed on a number of platforms. HTAi runs a series of "local" meetings called policy forums; a comment which arose in the Asia Policy Forum in 2015 (Singapore, November 2015) was, *"If the only information put in front of the decision-making committee relates to comparative effectiveness and cost-effectiveness,¹ then we should not be surprised that these are the only things the committee considers"*. This demonstrates the importance of transparent decision-making processes which explicitly make reference to the "other" elements included in a deliberative process of decision making. Prof. Tony Culyer recently commented on the limits of cost-effectiveness analysis in a commentary piece for the Medical Association of Thailand, again highlighting the importance of the decision-making process: *"How much more complex is the combining of a much wider set of desired elements. They will not combine themselves to produce health system guidance, instead, combining and interpreting them requires a deliberative process"* (Culyer, 2014).

The members of this panel session presented their perspectives on broadening the basis for decision-making processes in HTA. They represent countries where decision-making is evolving to meet the challenges of innovative technologies in two very mature health systems (the UK and the Netherlands), as well as one of the most experienced Asian HTA environments (Korea).

3. STRUCTURED DECISION-MAKING APPROACHES TO THE INCLUSION OF MULTIPLE CRITERIA IN HTA

Prof. Nancy Devlin, Director of Research, Office of Health Economics (OHE), UK

In order to explore how structured decision making can contribute to HTA, Prof. Devlin described how multiple criteria can be incorporated into HTA decision-making using multiple-criteria decision analysis (MCDA).

Multiple criteria in HTA

Improving health is, in general, the primary goal of health care. However, health systems have multiple objectives which go beyond improvement in population health, for example: equity considerations (not only how much health is produced but how it is distributed) and societal preferences for prioritising certain diseases or patients over others (e.g. children versus adults). While maximising the number of quality-adjusted life years (QALYs) is a pragmatic way of assessing value for money, this clearly does not capture everything that matters to society. HTA systems have traditionally relied on a deliberative process to weigh up different kinds of evidence on the various criteria of relevance to HTA; in some cases quantitative evidence factors are weighed up alongside qualitative considerations and there is often little clarity about the importance attached to the various factors which influenced the decision. HTA systems across the world vary

¹ Note that assessment of effectiveness and cost-effectiveness data is typically a key part of the evidence review (the technical evaluation part) of HTA.

in the extent to which they are explicit and consistent in identifying these other criteria that factor into decisions, and how they are reflected in the decision-making process.

A key point to note is that multiple criteria are *already* taken into account in decision making for HTA, to a more formal or less formal extent. Therefore the question is not *whether* multiple criteria should be used in HTA, but *how best* should multiple criteria be taken into account?

Figure 2 sets out a continuum of options for taking into account multiple criteria. It shows a spectrum between fully quantified – using explicit algorithms which are fully transparent and applied identically to each decision – and purely qualitative/deliberative processes, where trade-offs between the criteria used in decision making by a committee may not be made explicit. It should be noted that, at present, HTA agencies appear to have some discomfort with the fully quantitative approach – the reasons for which will be discussed.

Figure 2. Spectrum of deliberation and quantification of multiple criteria in HTA



Criteria decided <i>ex ante</i>	Core criteria – but with potential to make exceptions	Criteria decided on an <i>ad hoc</i> basis
Fixed criteria	Criteria vary with explicit justification	Criteria may vary
Fixed weights	Trade-offs/weights normally the same – but may vary, and are always explicit	Trade- offs between criteria vary
Explicit and fully transparent process	Process explicit and full transparency	Process not pre-agreed; basis for decisions not explicit or transparent

The pertinent question, therefore, is how far along this spectrum should we go? It is likely that “one size does not fit all”: the criteria that are relevant, the importance placed on them, and the nature of the decision process itself will all depend on the social and political context of the health care system and society within which HTA is taking place. A pragmatic approach could be to aim for somewhere in the middle, using structured decision-making approaches to assist and inform (rather than replace) the judgements made by HTA committees. In this middle ground, there could be a core set of criteria and explicit processes, but with some flexibility for the committee to vary the criteria used in each case, or the weight attached to them, where there is justification to do so. The committee would thereby retain the ability to make exceptions when appropriate, while being transparent and explicit about that.

The potential merits of structured decision making

Desirable features of an HTA process, which structured decision making could support, include

- Consistency and replicability across its decisions
- Transparency e.g. to stakeholders, including taxpayers, patients, the health care system whose budgets are affected by HTA and industry in order to signal what innovations are of value
- Accountability.

