Presentation of Economic Evaluation Results

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The first HTA guidelines for Thailand included a chapter outlining a set of guidelines on how best to report the findings of health economic evaluations, based on a review of best practice and existing guidelines on the presentation of economic evaluation results from around the world. In this second edition of HTA guidelines for Thailand, the recommendations build on the first edition by using a case study to illustrate how the guidelines can be applied in a real research context. The guidelines propose that all reporting include ten key elements: defining the scope of the study, selection of comparator(s), defining the type of economic evaluation, measurement of costs, measurement of clinical effects, handling time in economic evaluation studies, handling uncertainty and sensitivity analysis, presentation of the results, discussion of the results, and disclosure of funding and authors conflict of interest.

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The first HTA guidelines for Thailand included a chapter outlining a set of guidelines on how best to report the findings of health economic evaluations[1], based on a review of best practice and existing guidelines on the presentation of economic evaluation results from around the world[2-11]. In this second edition of HTA guidelines for Thailand, the recommendations build on the first edition by using a case study to illustrate how the guidelines can be applied in a real research context. The case study that was used examined the cost-utility and budget impact of allogeneic hematopoietic stem cell transplantation for severe thalassemic patients in Thailand[12]. For detailed information on the theory of reporting for economic evaluations, and a full version of the recommendations, please refer to the first edition of the guidelines[1]. A summary of the guidelines are given below, together with examples from the case study.

Concepts and Principles: Presentation of economic evaluation results

Defining the scope of the study

All introduction sections of study reports should include a summary of the background of the present study, study rationale, and the economic and a summary of the clinical importance of the study (prevalence, incidence, mortality rate, etc.). A summary of the economic burden of the intervention should also be provided, alongside a detailed description of the study design, and a description of the program or intervention under consideration. If a research question is identified, it should be in a format that can be answered with the results of the study. The research question should help to define the objective of the study, which should also be addressed in the introduction. In addition, because they affect cost calculation[7], the scope and boundaries of the research should be defined, including those related to the population, the type of effects or outcomes analysed, the time horizon, and the perspective adopted, the author gives a brief summary of these aspects in the example analysis. A summary of how the scope of the study was presented in the case study is given below.

The source of the problems associated with the treatment of patients with severe thalassemia was clearly identified by describing the nature of the disease and the incidence of the condition; this helped to justify the significance of the present study. Although hematopoietic stem cell transplantation (HSCT) is well-known as the only cure for severe thalassemia, it is very expensive when compared to the standard treatment-blood transfusion and iron chelating therapy (BT-ICT). In Thailand, three health

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insurance schemes offer healthcare coverage to approximately 100 percent of the population-the Social Security Scheme, the Civil Servant Medical Benefit Scheme, and the Universal Coverage Scheme. At the time the research of the case study was conducted, only the Social Security Scheme and the Civil Servant Medical Benefit Scheme provided HSCT coverage for severely thalassemic patients. To assess whether HSCT provision was cost-effective and thus should also be included in the Universal Coverage Scheme, the National Health Security Office (NHSO) requested that a study be conducted into the cost-effectiveness of HSCT. The study compared the cost-effectiveness of HSCT with that of BT-ICT, the standard treatment option. A societal perspective was adopted, and a budget impact analysis was conducted from a governmental perspective to assess whether HSCT was sufficiently cost-effective to be included in the benefit package of the Universal Coverage Scheme. A cost-utility analysis using a model-based approach was applied to estimate the cost and quality adjusted life years (QALYs) throughout a lifetime period.

Selection of comparator(s)

All study reports should include details of all comparators and an explanation of why they have been chosen. This information is intended to guide real clinical practice. A summary of how this was presented in the case study is given below.

The main treatment options that were available for patients with severe thalassemia, as outlined in clinical practice guidelines-BT-ICT and HSCT-were described in detail, and a summary of the advantages and disadvantages of each option was given.

