Special Article

Policy Making and Roles of Health Technology Assessment

Sripen Tantivess PhD*

* *International Health Policy Program, Bureau of Policy and Strategy, Ministry of Public Health, Nonthaburi*

The processes of policy development and implementation in the public sector are complex and dynamic as several actors with different interests are involved. To pursue their benefits, these individual and organizational participants compete with each other, and those with a relatively high degree of power can lead the policy decisions. Results of and recommendations derived from economic evaluation and other forms of health technology assessment (HTA) are expected to have an important role in policy making and professional practice. However, it appears that on many occasions, such scientific evidence is neglected. Complex calculations, arbitrary assumptions, debatable choices of whose perspectives to pursue, difficult-to-understand methods, research designs and underlying philosophy/concepts, and time-consuming processes are claimed as key factors discouraging policy makers and practitioners from making use of HTA findings. Ethical considerations and the perception that HTA-based clinical guidelines undermine professional autonomy are also crucial.

Keywords: *Public policy, Policy process, Health technology assessment, Economic evaluation, Priority setting, Evidence-based medicine, Ethics*

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The effort to examine the appropriateness of health policies and interventions in a systematic way is increasingly apparent at different levels of government: global, national, sub-national and even within health care settings. In some societies, largely in the developed world, health technology assessment (HTA) has been established and accepted as a tool for the better selection, procurement and use of health interventions[1]. At the global level, evaluation of health technologies in different facets, such as the efficacy, safety, implementation feasibility and financial consequences, is undertaken as a crucial step of policy formulation such as in the development of the World Health Organization (WHO) Model List of Essential Medicines, guidelines for prevention and management of diseases, as well as policy recommendations and best practices to address health problems[2]. Furthermore, HTA, as well as other research studies, can have a significant role in evidence-based medicine, which aims to ensure the quality of professional practice through the use of the best evidence currently available in making decisions about health care to be delivered to individual patients[3].

The literature illustrates potential policy utilities of HTA as its findings can be used to advise or inform the approval of pharmaceuticals, vaccines, devices and other technologies; the formulation of health benefit packages for reimbursement and coverage; the priority-setting of and resource allocation to public health programs; and the development of treatment guidelines. However, in real-life policy and professional decisions, HTA results are occasionally neglected, and this scientific evidence therefore, plays a less important role than the researchers and respective authorities have expected. The present paper reviews key features of public policy processes, and also discusses the nexus between policies and research including the evaluation of health interventions. It aims to provide better insights into the politics of policy making and actual roles of HTA in health sector reforms and professional practice.

Correspondence to: Tantivess S, International Health Policy Program, Bureau of Policy and Strategy, Ministry of Public Health, Nonthaburi 11000, Thailand. E-mail: sripen@ihpp.thaigov.net

Fundamental concepts in policy study

The term 'public policy' has been defined differently by different scholars. Among others, Dye[4] describes public policy as *'Anything a government chooses to do or not to do'*. Public policies are the actions of governments including public organizations and individual government officials. The decisions to do nothing, i.e. to maintain a *status quo*, are also regarded as public policies. Generally, it is not difficult to understand the content of a policy introduced to address problems in the public domain. Nevertheless, the more important aspects, which are usually of interest to the general public as well as policy analysts, include why and how governments make decisions on some issues, in particular ways[5].

As policy processes are complex, involving several repetitive and interconnected steps, a stagist model is normally employed by policy researchers. Such an approach divides policy processes into simple phases for analytical purposes. For instance, Hogwood and Gunn[6] propose a framework of discrete stages, beginning with agenda-setting and option analysis, going on to policy formulation, implementation, monitoring, and evaluation. Another helpful model to understand public policy is the so-called 'policy triangle' which suggests the influence of actors and context on the development of policies in particular stages[7]. Actors or policy participants are different in terms of their position, power, roles and interests. Furthermore, different actors, as groups or individuals, command certain degrees of power, and those more powerful than others can take a leading role in policy making to meet their interests[8]. Meanwhile, interactions between policy participants and contextual environment such as economic status, natural disasters, technology, religions, culture, and international regulations can shape public policy content, processes and outcomes[9].

