Quality Assessment of Health Economic Evaluation

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In Thailand, the results of economic evaluations have increasingly been used to help improve the transparency of health technology prioritization and to inform the resource allocation decision-making process. However, variable quality can mean that application of study results can be limited. To help improve uniformity and widen the application of results, quality assessment of health economic evaluations is crucial. By subjecting health economic evaluations to a rigorous quality assessment process, decision-makers can choose to only use findings from studies that reach the appropriate standard as the basis for policy-making. This article gives a summary of the three key areas to examine when assessing quality–1) data sources, 2) result reporting and 3) and analysis methodology. It is hoped that this will help provide critical guidance to users of economic evaluation results to ensure that they understand and are able to perform quality assessment prior to applying study findings.

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Health economic evaluation (HEE) is one of the approaches used in health technology assessment (HTA). In Thailand, the results of economic evaluations have increasingly been used to help improve the transparency of health technology prioritization and to inform the resource allocation decision-making process[1,2]. Subjecting HEEs to quality assessment ensures that studies are of the requisite standard and helps determine whether they are fit to inform policy decision-making. Increasingly, policy-makers are using the evidence garnered from heath economic evaluations to inform their policy decisions. This can be seen, for instance, in the drug regulation authority's drug registration process and the selection process for inclusion of drugs on the National List of Essential Medicines or hospital formulary, both of which rely in part on data from economic evaluations. Clearly then, it is important that health professionals have access to information regarding the quality of the health economic evaluations from which they are taking data.

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Why assess the quality of health economic evaluation studies?

Data from health economic evaluations (HEE) should only inform policy decision-making when users understand the three main reasons why assessing the quality of these health economic evaluations is important.

First, quality assessment ensures that only appropriate HEE studies are used to inform policy. This means that only HEE studies that compare the costs and outcomes of at least two health interventions should be used. However, most studies that refer to themselves as a cost-effectiveness analysis do not fulfil these criteria. Any study that either evaluates only costs or does not compare two or more interventions should be regarded as invalid as a basis for policy decisions regarding cost-effectiveness. A diagram of this process is shown in Fig. 1.

Second, quality assessment ensures that the quality of the information generated by the HEE is of the requisite high quality. Teerawattananon et al's recent study assessing the quality of result reporting in HEE studies within the Thai context found that both the quality and quantity of HEE studies in Thailand was still limited[3]. Their study also revealed significant variation in the methods used, meaning that the comparison of data from different studies is very difficult; this is surely due in part to the absence of

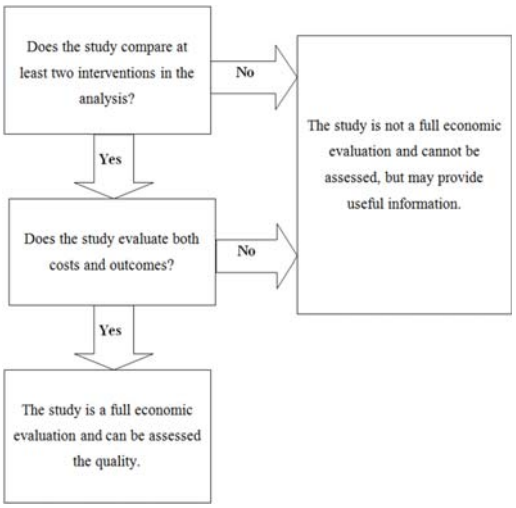

Fig. 1 Method to select health economic evaluation studies for quality assessment.

economic evaluation guidelines specific to Thailand. HEE information of a high quality should only be regarded as of use to policy decision-makers where it is performed correctly and reported accurately; a lack of high quality HEE studies should be regarded as a barrier to effective policy decision-making[6-12].

Third, quality assessments allow the reliability of the HEE results to be evaluated appropriately. Since HEE studies can be performed using a modeling approach and researchers can input parameter data to predict the cost-effectiveness of a given health interventions, there is a tendency for manipulation of the results to occur, which can lead to unreliable HEE results. Quality assessment of HEE studies limits this and ensures greater result reliability.

A method for selecting health economic evaluation studies for quality assessment

Once HEE studies have been identified, each study should be examined to see if it fits the criteria for quality assessment. Any studies that fail to fulfil the criteria should not be used for quality assessment, although they should still be retained for reference. There are two criterion that need to be fulfilled (Fig. 1): 1) the study must compare at least two choices of interventions and 2) the study must evaluate both costs and outcomes.

Guidelines for health technology assessment in Thailand (second edition): Recommendations for quality assessment of economic evaluation studies

Once the appropriate studies have been identified, quality assessment can begin. The quality assessment examines three areas: 1) data sources 2) result reporting and 3) analysis methodology.