Defining the type of economic evaluation

All study reports should report clearly on the type of economic evaluation method used (from the four main types of economic evaluation method: cost-minimization analysis, cost-benefit analysis, cost-effective analysis, and cost-utility analysis), along with an explanation of how the method is the most appropriate to address the research questions. A summary of the study design should also be given (i.e. whether an economic evaluation model or economic evaluation with clinical trials is used). Where a mathematical or simulation model is used, all assumptions should be detailed, and the method used should be specified (i.e. whether a decision tree model, state-transition/Markov model, or a probabilistic simulation model is used). A diagram of the event pathway of the model and the software used should also be presented. Where the Markov model is used, health states, cycle length, mechanisms for movement between states in simulation models, and any special features of the analysis should be explained. For studies where a model is used, any tests that have been conducted to demonstrate the accuracy of the programming and to establish the face validity of the model calculations should be described in brief. By providing details on how the tests relate to the performance of the model using extreme assumptions, the predictability of the model's results is demonstrated. A summary of how the type of economic evaluation used in the case study was presented in the case study is given below.

Fig. 1 shows the schematic diagram of the Markov model used in the case study. The following five health states with different costs and QoL scores were defined for both related and unrelated HSCT patients: 1) the first year of HSCT (where patients had the highest costs and worst QoL), 2) the second year of HSCT (where patients had higher costs due to follow-up visits and immunosuppressive therapy), 3) years following successful HSCT (where QoL is approximately equal to that of the healthy population and costs were vastly reduced), 4) where HSCT has failed (resulting in a switch to BT-ICT), and 5) death. Two health states were defined for blood transfusion-dependent patients: 1) BT-ICT (characterised by low QoL, and the costs of ongoing care), 2) death. In the diagram, arrows represent possible transitions from one state to another and details are given that explain the health state transition. In the model, cycle length was defined as one year, and costs and health outcomes were estimated over a 99-year period, to cover the

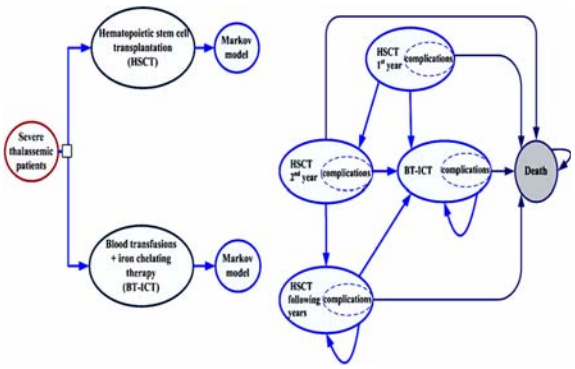

Fig. 1 Schematic diagram of the Markov model used in the case study.

maximum expected lifetime horizon. All assumptions were specified. Specifically, it was assumed that all severely thalassemic patients were treated with blood transfusions during the first year of life, that ICT was administered via subcutaneous infusion only, and that the probability of death in HSCT failure patients when switching to blood transfusions was similar to that in blood transfusion patients that did not undergo HSCT.

Measurement of costs

In the cost calculation section of study reports, the study perspective should be described, and all costs and data sources used should be detailed. For instance, cost data could be collected from electronic databases maintained by hospitals, from interviews with patients, or by referring to standard cost lists for health technology assessment. Reporting on the sources of cost data in this way helps readers assess the quality of the cost data used in the study. In addition, the types of costs (direct and/or indirect) should be stated. It is also suggested that the average cost per unit of each resource should be given along side range values, the number of units consumed, the year in which the costs are presented in the study, the type of currency used, and exchange rate used. This information allows readers to interpret the incremental cost-effectiveness ratio and compare it with the results of other studies. Adjustments for inflation-such as use of the medical component of the Consumer Price Index (CPI)-should be specified where applicable. It is important that report include information on whether cost or charge data have been used, and whether the ratios of cost to charge have been applied. A summary table presenting all cost data used and the source of data for each estimate should be presented, as in the example given in Table 1.

Measurement of clinical effects

A summary of the effectiveness estimates determined according to reference case values used in the analysis should be presented in a table as a convenient reference for readers. All clinical variables should be presented in accordance with the method of economic evaluation used. For instance, if a cost-utility analysis method is applied, utility values should be presented. All mean values of effectiveness parameters and ranges used in the uncertainty analysis and sources of data should be reported. This will help the reader garner an understanding of the source of the analysis's effectiveness, which is an essential part of evaluating the quality of the analysis and hence the appropriate use of its results.

