Special Article

Presentation of Economic Evaluation Results

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In Thailand, economic evaluation results are being increasingly used for making health care resource allocation decisions. To assess the usefulness of economic evaluation information, users of studies such as policy decision makers or health care providers need to know whether the methods used in the study are appropriate and whether the results are valid. The quality of previous economic evaluation studies, however, was quite poor. The objectives of this article are to review the similarities and differences in reporting formats based on existing reporting formats suggested by published methodological guidelines for economic evaluation, and to provide recommendations for economic evaluation result presentation for Thai Health Technology Assessment guidelines. The article presents a recommended reporting format including ten key elements necessary for economic evaluation techniques. The recommended format will increase the transparency of studies as well as facilitate comparisons between studies. This may eventually lead to high-quality and reliable economic evaluation studies available for policy decision making in Thailand.

Keywords: *Result presentation, Economic evaluation, Thailand, Reporting format*

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Economic evaluation studies is used to improve decisions about the allocation of health care resources. In order to evaluate the usefulness of economic evaluation results, users of studies i.e., policy makers and health care providers, need to know whether the methods used in the study are appropriate, whether the results are valid and whether the results can ultimately be applied to their settings. Currently, some published methodological guidelines for economic evaluation recommend that reporting formats need to present results. There are a number of reasons why a standardized reporting format for economic evaluation would be useful[1]. The first reason is that the transparency of studies will be increased because it will be more straightforward to accurately evaluate whether the methods are proper and to determine what the researchers have analyzed[2]. Second, it may help to compare the results between studies. For example, if the results of cost-effectiveness ratios were presented in a similar format, the users or readers would be more certain that the differences in the ratios between studies indicated the characteristics of the interventions being evaluated rather than differences in study methodologies. Lastly, a standardized reporting format would improve the quality of studies as analysts will be required to specify the important methodological considerations in the report.

Consequently, the reporting format for presentations of economic evaluation results is tremendously important and necessary, especially in Thailand, a developing country where economic evaluation results have been increasingly used for policy decision-making. This is true because the quality of previous economic evaluation studies in Thailand was poor[3]. The objectives of this article are to review the similarities and differences in reporting formats based on existing reporting formats suggested by published methodological guidelines for economic evaluation, and to provide a recommendation for economic evaluation result presentations for Thai Health Technology Assessment (HTA) guidelines.

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Similarities and Differences of Existing Reporting Formats

Based on the published methodological guidelines for economic evaluation, there are a number of similarities along with several differences among available existing reporting formats. A number of reporting formats are used by the Commonwealth of Australia, the Ontario Ministry of Health[4], the Canadian Co-ordinating Office for Health Technology Assessment[5], and the National Institute for Clinical Excellence[6] for the provision of economic data before the reimbursement of pharmaceuticals. In addition, the reporting formats recommended by the US Public Health Service Panel on Cost-Effectiveness in Health and Medicine[7], and the British Medical Journal (BMJ) Working Party on Economic Evaluation[8], are more focused on the methodological standards in published studies and on how to interpret the results of economic evaluation by decision makers. Moreover, the reporting format proposed by the Task Force on Principles of Economic Analysis of Health Care Technology emphasises the importance of methodological issues and the relationship between researchers and sponsors[9].

Several reviews have compared the similarities and differences between economic evaluation guidelines[10-12]; even though there are differences among various proposed reporting formats, these reporting formats recommended by existing guidelines include common details regarding:

1) the background/rationale of the problem;

2) the viewpoint of the analysis;

3) the reasons for selecting the type of analysis;

4) the population to which the analysis applies;

5) the comparators being assessed;

6) the source of the medical evidence and its quality;

7) the range of costs considered and their measurement in physical and monetary terms;

8) the measure of effectiveness/benefits in the economic study;

9) the methods for adjusting the timing of costs and benefits;

10) the methods for dealing with uncertainty;

11) the incremental analysis of costs and benefits;

12) the overall results of the study and its limitations;

