THE UNIVERSITY OF TOKYO

ELABORATING DELIBERATIVE AND ALGORITHMIC PROCESS IN DECISION MAKING OF HEALTH TECHNOLOGY ASSESSMENT

Siti Sari Septiani

511 68209

Academic Advisor: Professor Isao Kamae

Paper Due Date: May 17, 2018

CONTENTS

ABSTRACT

The rising costs of new medicines and limited health care budgets for public health increase the need to rationalize allocation of public resources. Policy makers are faced with the challenge to decide which health technologies to invest in. In response to this, health technology assessment (HTA) appears to become an aid to thought which helps government to prioritize on what the publicly funded health system should provide in terms of universal care and system priorities of specific programs. HTA proposes well-grounded considerations in decision making to optimize resource allocation driven by medical innovation for those who are affected by specific ill health on the one hand, and resource allocation for the broad population on the other hand.

The effectiveness of a good process employed in HTA as a way of making good decisions is so far to be verified. Deliberative process in the priority setting of health care is effective, relative to algorithmic, in producing fair and legitimate decisions. This study objective was to evaluate the theoretical position, in an empirical approach, that deliberative process can produce fair decisions on applying new technologies in health care.

Regarded as priority setting in health care allocation, HTA is aimed to set fair and legitimate decisions. To get fair outcomes, fair process is inevitably required. Daniel & Sabin define the criteria of fair process named accountability for reasonableness, which consists of transparency, relevancy, appeal, and enforceability. When the process embraces these criteria, it is counted to secure the fair outcomes. The effectiveness of deliberative and algorithmic process in delivering fair decisions is measured by using accountability for reasonableness framework.

The HTA agencies selected for this study, the UK National Institute for Health and Care Excellence (NICE) and Australia Pharmaceutical Benefits Advisory Committee (PBAC), are from developed countries, where HTA processes has been established extensively, and thus are considered to be mature. The processes employed by these countries are considered to represent the exemplar of deliberative and algorithmic, even though in the complex process of HTA, neither countries adopt algorithmic nor deliberative process altogether. Deliberation could have been embodied in the algorithmic process and vice versa. HTA itself is performed in the sequence of stages, each of which may consist of more than one steps. The UK NICE was chosen as the one embracing algorithmic process due to its heavy reliance on

incremental cost-effectiveness ratio (ICER) threshold, which plays a significant role in decision making by NICE. Whereas PBAC represents agency using deliberative process since it allows participation of stakeholders in decision making to carefully consider not only a scientific evidence, but also social values. The processes of NICE and PBAC are then analyzed with accountability and reasonableness criteria to perceive which amongst the two is a fair process leading to fair outcome.

INTRODUCTION

It is recognized unanimously that the fundamental problem in economics is concerned with scarcity. The infinite wants are faced with finite means. In health economics, this proposition becomes more challenging in the evolving world with growing needs of aging population and the ever-increasing cost of research and development. Confronting this fact with limited resources, policy makers encounter difficult choices to decide which health technologies to invest in.

In response to this, health technology assessment (HTA) appears to become an aid to thought which helps government to prioritize on what the publicly funded health system should provide in terms of universal care and system priorities of specific programs. The International Network of Agencies for HTA describes HTA as a systemic evaluation of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, aimed mainly at informing decision-making (1). HTA proposes well-grounded considerations in decision making to optimize resource allocation driven by medical innovation for those who are affected by specific ill health on the one hand, and resource allocation for the broad population on the other hand. HTA is also in favor of the global agenda of universal health coverage as a priority-setting mechanism to inform coverage decisions for health benefit packages. From political perspective, the rise of HTA is the embodiment of technocratic fix to resolve public issues by scientific measures and procedures rather than by elected individuals' judgment (2).