A purely qualitative deliberative process where an individual HTA committee member weighs up multiple types of complex information is cognitively demanding, and the literature indicates that individuals can be subject to various kinds of bias. Where an HTA process is based on a group decision, the decision could also be influenced by chairing style, dominant personalities, group dynamics and the size of the committee. Therefore the use of MCDA may outperform the use of intuitive judgement alone (Devlin and Sussex, 2011).

The various policy initiatives that have arisen to supplement HTA reflect the need to take into account multiple criteria simultaneously and in a systematic way. For example, value-based assessment was proposed in the UK to take account of burden of illness and wider societal impact, among other things. Plans were never implemented, but this demonstrated the interest in formally incorporating criteria other than cost-effectiveness into decisions about pricing and reimbursement. In a global context, the guidance on priority setting in health care (GPS-Health), initiated by the World Health Organisation (WHO), offers a map of equity criteria that should be considered in addition to cost-effectiveness (Norheim et al., 2014).

As well as accounting for multiple criteria, HTA has increasingly sought to involve a wide range of stakeholders including patients and clinicians, but it is unclear how stakeholders' views influence final decisions. MCDA offers a means by which stakeholder perspectives can be included in decision making in a more structured, systematic way.

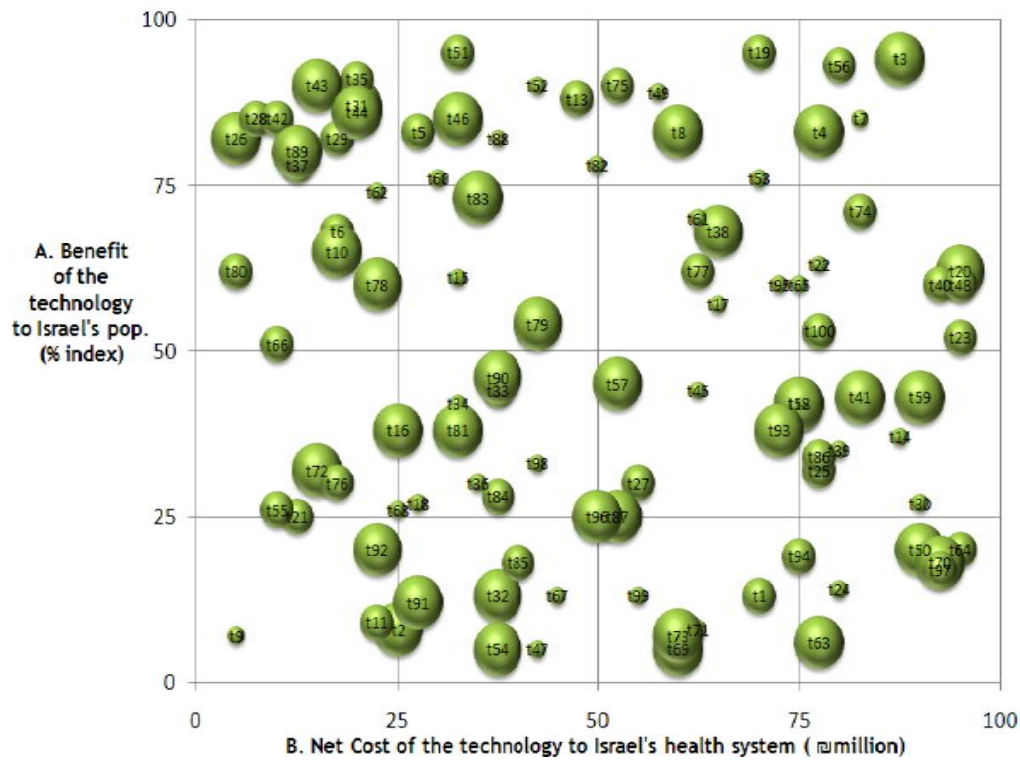
Growing interest in MCDA globally

MCDA can provide a set of techniques to structure decisions, and a transparent way to implement and demonstrate the relative weights being applied to the criteria of decision making. There is a growing interest in MCDA internationally which is reflected in efforts such as the ISPOR best-practice task force on MCDA (Marsh et al., 2016; Thokala et al., 2016). There are also a growing number of sessions at conferences and clear interest in the technique, yet there are still important reservations about adopting MCDA approaches, particularly within HTA agencies. This is often due to a misunderstanding that MCDA relates only to the fully quantified, prescriptive end of the MCDA spectrum.