Agenda setting

The role of politics can be observed in every step throughout the policy development and implementation. In the agenda-setting stage, policy makers pay attention to problematic issues, so that the chance for the selection of corresponding solutions increases. Following Kingdon[10], if policy makers do not consider or recognize an issue as a problem, said issue cannot reach the government agenda. The high numbers of afflicted population, prevalence, Disability Adjusted Life Year (DALY) loss, and rapid transmission may draw attention of the public and the government to a disease, and encourage policy makers to seek the corresponding prevention/treatment measures. However, people consider a particular issue and construct it in different ways. As Baumgartner and Jones[11] put it, a condition may be recognized as a public policy problem if it has an image that indicates a demand for the government's intervention. The authors point out that such a perspective resembles what other scholars call 'problem definition'.

In addition, characteristics of available policy options and political factors are important in this phase. Major concerns of decision makers are placed on technical and management feasibility, affordability, social acceptability and the political desirability of policy alternatives. In the absence of an appropriate solution, problematic issues tend to be neglected[10]. Similar to the problems, solutions or policy choices are constructed and interpreted differently. Other than the recognition and definition given to particular issues, social movement, public opinion and shifts in key actors such as the regime and responsible committees/officials are crucial, driving or hampering changes in governments' agenda items. For instance, in HIV/AIDS policy over the past two decades, civil society organizations have gained widening access to medical services and social support for people living with the disease. From the mid-1990s, civic coalitions around the world put forth a strong, concerted effort to encourage international organizations and country governments to scale-up antiretroviral treatment in resource-poor settings[12].

Policy formulation

After the problematic issues reach government agendas, policy formulation is undertaken by governments. In this phase, respective officials or appointed task groups explore, examine and accept or reject a given policy option[13]. Particular public policies may come from the proposals posited at the agenda-setting stage, or may be developed later in government offices. In most situations policy makers tend not to seek fresh knowledge, i.e. conducting or commissioning research to inform policies, but to draw lessons on their past experiences, implementation feedback and other organizations[14]. When the information on potential policy prototypes has been gathered, policy makers need to consider whether or not, and how to introduce such lessons into their settings.

Lesson drawing may involve not only copying but also different degrees of adaptation, and therefore the policy innovations may be different from its template[14,15]. This is because the adoption of a policy

is contingent on several conditions, especially the internal factors of the policy importer setting, such as the effects of socio-cultural factors, policy legacies, political context and economic status[14]. Similar to the agenda setting stage, the benefits, feasibility and political consequences in introducing each policy option are assessed[16], and as a result, undergo some transformation. As policy formulation is carried out by government officials, their concerns, including bureaucratic implications, for example individuals' career objectives, competitive positions and budgets between governmental units, as well as administrative capacity, compliance and responsiveness may affect how far policies are adapted[17].

Policy implementation

The term 'policy implementation' refers to the process by which a policy is put into effect. During this stage, policy makers at the top of an administrative hierarchy, such as a government or parliament, expect bottom-level bureaucrats to carry out the policy as formulated[18]. In practice, however, owing to several factors such as unrealistic policy prescription, ambiguous policy objectives, poor communication and collaboration between responsible organizations, inadequate time and resources in implementation units and impeding work environment, the policy may be adjusted, elaborated upon or even rejected by government officials at a peripheral level[19]. As suggested by Hill[20], implementation gaps may stem from the differences in the interpretation and understanding of problems, policy goals and prescribed instruments between central-level policy makers and peripheral actors.

Public policy scholars emphasize the role of actors who are responsible for the translation of policy into practice: the implementation stage is part of a policy-making continuum: the policy is remade and fine tuned by those expected to be its implementers. As Walt (8:155) maintains, *'implementers often play an important part in policy implementation, not merely as managers of policy percolated downwards, but as active participants in an extremely complex process that informs policy upwards too'*. Meanwhile, many have pointed out that implementation is an interactive process, characterized by negotiation and conflict among participating actor networks, and therefore as political as the policy formulation stage[17]. Empirical evidence in the health sector shows that getting a policy into action involves many actors outside implementing units; for example, national and domestic politicians, representatives from a range of multi-level government agencies, private business, and civil society organizations, including professional organizations[21,22].

Lipsky's work on public servants' behavior suggests that *street-level bureaucracy* is where implemented policy is distorted from its prescription in several ways including in policy directions, guidance and in professional practice guidelines[23]. His study illustrates the discretionary practice in service delivery developed by public officials, which aim to address implementation constraints and complexity, excess demands, conflicting and ambiguous policy objectives, uncertainties about new jobs, and occupational stress. Eventually, such coping mechanisms become routine and then established practices in the organizations. Lipsky further argues that program managers and superior officials have found some difficulties in controlling the street-level bureaucrats' behavior and fostering policy compliance.

