Social and Ethical Analysis in Health Technology Assessment

Sripen Tantivess BSc, MPH, PhD*

** Health Intervention and Technology Assessment Program, Ministry of Public Health, Nonthaburi, Thailand*

This paper presents a review of the domestic and international literature on the assessment of the social and ethical implications of health technologies. It gives an overview of the key concepts, principles, and approaches that should be taken into account when conducting a social and ethical analysis within health technology assessment (HTA). Although there is growing consensus among healthcare experts that the social and ethical ramifications of a given technology should be examined before its adoption, the demand for this kind of analysis among policy-makers around the world, including in Thailand, has so far been lacking. Currently, decision-makers mainly base technology adoption decisions using evidence on clinical effectiveness, value for money, and budget impact, while social and ethical aspects have been neglected. Despite the recognized importance of considering equity, justice, and social issues when making decisions regarding health resource allocation, the absence of internationally-accepted principles and methodologies, among other factors, hinders research in these areas. Given that developing internationally agreed standards takes time, it has been recommended that priority be given to defining processes that are justifiable, transparent, and contestable. A discussion of the current situation in Thailand concerning social and ethical analysis of health technologies is also presented.

Keywords: *Social analysis, Ethical analysis, Health technology assessment*

J Med Assoc Thai 2014; 97 (Suppl. 5): S81-S86
Full text. e-Journal: *http://www.jmatonline.com*

In most countries, policy-making decisions concerning allocation of resources to new healthcare technologies are made on the basis of evidence that assesses the clinical effectiveness, safety, and value for money of the technology under consideration. However, these are not the only issues that need to be taken into account when making decisions about the adoption of various technologies. Indeed, there is increasing evidence that policy-makers should also consider the potential negative social and ethical effects of adopting a given technology[1]. Although social and ethical analyses have been a recommended part of health technology assessments (HTAs) since the 1970s[2], the number of studies on ethical analysis in HTA is still relatively small, compared with the total number of HTA publications. This might be owing to the absence of internationally-agreed principles, concepts, and methods[3,4], as well as inadequate understanding, knowledge, and skills among HTA researchers.

In Thailand, however, social and ethical reasons have occasionally been cited to justify the inclusion of health interventions in government-financed benefit packages, including the revision of the National List of Essential Medicines (NLEM)[5]. In some instances, social and ethical reasons played an even more important role in coverage decisions than did the cost-effectiveness and fiscal impact of the technology under consideration. Nevertheless, no explicit guidance has yet been developed for how to conduct these kinds of analyses, nor for how to apply the findings to the policy development process (the first edition of HTA guidelines for Thailand did not include recommendations on social and ethical analysis).

To go some way to address this lack, and to begin the process of developing evidence-based and informed guidance for policy makers and researchers, this paper surveys the domestic and international literature concerning the evaluation of social and ethical implications of health technologies and outlines the main concepts, principles, and approaches. An initial discussion on how these relate to the current situation

Correspondence to:
Tantivess S, Health Intervention and Technology Assessment Program, Ministry of Public Health, 6th Floor, 6th Building, Department of Health, Ministry of Public Health Tiwanon Road, Nonthaburi 11000, Thailand.
Phone: 0-2590-4549, Fax: 0-2590-4369
E-mail: sripen.t@hitap.net

in Thailand is also presented.

Why social and ethical assessment of health technology is important

There is widespread agreement among HTA experts that integrating social and ethical elements in HTAs is an important way to improve transparency[6] and provide understanding on the context into which certain technologies will be introduced[7]. Crucially, since the introduction and implementation of innovative technologies, will inevitably result in changes in their supply and demand, inequitable accessibility may also result. For this reason in particular, conducting HTAs without an ethical analysis is to ignore a crucial dimension of the technology under consideration[8]. Although clinical benefits and cost-effectiveness are key concerns of policy-makers, their assessment often requires specific expertise, which is usually communicated in specialized language. In contrast, ethical analysis involves issues and language that is commonly understood, and the discussion of which encourages wider participation and improved transparency, resulting in well-accepted decisions and more effective implementation.