Despite reservations, some HTA agencies have explored how MCDA might be applied in practice. In the UK, "structured decision making" was included for the first time in NICE's 2013 methods review (Claxton and Devlin, 2013; NICE, 2013), and in certain areas such as the appraisal of highly specialised technologies, explicit criteria are outlined (this is currently under consultation). There are examples in the literature of one-off pilots in Israel (Golan and Hansen, 2012), Colombia (Cleemput et al., 2015), Italy (Radaelli et al., 2014), Thailand (Youngkong et al., 2012) and Germany (IQWiG, 2013). Pilots are also under way in other countries (for example, in Belgium). MCDA has also been piloted by the European Medicines Agency for use in benefit risk assessment (EMA, 2010; Phillips et al., 2011).

In Israel, for example, the Public National Advisory Committee known as the "Health Basket Committee" selects new technologies to be included in the basic list of health care for Israelis. The committee carried out a pilot whereby a framework of prioritisation was introduced based on the explicit consideration of many variables, including value for money (Golan and Hansen, 2012). Many factors of "benefit" were included, such as equity benefits, quality of evidence and strategic/legal factors, which were aggregated via a points system. The "value-for-money" chart that was derived to support decision making is shown in Figure 3.

Figure 3. Value-for-money chart



Source: Adapted from Golan and Hansen (2012), p. 1.

The sizes of the bubbles in Figure 3 relate to the quality of evidence. The graphic is intended to be used to help decision makers decide which interventions should be included in the health care basket. The graphic does not dictate decisions, but is used to inform a deliberative process by presenting information in a structured way to support decision making rather than replace judgement.

In Italy, MCDA has been piloted at the regional level. The Lombardia region has introduced a system combining elements of the EUnetHTA Core model for assessment and an MCDA approach (EVIDEM). It has been used as a decision-making aid which includes 20 different criteria, including disease-, treatment-, finance- and society-related aspects. So far it has been used for 26 technologies and appears to be successful (Radaelli et al., 2014).

In Thailand the approach has been used to help the Thai health care system select the technologies to be included in coverage. They have been very clear about the criteria utilised in decision making, which include value for money and budget impact, which has been reported to improve transparency and fairness (Youngkong et al., 2012).

Pilot studies for MCDA have also been implemented in Germany, by the Institute for Quality and Efficiency in Health Care (IQWiG). The aims of the pilot studies were to identify patient-relevant outcomes, elicit patient preferences and enable aggregation of outcome-specific efficiency frontiers based on obtained weights. The pilots found that MCDA can be useful in supporting the HTA process, particularly in providing an improved process for incorporating patient preferences (Thokala et al., 2016). However, challenges remain, such as making sure that the patient viewpoint is representative and transferable to the entire patient population (IQWiG, 2013).

However, despite numerous pilots, increasing interest, and fairly widespread use of MCDA *outside* healthcare decision making, to date no HTA system in the world has fully adopted MCDA.

Why hasn't MCDA been implemented in HTA?

We can speculate on the various reasons why MCDA has not been implemented in HTA. HTA organisations may be uncomfortable with the requirement of being fully explicit about the basis for their decisions. Unless there is a willingness on the part of decision makers to be transparent and explicit about the basis for their decisions, there is unlikely to be an appetite for using structured decision making approaches.

There also appear to be some fundamental misunderstandings by HTA bodies about MCDA and its use in structured decision making – for example, concerns have been voiced that MCDA would replace HTA committees, substituting people and judgements with mechanisms and algorithms. This is not the case, as MCDA is not intended to replace the judgements of HTA committees; judgement will always be required and MCDA simply provides a means of helping committees achieve greater clarity on their collective views about the criteria and the weight they attach to them. Further, it is possible that there is a degree of conservatism around moving away from the simple cost-per-QALY system of decision making, which is well accepted and widely implemented. Indeed the QALY-based system has been a huge achievement, and so it is understandable to some extent that moving away from it causes nervousness. However, as noted earlier, QALYs clearly do not take into account everything of importance in HTA, so moving towards structured decision making is a natural next step in the evolution of improved HTA processes. Finally, there are still some methodological issues that remain: for example, there is no universally accepted view on which criteria should be chosen, how weights should be calculated, or how uncertainty should be incorporated. Indeed, there is unlikely to be one solution that fits all HTA agencies. Some of those issues still to be addressed are summarised in Figure 4.

