Guidelines for Health Technology Assessment in Thailand (Second Edition)-The Development Process

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The first Thai-specific HTA guidelines were completed in 2008 with the aim of ensuring that all HTA data was accurate, of high quality, and relevant for making decisions pertaining to healthcare resource allocation. Based on a quality assessment of 89 economic evaluation studies in the Thai context published in international academic journals between 1982 and 2012, the analysis revealed a significant increase in quality of data sources and result reporting in studies published after the dissemination of the first Thai HTA guidelines. As the first Thai HTA guidelines were developed in 2008, a number of areas for improvement have been identified. Therefore, the objective of this chapter is to describe the development process of this second edition of HTA guidelines for Thailand which builds on the success of the first edition, while attempting to address some of the identified limitations of the first edition and reflect the changes that the health care and policy contexts have undergone in the intervening years. It is hoped that this second edition will continue to build on these successes so that policy decision making becomes increasingly evidence-based.

Keywords: *Economic evaluation, Guidelines, Pharmacoeconomic*

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The development of health technology assessment (HTA) guidelines is a key part of any HTA research and development process. The first Thai-specific HTA guidelines were completed in 2008, with the aim of ensuring that all HTA data was accurate, of high quality, and relevant for making decisions pertaining to healthcare resource allocation. The first HTA guidelines made practical suggestions for improving the quality of health economic evaluation research and gave recommendations on key methodological issues given the particular resource and information limitations of the Thai healthcare system.

The first Thai HTA guidelines also offered guidance and resources to help researchers choose appropriate methodologies and data sources for their HTA research. By recommending a set of methodologies and data sources across HTA research, it was also hoped that there would be greater transparency, by improving the consistency and quality of research and improving research assessment, by allowing comparison against a set of pre-determined guidelines. While guidelines themselves cannot, on their own, guarantee that policy-makers will use HTA data when forming their decisions, they should help improve the quality of available HTA data and hence the extent to which policy decisions are informed by reliable scientific evidence.

The publication of the first edition of HTA guidelines has been recognized as a significant step forward in improving HTA research and development (and thus policy-making). They have received widespread acceptance in the scientific and policy making communities in Thailand, and have been approved by the Subcommittee for Development of the National List of Essential Drugs and the Subcommittee for Development of the Health Benefit Package and Service Delivery of the National Health Security Office. However, it is important to note that guidelines such as these should always be regarded as dynamic tools that will require refinement over time

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and should be adapted according to the changing nature of Thailand's healthcare context. Since the publication of the first edition, a number of areas for improvement have been identified, and the need for a second edition that reflected the changing context was recognized.

The first Thai HTA guidelines focused exclusively on making HTA recommendations from an economic standpoint; no consideration was given to other issues that have been deemed relevant for HTA, such as budgetary, social, and ethical impacts. In addition, it was widely agreed that the first Thai HTA guidelines, particularly the theoretical justification, were somewhat complicated and hard to understand. In developing the second set of guidelines, it was agreed that greater attention should be given to HTA application rather than theory, to ensure that the content was relevant and easily comprehensible.

In addition, as the first Thai HTA guidelines were developed in 2008, a number of elements were identified as out of date. For example, they included no reference to a standard cost list (a reference tool for cost assessment) and no information on the current cost-effectiveness threshold in Thailand. The first set of guidelines also relied on the EQ-5D questionnaire as an assessment of quality of life, which-while useful-has been replaced in many areas by the recently-developed, more refined assessment tool, the EQ-5D-3L questionnaire. The guidelines also make no mention of indirect comparison meta-analysis, a tool that is widely used for the indirect comparison of the clinical outcomes from a randomized controlled trial, nor do they make reference to the economic evaluation of specific conditions that require specific methodologies to simulate the progression of the disease (such as certain infectious diseases, which require dynamic models). They also give no guidance on interventions such as screening and diagnosis or medical devices. The development of this second edition of HTA guidelines for Thailand builds on the success of the first edition, while attempting to address some of the identified limitations of the first edition and reflect the changes that the health care and policy contexts have undergone in the intervening years.

Developing the second edition

The development of the second set of HTA guidelines began in June 2012, when researchers at the Health Intervention and Technology Assessment Program (HITAP) undertook a systematic review of health technology assessment research in the Thai context. The researchers focused particularly on economic evaluations and compared those published before the introduction of the first Thai HTA guidelines (1982 to December 2008) with those published afterwards (January 2009 to September 2012). To investigate how effective the HTA guidelines were, the researchers examined the extent to which the methodology of studies published after the introduction of the guidelines was consistent with the recommendations given. As well as comparing the studies with the recommendations, quality was also assessed using the quality assessment framework developed by Teerawattananon et al[1], and by assessing the quality of reporting (using criteria developed by Drummond et al[2,3]) and quality of data sources (using criteria developed by Cooper et al[4]) because the results from these criterion could reflect the quality of the studies. Fig. 1 shows the process through which the second edition of Thai HTA guidelines was developed.