If program-specific primary data are utilised in the model, the report should include details of the general strategy used, the inclusion and exclusion criteria applied, and the important assumptions that were made. For example, to extrapolate survival beyond the end of the empirical data, a survival analysis may have been used. If this is the case, any relevant assumptions that were made should also be addressed in the report. If a survey is used, the response rate should be reported. In addition, any information on health states or utility that may have been collected previously by measuring health states directly within the study, or by asking experts to determine the health states, should be outlined. The instruments that have been used for measurement (e.g. the Health Utilities Index or the EuroQoL), a summary of the measurement tool, as well as the methods used to value outcomes (e.g. rating scale or time trade off) should be reported. In the analysis, if experts are required to provide input (e.g., 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.

Handling time in economic evaluation studies

When a study period is longer than one year, the costs and health effects must be discounted. In these cases, the study report should state whether both costs and health effects are discounted and give the discount rate, along with a justification of the choice. If no discounting is performed in the study, an explanation of why this is the case should be provided. A summary of how the handling of time in the case study was presented in the case study is given below.

Both costs and outcomes were discounted at a rate of 3%, as recommended by the first Thai HTA guidelines.

Handling uncertainty and sensitivity analysis

All study reports should include a description of the methods that were used to evaluate the effects of uncertainty in the analysis–i.e. whether a univariate sensitivity analysis (a one-way sensitivity analysis and threshold sensitivity analysis), a multivariate sensitivity analysis, or probabilistic sensitivity analysis was used. All important results should be given, along with the confidence interval of the cost-effectiveness ratio. The choice of variables, the ranges used in the sensitivity analysis (e.g. confidence interval or standard error) and

Table 1. Input parameters used in the model

Parameters	Distribution	Mean	SE	References
Yearly discount rate (%)				
Costs (range)		3.00 (0-6.00)	-	[14]
Outcomes (range)		3.00 (0-6.00)	-	[14]
Transition probabilities				
BT-ICT				
Annual probability of death at age 0-1	Beta	0.010	-	[23]
Annual probability of death at age 2-5	Beta	0.003	-	[23]
Annual probability of death at age 6-10	Beta	0.002	-	[23]
Annual probability of death at age 11-15	Beta	0.010	-	[23]
Annual probability of death at age 16-20	Beta	0.025	-	[23]
Annual probability of death at age 21-30	Beta	0.015	-	[22]
Annual probability of death at age 31 and over	Beta	0.345	-	[21]
HSCT				
Parametric survival: death				
Constant for baseline hazard	Lognormal	-8.07	2.00	Cohort
Age coefficient for baseline hazard	Lognormal	0.16	0.06	Cohort
Ancillary parameter in Weibull distribution	Lognormal	-0.61	0.41	Cohort
Parametric survival: failure				
Constant for baseline hazard	Lognormal	-7.18	1.55	Cohort
Type of HSCT coefficient for baseline hazard	Lognormal	2.60	1.08	Cohort
Ancillary parameter in Weibull distribution	Lognormal	-0.74	0.34	Cohort
Resource cost parameters (THB)				
Total direct medical cost of related HSCT in the 1st year	Gamma	491,985	50,288	Hospital database
Total direct medical cost of related HSCT in the 2nd year	Gamma	42,694	15,535	Hospital database
Total direct medical cost of related HSCT in the following years	Gamma	11,638	3,240	Hospital database
Total direct medical cost of unrelated HSCT at the 1st year	Gamma	735,839	183,560	Hospital database
Total direct medical cost of unrelated HSCT at the 2nd year	Gamma	45,840	20,094	Hospital database
Total direct medical cost of unrelated HSCT in the following years base	Gamma	6,385	1,037	Hospital data
Total direct medical cost of BT-ICT per year	Gamma	35,788	4,156	[4]
Total direct non-medical cost of HSCT at the 1st and 2nd year	Gamma	259,994	95,535	Survey
Total direct non-medical cost of BT-ICT and the following year of HSCT	Gamma	37,384	7,040	Survey
Total productivity loss of HSCT in the 1st and 2nd year	Gamma	77,468	70,464	Survey
Total productivity loss of BT-ICT and the following years of HSCT	Gamma	19,171	6,692	Survey
Utility parameters				
Utility of BT-ICT patients	Beta	0.61	0.16	[24,25]
Utility of HSCT patients in first and second year	Beta	0.61	0.16	[24,25]
Utility of HSCT patients from third year on	Beta	0.93	0.05	[26]

BT-ICT = blood transfusion combined with subcutaneous iron chelating therapy; HSCT = hematopoietic stem cell transplantation; THB = Thai baht in 2008 value

reasons why selecting these variables also should be reported. If a probabilistic simulation model is used, any tests of the assumptions made concerning the distributions of variables and their statistical independence should be included.