From the list above, there is a consensus on the requirement to report major components of study methodologies. However, there is no complete agreement on how each methodological issue should be handled. Based on the review of 25 published guidelines for economic evaluation, Hjelmgren *et al*[11] found that the guidelines were in agreement of about 75% of methodological aspects. Disagreement between guidelines was highlighted in the choice of perspective, resources, costs that should be included in the analysis, and methods of evaluation that resources used. These differences were due to the dissimilar health systems of each country and the different purposes of the guidelines. For example, Tarn *et al*[13] reviewed and compared 28 pharmacoeconomic guidelines from 23 countries based on 32 key features. Regarding the standard reporting format, they found that nine guidelines (the Baltic countries (Latvia, Lithuania, Estonia), Finland, France, Ireland, New Zealand, Scotland, Spain, Sweden, and, England & Wales) did not include a standard reporting format while eleven guidelines (the Baltic countries (Latvia, Lithuania, Estonia), Canada, Germany, Ireland, Poland, Portugal, Hungary, Sweden, Belgium, the Canadian Common Drug Review, and the US) recommended the disclosure of funding or an author's potential conflict of interest.

Recommendations on Thai Health Technology Assessment (HTA) Guidelines

Most guidelines specify a required reporting format to present the results from economic evaluations. Regarding the Thai HTA guidelines, a common recommendation is that all ten key elements should be clearly stated as follows.

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) Handling time in economic evaluation studies

7) Handling uncertainty and sensitivity analysis

8) Presentation of the results

9) Discussion of the results

10) Disclosure of funding and author's conflict of interest

1) Defining the scope of the study

A framework is an introduction commonly providing the background of the study, the economic

and clinical importance of the study, and a description of the study design. The rationale of the problem should be addressed and the program or intervention being analyzed should be carefully described. Moreover, the objective of the study should be addressed. Enough details should be provided for readers to be able to evaluate the appropriateness of generalizing the results of the analysis.

The perspective of the study should be clearly indicated at the beginning of the report because it is an important part of the study which defines the costs and effects related to the analysis. In addition, the scope and boundaries of both the analysis and the time horizon should be clarified. The boundaries are defined by the groups of people included and the type of effects analyzed. The time horizon describes how long the resource use and effects are to be measured for.

2) Selection of comparator(s)

The explanation of the intervention contains the characteristics of the target population, the care settings, the mode of service delivery, and the timing of the intervention. The characteristics of the target populations may include age, gender, race, socioeconomic status, clinical history, geographic location or other descriptors. The care settings, such as hospitals, ambulatory clinics, or primary care practices should be described. The mode of service delivery such as equipment, personnel, and other aspects of the strategy used, should be also indicated.

The description of the comparators should be specified and the reason why the comparators are selected should be addressed. The comparators are the best available alternative as defined by clinical guidelines, an inexpensive alternative, or a "do-nothing" alternative. An explanation of these alternatives may help readers understand how they relate to current practice.

3) Defining types of economic evaluation

The type of economic evaluation used in the analysis (*i.e.* cost-minimization analysis, cost-benefit analysis, cost-effective analysis, or cost-utility analysis) should be reported including the strategy, structure, and important assumptions. It is also important to indicate the outcome(s) of interest.

If the mathematical or simulation model is used, the method (*e.g.* decision tree model, state-transition or Markov model, or a probabilistic simulation model) and all assumptions used in the model should be specified. If the Markov model is used, health states, cycle length, mechanisms for movement between states in simulation models, and the special features of the analysis should be explained. A diagram of the event pathway of the model and the software used should also be presented. In the case of using a model, the tests performed to demonstrate the accuracy of the programming and to establish the face validity of the model calculations should be described in brief. Moreover, the tests on the performance of the model using extreme assumptions will demonstrate to the readers that the model gives predictable results.

4) Measurement of costs

The cost section should include the year in which the costs are presented in the study and the type of currency used. The year will allow the readers to interpret the cost-effectiveness ratio, or compare it with the results of other studies. All costs due to the intervention and related events following the intervention in reference case-values, should be reported. Adjustments for inflation such as use of the medical component of the Consumer Price Index (CPI) should be specified where applicable. In addition, it is recommended that the types of costs, such as direct and/or indirect be stated. It is also suggested that the cost per unit of each resource, the number of units consumed, the method for cost valuation, and the source of data for each estimate in a table be presented. It is essential to report whether the cost or charge data have been used, and whether the ratios of cost to charge have been applied. It is also necessary to mention the quality of the cost data as well.