In July 2012, HITAP, the body that serves as the coordinator of Thai HTA guidelines, arranged a consultation meeting for experts and stakeholders, including the Subcommittee for Development of the National List of Essential Drugs, the Subcommittee for Development of Health Benefits Package and Service Delivery of the National Health Security Office, graduate students, professors, researchers, academics, and other public and private stakeholders. During the meeting,

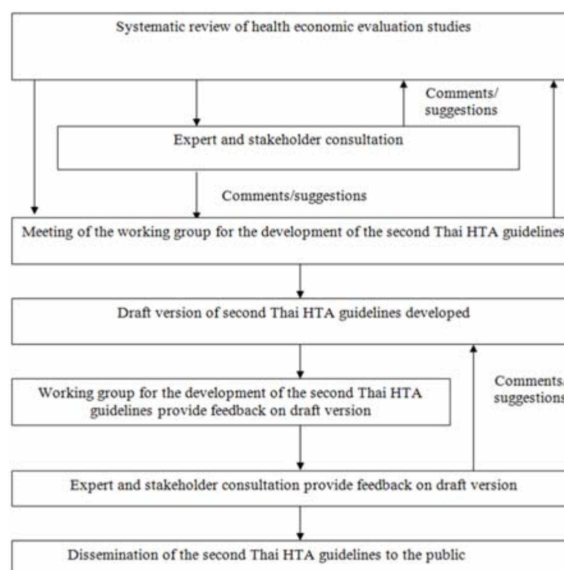

Fig. 1 Development process.

participants discussed what, aside from economic concerns, should be taken into consideration when developing the second set of HTA guidelines. They also explored the findings of several HTA studies conducted by HITAP and discussed what implications these studies might have for the development of the second edition. The benefits and limitations of the first set of guidelines were discussed, and a number of issues were identified, including the need for content modernization and the fact that there was, at present, inadequate information on how to apply the guidelines. The second HTA guideline development working group then revised the guidelines in light of all of the comments and suggestions that had been made. In November, 2012, a second expert and stakeholder consultation was held to consider the appropriateness of the draft version of the second set of guidelines. The comments and suggestions from this meeting were then incorporated into the draft to produce a final version.

Conceptual framework

Health technology assessments are policy research tools that investigate the long- and short-term effects of health technologies in a systematic way from a multidisciplinary standpoint. It is used to capture the whole range of effects–direct and indirect, intentional and unintentional, any effect resulting from the development, diffusion, and application of the technology etc.–so that decisions can be made about the value of a given technology[2]. Following the initial consultation with experts and stakeholders that was held in July 2012, it was agreed that the second Thai HTA guidelines should be developed with the aim of increasing the quality and standard of HTA in Thailand, rather than as a manual for performing HTA research. In addition, the second Thai HTA guidelines should build on the first guidelines by looking at health technology assessment from a budgetary, social, and ethical standpoint, as well as an economic standpoint.

The second edition of the Thai HTA guidelines gives greater guidance on how the guidelines should be applied, including recommendations on which data sources and tools are most appropriate based on explanatory examples from HTA research. The guideline document is concise, consisting of an introduction, an outline of concepts and principles, and a summary of recommendations. HTA theory is referred to only briefly in this second edition, since this was covered in detail in the first edition; instead, the focus of this latest set of guidelines was the improvement of research quality by increasing the availability of high quality HTA data in the hope that it will play an increasing role in the formation of policy. An overview of the content of the 2012 publication–"Guidelines for Health Technology Assessment in Thailand-Second Edition"–the final document that emerged from the process, is shown in Fig. 2 below.