Quality assessment of data sources

Economic evaluation studies rely on numerous clinical and cost data sources. The quality of the data garnered from these sources will affect the quality of the analysis; thus, assessment of their quality is crucial. The quality of cost data sources in economic evaluations is assessed according to the hierarchy of evidence (see chapter "Measurement of Costs for Health Economic Evaluation" in this volume) and the quality of clinical data is assessed according to the hierarchy of clinical evidence (see "Measurement of Health Outcomes" in this volume).

Quality assessment of result reporting

The quality of the result reporting is assessed using the criteria developed by Drummond et al[4,5]. A summary of these criteria is given below:

- The study perspective is clearly defined.
- The characteristics of the compared intervention are described.
- Discounting for both costs and outcomes of the study period is greater than one year.
- Incremental cost-effectiveness ratio (ICER) is calculated.
- Uncertainty analysis is performed.
- All funding sources are disclosed.

Quality assessment of analysis methodology

A number of guidelines have made recommendations on how best to assess the quality of the methodology used in economic evaluations. These can be divided into two types: guidelines established by the national bodies responsible for performing economic evaluations in each country (e.g. Australia[14], Canada[15], Denmark[16], Norway[17], Hungary[18], England and Wales[19], and Thailand[13]) and guidelines developed by health economists (i.e. Drummond et al[4,5], Gold et al[20], and Tan-Torres[21]).

To ensure that all economic evaluations are transparent, easily comparable, and of high quality, in this second edition of HTA guidelines for Thailand, we outline a specific reporting format for researchers to follow, comprising of ten key elements, all of which should be included. A report checklist has been developed to help guide this process (Table 1). The report checklist can be used alongside the guidelines to assess whether HEE studies can be used by decision-

Table 1. Checklist for quality assessment for health economic evaluation studies

Title of study		
Name of journal, volume, year, page		
1. The study assesses both costs and outcomes	[ ] Yes	[ ] No
2. The study compares at least two interventions	[ ] Yes	[ ] No
If answers are "Yes" for both questions, please continue to the below checklist If answer is "No" for any question, the study is not full economic evaluation		

Criteria for quality assessment for economic evaluation studies	Answer[1]			Comments
	Yes	No	N/A	
Study design				
1. State the background of the problem				
2. State the economic importance of the study				
3. State the clinical importance of the study				
4. State the objective of the study				
5. State the target population for intervention				
6. State the perspective of the study				
7. State the time horizon				
8. State the type of economic evaluation methods (i.e., CMA, CBA, CEA, or CUA)				
9. The type of economic evaluation method is appropriate to the study objective				
10. State the design of the analysis				
11. State the description of all interventions in the analysis				
12. State the rational of selecting the comparators in the analysis				
Cost and effectiveness data				
13. Identify the outcome measured in the study				
14. State the sources of effectiveness data			=……..	If yes, the lowest rank
15. State the study design of effectiveness data (if one study was used.)				
16. State the description of meta-analysis in synthesizing effectiveness data (if multi-study were used.)				
17. State the valuation of utility			=……..	If yes, the lowest rank
18. Summarize effectiveness parameters in table				
19. Cost data components are in accordance with study perspective				
20. State the sources of cost or charge data			=……..	If yes, the lowest rank
21. Describe the method of collecting indirect cost and direct non-medical cost				
22. State the resource use separately from the cost data				.
23. State the valuation of resource use and unit cost				
24. State the year of valuation for all costs				
25. State details provided of any adjustment for inflation/deflation for all costs				
26. State the currency unit of cost data				
27. In the case of exchanging money values, state the exchange rate				
28. State the method of transforming charges into costs or costs into charges				
29. In the case of using data from expert opinion, state the sources and methods used to collect the data				
30. In the case of the study period being longer than 1 year, state whether discounting has been performed for costs and/or effect.				

Table 1. cont.