Integrating research into policy development

It is generally recognized that research findings including HTA, are beneficial in supporting evidence-based decisions at every policy stage, from agenda setting to the monitoring and evaluation when policies are implemented. This is, to some extent, in the same vein as that which a rationalist ideal argues; government agencies need comprehensive information on policy alternatives, and rational decisions are those drawn on the evidence objectively demonstrating cost minimization and benefit maximization of the selected options[13]. However, actual policy processes are not always rational since, as aforementioned, several elements, apart from research findings and other scientific information, collectively influence policy decisions[24].

An illustration can be drawn on the priority setting for reproductive health in Ghana, where breast cancer has been given a higher priority than cervical cancer despite the fact that available evidence on disease burdens and cost-effectiveness of screening and treatment interventions suggests that the government should invest in a cervical cancer program rather than the breast cancer initiative[25]. As this study points out, such debatable priority setting has resulted from campaigns run by women's groups at a national level who encourage breast-cancer problem solving, which are more powerful than those involved in the cervical-cancer counterpart. Even in developed societies such as the UK, where evidence-based decisions have been

promoted, the actual policy making in the health sector still faces the challenges of political imperatives and research evidence interaction[26].

Research-derived information may be employed by policy makers, interest groups and even researchers themselves to legitimize the policies they pursue[10]. In many instances, this requires a rigorous, tireless effort of 'policy entrepreneurs' who advocate particular policy choices. The case of universal health coverage policy development in Thailand offers a good example. In the early 1990s, groups of health economists started conducting domestic studies and also reviewing international experience on health system financing, different types of insurance plans and payment mechanisms, and their implications on the budget requirement and health care providers' responses[27]. The data on cost escalation of the fee-for-service scheme for government workers and inequitable spending per capita of beneficiaries of different health benefit programs in the country were highlighted as justification of these researchers' proposal to reshuffle the financing systems. After a long advocacy, the reformists succeeded in driving the universal health coverage issue on to the government agenda in 2000, and coupled their research findings with national policy decisions thereafter[28].

The concepts of policy communities and policy networks may help us to understand the research-policy nexus. Such notions maintain that public policies are decided and developed within closed policy subsystems, involving small numbers of actors including politicians, government officials, and representatives from interest groups, who have common goals and basic values[29]. Changes in members of policy communities, associated ideals, and therefore the interpretation of problems and solutions, can result in policy innovations. However, policy communities are well-integrated and not open for different interests to participate in their activities, including policy making. This is the major reason why radical shifts in public policies hardly happen[11].

Epistemic communities, including groups of experts, researchers and think tanks, are distinctive types of policy networks, of which the members share a professional background and expertise[30]. These scientists' goals are to promote their ideas on to the government agenda and integrate their detailed proposals into policy formulation. Policy alternatives proposed by experts, although based on sound research and evidence, inevitably compete with those pursued by other actor clusters with different ideals and preferences. Specialists in respective fields are usually invited by government agencies to work out program configurations, especially those in highly technical policy domains such as health and biomedical sciences. This is a channel to increase the chance for research-policy integration. However, on many occasions, problematic issues are constructed by other interests and conveyed to stakeholders as well as governments and the general public in particular ways, in which technical expertise and scientific information are not required in policy decisions[11]. This restricts the role of experts, and therefore hampers the impact of research on policies and practice. It is noteworthy that the contests between issue definitions, policy options and an explanatory role of the policy network model can be applied to understand policy making at global, national and domestic levels.

Scholars have discussed the reasons for the lack of research-policy integration at length. As Braybrooke and Lindblom[31] assert, the rational approach cannot address all problems in the real-world due to: a limited problem-solving capacity, inadequate information, unaffordable assessment costs, lack of reliable evaluative methods, the role of value in policy making, needs for effective strategies to convince policy makers, and a variation in the features of arising problems. Inefficient evidence production as well as poorly-performed monitoring and evaluation, which hinder the role of research in public health policy, are problems of not only resource-poor settings but also industrialized societies[26,32]. Meanwhile, Chunharas[33] maintains that different types of knowledge, not solely those derived from research studies, are helpful in guiding policy decisions. As the author further emphasizes, in addition to research findings, policy makers and other stakeholders may introduce lessons drawn on personal experience and those available in documents and other forms of databases in the policy formulation and implementation stages.