5) Measurement of clinical effects

An understanding of the source of effectiveness in the analysis is essential to evaluate the quality of the analysis and the appropriate use of its results. The effectiveness content should be discussed regarding the evidence of effectiveness of the intervention, the nature of the relevant disagreement, and the direction of the evidence. The rationale and necessary assumptions should be presented to provide estimates of effectiveness for the analysis when primary research or studies from supporting literature are used. Also the inclusion and exclusion criteria of the literature review should be notified. If program-specific primary data is utilized, the general strategy used and important assumptions made should be clarified. For example, to extrapolate survival beyond the end of the empirical data, survival analysis may

have been used. If this is the case, the assumptions should be addressed in the report. If a survey is used, the response rate should be reported. The effectiveness section includes the assumptions required and the mechanisms used to incorporate data into an analysis. It is helpful to summarize estimates of effectiveness at the reference case values used in the analysis in a table for convenient reference by the readers.

Information on health states or utility may have been collected previously by measuring health states directly within the study, or by asking experts to determine the health states. The instruments that have been used (*e.g.* the Health Utilities Index or the EuroQoL), the information explaining the measurement, as well as the methods used for value-outcomes (*e.g.* rating scale or time trade off), should be reported. It is recommended that the different health states used in the study and the related preference weight in a table format be presented.

In the analysis, if experts are required to provide input (*e.g.* estimate probabilities, costs, preference weights, etc.), the basis for selecting the experts, the source of their expertise, the number of experts contributing, the reason for using expert judgment, and the process used to obtain their input should be clearly described.

6) Handling time in economic evaluation studies

When a study period is longer than one year, it requires costs and health effects to be discounted. In these cases, it should be stated whether both costs and health effects are discounted as well as giving a statement of the discount rate.

7) Handling uncertainty and sensitivity analysis

Both the methods used to evaluate the effects of uncertainty in the analysis and the important results with confidence interval of the cost-effectiveness ratio should be presented. The choice of variables and the ranges used in the sensitivity analysis also should be reported. If the Monte Carlo simulation is used, the tests of the assumptions made concerning the distributions of variables and their statistical independence should be included.

8) Presentation of the results

Reference case results should be presented as a table of costs and effects of all the alternatives. For each alternative, it is recommended that per capita of total costs, total effectiveness, incremental costs, incremental effectiveness, and incremental cost-effectiveness ratios (ICER) be reported in an accompanying table. Although the discounted results using the discount rate at reference case are presented as the main results, the presentation should include both the discounted and undiscounted results.

If possible, the aggregate and disaggregate results on costs, outcomes and cost-effectiveness ratios should be presented to provide information about the effects of the intervention at both a population and individual level. It is suggested that years of life saved and quality adjusted life years saved (QALYs) should be reported in order to provide readers with an understanding of the relative importance of life-lengthening and the quality-enhancing benefits of the intervention. Additionally, costs and cost-effectiveness ratios should be presented in Thai currency (baht) on the cost per unit of effectiveness with the year of the cost calculation, for example 50,000 baht per QALY saved (2008 baht value). The costs and incremental cost-effectiveness ratios should also be rounded to whole baht or to the nearest thousand, and the effectiveness should be rounded, where appropriate. If there is a dominant option (*i.e.* a higher cost and lower effectiveness than other options), it should be specified in the table that the option is "dominant" instead of reporting the ratios. It is not recommended to report the average or absolute cost-effectiveness ratios for each alternative, because the readers may be confused and it may lead to a misinterpretation of the results[3].

It is also suggested that graphical presentations of the study results would be helpful for general readers. If the incremental cost-effectiveness results are presented graphically, the incremental costs (two consecutive interventions) should be displayed on the vertical axis and the incremental effectiveness (*i.e.* QALY) should be on the horizontal axis, so that the slope of the line segment represents the increment cost-effectiveness ratio. In addition, if a probabilistic sensitivity analysis is performed, cost-effectiveness acceptability curves, which present the relationship between the value of ceiling ratios (willingness to pay for a unit of outcomes) and the probability of favoring each treatment strategies, are also recommended.