Each HTA agency has different scope and methodology to execute the process based on affordability, social, and political rationales which are unique to each jurisdiction. It is likely that we can see some convergence in the methods, or at least further collaboration, but throughout case studies conducted by Odonnell et al. regarding the implementation of HTA around the world, it is confirmed that no one model could be universally applicable or even acceptable to all societies (3). Due to difference in emphasis in each country and since the method of HTA continues to develop, it is unsuitable to compare which jurisdiction accomplish better decision on a methodological basis. In the field of HTA, we can find majority research focused on the configuration of the systems but few research on outcomes. The effectiveness of a good process as a way of making good decisions is so far to be verified. A better process would be useful to set better decisions. In the decision making regarding the value of medicines, two types of challenges acknowledged other than technical

evidence; scientific uncertainty and value judgments, that should be taken into account using deliberative or algorithmic process. Deliberative process in the priority setting of health care is effective, relative to algorithmic, in producing fair and legitimate decisions. This study objective was to evaluate the theoretical position, in an empirical approach, that deliberative process can produce fair decisions on applying new technologies in health care.

METHODS

The central puzzle of this paper lies on the question of 'what is a better process' and 'how would we recognize one' in HTA. The process itself has three key features. It is a means by which evidence is generated or brought before decision makers, a means to enable wisdom and experience of other decision makers to be brought to the table, and a means to ensure that distinct views are properly represented to minimize the chances that any particular interest group should unfairly capture the process (4). A deliberative process is a process that allows a group of actors to receive and exchange information, to critically examine an issue, and to arrive at an agreement that informs decision making (5). It is characterized by the careful consideration and discussion of the advantages and disadvantages of various options (6). It departs from the presumption that evidence is completely authoritarian, and hence people's judgment must be involved to appraise the evidence (7). Experts and stakeholders work to bridge the world of scientific research and policy making and participate in the decision making itself. At the highest level, deliberation has been seen as a desirable attribute of democracy (8). As tool of democratic governance, deliberative process involves civil society as well as various actors affected by policy.

In contrast to deliberation stands the algorithm; a process which allows translation of evidence into decision through a sequential fashion. An algorithm is a systematic mathematical procedure sequentially linking various strands in a decision problem to an outcome (7). The procedure designed to perform a process has already been made where subsequent step depends on the outcome of the previous one. Algorithm, by its nature, is suitable for solving structured problems as the same output will be produced with the same input. In HTA, when decision makers specify that a quantitative result generated from calculation of health outcome with and without treatment serves as premise to decide recommendation, it is an evident practice of

algorithmic process. There is broad recognition that this process is not aimed to be used when value judgment should be held.

In pluralist societies, it is unlikely to get consensus on principles that should govern priority setting. For example, with certain amount of resources, some will prefer to allocate for one person severely in need and others might think of maximizing aggregate outcomes by rationing the utility to more people. To get fair outcomes, fair process is inevitably required. Daniel & Sabin define the elements of fair process in the scheme of accountability for reasonableness (9). A fair process entails transparency about the reasoning and criteria underlying decisions, not just for the members of decision-making group, but for all people affected by the decision. The rationales and evidence that are considered in the process must relevant with the objective to be achieved. Whenever new evidence or arguments are put into perspective, there must be mechanism to challenge and revise the decisions. Following those three conditions is enforcement to make sure that all conditions are met. What Daniel & Sabin concluded as accountability for reasonableness – which consists of transparency, relevancy, appeal, and enforceability elements – is counted to secure the fair outcomes. If the process is fair, there is substantial plausibility to accept the outcomes as fair.

Since it is hard to make the criteria to judge 'the right (or wrong) decisions' in the priority setting of health care, the procedural approach is employed. Because priority setting is a management process, it is possible to measure its performance. To make explicit which process in the HTA generates fair outcome, framing decision process with tools is preferable. This study will measure the effectiveness of deliberative and algorithmic process by using accountability for reasonableness framework.

The HTA agencies selected for this study, the UK National Institute for Health and Care Excellence (NICE) and Australia Pharmaceutical Benefits Advisory Committee (PBAC), are from developed countries, where HTA processes has been established extensively, and thus are considered to be mature. Based on the survey conducted by WHO, high-income countries are most likely to have formal HTA process and make use of the result for reimbursement purpose or to decide what to include in a package of benefits (10). In the middle-income countries, the focus of HTA lies on enhancing capacity building, standardization of methods or development of clinical guidelines (10). They often do not have a clear framework for implementation of HTA

results in decision making process (11). Electronic literature review was performed to get an accurate and factual description of the HTA processes in the selected countries.