Others such as Trostle et al[24] provide insight into the promoting factors and impediments in applying research to policy making. Drawn on Mexican experience, this study suggests that these factors include: quality of studies perceived by policy makers; language used in research reports and communications; timelines of study results; the concreteness and applicability of research findings; the technical background of policy makers; the involvement of some interests in the research projects; (un)familiarity to use scientific evidence in policy decisions (this is referred to as 'political culture'); available channels for formal and

informal communication between researchers and policy makers; changes in top-level management of the health systems; excessive State centralization; and rotation of scientists into policy making positions. By this, it means that research with rigorous design, methodology and quality assurance is insufficient in guiding and shaping public policies. This is because other factors including policy makers, researchers, dissemination and communication of research findings, and health and political system environments also play important roles.

The Overseas Development Institute suggests that the links between research and policy are associated with three main groups of factors: the political context; the credibility of the evidence; and the relationships between policy and research communities[34]. The ODI framework sheds light on why the Thai researchers and policy makers were successful with their plans, resulting in the instigation of the universal health coverage plan. As Mills[35] puts it, the conducive elements of research-policy nexus in such cases include a strong political imperative behind the policy; highly credible research evidence; and longterm collaboration between politicians, bureaucrats and researchers, who shared common goals and trusted each other.

Health technology assessment and policy making

The needs for medicines, medical devices, therapeutic procedures and other health interventions which are safe, effective and, at the same time, offer the best value for money, are common in the health systems of developed and less-developed countries. HTA is expected to address these needs since its findings may serve as rigorous evidence to inform policy making and professional practice[36]. Following Banta and Luce[37], an HTA report can affect investment decisions; third-party payment policy; the adoption of new technology; the allocation of health care resources; clinician and patient behavior; and the rate of use of a technology. The literature, however, suggests that HTA results, though available, are underused and therefore have little impact. As van den Heuvel et al[38] note, for example, political arguments and interest groups played a crucial role in the introduction of new medical technologies in the Netherlands' health service, while HTA was less influential. Emphasizing the decisions made at the peripheral level, another illustration draws on a study by Hashimoto et al[39], and suggests that the adoption of coronary stenting in teaching hospitals in the USA and Japan was affected by payment systems and incentives, cultural attitudes, and local patients' characteristics.

Like policy utilization of research in other areas, HTA implications for policy development can be explained through the above-mentioned policy analysis models. In addition, HTA-informed and other research-based policy decisions are similar in terms of enabling and impeding elements. The body of literature with the focus on policy utilization of HTA of different approaches, especially economic evaluation, is expanding. However, it should be noted that the acceptance of HTA-generated recommendations among policy makers, professionals and the public varies across HTA studies with different objectives, methodologies and purposes. For example, the estimation of financial burdens of a new technology introduction seems to be less controversial than the cost-effectiveness or cost-utility analysis of said intervention. Moreover, the policy participants' interpretation of and response to 'assessment' findings and 'appraisal' results of the same policies/interventions may be totally different.

In Thailand and elsewhere, important barriers to using economic evaluation to inform health policies and care delivery are the perceptions towards economic analysis among policy makers and practitioners, who involve their knowledge of economic evaluation technique, trust in the methods, and the availability of information in the settings[40]. For some, cost-effectiveness analysis and pharmacoeconomics are viewed as 'non-science' or a 'pseudo-discipline'[35, 41]. Complex calculations, arbitrary assumptions, debatable choices of whose perspectives to pursue, difficult-to-understand methods, research designs and underlying philosophies/concepts, and time-consuming processes are among the reasons why politicians, health officials and professionals feel reluctant to adopt economic analysis as a policy making tool.

Following Cookson, Hutton[42] and Schultz[43], there are concerns about the validity of economic analysis evidence, especially the costs and effectiveness information, due to many limitations including unavoidable ethical and methodological difficulties. These include, for instance, incomplete economic data collection alongside clinical trials; a wide variation of economic assessment methodologies employed in different settings and studies; and exclusion of behavioral factors such as irrational prescription and utilization of health interventions from the estimations of costs and outcomes. The lack of confidence in the transferability of HTA across countries was one of the important barriers to use its findings among policy

makers (36). Critics of the transparency and peer review scrutiny in the reporting of research results are also significant.