Figure 4. Issues to be addressed in the context of HTA

Criteria	Weights	Uncertainty	Budget constraint
<ul style="list-style-type: none"> Established in advance. The same across all decisions? Or varying from case to case? How to establish a legitimate set of criteria? Current practice in HTA? Stated objectives of the health care system? Consultation with the general public? 	<ul style="list-style-type: none"> Whose preferences should be used to establish the weights/trade-offs? Weights to reflect the views of those in HTA committees – or supplement these with quantitative evidence (stated preferences) of patients, the general public? 	<ul style="list-style-type: none"> Uncertainty a separate criterion – or uncertainty handled via sensitivity analysis? 	<ul style="list-style-type: none"> How to reflect cost? Separate criterion, as in EVIDEM? Or MCDA to create a composite measure of value, to be weighed up against cost? How is opportunity cost to be addressed in decision making involving multiple criteria? What are the implications for the cost-effectiveness threshold?

Conclusions and next steps

Structured decision making approaches can offer considerable advantages in HTA by providing a coherent and unifying framework for decision-making about new health care technologies. Further work is required in the field of MCDA, specifically around establishing appropriate methods and addressing methodological questions relating specifically to the use of MCDA in HTA. In order to support the global community in implementing MCDA, a framework needs to be developed that supports judgement, and helps judgement to be exercised in an explicit and consistent way. The specific approaches that work best will vary depending on the sociopolitical characteristics of the health care system. However, given its advantages, we must move beyond asking "can we do this?", as it clearly is feasible to use MCDA in HTA, to asking "what does a successful HTA decision-making process look like from the decision maker's point of view?". Finally, we must recognise that implementing a new decision-making framework is likely to impose costs and well as benefits, and we must ensure that any framework used going forwards is evaluated to ensure it makes the best use of the available resources.

4. USING HTA FOR LEGITIMATE REIMBURSEMENT DECISION MAKING

Dr Wija Oortwijn, ECORYS, the Netherlands.

Dr Oortwijn built on the topics introduced in the previous presentation, and shared the experiences of the Dutch appraisal committee, including the steps taken in finding the best way to conduct a "deliberative process" in HTA.

Introduction: health system challenges

Health systems across the globe are struggling with the objective of delivering health care that is of high quality, innovative and sustainable, while managing constrained health care budgets, and safeguarding equity, access and choice. Prioritisation decisions are required to determine the allocation of scarce resources.

Dimensions of this allocation issue include, for example, spending on health care in relation to other public needs, how to prioritise individual health interventions, who should be allowed access to health interventions, and what criteria and considerations should be taken into account to make these decisions. HTA can support this decision making.

Elements of decision making in HTA

Criteria for decision making in HTA generally include health outcomes and economic data, often summarised into an incremental cost-effectiveness ratio (ICER) and/or budget impact. However, increasingly, HTA agencies are recognising the need to incorporate other criteria, such as ethical, social/cultural and legal issues. Yet HTA still has certain limitations when assessing health interventions which perform differently depending on the way they are implemented and/or which may have different effects on different patients/consumers. These further considerations are often indirect and can be unintended; nevertheless they should be considered to allow value-based decisions to be made. While these factors are recognised, there is generally low transparency in how decision-making criteria or information are utilised (Tanios et al., 2013).

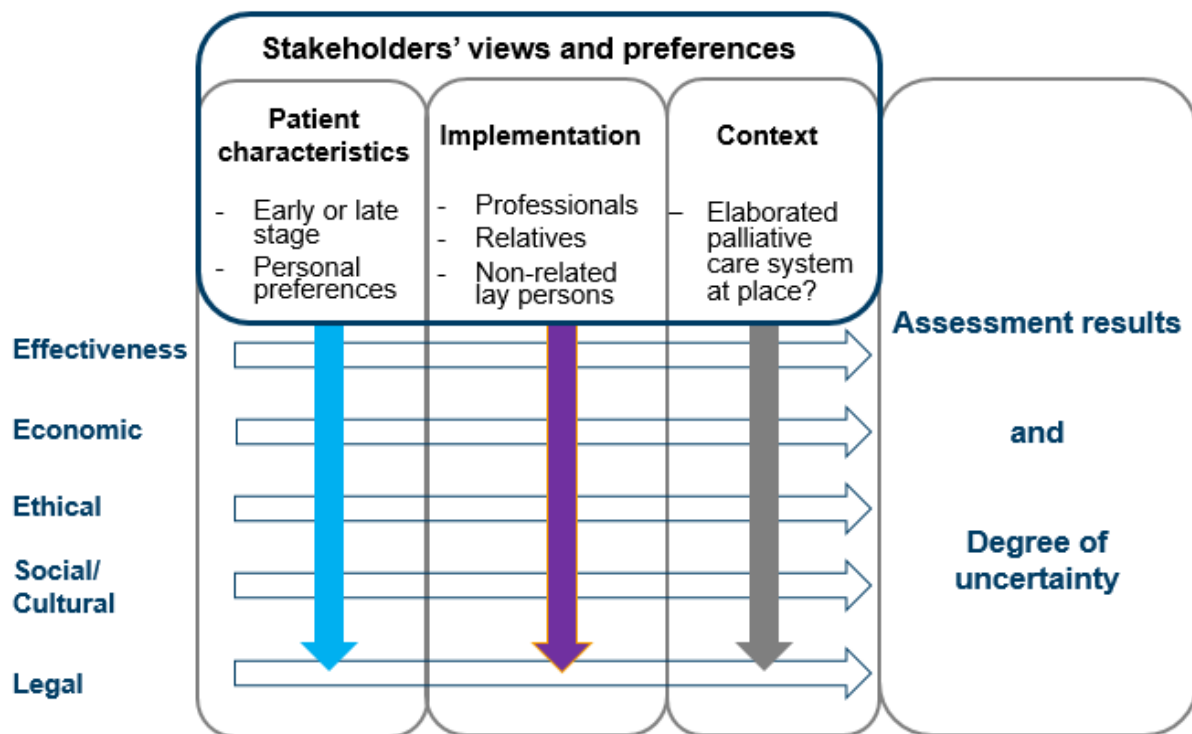
Palliative home-based care offers a good example of the multiple dimensions that should be considered in HTA. These include