Quality assessment of HTA research

A quality assessment was conducted in January 2013 of 89 economic evaluation studies in the Thai context published in international academic journals between 1982 and 2012. The studies were divided into two groups–those that were published before the dissemination of the first Thai HTA guidelines (January 1982 to December 2008) and those that were published after (January 2009 to September 2012). Quality assessment data on studies conducted between 1982 and 2005 was taken from Teerawattananon et al's 2007 review[1]. Their systematic review of literature relating to Thailand revealed a number of methodological flaws with previous 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

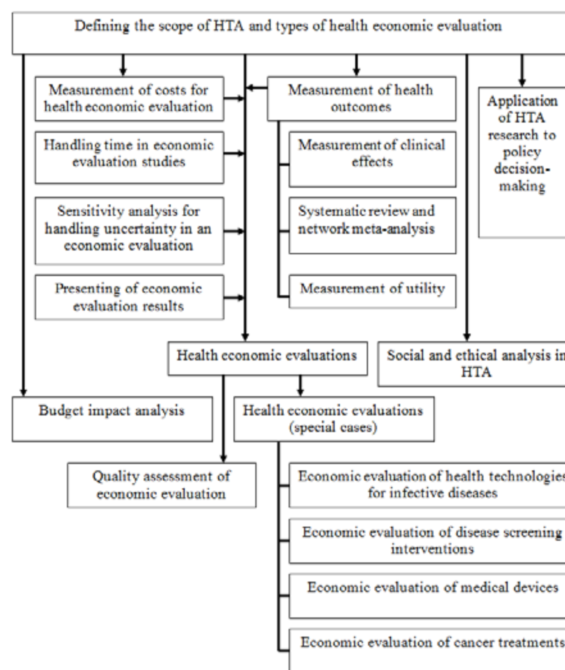

Fig. 2 Overview of the 2012 publication "Guidelines for Health Technology Assessment in Thailand-Second Edition".

significant variation in the methods that were used, making the comparison of results between studies very difficult. One way in which Teerawattananon et al suggested tackling these challenges was through the establishment of standard guidelines for conducting HTA.

Following the implementation of the first Thai HTA guidelines, a comparative analysis was conducted to examine whether research quality increased after the publication of the guidelines. This was done by assessing the extent to which important issues recommended in the first Thai HTA guidelines were adopted by subsequent studies, and by analysing quality of reporting according to criteria developed by Drummond et al[2,3] and quality of data sources according to criteria developed by Cooper et al[4]. Key factors that were examined in the analysis included whether the study had adopted a clearly-defined perspective and whether the present study compared two or more interventions. The use of incremental cost-effectiveness ratios (ICERs), uncertainty analyses, and discounting methods (where the study period was longer than one year) were also assessed for relevance, and the implications of any funding support were taken into account. Using the scale developed by Cooper et al, all data sources that were used were ranked from 1-9 according to their reliability (where 1 is most reliable).

Assessing reporting quality

Table 1 shows the results of the comparative analysis that was conducted on the quality of research reporting in economic evaluation studies published in international journals before and after the dissemination of the first Thai HTA guidelines. The criteria that was used was taken from Drummond et al[2,3]. The analysis revealed a significant increase in quality in studies published after the dissemination of the first Thai HTA guidelines.

Assessing data source quality

Table 2 shows the results of the comparative analysis that was conducted on the quality of data sources economic evaluation studies before and after the dissemination of the first Thai HTA guidelines. The criteria that was used to assess the quality was taken from Cooper et al[4]. The quality of all data sources was ranked from 1 (best) to 6 (worst) and 9 (not stated). Important data sources that were evaluated included clinical effect size, baseline clinical data, adverse events and complications, resource use, cost and utility. The analysis revealed an increase in quality in a number of data sources following the dissemination of first Thai HTA guidelines, including clinical effect size, adverse events and complications, and baseline clinical data (for more details on the ranking of data sources, including those concerned with clinical effect size, and adverse events and complications, see Measurement of Clinical Effects on the first guidelines)[5].

However, the quality of some data sources, namely resource use and cost, was found to have decreased after the dissemination of the guidelines. This is probably due to the fact that most researchers were compelled to collect their own resource utilization and cost data due to a lack of published research at that time−leaving significant room for inconsistency across studies. As the number of studies on resource use and cost has increased, it is likely that quality in these fields will increase too. The quality of utility data sources was found to have increased following the dissemination of the first Thai HTA guidelines (for more details, see Measurement of Utility on the first guidelines)[5].