Economic evaluation and its influence on priority setting and resource allocation have been scrutinized for their political aspects. As the major goal of the economic approach is to pursue 'efficiency' through the maximization of benefits and containment of resource use, such utilitarian-based analysis and its results contradict many ideologies, for example human rights, equity, ethics and professional autonomy[44,45]. Owing to the differences in these ideals, policy makers and some interests may disagree with, or hesitate to follow, the policy recommendations generated by the economic evaluation of health interventions. It is obvious that in health systems where the ultimate goals are to reduce health inequalities of underprivileged populations or to address illnesses with high burdens as the priority, cost-effectiveness evidence is likely to be ignored. In the absence of multi-criteria decision analysis, it would be difficult for policy makers to accommodate these conflicting goals of health care provision, and a trade-off between these policy goals seems to be inevitable[46].

Professionalism including autonomy, discretionary power and ethical concerns are crucial in making the decisions to provide or not to provide particular services[47]. As Teerawattananon[40] points out, it is uncommon for health professionals to consider efficiency or value for money as selection criteria of medicines and other treatment they prescribe. Moreover, the practitioners' awareness of social expectations on equitable access to health services and their professional role can affect their practice to a certain extent. While evidence-based policy/guidelines are concerned with the needs for and implications of particular treatment in the population, health workers have to relate the evidence to the conditions of their patients, and make decisions by weighing the pros and cons on an individual basis[48]. In many instances, physicians find it difficult to explain to patients and caregivers why some interventions are omitted. Negative reactions to the introduction of evidence-based medicine, including use of HTA findings, are generated through the perceptions that such ideas are 'dangerous to innovation', a tool for cost-containment, and suppress clinical freedom[3]. As Jacobson and Kanna[49] maintain, developing clinical guidelines on cost-effectiveness evaluation is an *'intrusion into physician autonomy'*. In essence, evidence-based medicine, when implemented in particular settings, allows for the participation of different actors, such as governmental authorities, purchasers and third-party payers, who can use their financial influence in clinical decisions[50].

Political policy makers are crucially concerned by the publicity of policy decisions and the expectations of the general public[1]. Although what is suggested on the grounds of anticipated clinical and economic consequences may be the best policy choice in certain situations, politicians normally take into account policy implications in wider aspects, especially in terms of social acceptability, the public preference and the political desirability of introducing particular health technologies/policies. If politicians take a leading role in policy formulation, they may choose these policies which are not only feasible to implement, but also attractive among their constituencies in order to gain popularity and be re-elected in later elections[51]. In addition, policy makers usually face competing requests for resource allocation to several technologies/programmes so that they have to make decisions in such a context on which no HTA evidence is available[48].

In addition to political motives, which drive the decisions against policy options recommended by HTA researchers, the structural context of the policy subsystems is crucial. In those societies where economic evaluation and other HTA activities are mistrusted by important institutions, such as legislative authorities and courts, it is difficult for the Health Ministry, public health program managers, insurance plans and professionals to use such analysis in decision making[1]. In some countries, health benefit plans are subject to legislation, and legislative bodies can mandate these health programs to provide certain services, which may or may not be proved cost-effective according to HTA processes[52]. These mandates are usually influenced by organized interests as well as pressure groups such as patient networks, professional associations and the pharmaceutical industry. Moreover, apart from sufficient funds, implementation feasibility which, in large part, involves health system capacity in terms of experienced workforces, knowledge, management and infrastructure are determining factors in policy choices[53].

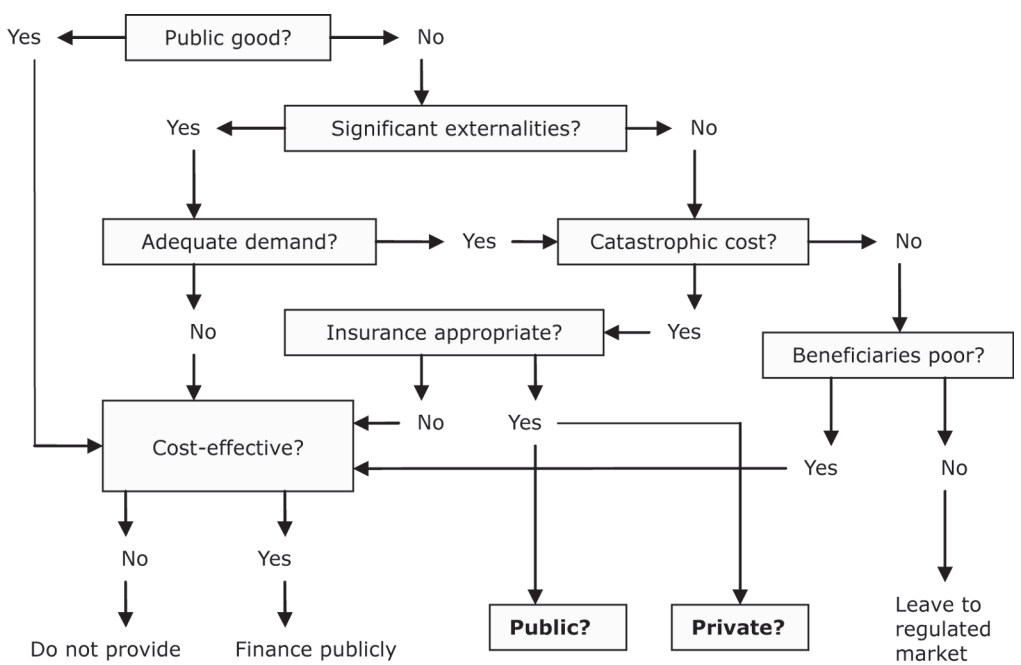
Recommendations made by the World Health Organization offer a clear illustration of the role of efficiency-oriented HTA. As suggested in the 2000 World Health Report (54), cost-effectiveness alone is not adequate to achieve a health system goal of inequality reduction. This means that other criteria are needed in deciding what technologies to invest in and