- Patient characteristics and preferences. Early or late stage? In pain? In despair? Family around?
- Comparator. Another complex health intervention?
- Topics for assessment. Cost-effectiveness, social, cultural, legal impact? Impact on relatives?
- Outcomes. >500 outcome parameters, e.g. quality of life, spiritual improvement, etc.?
- Implementation. By a nurse? A doctor? A relative? At home? In a hospice?
- Context. Rural area? Degree of professionalisation of service?

Patient characteristics, implementation and context all represent modifying factors, which, as well as being important in their own right, may influence the effectiveness and even cost of an intervention. In addition, HTA usually assesses and appraises aspects side by side while decision making needs an integrated perspective on the value of a health intervention (Gerhardus, 2016).

This is presented graphically in Figure 5.

Figure 5. Incorporating modifying factors and stakeholder views in HTA



The question is *how* to successfully integrate the different dimensions in HTA, for which there can be several approaches, including MCDA approaches, analytic approaches, preference-elicitation approaches and consensus methods (Wahlster et al., 2015).

The Dutch experience

There are a number of principles, established by government, which guide decision making in the provision of health care in the Netherlands: (1) equal access for all citizens, (2) solidarity (no risk selection and obligation to insure) and (3) ensuring quality of life. According to the Ministry of Health (MoH), "less essential care ought to be removed from the basic benefit package". Social values are implicit within the guiding principles, but it is not always clear how or if these link together, and how they should be used within decision making.

The National Health Care Institute (ZIN) is an authority which advises the MoH on the inclusion or exclusion of health interventions in the "benefit package". Both the assessment and appraisal of health interventions are coordinated by ZIN. The MoH has to take into account the boundaries of the health care budget (i.e. limited growth), but this is not necessarily within the remit of ZIN. Ideally, the remit of the HTA agency would align with the objectives of the decision maker. When this is not the case, even if the HTA process itself is fair and transparent, there could still be inconsistencies and inefficiencies in decision outcomes.

The criteria for appraisal include

- Necessity: does the illness or the required care justify – given the context in society – a claim for solidarity?
- Effectiveness: does the intervention do what is expected of it?
- Cost-effectiveness: is the ratio between costs and effects – from a societal perspective – acceptable? This is dependent on the burden of the disease.
- Feasibility: is the inclusion in the benefit package feasible, now and in the long term?

These criteria apply to all health interventions and feed into the appraisal. However, interpretation, and therefore application, of the criteria are not always straightforward and may change over time. For example, consider necessity: in stating that less essential care ought to be removed from the basic benefit package, the MoH have not made absolutely clear what is meant by "essential care". Oral contraceptives have been included in the past, but were excluded from the benefit package in 2004 as they were deemed "not essential" care. In 2007 they were successfully reintroduced following political arguments, but in 2011 were excluded again for those aged over 21, as they were deemed non-essential care for those patients (Kroneman and de Jong, 2015). It seems, therefore, that in some cases political arguments can overrule the appraisal criteria.