Presentation of the results

Presentation of incremental cost-effectiveness ratio (ICER) results

Reference case results should be presented as a table of costs and effects for 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 provided in an accompanying table. Discounted results (using the discount rate at reference case) should be presented as the main results, while the undiscounted results may be put in the appendix. The following results should be presented:

1. Total cost per capita
2. Effectiveness per capita presented as both life years (LYs) and quality adjusted life years (QALYs). This helps readers understand the significance of extending life expectancy and improving quality of life as a result of each alternative.
3. Incremental cost per capita
4. Incremental effectiveness per capita and
5. Incremental cost-effectiveness ratio (ICER) per capita

The costs and incremental cost-effectiveness ratios should also be rounded up, either to a whole baht or to the nearest thousand, whichever is deemed most appropriate given the scale of the costs. The effectiveness data should also be rounded up where appropriate, as can be seen in the example in Table 2. Disaggregated results on costs, outcomes, and cost-effectiveness ratios should be presented so that the reader has an adequate understanding of the costs and effects of the intervention. For instance, total medical costs and total non-medical costs or QALYs, classified by disease severity should be disaggregated and included in the study report. The number of LYs saved and QALYs saved should be reported to help readers understand how the life-lengthening and quality-enhancing benefits of the intervention compare.

Moreover, the ICER results at both a population and an individual level should be reported. It is not recommended that the average or absolute ICERs for each alternative be reported, as this may lead to confusion and then misinterpretation of results[1]. For instance, in the case study, ICER results were disaggregated according to the age of the patient (ranging from 1 to 28 years); this was because the patient's age was found to have an impact on the success rate of HSCT, which in turn affects the cost-effectiveness of HSCT (Table 2). ICER results should be presented in THB, in terms of cost per unit of effectiveness according to the year of the cost calculation, for example 100,000 baht per QALY gained (2013 baht value).

Where the ICER results are negative, study reports should not frame the findings as negative or absolute values. Since negative values can imply two different meanings (i.e. higher cost and lower effectiveness or lower cost and higher effectiveness than other options), confusion may arise from the use of negative or absolute terminology. To avoid this, rather than reporting the ratios, the terms' dominated' should be used where the option has higher cost and lower effectiveness and 'dominant' where the option has lower cost and higher effectiveness compared to other options.

Table 2. ICER of unrelated HSCT compared to BT-ICT, classified by patient age

Age (year)	Incremental cost million THB	Incremental QALY QALY gained	ICER of unrelated HSCT compared to BT-ICT THB per QALY gained*
1	0.96	4.57	209,000
5	0.94	4.16	225,000
10	0.91	3.05	297,000
15	0.84	0.87	953,000
17	0.80	0.26	3,270,000
18	0.78	-0.01	Dominated**
19	0.73	-0.57	Dominated**
20	0.68	-1.12	Dominated**
25	0.59	-2.28	Dominated**
28	0.60	-2.22	Dominated**

ICER: incremental cost-effectiveness ratio; HSCT: hematopoietic stem cell transplantation; BT-ICT: blood transfusion combined with subcutaneous iron chelating therapy; THB: Thai baht (in 2008 value); and QALY: quality adjusted life year.
* ICERs are rounded up to nearest 1,000 THB.
** Negative ICER due to higher effectiveness and lower costs of BT-ICT compared with HSCT

In most cases, graphical presentations of study results are recommended, as this can aid comprehension of the results. If the ICER results are presented graphically as a cost-effectiveness plane, the incremental costs (two consecutive interventions) should be displayed on the vertical axis and the incremental effectiveness (i.e., QALYs) should be on the horizontal axis, so that the slope of the line segment represents the incremental cost-effectiveness ratio.

Presentation of uncertainty analysis results

If a one-way sensitivity analysis method is performed, a tornado diagram showing the percentage change in the ICER attributable to the change of each individual parameter should be presented. The numbers at each end of the bars should indicate the most extreme values used in the sensitivity analysis, as shown in Fig. 2.