RESULTS

The UK and Australia have been at the forefront of the establishment in the field of HTA. The processes employed by these countries are considered to represent the exemplar of deliberative and algorithmic. In fact, even when there is distinct definition, it is almost confounding in practice to account which process is adopted to devise a policy. HTA itself is performed in the sequence of stages, each of which may consist of more than one steps. The stages are usually divided into three phases, following the mostly referred HTA system in the world, the UK NICE. First is the scoping phase, where identification of issue of interest takes place. This may include invitation to interested parties, consultation, and workshop before the final report is referred. In the UK, NICE can only begin to appraise a technology at the request of Secretary of State for Health (12). When the Minister selects the topic suitable for referral, NICE will then develop draft remit and draft scope to be discussed with interested parties before eventually sending the report to the Minister. NICE report will help Minister to decide whether or not the technology should be appraised by NICE. In Australia, the initiation of a technology assessment can be submitted by anyone. Applicant can make a submission to PBAC for inclusion of its technologies in pharmaceutical benefits scheme (PBS) or medicare benefits schedule (MBS) without prior consent from the government (13). Scoping does not take place in many HTA system, including PBAC. The UK NICE has a more thorough yet restricted scoping phase. Second is the assessment phase. In this phase, evidence and information are collected from sponsors and stakeholders and evaluated subsequently through systematic review. NICE seeks relevant evidence from several sources while also receiving principal evidence from the company. The review of this evidence is under the remit of Evidence Review Group for single technology, and Assessment Group for multiple technology (12). PBAC also commissions university-based assessors to review the evidence provided by the company (13). Following the assessment phase is appraisal, where a judgment on whether or not the technology should be recommended will be determined. The Appraisal Committee, the team who is responsible in NICE in this phase, bases its recommendation on the evidence, including statements from

consultees and commentators, and the view expressed by clinical specialists, commissioning experts and patient experts at the Committee meeting (12). The concept underlying the decision made is that of the opportunity cost of program that could be displaced by the new technologies. NICE established Citizen Council, a group of 30 people drawn from all walks of life who bring the public's view to NICE decision-making (12). NICE has an explicit incremental cost-effectiveness ratio (ICER) threshold to base the decision (£20,000-£30,000 per QALY gained). NICE guidance legally binds NHS England, clinical commissioning groups, and local authorities to comply with positive recommendation and provide the technology within three months after the published date (12). In stark contrast to NICE, PBAC has no fixed threshold, no reference case to specify the method used in economic evaluation, and non-binding recommendation. PBAC's decision is based on five quantitative factors (comparative health gain, comparative cost-effectiveness, patient affordability, predicted use in practice and financial implication for pharmaceutical benefits scheme and budget impact) and less-readily quantifiable factors (confidence in the evidence, equity, severity, presence of alternatives, ability to use the technology to patients likely to benefit the most, public health issue, and any other relevant factors) (13).

In the complex process of HTA, neither countries adopt algorithmic nor deliberative altogether. Deliberation could have been embodied in the algorithmic process and vice versa. For example, the determination of threshold might have been reached earlier in the deliberative stages, or weighing the evidence in the systematic review through discussion. Even if algorithm has had deliberation embodied in its construction, it is not necessarily regarded as deliberative. In the case of NICE, they allow information exchange between stakeholders and involve comments and consultation as well. In the Appraisal Committee, there is a lot of interchange that enables consideration of all relevant matters, though it may not always be used. Nonetheless, neither comments nor consultation involves mutual deliberation because the commentators and consultees are not engaged in the decision making. The use of QALY as the main outcome measure indicates NICE's proclivity to endorse algorithm. As the guidance explicitly puts it, "*an additional QALY should receive the same weight regardless of the other characteristics of the individuals receiving the health benefit*" (12), it implies that with the same input information, the same output will be produced, which is the property of algorithmic process. Some papers which analyzed the pattern of decision making by NICE show a consistent result that NICE

reckons on thresholds. An increase in the ICER increased the odds of non-recommendation, and this effect was highly statistically significant (14, 15, 16). PBAC also employs formulaic methods in the economic evaluation but no prior reference was made to build the decision. It has no definite beginning and end in the process as more criteria are taken into account in the decision making. From the upstream process, various actors are allowed to jointly define the problem and scope of the research, not merely under direction of health authority.

