Special Article

Thai Health Technology Assessment Guideline Development

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Health Technology Assessment (HTA) is a comprehensive form of policy research that provides information on the consequences of the application of health technology. It is used primarily to guide health care resource allocation decisions. In Thailand, there is increasing impetus to use HTA information to allow more explicit and transparent health care priority setting. A previous study indicated that serious attention needed to be given to the quality of reporting and the use of information in the analyses. These problems could be reduced by setting up standard guidelines for conducting HTA to stimulate the provision of standardized, reliable and good quality information for policy makers. Nevertheless, Thailand has not yet set up such guidelines. This may lead to low quality evaluations. Therefore, the objective of this article was to describe the rationale for guideline development, supporting principles, guideline development process, sources of information, and future challenges for HTA.

Keywords: *Health technology assessment, Rationale, Guideline development*

J Med Assoc Thai 2008; 91 (Suppl 2): S11-5
Full text. e-Journal: *http://www.medassocthai.org/journal*

"In this world nothing can be said to be certain, except death and taxes

……..and scarcity of resources"

Alan Maynard adding on the famous Benjamin Franklin statement; our certain fate: rationing in health care (1998)

Rationales for guideline development

There are insufficient resources to provide all patients in all circumstances with the best possible healthcare. The growing health needs of an aging population and acceleration in technological development in the area of health is producing an ever-increasing demand on limited health resources. This is particularly crucial in developing country settings where resources are very limited. Health Technology Assessment (HTA) is a comprehensive form of policy research that provides information on the consequences of the application of health technology. It is used primarily to guide health care resource allocation decisions[1,2].

In Thailand, there is increasing impetus to use HTA information to allow more explicit and transparent health care priority setting. However, the systematic review of literature relating to Thailand conducted by Teerawattananon et al[3] revealed a number of methodological flaws with prior HTA publications. The review highlighted that serious attention needed to be given to the quality of reporting and the use of information in the analyses. In addition, it demonstrated a large variation in methods used which made it very difficult to compare results between studies. These problems could be tackled and reduced by setting up standard guidelines for conducting HTA. Thailand, however, has not yet set up such guidelines and this may lead to low quality evaluations. If HTA information is useful for making health care technology policy only when performed correctly and reported accurately, these findings clearly depict information barriers that would diminish the use of HTA information when used to assist in health decision-making processes.

The lack of a uniform methodology in conducting HTA can be seen as a major weakness that

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diminishes its ability to assist in the health decision-making process[4-10]. Methodological guidelines are, therefore, a way to stimulate the provision of standardized, reliable and good quality information for the target audiences[11-15]. These guidelines will increase the transparency of studies by allowing readers or users to assess precisely what the analysts have done and whether the method was appropriate. These guidelines will also help to ensure standards that enable comparisons across health care interventions because the difference in, for example, a cost-effectiveness ratio is likely to reflect true differences between the interventions being evaluated rather than differences in study methodologies.

The development of these guidelines reflects the need of the Thai setting to have its own HTA guidelines rather than using existing international and/or peer review journals' guidelines. There is especially true since the different settings have different limitations on resources and capacities. Also, different countries, governments and HTA agencies may decide to apply different fundamental principles to decisions, such as whether to place a greater value on efficiency or equity dimensions, whether and how to value health care costs etc.

It was decided in the first place that Thai HTA guidelines will pay special attention to the methodologies for conducting health economic evaluation (i.e., an approach used to analyze the costs and benefits of different health care interventions) because it is a relatively new discipline in Thailand and a large variation in the method used was observed. Furthermore, the current policy dialogues stress the need for institutional capacity strengthening to provide economic evaluation evidences to guide decisions on drug registrations by the Thai Food and Drug Administration, and the adoption of drugs into the National Essential Drug List. Thus, ensuring good quality economic evaluations and a standardization of the study framework are the main objectives of the guidelines, while the issues of feasibility, affordability and ethics (including equity) will be overviewed at the end of this guideline.