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 favouring each treatment strategies, should also be presented in the study report, as shown in Fig. 3. These graphs demonstrate the probability of each intervention being cost-effective at different ceiling ratios, classified by age (year) at the start of treatment. (A) Patient aged 1 year, (B) Patient aged 10 years, (C) Patient aged 15 years, and (D) Patient aged 17 years. Dashed lines represent the thresholds for the adoption of health interventions in Thailand.

Presentation of budget impact results

For studies where a budget impact analysis is conducted, the study report should include information on the possible budget impact on total healthcare costs in both public and private sectors. The data should be given in a table that includes the year of calculation, expected total annual budget for each alternative, incremental budget per year, and expected total budget throughout the relevant period. The results of the budget impact analysis should also be rounded up to the nearest whole baht or the nearest million, depending on which is deemed most appropriate given the scale of the costs, as shown in Table 3.

Discussion of the results

The discussion section should provide an overview and interpretative summary of the results as well as a summary of any assumptions that were

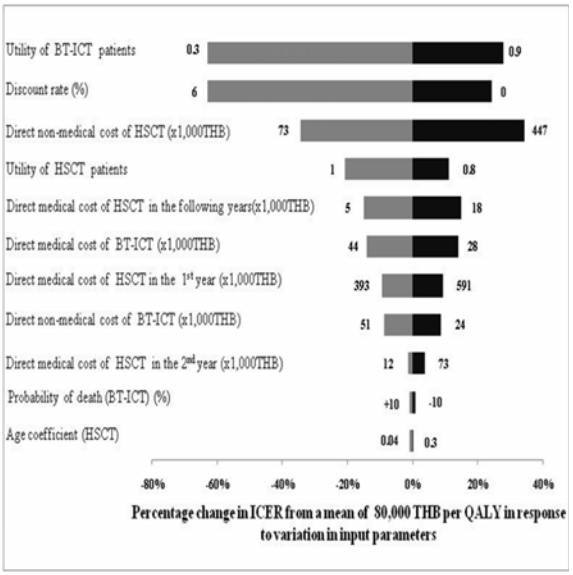

Fig. 2 Tornado diagram.

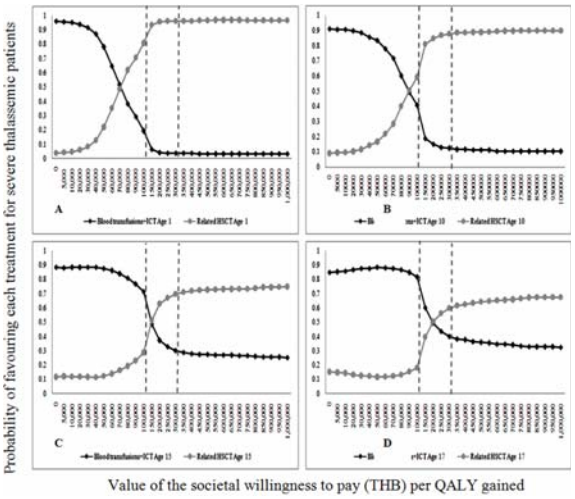

Fig. 3 Cost-effectiveness acceptability curve for related HSCT compared with BT-ICT.

adopted. The impact of the findings on the results and the assumed impacts to the health system, health expenditures, and health equity should be discussed. A descriptive interpretation of the ICER results for the reference case should be given, and the results of the sensitivity analysis of key parameters should be discussed. If some parameters are suspected of causing biased results, the effects of those should be discussed.

The cost-effectiveness of an intervention can only be determined relative to other interventions. It is

Table 3. Estimated budget impact during fiscal years 2008 to 2022 of provision of HSCT to 200 severely thalassemic patients (aged 1-10) per year

Estimated budget impact (million THB)			Incremental budget
Fiscal year	BT-ICT	Related HSCT	
2008	7	98	91
2009	14	104	90
2010	20	103	83
2011	26	102	76
2012	32	101	69
2013	37	100	63
2014	42	99	57
2015	46	99	53
2016	50	98	48
2017	54	97	43
2018	58	96	38
2019	61	95	34
2020	64	93	29
2021	67	92	25
2022	69	91	22
Total	647	1,468	821

BT-ICT = blood transfusion combined with subcutaneous iron chelating therapy; HSCT = hematopoietic stem cell transplan tation; THB = Thai baht (2008 value)

difficult to make certain statements regarding the incremental cost-effectiveness ratio of an intervention by examining it in isolation. 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'. Whether or not an intervention should be adopted will depend on multiple factors determined by the context. It is therefore not recommended to use only the cost-effectiveness criteria as the information for policy decision-making.