The processes of NICE and PBAC are then analyzed with accountability and reasonableness framework to perceive which amongst the two is a fair process leading to fair outcome, and the result is summarized in Table 1.

ACCOUNTABILITY FOR REASONABLENESS CRITERIA	NICE	PBAC
Transparency The decision and its rationales must be open to all people affected by the decision.	- The process is well-structured with opportunities for stakeholders to provide input. - Key documents published at the website for each phase. - The economic model was limited to public. - Adoption of commercial-in-confidence and academic-in-confidence data.	- The criteria underlying decisions are explicitly stated in the Guideline. - Provision of public summary documents. - Providing explanation & justification of the decision.
Relevance Fair-minded people should accept many kinds of evidence and reasons as relevant.	- Reliance on cost-effectiveness criteria with explicit thresholds. - The establishment of Citizen's Council to discuss social values.	- Considering five quantitative factors and some less-readily quantifiable factors. - "Rule of Rescue" criteria
Appeal There is a process to reopen deliberation for those affected by decisions and thus offering decision makers an option to revise the decisions.	- Restrictive appeal provision. - All consultees have the opportunity to consider an appeal against the final recommendations, but not commentators.	Any applicant whose submission to the PBAC has not resulted in a positive recommendation to list or extend the indication of the pharmaceutical on the PBS can make a submission to the Independent Review process.
Enforcement There must be some means of ensuring that the first three conditions are met.	N/A	N/A

Table 1. Comparison of HTA process conducted by NICE and PBAC based on accountability for reasonableness framework.

Transparency

NICE has a clear schedule for each phase and publishes most documents on the website (the guidance, list of consultees and commentators, Assessment Group Report, and final appraisal determination). Some documents are not made public, for example the economic model. Read-only copies of models are provided to consultees and commentators upon their request in writing, with the caveat that they must not publish the model wholly or in part and are not permitted to re-run the model with alternative assumptions or inputs (12). Other unpublished documents are commercial-in-confidence and academic-in-confidence data. The underlying reason is that public disclosure could have a significant impact for the companies or researchers. NICE's commitment on openness and transparency is shown by opening Appraisal Committee Meeting to members of the public and press, although from two sessions of meeting, only one session is overt for public.

PBAC's publicity records are provided in the form of Public Summary Document (PSD) available on the Department of Health website, which includes a requested listing, evidence, the recommendation and its basis. The criteria considered for recommendation are explicitly stated in the Guideline. Other than PSD, PBAC provides explanation and justification of the decision, which may involve a two-way dialogue occurs during multiple stages of the assessment process.

Relevance

The fundamental principles underlying NICE decisions are clinical- and cost-effectiveness. Although other criteria are also mentioned to be considered by Citizens Council, there is a heavy reliance on cost-effectiveness with explicit threshold. NICE seeks to maximize the health benefit gained from a fixed NHS budget by applying efficiency-first approach through cost-per-QALY threshold. The main argument of using threshold is that it may uphold consistency in decision making, and thus leading to a more equitable outcome across many technologies that NICE appraised (17). The threshold is also an indication for manufacturers about the amount the payer wants to reward their research and development (17).

The criteria used by PBAC in their decision making are more extensive. They realized it is difficult or perceived undesirable to quantify some criteria across technologies or contexts. The practice of Rule of Rescue is a manifestation of social value inclusion in the judgment, that is to rescue individuals in severe condition or

facing avoidable death, with disregard for the opportunity costs of doing so. NICE, on the contrary, thinks that the need of individual patients must be weighed with the need of present and future users of the NHS.