The principles supporting the development of the guideline

There were some prior requirements of these methodological guidelines. These requirements were driven by the desire to improve the quality and use of HTA studies in decision making on the diffusion of health technologies in Thailand. Firstly, the guidelines should address all major methodological aspects that the authors might face when conducting economic evaluation to minimize the risk of using unjustified or biased information. The guidelines should be clearly stated and allow readers to validate their study design and conduct using their recommendations. In addition, the guidelines should be well equipped for future adjustments that incorporate new academic findings and consensus, and to accommodate changes in the decision making context, whenever the guidelines are involved in the decision-making process.

Secondly, the guidelines should support the study to meet the need for informing the decision process for the allocation of health care resources, and achieve the necessary standard of economic evaluation study. The guidelines should address the main concerns of decision makers and recommend practical approaches to arrive at those outcomes. Lastly, the guidelines should facilitate the use of local information with recognition of the limitations of resources and information that are specific to the health care system in Thailand.

Table 1. Sources of information

Type of information	Sources	Reference
Formal guidelines	Australia (Common Wealth Department 1995)	21
	Canada (1997)	22
	Denmark (2001)	23
	Norway (2002)	24
	Hungary (2002)	25
	England & Wales (2004)	26
Informal guidelines	Gold et al (1996)	27
	Drummond et al (1997)	28
	Tan-Torres et al (2003)	29

The guideline development process and sources of information

At the end of 2006, the Health Intervention and Technology Assessment Program (HITAP) consulted experts from both academic and research institutions across the country to make a concrete plan for the development of the first methodological guideline for conducting health economic evaluation in Thailand. The development of this guideline began with a review of existing guidelines (Table 1) including those developed by governments and standard health economic evaluation textbooks in order to determine the similarities, differences, strengths and weaknesses of each major component. The inclusion criteria for selection of the guidelines to be evaluated were based on a subjective view of the authors on the methodological basis of the guidelines themselves and also the availability of the guidelines through library and electronic sources.

Recently, a number of previously developed guidelines have been produced in different formats. Many countries, such as Australia, Canada, Denmark, Norway, Hungary, England and Wales, have developed economic evaluation guidelines with different details but similar objectives. That is to provide a uniform methodology approach to improve the quality and standardization of health economic evaluation studies. Although many existing guidelines from other countries are available, there is still a limitation if those guidelines are applied to developing countries such as Thailand due to the limitations on resources and capacity when compared to developed countries[16-20].

Previously, a number of guidelines with different formats were proposed by the Panel on Cost-Effectiveness[30] and NICE guidelines[26]. A "reference case" was proposed which contains a standard set of methodological practices that researchers are advised to follow in the field of economic evaluation study. On the other hand, some guidelines[28,31] present a "critical appraisal checklist" which generally comprises relevant questions about an economic evaluation to identify and assess the strengths and weaknesses of individual studies. Guidelines developed in Australia[21] and Hungary[25] offered neither a reference case nor a standard checklist but a range of methodological options to be considered for applying in evaluations. This guideline chooses to use a reference case approach similar to that used in both the US and the UK since it intends to provide detail on the design and conduct for economic evaluations.

The scope and major components of Thai HTA guideline were defined as follows. The detailed contents of the guideline were focused on the term "economic evaluation", which refers to a study that considers both the comparative costs associated with the provision of health care interventions, and the comparative clinical effects, measured either in clinical units, health preferences, or monetary benefit[28].

The experts reviewed each of the key components specified by the team, and drafted the guidelines. During the second half of year 2007, a series of consultation meetings were carried out to present the draft to various stakeholders including experts from participating ministries i.e. the Ministry of Public Health, the National Health Security Office, the Social Security Office, the Thai Health Foundation, the Ministry of Finance, academic institutions and health care providers as well as representatives from various pharmaceutical companies. Suggestions from stakeholders were also included before the final publication.