Where the results of a health economic evaluation may answer a specific policy question, the relevance of the study's results should be clearly explained. Not all interventions should be evaluated only in terms of value for money. Therefore, widely-used alternatives should also be discussed in order to apply cost-effectiveness results in a broader context. A comparison of results from other economic evaluation studies of similar or related interventions should be included, and a discussion of the similarities and differences between the results of the studies should be clearly explained. To ensure results are comparable across studies, all currency rates and values should be converted to rates equivalent to those used in the author's study, by applying 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 assumed.

It is important that the present study report include acknowledgement that other factors, a side from cost effectiveness, are important when assessing a technology. For instance, it is important that the discussion take into account the potential budgetary impact for public and private healthcare expenditure if the technology is adopted. This discussion should assess 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 that will be needed when the intervention is implemented. It may be important to discuss whether the introduction of the intervention will lead to increased or decreased need for related health care services. Furthermore, the discussion should also take into account equity or ethical considerations related to the introduction of the new intervention, for example potential impacts on access or utilisation of healthcare, reduced or

increased inequality in health status, and effects on disadvantaged social groups, should also be discussed.

Moreover, the limitations of the present study should be discussed to help interpret and generalize the results. All assumptions that have been made, whether based on expert opinions, theoretical models, or incomplete data, should also be stated as limitations. Often, the limitations result from nuances or complexity within the study results, which make the findings difficult to apply directly to policy decision-making.

Disclosure of funding and author's conflict of interest

The present study should reveal the source of financial support of the present study to ensure transparency. The relationship between the authors and financial supporters and/or the authors' potential conflict of interest with the funding sources should also be specified. In general, financial support may be stated in the acknowledgement section.

Guidelines for Health Technology Assessment in Thailand (second edition): Recommendations for presenting economic evaluation results

The Thai HTA guidelines recommend that the following ten key elements be included in any presentation of an economic evaluation study.

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 (i.e. ICER, uncertainty analysis and budget impact analysis)

9) Discussion of the results, limitations, impact to health system, expenditure and equity

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

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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.

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การรายงานผลการประเมินความคุ้มค่าทางสาธารณสุข

อุษา ฉายเกล็ดแก้ว

แนวทางการรายงานผลการประเมินความคุ้มค่าทางสาธารณสุขในบทนี้ได้ปรับปรุงเนื้อหา จากในคู่มือการประเมินเทคโนโลยีด้านสุขภาพสำหรับประเทศไทยฉบับแรกที่มุ่งเน้นข้อเสนอแนะที่สำคัญเกี่ยวกับการรายงานผลการประเมินความคุ้มค่าทางสาธารณสุขโดยอ้างอิงจากการทบทวนวรรณกรรมของแนวทางการรายงานผลการประเมินความคุ้มค่าทางสาธารณสุขที่มีอยู่ทั่วโลก และมีการยกตัวอย่างโดยใช้งานวิจัยเป็นกรณีศึกษาเพื่อแสดงให้เห็นอย่างเป็นรูปธรรมว่า แนวทางการรายงานผลการประเมินความคุ้มค่าทางสาธารณสุขสามารถนำไปประยุกต์ใช้ในงานศึกษาได้อย่างไร การรายงานผลการประเมินความคุ้มค่าทางสาธารณสุขควรระบุส่วนประกอบที่สำคัญไว้อย่างชัดเจนและครบถ้วน ทั้ง 10 ส่วนประกอบ ได้แก่การกำหนดขอบเขตของการศึกษา การเลือกทางเลือกที่ใช้สำหรับการเปรียบเทียบ การกำหนดวิธีการประเมินความคุ้มค่าทางสาธารณสุข การวัดต้นทุน การวัดประสิทธิผล ทางคลินิก การจัดการกับเวลาในการประเมินความคุ้มค่าทางสาธารณสุข การจัดการกับความไม่แน่นอนและการวิเคราะห์ความไว การรายงานผลการศึกษา การวิจารณ์ผลการศึกษา และการเปิดเผยแหล่งทุนสนับสนุนงานวิจัยและการมีส่วนได้ส่วนเสียของผู้วิจัยกับแหล่งทุนสนับสนุนงานวิจัย