provide. Such criteria address different social elements through a set of questions: if interventions of focus are public goods, with significant externalities and adequate demand and whether or not they may cause financially catastrophic consequences, especially among the poor (Fig. 1).

Role of HTA evidence in Thailand: The case of antiretroviral policy development

To provide an illustration of how and to what extent HTA has been utilized in Thailand, the development of an antiretroviral therapy (ART) program[55] is presented as a case study. The HIV epidemic in this country started in the late 1980s, and had afflicted almost 1 million people by the mid-1990s. A publicly-funded initiative to deliver antiretroviral-based medication has been implemented since 1992, with two significant shifts in program features in 1996 and 2001. The first policy change was informed by an economic evaluation, suggesting therapy provision under the national initiative would soon be unaffordable as the numbers of AIDS patients continued to rise while antiretrovirals (ARVs) were expensive, and that ART was much less cost-effective than the use of zidovudine and infant formula to prevent mother to child HIV transmission. Owing to such calculations, the Health Ministry replaced the existing ART service with a clinical trial project, and maintained the number of treatment recipients at 2,000 a year.

The policy shift in 2001 took place when a newly-elected government decided to provide universal access to a highly active antiretroviral therapy (HAART), which meant the government had to expand the service to cover 100,000 patients at the least. According to Tantivess[56], such policy innovation was encouraged by several elements including local production of first-line ARVs and subsequent drug price reductions; campaigns run by non-governmental organizations (NGOs); involvement of health system reformists; and global efforts to promote access to HIV treatment in resource-poor settings. It is noteworthy that although drug costs had dropped significantly, HAART did not offer value for money when compared with to HIV prevention[57,58]. This suggests that the policy to scale up ARV therapy in Thailand, as well as other societies, has not been driven by efficiency-promoting ideal, but human rights, ethics and equity[55]. Furthermore, a concerted effort by NGOs, including people living



Source: World Health Report 2000 (54:55)

Fig. 1 Questions to be addressed in public resource allocation to health care

with HIV/AIDS, coalitions, health officials and HIV specialists had a crucial role in not only agenda setting and adoption of universal treatment policy, but also the processes of formulation and implementation thereafter.

As Tantivess and Walt[55] emphasize, this case study may not be generalizable since ART is unique. The demand for ARV-based medication is substantial, while the drugs are expensive. Treatment is indicated in incurable disease for which prevention measures are much more cost-effective. ART delivery is complex, and may cause both positive and negative spill-over effects. Finally, there has been global commitment to expanding access to ARVs. These features, to a certain extent, shaped the decisions of the national treatment initiative in Thailand, and are not comparable with decision making in other health interventions.

To sum up, the allocation of health care resources to ART delivery in Thailand over the past decade was largely shaped by the considerations of financial feasibility. In the first policy shift, the influence of economic information was obvious. On the other hand, the recent reforms were guided by other motivations and the strong advocacy of actor networks. However, the importance of affordability in association with ARV price reduction could not be ignored in both cases.

HTA and ethical dimension of resource use in health system

According to the American Heritage Dictionary of Cultural Literacy 2005 edition, ethics is referred to as *'the branch of philosophy that deals with morality. It is concerned with distinguishing between good and evil in the world, between right and wrong human actions, and between virtuous and nonvirtuous characteristics of people.'* When applying ethical principles in policy making, it means that the poor and other underprivileged groups will be given priority to obtain social benefits as well as being protected against financial risk. In the health domain, it is suggested that health care financing should be managed to achieve two objectives: the best attainable average level (or goodness) and the smallest feasible differences among individuals and groups (or fairness)[54].