The implementation of new health technologies may also have social, legal, and political consequences, including those that may affect organisations. To ensure that these consequences are anticipated and addressed, experts recommend that HTA be expanded so that appropriate analysis in relevant disciplines be conducted to anticipate what, if any, consequences of this kind might arise from the introduction of a new technology[9]. Guidelines published by the European Network for Health Technology Assessment (EUnetHTA) identify a number of key ways in which the introduction of new health technologies might affect patients, their family, and caregivers, in areas such as professional life, skills, and social position[7]. While this does show an awareness of the social and ethical issues involved in introducing a new technology, this is still a largely isolated example; specific published guidance on social and ethical evaluation of health technologies remains limited.

Concepts and principles of analysis

Although research on social and ethical implications has been recognized as an important component of HTA for decades, there is, as yet, no common agreement on its principles and methodology. It is also unclear under what conditions a technology should be subject to this kind of analysis, who should be responsible for such analysis, and whether and to what extent key stakeholders and the general public should take part in the processes[3].

Ethics refers to philosophical study on the nature and grounds of moral judgments and standards and rules of conduct, both actual and practical[10]. Put simplistically, ethical inquiries involve examining the differences between actions, behaviors, and ways of living, which are classified accordingly on a scale of good to bad. As coverage decisions determine access to and benefit from health technologies–which can both prolong life or cause adverse reactions–such policies should be regarded as ethical issues. The justification of whether the use of a selected technology is 'right' or 'wrong' depends on the social, cultural and political context within which the technology is to be implemented[11]. For example, blood transfusion, abortion, and sex education are permitted in some countries, while unacceptable in other societies for religious or moral reasons.

An ethical analysis of health technologies should not rely on theories from one discipline alone; instead, a number of theories, all of which are accepted widely in the society under consideration, should be used[11]. A review of the existing literature on ethical analyses of new technologies suggests that the most widely-introduced ethical principles are as follows: 1) biomedical ethics, which comprise respect for autonomy, i.e. the rights of people to acquire necessary information and make their own decisions to seek care and use certain technologies; 2) non-maleficence, i.e. the duty of health providers to avoid causing harm, suffer, injury, disability, or fatality intentionally; 3) beneficence, i.e. to enable people to have a 'good life', including harm reduction and prevention of negative consequences; 4) justice, which involves fair allocation of fundamental social burdens and benefits, i.e. to provide access to essential health services to all people, regardless of personal characteristics such as nationality, colour, and socioeconomic status[12]. Biomedical ethics also relate to human dignity–a fundamental right of mankind.

According to EUnetHTA Guidelines, social analyses of health technologies should emphasise "patient-centred" principles, by examining the impact the health technology will have on individuals, including patients, caregivers and family members. This includes analyzing the extent to which doctors and healthcare providers provide patients with information about the technology, assessing the level of patient and caregiver understanding, and exploring the

feasibility of patient participation in decision making. HTA should also include assessment of how the intervention might affect the major areas of the life of the patient or caregiver, for instance, any impact it might have on work life, family life, leisure time, and religious and cultural activities.

The EUnetHTA guidelines also emphasize the point that every step of HTA includes social or ethical issues, including the selection of the technology; stakeholder participation; identification of social and ethical queries, and the selection of study design, method, and references. Every process in the HTA will have ethical ramifications and, as such, every stage in the assessment process should be cognisant of these issues. HTA experts agree that any assessment of the effectiveness and safety of a health technology should involve not only technical expertise, but also social and ethical consideration of the consequences of both adopting the technology and HTA process itself[6,13].

Assessment processes and approaches

As discussed earlier, EUnetHTA suggests that ethical implications should be considered at every stage of an HTA, from identification of the research questions to report writing and publication. They also suggest that the ethical analysis not be conducted in isolation but, instead, in tandem with all other assessments, as every HTA process, including clinical trials and economic evaluations, are value-laden[7]. However, some experts have suggested that ethical assessment, as a unique type of investigation, should never be performed together assessments of the clinical, social, economic and legal implications of technology[14]. Others argue that in absence of common agreement on the most appropriate methods for ethical analysis, emphasis should be placed on transparent, fair, reliable, and contestable processes for resource allocation, rather than detailed assessment guidelines.