Criteria for quality assessment for economic evaluation studies	Answer[1]			Comments
	Yes	No	N/A	
31. In case of the study period being longer than 1 year, state the discount rate				
32. State the rationale of using the chosen discount rate				
33. In cases of discounting has not been performed, state the rationale				
34. Summarize cost parameters in table				
Model (if applicable)				
35. Describe the event pathway in the model				
36. Show a diagram of event pathways in the model				
37. State the software used in the model				
38. State the details of model validation that have been provided				
39. State the time horizon used in the model				
40. For Markov models, state the cycle length of the model				
41. State all assumptions used in the model				
Uncertainty or Sensitivity analysis				
42. Perform the sensitivity analysis				
43. State the sensitivity analysis method				
44. State the choice of variables and the ranges used in the sensitivity analysis				
45. Describe the rationale of chosen parameters in the sensitivity analysis				
Result presentation				
46. When performing the incremental analysis, all relevant interventions are included.				
47. Report the results of the incremental analysis				
48. Present the results of the undiscounted reference case values i.e., total cost, total effectiveness, incremental cost, incremental effectiveness, and incremental cost-effectiveness ratio				
49. Explain the summary of the reference case results				
50. Present the important disaggregated and aggregated results				
51. Present the result in graph i.e. the cost-effectiveness plane				
52. Present the sensitivity analysis i.e. tornado diagram or cost-effectiveness acceptability curve				
53. State the conclusion of sensitivity analysis				
54. In case of the budget impact analysis performed, state the analysis result				
Discussion				
55. State the answers for research questions				
56. State the conclusion in accordance with the reported results				
57. State the conclusions and appropriate precaution of the study				
58. Explain the feasibility of the application of study results on policy decision making				
59. Discuss the important ethical implications				
60. Explain the limitations of the study				
61. Compare the results with other studies' results				
62. State the impact on annual budget				
63. State the funding sources for the study				
64. State the author's conflict of interest with the funding sources				

[1]Answer "Yes" if the study clearly specify according to criterion
Answer "No" if the study not clearly specify according to criterion
Answer "Not applicable" if the criterion not applicable to the analysis i.e. The criteria of modeling approach are not applicable for non-model study.
When answer "No", description of missing or irrelevant data should be specified.

makers as a basis for policy. The checklist is not limited to administrators and policy-makers at the national and local level. Indeed, if stakeholders such as pharmaceutical companies were required to submit HEE information about their products alongside the clinical information which they already have to supply, they could use the checklist as a key tool to generate data that might be very beneficial to those who decide which technologies are included in health benefit packages. However, the checklist should only be regarded as a tool to help guide the preliminary phase of quality assessment; it is not intended to be used to judge the quality of study's methodology or results.

Method for scoring the quality of economic evaluation studies

Many studies have used the checklist to allocate a score to each question, after which the individual scores are added together to arrive at a total final score that is indicative of a study's overall quality. A review of the existing literature identified six studies that outlined suggested scoring systems for the quality assessment of health economic evaluations. However, no uniform scoring approach was found that is both valid and reliable for the quality assessment of methodology used in economic evaluation. As such, the use of a scoring system for the quality assessment of methodology used is not recommended[22]. Instead, results from the quality assessment should be presented in the same format as the checklist, with a description of the results and how they compare to the criteria presented alongside. Moreover, full explanation of the methodology used and the results should be given, along with a description of the key strengths and weaknesses of the present study that may affect the reliability of the results.

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Potential conflicts of interest

None.

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การประเมินคุณภาพของงานวิจัยด้านการประเมินความคุ้มค่าทางสาธารณสุข

อุษา ฉายเกล็ดแก้ว, กันต์กมล กิจตรงศิริ

ในประเทศไทยมีการใช้ข้อมูลการประเมินความคุ้มค่าด้านสาธารณสุขเพื่อช่วยเพิ่มความโปร่งใสในการจัดลำดับความสำคัญของเทคโนโลยีด้านสุขภาพและกระบวนการตัดสินใจเพื่อจัดสรรปันส่วนทรัพยากร อย่างไรก็ดีงานวิจัยด้านการประเมินความคุ้มค่าทางสาธารณสุขนั้นมีคุณภาพที่หลากหลายอาจส่งผลให้เกิดข้อจำกัดในการนำผลการศึกษาไปประยุกต์ใช้ ดังนั้นการประเมินคุณภาพงานวิจัยด้านการประเมินความคุ้มค่าทางสาธารณสุขจึงมีความสำคัญ ทั้งนี้เฉพาะการศึกษาที่มีคุณภาพดีเท่านั้นที่ควรถูกนำมาใช้เพื่อสนับสนุนการตัดสินใจเพื่อจัดสรรปันส่วนทรัพยากรทางสุขภาพอย่างมีประสิทธิภาพ วัตถุประสงค์ของบทความนี้เพื่อเสนอแนะแนวทางที่สำคัญในการประเมินคุณภาพของงานวิจัยด้านการประเมินความคุ้มค่าทางสาธารณสุข ได้แก่ 1) แหล่งที่มาของข้อมูล 2) การรายงานผลการการศึกษา และ 3) วิธีวิจัย โดยมุ่งหวังว่าบทความนี้จะช่วยเป็นแนวทางสำหรับผู้ที่จะใช้ประโยชน์จากผลการศึกษาการประเมินความคุ้มค่าทางสาธารณสุข เพื่อทำให้มั่นใจได้ว่าสามารถประเมินคุณภาพงานวิจัยได้ก่อนที่จะนำมาใช้ประโยชน์ต่อไป