In addition, cost-effectiveness criteria do not appear to be applied consistently, or else cost-effectiveness criteria conflict with other criteria and the decision-making rules in such circumstances are not transparent. For example, a treatment for Pompe disease had an unfavourable cost-effectiveness ratio but was included under the principle of solidarity, yet Viagra, which demonstrated good value for money, was not reimbursed as it was considered to be a "lifestyle" drug. This has created confusion around how decisions are made and the fair allocation of resources. It is apparent that appraisal committees struggle with defining and applying the criteria within the deliberative process.

Towards a framework for decision making

Optimally, we should have a transparent system that is consistently applied, with equal participation of different stakeholders. Daniels and Sabin (2008) developed a framework (the so-called Accountability for Reasonableness (A4R) framework) that includes these principles.

The Dutch appraisal process has adopted the principles of A4R that is focused on procedural justice. It is very important to understand the context, including how and why decisions are made, how criteria are defined, and what the ethical considerations underlying the criteria are. It is also important to understand whether and how these align with the guiding principles of the health care system. A future which facilitates this could be the application of MCDA for certain criteria, or even MDAA: multi-decider argumentative analysis.

5. APPLICABILITY TO ASIA OF "NEW AGE" DECISION MAKING: THE KOREAN EXPERIENCE

Prof. Eui-Kyung Lee, Sungkyunkwan University, Korea.

In this talk Prof. Eui-Kyung Lee shared experience in and insights into the Korean system and the Korean experience of decision making and HTA.

HTA for new drugs in Korea

In 2006 a new pharmaceutical reimbursement system was introduced in Korea which represented a move from a negative listing to a positive listing system (PLS). This change introduced the use of cost-effectiveness as a "fourth hurdle" beyond safety, efficacy and quality. Further, submission of pharmaco-economic studies became mandatory in 2008, in order to achieve a premium price for a "clinically superior" drug. The introduction of HTA has contributed to a shift from opinion-based to evidence-based decision making in Korea, where scientific evidence is reviewed through a "social-values lens" in order to arrive at a decision on listing.

The decision-making process is split into two parts:

- **(1) Reimbursement stage.** The manufacturer or the importer submits an application to Health Insurance Review & Assessment (HIRA), who review applications and send these to the Drug Reimbursement Evaluation Committee (DREC), which is an independent review committee. Many factors are included in the appraisal process, which lasts up to 150 days, such as clinical utility, cost-effectiveness and reimbursement status in other countries, amongst others. While multiple criteria are taken into account, this is not through any formal type of MCDA. The process is not always transparent or systematic.
- **(2) Price negotiation stage.** The National Health Insurance Service (NHIS) starts the price negotiation, which takes up to 60 days, and is passed through the Health Insurance Policy Deliberation Committee, who agree to list the product. Again, multiple factors are taken into account, such as budget impact, prices in foreign countries (particularly OECD, Taiwan and Singapore) and domestic R & D costs.

In 2002 the share of pharmaceutical expenditure as a proportion of total health expenditure was 25%. This increased to nearly 30% in 2008, but then decreased again following the introduction of HTA (the PLS), and other policy measures for drug

expenditure rationalization. In addition, Korean drug prices were around 74% of the OECD average (adjusting for purchasing-power parity) before the new system was introduced, and have fallen to 62% since the introduction of the PLS. This indicates that the new system appears to have reduced pharmaceutical expenditure and placed a downward pressure on prices.

A recently published article by Bae et al. (2016) examines the eight-year experience of using HTA in drug reimbursement in South Korea. The authors consider the reimbursement decisions to date and corresponding acceptance rates, finding an overall acceptance rate of around 69%. The acceptance rate for drugs with proven clinical superiority (68%) is lower than that for drugs which are proven to be non-inferior/similar (74%). This is likely to be due to the structure of the system: non-inferior drugs must be submitted at lower prices and do not require economic evaluation, while the "superior" drugs must pass through a longer and more complicated process which incorporates full economic evaluation.

The study also reported the results of a survey of approximately 100 industry and non-industry representatives, eliciting their opinions on the current HTA and decision-making system. Unsurprisingly, the results differed markedly between the two groups (Bae et al., 2016). For example, 49% of non-industry respondents thought the decision-making process was transparent, versus 22% of industry respondents. Some 32% of non-industry respondents agreed that the process and reasons behind decisions are open to the public, compared with only 6% of industry respondents. Some 61% of industry respondents indicated that the goal of PLS was cost control, versus just 21% of non-industry respondents. Whereas 76% of non-industry respondents selected "value-based decision-making" as the primary goal of PLS, only 25% of industry respondents selected that option. Finally, 60% of industry respondents felt that access to medicines had deteriorated since the introduction of PLS, versus 33% of non-industry respondents (Bae et al., 2016).