Several academics have suggested that the general research methods usually deployed in HTAs (such as conducting primary research, transferring secondary data from existing studies and literature, and seeking expert advice[3]) are inappropriate for use in ethical analyses due to the philosophical nature of these kinds of investigations[14]. Moreover, although international organizations such as the International Network of Agencies for Health Technology Assessment (INAHTA) and EUnetHTA have formulated guidelines for evaluating ethical implications of health technologies (in 2005 and 2008, respectively), these have been subject to criticism.

In practice, researchers propose sets of questions, developed on the back of ethical principles and theories. For example, Hofman[15] formulates 33 questions in 5 categories, comprising questions on moral issues, stakeholders, technology, assessment approaches, and technology assessment. In a similar vein, EUnetHTA recommends 14 questions on key ethical aspects of technology, autonomy, human dignity, beneficence and non-maleficence, justice and equity, and rights and legislation[7]. For an evaluation of social implications, this HTA organisation network suggests 9 questions that focus on three areas-major life areas, individual impacts, and patient-healthcare provider communication. Table 1 presents selected questions from EUnetHTA's Guidelines that refer to social and ethical issues.

Analysis of social and ethical implications of health technology in Thailand: Current situation and challenges

As mentioned previously, there are currently no national guidelines for conducting social and ethical analyses of health technologies in Thailand. Indeed, the demand for related evidence among policy-makers and stakeholders is lacking. Despite this, ethical issues have occasionally come to the fore, particularly in terms of inadequate access to high-cost technologies. Civil society organisations, patient groups, and health professionals have begun to campaign to end what they see as inequitable access to various treatments, including medicines for antiretroviral treatment[16] and renal replacement therapy for end-stage renal disease[17]. Certain groups have also advocated the government to expand the use of TRIPs flexibilities[18,19], and there have been protests against the expansion of intellectual property protection beyond TRIPs in the Thai-USA and Thai-EU Free-Trade Agreements.

Clearly, over the past few decades, social and ethical statements have played a significant role in Thailand's health policy processes. Although no official mechanism has ever been in place to address such issues, a number of studies have generated useful, policy-relevant evidence on social and ethical issues of healthcare. Key studies include an equity analysis of how contributing to national health benefit schemes affects people in different income groups, a study that estimated the heath and economic loss among poor households that resulted from inadequate access to renal replacement interventions[20], and a study focusing on the consequences of extending the pharmaceutical markets beyond the exclusivity of the

Table 1. Selected questions on the social and ethical aspects of health technologies (from EU net HTA's Guidelines)

	Topic	Questions
Social aspect	Major life areas	Which social areas does the use of the technology influence? Who are the important others that the use of the technology may affect in addition to the patient?
	Individual	How do patients and important others react and act upon the technology?
	Communication	What is patients' and important others' knowledge and understanding of the technology? How is the information regarding the use of the technology processed and exchanged?
Ethical aspect	Ethical aspect of technology	Can the technology challenge religious, cultural, or moral convictions or beliefs of some groups or change current social arrangements? What can be the hidden or unintended consequences of the technology and its applications for different stakeholders?
	Autonomy	Is the technology used for patients/people that are especially vulnerable?
	Human dignity	Does the implementation or use of the technology affect human dignity?
	Beneficence/non-maleficence	What are the benefits and harms for patients, and what is the balance between the benefits and harms when implementing and when not imple menting the technology? Who will balance the risks and benefits in prac tice and how? Can the technology harm any other stakeholders? What are the potential benefits and harms for other stakeholders, what is the balance between them? Who will balance the risks and benefits in practice and how?
	Justice and equity	What are the consequences of implementing/not implementing the technology on justice in the health care system? Are principles of fairness, justness, and solidarity respected?
	Rights	Does the implementation or use of the technology affect the realisation of basic human rights?
	Legislation	Is legislation and regulation to use the technology fair and adequate?

World Trade Organisation's TRIPs agreement[21]. Nevertheless, while useful, these studies only cover the social and ethical implications of specific technologies and issues.