In practice, however, it is difficult to develop a consensual framework to guide fair or ethically-sound resource allocation. This is because, as noted by Daniels[59], different arguments have been raised to debate, for example, what constitutes fair outcomes; what distributive principles should be used (e.g., to pursue best outcomes, to help the sickest patients, or to treat the most urgent needs; and how such principles should be interpreted in particular situations. In addition, there are dilemmas concerning responsibility for health needs, as some suggest that the scarce resources should not be allocated to therapy for the diseases responsible by individuals[60]. The lack of comprehensive theory of justice has resulted in unresolved issues not only in allocating resources across public health programs and interventions, but also in rationing treatment to individual patients[61].

As recently mentioned, the introduction of HTA, especially economic evaluation and ethical principles, is normally viewed as conflicting, in particular with the allocation and use of health-care resources where life or death is the consequence. While the economic approach seeks to maximize benefits to the population within available resources, the ethical counterpart mainly focuses on fairness, by seeking a fair distribution of available resources among competing health needs[62]. Also, people may view the resource allocation guided by economic assessment as unfair, because the cost-effectiveness analysis focuses on the sum of costs and benefits and mostly ignores their differences across affected groups of people[60]. Meanwhile, some scholars assert that the introduction of an economic approach in determining resource distribution violates the *'special moral importance of health'*, since the attempt to quantify everything in numbers transforms the discussion on ethics and human rights into a *'complex, resource-intensive, and expert-driven'* process, which neglects the debate concerning underlying values[63].

A chapter in the book titled 'Disease Control Priorities in Developing Countries' points out that resource allocation should meet two main ethical criteria[60]. First, the resources should be allocated to maximize the benefits for the population. It is argued that economic analysis can be regarded as a measure of one ethical criterion for HTA, since the benefit-maximization principle is underpinned by a moral concern: the numbers of beneficiaries of any cost-effective technology would be larger than investing in its alternatives, which are not cost-effective. Second, the distribution of costs and benefits to distinct individuals or subpopulations should be equitable. The authors maintain that although equity concerns may conflict with cost-effectiveness, sometimes efficiency and equity can coincide. Furthermore, the inclusion of cost and benefit components in economic analysis are not

value-free or exclusively a technical issue, but result from the analysts' ethical judgments.

Many researchers suggest reinventing the concepts of HTA into a more comprehensive form of evaluation research, and expanding the evaluation landscape to involve other dimensions beyond those of safety, efficacy and cost-effectiveness[45]. These include the application of ethical theories, principles and rules to assess particular interventions in order to offer morally-justified solutions. As ten Have[45] asserted, ethics can contribute to HTA in two ways, which are identifying the relevant moral issues to be addressed in the evaluation of a particular technology and expanding the conceptual framework and research questions by examining the relationship between technical and non-technical elements. To implement ethics-impregnated approaches in HTA, several groups of actors other than policy makers and experts, especially afflicted people and civil society organizations, need to be involved in the priority-setting and investment in health. Participation of a broader range of stakeholders in policy decisions is a rising trend in current political sphere of many developed and developing countries[64].

Dealing with stakeholders in health technology assessment

The previous sections have reflected, in part, the political aspects of HTA, especially the integration of HTA findings into policy making and practice. It can be seen that not many groups of key actors are involved closely in the upstream processes of evidence producing. This is because the examinations of the benefits, costs and other consequences of health interventions are highly technical and so complex that only those who have expertise and/or interests in this area are willing to participate. This means that researchers and the health technology industry are prime stakeholders, while policy makers are also important.

At present, as HTA is defined to cover research with a broad range of focuses such as studies in biomedicine, behavior, economics, and social sciences, the range of researchers with the necessary expertise required has widened accordingly. Meanwhile, private businesses, including pharmaceutical and medical device companies, can be affected by HTA results in either positive or negative ways; the sale of their products may increase if the assessments suggest the interventions are cost-effective and affordable by major purchasers, and vice versa.