Appeal

Both agencies provide appeal mechanism, but NICE has restrictive appeal provision. There is only relatively short window of opportunity since new evidence or simply disagreement with the recommendation will almost certainly not be accepted. This opportunity is precluded by condition that appeal should be submitted in writing within 15 working days after the issuing date of recommendation. It is not exaggerated to conclude that NICE has restrictive appeal mechanism if we pair this tight timeline with hundred-page appraisal report (in some cases it could reach more than 600 pages) and limited transparency of economic model and some data. Despite plentiful opportunities for stakeholders to participate in the process provided by NICE, commentators, which consist of broader elements than consultees, do not have an opportunity to raise an appeal against final recommendations.

In Australia, there is an Independent Review team under the Pharmaceutical Benefits Scheme (PBS) who provide an opportunity to anyone whose technologies were not granted positive recommendation by PBAC or when PBAC has declined to recommend an extension of the listing of an already listed drug. Applicant can lodge an appeal anytime and this independent process will follow structured schedule managed by a convenor, who is responsible for ensuring the efficient conduct of each review.

Enforcement

There is no hint that NICE and PBAC have certain mechanism to assure the first three conditions above. Even though there are persons with specific function to ensure that certain phase is conducted in accordance with the guideline like Program Director in NICE and Convenor in PBAC, it is not an implementation of quality assurance system suggested by Daniel and Sabin in their framework. According to them, a proper enforcement should be implemented to ensure that the framework is not merely a theoretical exercise. This could be voluntary or public regulation (9).

DISCUSSION

HTA is regarded as priority setting in health care. The goal of priority setting is fairness (18) and in attempt to achieve it, a fair process must be adhered. In a fair process, involving multiple perspectives is important. Although having a wide-range of individuals may challenge the process with competing objectives regarding their vested interests, this inclusiveness will identify relevant values, improve understanding of each other's values, and at the end achieve a maximum coherence (19). So, instead of directing the discussion to reach mutual consensus, a shared understanding of the issues is expected to create a sense of common purpose. Both NICE and PBAC are very well in engaging related stakeholders and community views into the process. Citizens Council was established by NICE as a means to gather social values. But when this is fed into an algorithmic process, the social and ethical discussion from public engagement are not accorded as much attention as scientific evidence. In HTA, there are three types of input; scientific evidence, social values, and uncertainties (7). Deliberative process is useful where there is uncertainty about technical evidence or where issues relating to fairness and value judgment need to be taken into account. In addition, deliberative process excels the algorithmic in this context since it sets a conducive situation to facilitate learning amongst stakeholders by understanding the different ways in which they frame the policy problem, and hence acceptance by multiple stakeholders could be reached. Without social interaction along with scientific evidence, HTA will not be an effective aid to priority setting.

In the accountability for reasonableness framework, participatory approach is regarded as important but not sufficient. It must be performed in a transparent way. The more inclusive and transparent the process, the more legitimate it will be. This is even more crucial as legitimate decision is another objective of priority setting (19). In attempt to build a transparent process, NICE and PBAC provide the public with information on their websites regarding the criteria, evidence and guideline, as well as opening the meetings to public and press. Some of NICE's documents do not suffice to public. Even though the underlying reason of public disclosure limitation may be reasonable, this might prevent public academic debate or advance to the methodology used. However, people would reasonably accept the fact that NICE is a legitimate authority for HTA recommendation, but abandoning the fair procedure could render the issue of distrust because trust does not automatically come with authority (9). The idea of legitimacy itself is to enforce compliance and avoid opposition to the decision.

Transparency of the process will build social acceptance of policy making structures, and hence maintain the legitimacy.