Social and ethical aspects are also addressed in a number of qualitative studies, including those conducted as part of an HTA. For example, one recent study examined the feasibility of stem cell transplantation for the treatment of severe thalassemia under Thailand's Universal Health Coverage (UC) plan[22]. The findings suggest that, although inclusion of this technology in the UC benefit package may result in increased accessibility, the country's capacity to provide stem cell transplantation is limited, and patients in low socioeconomic groups are less likely to comply with selection criteria for transplantation than those who are better off. This kind of inequity issue, which very important, is not captured in the two predominant forms of analysis favoured by policy-makers and is often not captured by most HTA.

The absence of national guidelines on conducting social and ethical analyses as part of HTAs may well result in opaque decision-making, and allow the assessment process to be influenced by policymaker bias and other unacceptable determinants, such as the preferences of manufacturers of technologies. In such cases, policy decisions might have negative consequences for patients, caregivers, and society, including unique table patient access and unfair treatment. The under privileged in society are likely to be disproportionately affected. Reviews of the current situation, arguments, and limitations concerning capacity for social and ethical assessment of health technologies indicate that Thailand needs to urgently address whether social and ethical analysis should be part of HTA. This depends, in part, on demands for related evidence among policy-makers and key stakeholders in the area of health priority setting and resource allocation, as well as related research capacity in the country.

Guidelines for Health Technology Assessment in Thailand (second edition): Recommendations for social and ethical analysis

HTA institutes in Thailand should adopt transparent, reliable, and contestable assessment processes, which allow the participation of all stakeholders. HTA research should be academically robust, with appropriate strategies to manage conflict of interest. In addition, researchers may consider whether the social and ethical questions and analytical approaches suggested in EUnetHTA Guidelines are appropriate for the Thai setting, and adopt elements where suitable. Moreover, wherever HTA methods may have social and ethical consequences, researchers should include a discussion of these issues in their reports.

Acknowledgement

The development of these guidelines would not have been possible without the technical support, challenging criticism and encouragement of many colleagues and institutions. As author, I wish to acknowledge all individuals and related organizations that contributed throughout the process for guideline development. In addition, I would like to give particular thanks to the funding support through the Health Intervention and Technology Assessment Program (HITAP) from the National Health Security Office, the Thailand Research Fund under the Senior Research Scholar on Health Technology Assessment (RTA5580010) and Thai Health Global Link Initiative Program (TGLIP), supported by Thai Health Promotion Foundation.

Potential conflicts of interest

None.

References

1. Gibson JL, Martin DK, Singer PA. Evidence, economics and ethics: resource allocation in health services organizations. Healthc Q 2005; 8: 50-9, 4.
2. Office of Technology Assessment. Development of medical technologies: opportunities for assessment. Washington, DC: United States Congress; 1976.
3. Lehoux P, Williams-Jones B. Mapping the integration of social and ethical issues in health technology assessment. Int J Technol Assess Health Care 2007; 23: 9-16.
4. Williams A. Economics, ethics and the public in health care policy. Int Soc Sci J 2009; 51: 297-312.
5. Tantivess S, Perez VR, Yothasamut J, Mohara A, Limprayoonyong H, Teerawattananon Y. Efficiency or equity: value judgments in coverage decisions in Thailand. J Health Organ Manag 2012; 26: 331-42.
6. Arellano LE, Willett JM, Borry P. International survey on attitudes toward ethics in health technology assessment: An exploratory study. Int J Technol Assess Health Care 2011; 27: 50-4.
7. EUnetHTA. HTA Core Model for Medical and Surgical Interventions, 1.0R [Internet]. 2008 [cited 2012 Oct 4]. Available from: http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/HTA%20Core%20Model%20for%20 Medical%20and%20Surgical%20Interventions% 201.0r.pdf
8. ten Have H. Ethical perspectives on health technology assessment. Int J Technol Assess Health Care 2004; 20: 71-6.
9. Hofmann BM. Why ethics should be part of health technology assessment. Int J Technol Assess Health Care 2008; 24: 423-9.
10. Taylor P. Principles of ethics: an introduction. Belmont, CA: Wadsworth Publishing; 1975.
11. Kristensen FB, Sigmund H, editors. Health technology assessment handbook. Copenhagen: Danish Centre for Health Technology Assessment; 2008.
12. Beauchamp T, Childress J. Principles of biomedical ethics. London: Oxford University Press; 2001.
13. Callahan D. Health technology assessment implementation: the politics of ethics. Med Decis Making 2012; 32: E13-19.
14. Duthie K, Bond K. Improving ethics analysis in health technology assessment. Int J Technol Assess Health Care 2011; 27: 64-70.
15. Hofmann B. Toward a procedure for integrating moral issues in health technology assessment. Int J Technol Assess Health Care 2005; 21: 312-8.
16. Tantivess S, Walt G. The role of state and non-state actors in the policy process: the contribution of policy networks to the scale-up of antiretroviral therapy in Thailand. Health Policy Plan 2008; 23: 328-38.
17. Dhanakijcharoen P, Sirivongs D, Aruyapitipan S, Chuengsaman P, Lumpaopong A. The "PD First" policy in Thailand: three-years experiences (2008-2011). J Med Assoc Thai 2011; 94 (Suppl 4): S153-61.
18. Treerutkuarkul A. Activists slam 'misleading' advert by US lobby group. Bangkok Post, 12 May 2007; Sect. 3 A.