The future challenges

Although the guidelines offer some practical guidance to improve the quality of HTA studies in Thailand, it remains to be seen whether HTA will become a useful tool for decision making regarding health care resources. On the one hand, the guidelines address all major methodological issues that might arise when conducting HTA and provide the opportunity to recognize a lack of experience and a lack of information along with other characteristics that are specific to Thai health care settings. On the other hand, other problems include a lack of understanding among potential users and social, political and institutional barriers that might inhibit the use of HTA information are still not overcome. For example, decision makers may lack the confidence to make decisions that are politically indefensible;

The key elements include the following components:

1.	Defining the scope of the study
2.	Selection of comparator(s)
3.	Defining the type of economic evaluation
4.	Measurement of costs
5.	Measurement of clinical effects
6.	Measurement of utility
7.	Handling time in the economic evaluation studies
8.	Handling uncertainty and sensitivity analysis
9.	Presentation of data and results
10.	Health system and equity perspectives in HTA
11.	Policy making and roles of HTA

therefore it is essential that the public understand and accept the use of HTA information.

In the present situation, HTA in Thailand is at the beginning phase and has not yet been widely applied in policy decisions. The guideline encourages the transparent selection of methods and evidence used in HTA studies. Although Thai HTA guideline cannot guarantee the use of HTA information in decision-making, using HTA evidence in policy will be easier if high quality and locally applicable data are readily available.

Acknowledgements

The development of these guidelines would not have been possible without the technical support, challenging criticism and encouragement of many colleagues and institutions. As editors, we wish to acknowledge all individuals and related organizations that contributed throughout the process for guideline development. In addition, we would like to give particular thanks to the funding support through the Health Intervention and Technology Assessment Program (HITAP) from the Thai Health Promotion Foundation, the National Health System Research Institute (HSRI) and the Bureau of Health Policy and Strategy, Ministry of Public Health.

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การพัฒนาคู่มือการประเมินเทคโนโลยีด้านสุขภาพสำหรับประเทศไทย

ยศ ตีระวัฒนานนท์, อุษา ฉายเกล็ดแก้ว

การประเมินเทคโนโลยีด้านสุขภาพเป็นการวิจัยเชิงนโยบายอย่างเต็มรูปแบบเพื่อให้ข้อมูลผลลัพธ์ของการประยุกต์ใช้เทคโนโลยีด้านสุขภาพ และนำมาใช้เป็นข้อมูลหลักเพื่อช่วยในการตัดสินใจด้านการจัดสรรปันส่วนทรัพยากรทางสุขภาพ ในประเทศไทยมีการขับเคลื่อนการใช้ข้อมูลการประเมินเทคโนโลยีด้านสุขภาพเพิ่มมากขึ้น โดยนำมาใช้จัดลำดับความสำคัญของมาตรการการดูแลสุขภาพให้มีความโปร่งใสและชัดเจนมากขึ้น การศึกษาที่ผ่านมาพบว่า จำเป็นต้องให้ความสนใจอย่างมากต่อคุณภาพของการรายงานผลลัพธ์และการใช้ข้อมูลสำหรับการวิเคราะห์ ปัญหานี้ลดลงได้โดยการกำหนดแนวทางการประเมินเทคโนโลยีด้านสุขภาพที่เป็นมาตรฐานเพื่อกระตุ้นให้ผลิตข้อมูลที่เป็นมาตรฐาน น่าเชื่อถือ และมีคุณภาพดีสำหรับผู้วางแผนนโยบาย อย่างไรก็ตามประเทศไทยยังไม่เคยมีการกำหนดแนวทางการประเมินเทคโนโลยีด้านสุขภาพซึ่งนำไปสู่การประเมินที่ด้อยคุณภาพ ดังนั้นจุดประสงค์ของบทความนี้คือ เพื่อบรรยายความสำคัญของการพัฒนาแนวทางการประเมินเทคโนโลยีด้านสุขภาพ หลักการที่สนับสนุน กระบวนการในการพัฒนา แหล่งข้อมูล และสิ่งที่ท้าทายในอนาคตสำหรับแนวทางการประเมินเทคโนโลยีด้านสุขภาพ