To achieve acceptance and compliance, decision makers must also bring the reasons that can be recognized as relevant and appropriate in order to justify to all who are affected by the decision. Both NICE and PBAC consider clinical and cost-effectiveness, but NICE maintains its heavy reliance upon cost-effectiveness by adopting a cost-per-QALY threshold. It arguably causes marginalization of other factors like social values. Relevancy means that all reasons are acknowledged appropriately by both advantaged and disadvantaged groups. In light of algorithmic process, all groups have to accept the provision for whatever reasons, in this case the threshold. On the deliberative view, no party is coerced to accept something for reasons that they think irrelevant. In this process, evidence is the key to inform stakeholders' understanding. Deliberative process is suitable to combine and interpret the different types of evidence (qualitative, quantitative, opinion, experience, traditions, case-studies, etc.). Since all evidence involve judgment and no single evidence is totally authoritative, evidence-informed decision making is much to be preferred than evidence-based decision making in HTA deliberative process. The implementation of rule of rescue in Australia is an example on how deliberative process is likely to capture social preference. Empirical data suggest that the public places a very high value on giving everyone a chance at receiving scarce resources, even if it is associated with a significant loss of efficiency in terms of maximizing total benefit (20). By virtue of maximize the minimal (maximin) position, Australia health authorities show that cost-utility analysis is necessary but should not be the sole basis in decision making.

The possibility to achieve fair outcomes, as a goal of priority setting, is not closed when the decision has been stipulated if the appeal mechanism exists. It aims to respect those whose views may not have been heard in the process and to revise decision in light of counter arguments. It seems that NICE strategy is to open an extensive stakeholders' opportunities in the beginning of the process and to narrow the challenge on decisions. This way may work well for the first aim, which is trying to minimize missing input of information and argument. But the emergence of new input or change in societal value will hardly find its way to penetrate NICE system. It is not only because lodging an appeal based on new evidence or simply disagreement will almost certainly not be accepted, but also some reasons underlying the original

decision are not publicly accessible. Even when a window of opportunity is open, the chance to undergo the route back into policy formulation process will be difficult without giving a balance weigh on some reasons underlying the decisions. This shows us that appeal mechanism would be able to exercise its purpose as element of fair process if the prior conditions are met (transparency and relevancy). All three conditions should, therefore, be ascertained take place in the process through enforcement mechanism, although this is not noticeable in NICE and PBAC. The existence of enforcement may not be captured from the guidelines of both agencies if the type is voluntary.

CONCLUSION

HTA, as an aid in priority setting, integrates different kinds of information and feeding these into the process. A fair process is believed to bring about fair outcome. Accountability for reasonableness framework proposed by Daniel and Sabin provides a measure by which the fairness and legitimacy of priority setting in health care can be evaluated. Deliberative process is preferable to be adopted in HTA since it enables learning process amongst stakeholders which involves not only scientific evidence, but also value judgment and uncertainty to be taken into account. On the other hand, algorithmic process creates a circumstances where decision makers are difficult to maneuver. It is suitable to solve structured problems, for example in a research environment without interaction with social decision making, but not when social values and uncertainty partake in the process.

REFERENCE

1. International Network of Agencies for Health Technology Assessment. Health Technology Assessment (HTA) Glossary. Stockholm: INAHTA Secretariat, Sweden; 2006. Available from: http://aaz.hr/resources/pages/55/INAHTA%20Health%20Technology%20Assessment%20(HTA)%20Glossary.pdf [accessed 3.04.18].
2. Syrett, K. (2016). Expanded HTA, Legitimacy and Independence Comment on "Expanded HTA: Enhancing Fairness and Legitimacy". *International Journal of Health Policy and Management,5*(9), 565-567. doi:10.15171/ijhpm.2016.75
3. Odonnell, J. C., Pham, S. V., Pashos, C. L., Miller, D. W., & Smith, M. D. (2009). Health Technology Assessment: Lessons Learned from Around the World—An Overview. *Value in Health,12*. doi:10.1111/j.1524-4733.2009.00550.x
4. Culyer, A. J. (2016, March 5). Hit Sunt Dracones: The Future of Health Technology Assessment – One Economist's Perspective. Retrieved April 9, 2018, from mdm.sagepub.com
5. Lavis, J. N. (2008). Knowledge Translation for Policymakers. In *CIHR IHSPR / IPPH 7th Annual Summer Institute* Cornwall, Ontario, Canada.
6. Hajer, M.A. and Wagenaar, H. (eds) (2003) *Deliberative policy analysis: Understanding governance in the network society*, Cambridge: Cambridge University Press.
7. Culyer, A. J. (2009, June). Deliberative processes in decisions about health care technologies: Combining different types of evidence, values, algorithms and people*. Retrieved April 14, 2018, from https://www.ohe.org/publications
8. Habermas, J. (1987) *The theory of communicative action*, Vols 1 and 2, Boston: Beacon Press.
9. Daniels N, Sabin J. Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. Philosophy and Public Affairs 1997;26:303-50.
10. WHO. (2015). WHO 2015 Global Survey on HTA by National Authorities. World Health Organization
11. Oortwijn, W., Determann, D., Schiffers, K., Tan, S. S., & Tuin, J. V. (2017). Towards Integrated Health Technology Assessment for Improving Decision