Perhaps MCDA, or structured decision making, could be used as a tool to improve the process, increase transparency, and generate some consensus across these different groups.

Policy measures for better access: actions in Korea

Following the introduction of HTA, there have been some concerns around access to new drugs in Korea. Various policy measures have been introduced to address the access problem, including: (1) the rule of rescue for essential drugs, (2) a flexible ICER threshold, (3) risk sharing and (4) exemption of pharmaco-economic evaluation.

1. Rule of rescue for essential drugs

In order to ensure accessibility to "medically essential" drugs, no cost-effectiveness evaluation is required and there is no price negotiation. However, it is very difficult to obtain the status of "medically essential" drug, as criteria are strict. There must be no alternative treatments; the drug must treat a severe life-threatening disease; it must be for use in a minority of patients, e.g. for a rare disease; and it must be proven to lead to a clinically meaningful improvement in outcomes. Only 4% of drugs (10/253) achieved this status between 2007 and 2014.

2. ICER threshold: fixed versus variable

Cost-effectiveness decisions in Korea are based on an implicit ICER threshold of \$20,000/QALY. This has meant that access to some new drugs has been limited,

particularly highly priced drugs for cancer or rare diseases. Therefore, since 2013, a higher threshold may be acceptable for drugs treating severe or rare diseases, and for treatments used at the end of life. This signifies a paradigm shift, from equal opportunities to access care for all patients (using a fixed threshold) to higher opportunities to care for some patients, e.g. those with severe conditions or large unmet need.

3. Risk sharing

Patient access programmes can be introduced for the medically important drugs which are less cost-effective or subject to higher uncertainty. Nine risk-sharing agreements are currently active in Korea. Eight of these involve discounts, whereby pharmaceutical companies refund the gap between list price and actual reimbursement price to NHIS. Drugs under this scheme currently are Cetuximab, Lenalidomide, Enzalutamide, Crizotinib, Eculizumab, Pirfenidone, Galsulfase and Soliris. One drug (Clofarabine) is currently under an agreement of coverage with evidence development.

4. Exemption from pharmaco-economic assessment

Exemptions apply for drugs for rare diseases or otherwise unmet need, or diseases where it is difficult to produce evidence. The drug must also be reimbursed in at least three of the "A7" countries: the USA, the UK, Germany, France, Italy, Switzerland and Japan. In such cases, the price is set at the lowest price of those seven countries. In addition, new drugs that accept 90% of the average weighted price are exempt from NHIS price negotiations. However, as with the rule of rescue, it is difficult for drugs to fulfil all of these criteria.

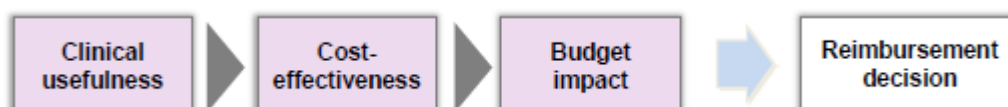
These policies, along with the HTA processes introduced, demonstrate that the Korean government has made significant efforts to improve the prioritisation process through the adoption of HTA and cost-effectiveness analysis. However, there are still many more elements of a holistic decision-making framework that are not considered.

Beyond value for money

A pertinent question for HTA agencies is: should HTA focus on value for money, or should it aim to address a broader set of objectives? It is evident from the introduction of the further policies to improve access, as described, that value for money is not the only criterion which is important in Korea. HTA must balance multiple competing values, including value for money, ensuring access, providing incentives for innovation, assuring equity for all patients and striving for fairness. The engagement of stakeholders should also be pursued, including the general population, patients, health providers and industry.

Another issue, which must be revisited if we are to move beyond value-for-money considerations alone, is the process of decision making. In Korea decision making is currently undertaken using a sequential step-by-step approach, as outlined in Figure 6. Cost-effectiveness is a significant hurdle, and is the only criterion for which there is an explicit decision rule (ICER versus cost-effectiveness threshold).

Figure 6. Step-by-step approach to decision-making



In reality, it can be difficult to capture all aspects of patient benefit in an economic evaluation, and important treatments of high value to society could be ruled out based on the cost-effectiveness criterion alone. An alternative, more holistic approach using MCDA could allow decision-makers to consider a wider set of explicit criteria at the same time and consider the trade-off between these (often conflicting) criteria, to enable a more complete assessment of value. This is pictured in Figure 7.