9) Discussion of the results

This section should start with a descriptive interpretation of the quantitative results of economic evaluation followed by a discussion of the overall effect of important assumptions and the results from the sensitivity analysis of key parameters. The limitations of the study, for example the assumptions based

on expert opinions, theoretical models, or incomplete data, should also be stated to help the readers interpret and generalize the results.

A comparison of results from other economic evaluation studies of similar or related interventions should be included. In doing so, the currency year used in other studies should be converted to the year used in the author's study using the Consumer Price Index (CPI). If the year of analysis is not specified in the report, it is suggested that three years before the date of publication be used. It is also important that the similarities and differences of results between studies be clearly explained

The cost-effectiveness of an intervention can only be determined relative to other interventions. It is difficult to make certain statements regarding the incremental cost-effectiveness ratio of the intervention alone. Whether an intervention should be implemented depends on the resources available, alternative uses of resources, and other constraints considered by decision makers. As a result, researchers should be careful when stating that an intervention is "cost-effective" or "not cost-effective".

It is proposed that the potential budgetary impact on public and private healthcare expenditure should be estimated and discussed. This should include the impact on annual budgeting and the cumulative impact over a relevant period. It is also important to highlight the possible savings or additional non-monetary resources needed when the intervention is implemented. In addition, it may be important to discuss whether the introduction of the intervention will lead to increased or decreased need for related health care services. Equity or ethical considerations related to the introduction of the new intervention, for example access or utilisation of healthcare, reduced or increased inequality in health status, effect on a disadvantaged social group, should also be discussed.

10) Disclosure of funding and author's conflict of interest

The study should reveal the source of financial support of the study in order to make it transparent. The relationship between the authors and financial supporters and/or the authors' potential conflict of interest with the funding sources should also be specified.

Final remarks

Guidelines demand a uniform approach for reporting results from economic evaluation to increase the transparency of studies, facilitate comparisons between studies, or improve the general quality of the evaluation undertaken. A common recommendation is that all ten key elements discussed earlier in the guidelines be clearly stated in the report.

To help guide general readers, the authors have developed a report checklist (see Appendix) which summarizes the above recommendations. It is suggested that this checklist be used alongside the guidelines to facilitate assessment on whether the methods used in the study are appropriate and whether the results are valid. It is also considered that the guidelines and report checklist may be potentially useful if national or local health care authorities require a submission of the economic evaluation studies conducted by stakeholders in addition to clinical data for the consideration of the adoption of health technology in health care benefit packages.

Acknowledgement

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การรายงานผลการประเมินความคุ้มค่าทางการแพทย์

อุษา ฉายเกล็ดแก้ว, ยศ ตีระวัฒนานนท์

ในประเทศไทย ผลลัพธ์ที่ได้จากการประเมินความคุ้มค่าทางการแพทย์ถูกนำมาใช้สำหรับการตัดสินใจเพื่อการจัดสรรปันส่วนทรัพยากรด้านการดูแลสุขภาพเพิ่มมากขึ้น ผู้ใช้ข้อมูลได้แก่ ผู้วางแผนนโยบาย หรือผู้ให้บริการทางสุขภาพจำเป็นต้องทราบว่าวิธีวิเคราะห์ที่ใช้ในงานวิจัยมีความเหมาะสมหรือไม่ และผลลัพธ์ที่ได้จากงานวิจัยมีความถูกต้องและแม่นยำหรือไม่ เพื่อสามารถนำมาประเมินการใช้ประโยชน์ของผลลัพธ์ที่ได้จากการประเมินความคุ้มค่าทางการแพทย์ งานวิจัยด้านการประเมินความคุ้มค่าทางการแพทย์ที่ผ่านมาค่อนข้างด้อยคุณภาพ วัตถุประสงค์ของบทความนี้เพื่อทบทวนความเหมือนและความแตกต่างของรูปแบบรายงานที่เสนอแนะโดยคู่มือการประเมินความคุ้มค่าทางการแพทย์ที่ได้รับการตีพิมพ์แล้ว และเพื่อให้ข้อเสนอแนะสำหรับรูปแบบการรายงานผลการประเมินความคุ้มค่าทางการแพทย์ในคู่มือการประเมินเทคโนโลยีด้านสุขภาพสำหรับประเทศไทย บทความนี้เสนอแนะรูปแบบการรายงานผลที่ประกอบด้วยส่วนประกอบหลักสำคัญสิบประการซึ่งจำเป็นต่อการประเมินความคุ้มค่าทางการแพทย์ รูปแบบการรายงานผลนี้จะช่วยเพิ่มความโปร่งใสของงานวิจัย ทำให้สามารถเปรียบเทียบผลลัพธ์ระหว่างงานวิจัยได้ท้ายที่สุดจะนำไปสู่การได้มาซึ่งงานวิจัยที่มีคุณภาพสูง น่าเชื่อถือ และสามารถนำมาใช้เป็นข้อมูลที่เป็นประโยชน์สำหรับการตัดสินใจเชิงนโยบาย