Making in Selected Countries. *Value in Health,20*(8), 1121-1130. doi:10.1016/j.jval.2017.03.011

12. NICE. Guide to the Processes of Technology Appraisal. London: NICE, September 2014.
13. Pharmaceutical Benefits Advisory Committee. Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (*version* 4.4). Canberra: Department of Health, Australian Government; 2013. Available from: http://www.pbac.pbs. gov.au/content/information/printable-files/pbacg-book.pdf [accessed 23.04.18].
14. Devlin, N. and D. Parkin (2004), 'Does NICE have a cost-effectiveness threshold and what other factors influence its decisions? A binary choice analysis', Health Economics, 13(5): 437–452.
15. Dakin, H. A., N. J. Devlin and I. A. O. Odeyemi (2006), '"Yes", "No" or "Yes, but"? Multinomial modelling of NICE decision-making', Health Policy, 77: 352–367.
16. Cerri, K. H., Knapp, M., & Fernandez, J. (2014). Decision making by NICE: Examining the influences of evidence, process and context – CORRIGENDUM. *Health Economics, Policy and Law,9*(04), 435. doi:10.1017/s1744133114000085
17. Pearson SD, Rawlins MD. Quality, innovation, and value for money. NICE and the British National Health Service. JAMA 2005;294:2618–22.
18. Martin, D. K., Giacomini, M., & Singer, P. A. (2002). Fairness, accountability for reasonableness, and the views of priority setting decision-makers. *Health Policy,61*(3), 279-290. doi:10.1016/s0168-8510(01)00237-8
19. Baltussen, R., Jansen, M. P., Bijlmakers, L., Grutters, J., Kluytmans, A., Reuzel, R. P., Wilt, G. J. (2017). Value Assessment Frameworks for HTA Agencies: The Organization of Evidence-Informed Deliberative Processes. *Value in Health,20*(2), 256-260. doi:10.1016/j.jval.2016.11.019
20. Ubel PA, Loewenstein G. Distributing scarce livers: the moral reasoning of the general public. Soc Sci Med 1996;42:1049–55.
21. Towse, A., Devlin, N., Hawe, E. and Garrison, L., 2011. *The evolution of HTA in emerging markets health care systems: Analysis to support a policy response*. OHE Consulting Report. London: Office of Health Economics.

22. Culyer, A. J., & Lomas, J. (2006). Deliberative processes and evidence-informed decision making in healthcare: Do they work and how might we know? *Evidence & Policy: A Journal of Research,* Debate *and Practice,2*(3), 357-371. doi:10.1332/174426406778023658
23. National Institute for Clinical Excellence. Guide to the technology appraisal process (reference N0514) London: NICE, April 2004.
24. National Institute for Clinical Excellence. Technology appraisal process: guidance for appellants (reference N0520). London: NICE, April 2004.
25. Daniels N, Sabin JE. Setting limits fairly—can we learn to share medical resources? Oxford: Oxford University Press, 2002
26. Department of Health. Guidelines for Preparing a Submission to the Pharmaceutical Benefits Advisory Committee (version 5.0). Canberra: Department of Health. September 2016.
27. NICE. Social Value Judgments. Principles for the Development of NICE Guidance 2nd Edition. https://www.nice.org.uk/media/default/about/what-we-do/research-and-development/social-value-judgements-principles-for-the-development-of-nice-guidance.pdf