19. The Nation. Mongkol: 'We can't give in with lives at stake'. The Nation, 5 May 2007; Sect. 2.
20. Prakongsai P, Palmer N, Uay-trakul P, Tangcharoensathien V, Mills A. The implications of benefit package design: The impact on poor Thai households of excluding renal replacement therapy. J Int Dev 2009; 21: 291-308.
21. Akaleephan C, Wibulpolprasert S, Sakulbumrungsil R, Luangruangrong P, Jitraknathee A, Aeksaengsri A, et al. Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: analysis of the effect of TRIPs-Plus proposal. Health Policy 2009; 91: 174-82.
22. Kotirum S, Leelahavarong P, Sanpakit K, Hongeng S, Teerawattananon Y, Tantivess S. Hematopoietic stem cell transplantation in severe thalassemic patients in two university hospitals in Bangkok: experiences of caregivers. J Health Syst Res 2012; 6: 193-206 (in Thai).

การประเมินผลกระทบด้านสังคมและจริยธรรมของเทคโนโลยีด้านสุขภาพ

ศรีเพ็ญ ตันติเวสส

บทความนี้ทบทวนเอกสารเกี่ยวกับการประเมินผลกระทบด้านสังคมและจริยธรรมจากการใช้เทคโนโลยี ด้านสุขภาพในแง่แนวคิด หลักการและวิธีการประเมิน ซึ่งพบว่าการประเมินเทคโนโลยีด้านสุขภาพมีนิยามที่ครอบคลุม การวิจัยเพื่อศึกษาผลที่เกิดจากการใช้เทคโนโลยีทั้งด้านคลินิก เศรษฐศาสตร์ สังคม และจริยธรรม อย่างไรก็ตามผู้กำหนดนโยบายทั่วโลกรวมทั้งในประเทศไทยมีความต้องการหลักฐานเกี่ยวกับประสิทธิผล ความคุ้มค่าและผลกระทบด้านงบประมาณเป็นหลัก ในขณะที่ไม่ให้ความสนใจต่อข้อมูลด้านสังคมและจริยธรรม แม้ว่าการพิจารณาเรื่องความเป็นธรรม ความยุติธรรมและประเด็นทางสังคมจะมีความสำคัญในการตัดสินใจจัดสรรงบประมาณ ด้านสุขภาพแต่การขาดหลักการและแนวทางประเมินที่เป็นที่ยอมรับในระดับนานาชาติเป็นสาเหตุหนึ่ง ที่ทำให้การประเมินผลกระทบเหล่านี้ไม่ก้าวหน้าเท่าที่ควร และเนื่องจากการสร้างข้อตกลงร่วมกันในเรื่องดังกล่าวเป็นเรื่องที่ทำได้ยาก จึงมีผู้เสนอให้เน้นกระบวนการจัดลำดับความสำคัญของเทคโนโลยีที่มีเหตุผล โปร่งใส และยอมให้มีการอุทธรณ์โดยผู้ที่ไม่เห็นด้วย นอกจากนี้บทความนี้ยังกล่าวถึงสถานการณ์ปัจจุบันเกี่ยวกับการประเมิน ด้านสังคมและจริยธรรมของเทคโนโลยีด้านสุขภาพในประเทศไทย