Appendix. Checklist for economic evaluation report

Please tick (√), fill in the blank, and write the number of the page which contains the details of each following topic

Intervention .....
Compared with .....
Indication of intervention .....

Checklist for Economic Evaluation Report	√	Page
1. Framework		
1.1 State the background of the problem		
1.2 State the economic importance of the study		
1.3 State the clinical importance of the study		
1.4 State the design of the analysis		
1.5 State the objective of the study		
1.6 State the target population for intervention		
1.7 State the comparator programs or interventions		
1.8 State the time horizon		
1.9 State the perspective of the study		
1.10 State the type of economic evaluation methods (i.e., CMA, CBA, CEA, or CUA)		
2. Cost and effectiveness data		
2.1 Identify the outcome measured in the study		
2.2 State the sources of efficacy data		
2.3 State the sources of cost or charge data		
2.4 In the case of using data from expert opinion, state the sources and methods used to collect the data		
2.5 State the resource use separately from the cost data		
2.6 State the method of transforming charges into costs or costs into charges		
2.7 State the types of costs (e.g., direct, indirect)		
2.8 State the year of valuation for all costs		
2.9 State details provided of any adjustment for inflation/deflation for all costs		
2.10 In the case of exchanging money values, state the exchange rate		
2.11 State the valuation of cost		
2.12 State the valuation of effectiveness		
2.13 State the valuation of utility		
2.14 In the case of the study period being longer than one year, state whether discounting has been performed for costs and/or effects		
2.15 In case of the study period being longer than one year, state the discount rate		
2.16 State the reference case values used in the analysis		
3. Model (if applicable)		
3.1 State the choice of model (e.g., decision tree, Markov, etc.)		
3.2 State the description of the model used		
3.3 State the time horizon of the model		
3.4 For Markov models, state the cycle length of the model		
3.5 State all assumptions used in the model		
3.6 Describe the event pathway in the model		
3.7 Show a diagram of event pathways in the model		
3.8 State the software used in the model		
3.9 State the details of model validation that have been provided		
3.10 Present the results of model testing		

Checklist for Economic Evaluation Report	√	Page
4. Uncertainty or Sensitivity analysis		
4.1 Perform the sensitivity analysis method		
4.2 State the sensitivity analysis method		
4.3 State the choice of variables and the ranges used in the sensitivity analysis		
4.4 Present the results of sensitivity analysis		
4.5 State the summary of sensitivity results to assumptions and uncertainties in the analysis		
5. Result presentation		
5.1 Present the results of the reference case both discounted and undiscounted values such as total cost, total effectiveness, incremental cost and incremental effectiveness		
5.2 Present the disaggregated results of cost and effectiveness		
5.3 Present the aggregated results of cost and effectiveness		
5.4 Explain the summary of the reference case results		
5.5 Present the cost-effectiveness acceptability curve		
6. Discussion		
6.1 Discuss the analysis assumptions and important ethical implications		
6.2 Explain the limitations of the study		
6.3 Explain the relevance of study results for specific policy questions or decisions		
6.4 Compare the results with other studies' results		
6.5 State the impact on annual budgeting and the cumulative impact over a relevant period		
6.6 State the funding sources		
6.7 State the author's conflict of interest with the funding sources		

Title of the article .....

Name of journal, volume, year, page .....