Figure 7. Holistic approach to decision-making



Source: Ko (2013) – Panel session at HTAi 2013, Seoul

In Korea, MCDA has begun to be considered at an academic level and some preliminary research is ongoing. Lee (2014) studied the preferences for decision criteria for cancer drugs, generating a weighted rank of disease severity, unmet need, population size, budget impact, clinical benefit, cost-effectiveness, innovation and therapeutic need. However, weights differed according to what method was used to elicit preferences (a discrete choice experiment versus the analytical hierarchy process). Therefore the results were inconclusive and methodological challenges remain. It is also unclear whether the criteria should be general or case-specific, and how uncertainty can best be captured.

Conclusion: "New age" decision making in HTA: is it applicable in Korea?

The HTA environment in Korea is changing. The challenges of providing better access are receiving more attention, insurance coverage is strengthening, and the future vision for the pharmaceutical industry is one that recognises its potential to contribute to economic growth. The determinants of value in HTA are closely linked with the socioeconomic and political environment, the health care system and the pharmaceutical industry. The HTA infrastructure must support these multiple perspectives as well as provide the necessary resources in terms of manpower, patient data requirements and basic scientific training and expertise.

In the future, broader social value will be considered. There is also an appetite to consider preferences from all "fair-minded" stakeholders, which is represented in the Accountability for Reasonableness (A4R) framework. This includes the preferences of the general public as well as patients. Indeed, there have been recent changes to legislation on patient safety, and patient involvement in HTA is growing.

Overall, MCDA and other techniques for structured decision making could be very positive for Korea. However there are still challenges to implementation, and few foreign experiences to learn from. Methodology options are diverse, ranging from quantitative approaches which require high levels of expertise, to qualitative or semi-quantitative

approaches which might offer a decision tool based on a checklist for rapid assessment. It is clear, however, that MCDA can be used as a supplementary tool to complement HTA and support the decision maker.

6. PANEL DISCUSSION

The panel session presentations were followed by panel and audience discussion. These are summarised by theme below.

Differences in perspective: HTA versus payers

In the case of the Netherlands, we saw examples of conflicting advice between Ministry of Health (decision maker) and HTA agency (ZIN). While MoH decisions usually follow the recommendations of ZIN, in some cases (for example where a drug would have significant budget impact) there have been differences. There are additional considerations, such as political pressures which could also play a role. In addition, risk-sharing agreements are implemented which are confidential and therefore not transparent; while the price does not necessarily need to be publicly available, the process itself should be.

In Korea, issues of transparency are also a problem with risk-sharing agreements, although such agreements are typically limited to cancer and rare diseases.

Time frame for implementation and leaders in MCDA

No HTA agency currently implements MCDA, but NICE in the UK and ZIN in the Netherlands are making progress in this direction. However, much of the current momentum is generated by academics and researchers in the field, rather than the HTA agencies themselves. There will therefore be a gap before implementation, and HTA agencies need to work with academics to develop approaches to address their concerns. Timelines and acceptability will come down to confidence in the methodology, and the best way to build this confidence will be to work collaboratively. In the UK, there is hope that NICE might be open to such collaboration in the coming year.

From the perspective of the Korean health care system, timelines are very difficult to predict. The introduction of MCDA was a major topic at a recent academic meeting, where the government was positive but expressed reservations around the complexity and interpretation of MCDA. Before implementation, methodological and practical issues must be addressed. In the Netherlands, pilot MCDA studies have been conducted in collaboration with ZIN, and academics have been working with the appraisal committee to discuss the advantages and disadvantages of possible MCDA approaches. Going forward it will be important to stimulate engagement with all stakeholder groups, or else MCDA research will remain an academic exercise.

7. SHARED PERSPECTIVES AND CONCLUSIONS

Methods of evidence synthesis and analysis are well studied within the field of HTA. However, less well researched are the processes and mechanisms for decision making, which should extend beyond clinical and cost-effectiveness alone.

While many HTA agencies have acknowledged that decision criteria beyond cost-effectiveness should be considered, special exceptions or considerations are rarely incorporated transparently and consistently.

MCDA offers a way to structure decisions, such that exceptions and trade-offs can be explicit and fully transparent. We have explored how this could improve perceived inconsistencies in current practice in various countries, which also share common challenges in the implementation of MCDA. HTA agencies appear to be reluctant to adopt a fully explicit and pre-specified model of decision making. However, MCDA can support (rather than replace) a deliberative process, by offering a structured and transparent framework for incorporating a broader set of criteria in decision making. First, though, researchers must collaborate with the HTA agencies to understand and ameliorate current reservations, and to overcome the methodological challenges that remain.

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