The preliminary data suggests that, following the dissemination of the first Thai HTA guidelines, the quality of the reporting and data sources used in economic evaluation studies in Thailand increased

Table 1. Quality of research reporting before and after dissemination of Thai HTA Guidelines

Reporting issues	Dissemination period	
	Before (%)	After (%)
Clear identification of perspective used in the study	28/52 (54)	33/37 (89)
Identification of compared interventions	44/50 (88)	37/37 (100)
Discounting method used for future cost and outcomes, if study period is longer than one year	9/23 (39)	22/24 (92)
Result presentation as incremental cost-effectiveness ratio (ICER)	22/49 (45)	28/33 (85)
Performing uncertainty analysis	21/52 (40)	34/37 (92)
Disclosure of funding support	35/52 (67)	27/37 (73)

Table 2. Comparison of quality assessment in data sources used in economic evaluation studies before and after the dissemination of the first Thai HTA guidelines

Rank	Clinical effect size(%)		Baseline clinical data(%)		Adverse event and complications data (%)		Resource use data (%)		Cost data(%)		Utility data(%)	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
1+	2	-	-	-	-	-	-	-	2	-	-	-
1	13	-	4	7	14	-	44	7	47	21	17	-
2+	6	14	-	-	2	-	-	-	-	-	-	-
2	11	17	27	38	17	17	16	28	17	38	-	-
3+	-	31	-	-	2	33	-	-	-	-	-	-
3	2	3	8	17	2	8	-	-	2	-	17	57
4	36	14	12	24	17	33	2	3	4	21	50	22
5	17	17	4	10	24	8	-	-	4	-	-	4
6	6	-	8	-	12	-	-	10	6	10	-	4
9	6	3	38	3	10	-	38	52	17	10	17	13

significantly, and other areas of research showed improvement. These improvements suggest that HTA guidelines can play a valuable role in improving research quality, and it is hoped that this second edition will continue to build on these successes so that policy decision making becomes increasingly evidence-based.

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 authors, we wish to acknowledge all individuals and related organisations 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 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.

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กระบวนการพัฒนาคู่มือการประเมินเทคโนโลยีด้านสุขภาพสำหรับประเทศไทยฉบับที่ 2

อุษา ฉายเกล็ดแก้ว, กันต์กมล กิจตรงศิริ

คู่มือการประเมินเทคโนโลยีด้านสุขภาพสำหรับประเทศไทยฉบับที่ 1 ดำเนินการแล้วเสร็จและได้รับการตีพิมพ์เผยแพร่ตั้งแต่ปี พ.ศ. 2551 โดยมีวัตถุประสงค์เพื่อใช้เป็นแนวทางสำหรับผู้ผลิตและผู้ใช้ข้อมูลการประเมินเทคโนโลยีด้านสุขภาพเพื่อใช้ในการตรวจสอบความถูกต้องและคุณภาพของงานวิจัยที่ใช้สำหรับการจัดสรรปันส่วนทรัพยากรด้านสุขภาพและเพื่อเพิ่มคุณภาพของงานวิจัยให้เป็นที่ยอมรับ จากการประเมินคุณภาพของวรรณกรรมด้านการประเมินความคุ้มค่าสาธารณสุขในบริบทที่เกี่ยวข้องกับประเทศไทยที่ตีพิมพ์ในวารสารวิชาการนานาชาติระหว่างปี พ.ศ. 2525 ถึง พ.ศ. 2555 จำนวนทั้งสิ้น 89 ฉบับ พบว่าเมื่อเปรียบเทียบกับระยะก่อนการเผยแพร่คู่มือฯ ฉบับที่ 1 งานวิจัยด้านการประเมินความคุ้มค่าด้านสาธารณสุขในประเทศไทยในระยะหลังการเผยแพร่คู่มือฯ ฉบับที่ 1 มีคุณภาพเพิ่มสูงขึ้นอย่างมีนัยสำคัญ ทั้งในด้านการรายงานผลการศึกษาและคุณภาพของแหล่งข้อมูล อย่างไรก็ตามเนื่องจากคู่มือฯ ฉบับที่ 1 ได้รับการพัฒนาตั้งแต่ปี พ.ศ. 2551 เนื้อหาหลายส่วนจึงควรได้รับการปรับปรุง ดังนั้นวัตถุประสงค์ของบทความนี้เพื่ออธิบายถึงกระบวนการพัฒนาคู่มือฯ ฉบับที่ 2 ซึ่งปรับปรุงเนื้อหาจากคู่มือฯ ฉบับที่ 1 โดยพยายามแก้ไขจุดอ่อนที่มีอยู่ในคู่มือฯ ฉบับที่ 1 และสะท้อนบริบทของระบบสุขภาพและนโยบายด้านสุขภาพที่เปลี่ยนแปลงไป โดยหวังเป็นอย่างยิ่งว่าคู่มือฯ ฉบับที่ 2 นี้จะช่วยส่งผลให้มีการนำเอาข้อมูลหลักฐานทางวิชาการมาประยุกต์ใช้ในการตัดสินใจเชิงนโยบายเพิ่มมากขึ้น