HTAs may be influential as their results and associated policy recommendations can be used to guide priority setting and resource allocation. In essence, policy makers, at different levels, can be regarded as a cluster of HTA stakeholders. Examples of actors in this group include: politicians, health officials, managers of health benefits/insurance schemes, hospital administrators as well as decision-making panels in particular domains. Moreover, health professional organizations, such as physicians associations, royal medical colleges and other academic institutes, can be classified into this group as they may take part in some areas of policy development, for instance in the formulation and adoption of clinical practice guidelines and professional handbooks, all of which take into consideration certain forms of HTA findings. Another set of HTA stakeholders comprises practitioners and the general public who are expected to apply HTA findings and recommendations, mostly disseminated through intermediaries such as education and information campaigns, in their professional practice and health behaviors, respectively.

The understanding of policy participants, their perceptions and positions towards HTA and certain results, interests, roles and power is crucial in encouraging HTA utilization. Stakeholder analysis is a useful approach to examine all these facets, and helps policy makers and managers to detect and prevent potential misunderstanding or opposition to the introduction of the policy[65,66]. Following Roberts and colleagues[67], policy innovations and changes in practice and behaviors can be managed by employing strategies to address the positions of selective policy participants; the power of important stakeholders; the numbers of policy advocates and opponents; and the construction of problems and policy alternatives among key stakeholders. Lessons drawn on research-policy nexus in many settings as discussed above are also helpful to bridge the gaps between the research and policy-making arenas. Mills[35], for instance, emphasizes the importance of perceived quality of research as well as strong relationships and trust between policy makers and researchers. In a similar vein, many suggest that the use of HTA in policy making is a shared responsibility between evidence producers and end-users[68], and full engagement of end-users throughout the assessment process in order to identify problems and reflect needs and underlying perceptions in local perceptions will help to increase the impact of HTA for policy[69].

Conclusion

The present paper argues that the decisions to pursue particular policies and practices are not always rational, but complex and dynamic. Research-derived recommendations, including HTA evidence, are not the sole factor underpinning such decision making. Policy participants, in groups and individuals, with different ideals and interests, are crucial mechanisms driving the policy processes, through the construction of the problematic issues and corresponding solutions. In certain instances, HTA findings may be accepted by policy makers and practitioners. This increases the tendency of policy utilization. In most occasions, the integration of HTA in public policy development and implementation is difficult, but not impossible. It depends on the conformity to major norms and values of socio-political systems, credibility of evidence, practicality of policy recommendations, and policy makers-researchers relationships.

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บทบาทของการประเมินเทคโนโลยีด้านสุขภาพในกระบวนการนโยบายสาธารณะ

ศรีเพ็ญ ตันติเวสส

การพัฒนานโยบายและการนำนโยบายไปสู่การปฏิบัติในภาครัฐเป็นกระบวนการที่ซับซ้อน และเปลี่ยนแปลงอยู่ตลอดเวลา ในขณะที่ตัวแสดงจำนวนมากซึ่งมีผลประโยชน์ที่แตกต่างกันเข้ามามีส่วนเกี่ยวข้อง ตัวแสดงเหล่านี้ทั้งที่เป็นปัจเจกบุคคลและองค์กรมีการแข่งขันกันเพื่อที่จะให้ได้มาซึ่งสิ่งที่ตนต้องการ โดยผู้ที่มีอำนาจเหนือกว่าผู้อื่นจะเป็นผู้นำในการตัดสินใจเชิงนโยบาย ผลการวิจัยและข้อเสนอแนะจากการประเมินเทคโนโลยีด้านสุขภาพได้รับการคาดหวังว่าจะมีบทบาทสำคัญในการกำหนดนโยบายและเป็นแนวทางในการประกอบวิชาชีพ อย่างไรก็ตาม หลักฐานที่ได้จากกระบวนการทางวิทยาศาสตร์เหล่านี้มักจะไม่ได้รับความสนใจนำมาใช้ประโยชน์ ที่เป็นเช่นนี้เนื่องจากการประเมินใช้การคำนวณที่ยุ่งยาก การตั้งสมมติฐานที่ไม่ชัดเจน การเลือกมุมมองของบุคคลหรือสังคมซึ่งหลายฝ่ายมีความเห็นไม่ตรงกัน ระเบียบวิธีวิจัย แนวคิดและปรัชญาที่เข้าใจได้ยาก รวมทั้งใช้เวลานานในการศึกษาวิจัย ประเด็นด้านจริยธรรมและความรู้สึกที่ว่าแนวทางการบำบัดรักษาโรคที่กำหนดขึ้นจากผลการประเมินทำให้สูญเสียความเป็นอิสระของวิชาชีพก็เป็นปัจจัยที่มีความสำคัญ