Measurement of Utility

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The Quality Adjusted Life Year (QALY) is the most widely recommended health outcome measure for use in economic evaluations. The QALY gives a value to the effect of a given health intervention in terms of both quantity and quality. QALYs are calculated by multiplying the duration of time spent in a given health state, in years, by the quality of life weighted, known as utility. Utility can range from 0 (the worst health state-the equivalent of death) to 1 (the best health state-full health). This paper provides an overview of the various methods that can be used to measure utility and outlines the recommended protocol for measuring utility, as described in the Guidelines for Health Technology Assessment in Thailand (second edition). The recommendations are as follows: Wherever possible, primary data collection using EQ-5D-3L in patients using Thai value sets generated from the general public should be used. Where the EQ-5D-3L is considered inappropriate, other methods such as Standard gamble (SG), Time-trade-off (TTO), Visual analogue scale (VAS), Health Utilities Index (HUI), SF-6D, or Quality of well being (QWB) can be used. However, justification and full details on the chosen instrument should always be provided.

Keywords: *Utility, EQ-5D, Quality of life, Quality-adjusted life year*

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The Quality Adjusted Life Year (QALY) is the most widely recommended health outcome measure for use in economic evaluations(1). The QALY gives a value to the effect of a given health intervention in terms of both quantity and quality. QALYs are calculated by multiplying the duration of time spent in a given health state, in years, by the quality of life weighted, known as utility. Utility, can range from 0 (the worst health state-the equivalent of death) to 1 (the best health state-full health). For example, if an individual lives for 10 years with an associate utility of 0.9, this would equal to 9 QALYs (0.9x10). It is also possible to have states regarded as worse than dead, which are represented by a negative value.

Utility value can be derived both directly and indirectly(2). The most common direct methods include Standard gamble (SG), Time-trade-off (TTO) and Visual analogue scale (VAS). Although direct methods offer certain benefits for deriving utility, they can be time consuming and difficult to apply. In contrast, indirect methods that use multi-attribute health status classification systems to derive utility, such as the EuroQol (EQ-5D)(3,4), Health utilities index (HUI)(5), SF-6D(6), and Quality of well-being (QWB)(7) are much more convenient and so more widely used. More details on each method can be found in the first edition of HTA guidelines for Thailand(8). It should be noted that the choice of method could significantly affect estimated values for utility(9,10). Thus, it is importantthat all HTAs define the methodology used as well as the values generated.

According to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)(1), SG, TTO, and EQ-5D are the three methods that are most widely recommended for measuring utility value in many countries. In the first edition of Thai's HTA guidelines, EQ-5D-3L was given as the preferred method(11).

EQ-5D-3L is a very widely used instrument that is used to measure health outcomes. First developed by the EuroQol group(3,4), the EQ-5D-3L has been translated into 102 official languages, including Thai(12). The EQ-5D questionnaire consists of two parts-the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system assesses five dimensions–mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

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Each dimension is assessed by according it one of three levels–no problems (level 1), moderate or some problems (level 2) and severe problems (level 3), giving a total of 243 defined health states that can be measured by the EQ-5D-3L. Each health state can then be described using a five-digit number, where each digit refers to the level of each dimension. For example, 11111, the best health state, refers to a patient who has no not able health problems (no problems in walking about, no problems with self-care, no problem with performing usual activities, no pain or discomfort, and not anxious or depressed). On the other hand, 33333, the worst health state, refers to the opposite end of the spectrum (confined to bed, unable to wash or dress without help, unable to perform usual activities, experiences extreme pain or discomfort, and experiences extreme anxiety or depression).

The EQ-VAS is a vertical visual analogue scale, similar to a thermometer, that is used to measure an individual's assessment of their current health-related quality of life, ranging from 0 (worst imaginable health state) to 100 (best imaginable health state). The Thai EQ-5D-3L can be found in the first edition of HTA guidelines for Thailand[11].

Each health state in the EQ-5D can be converted to a utility value using formula, which essentially attaches weight to each of the levels in each dimension. The formula is based on certain EQ-5D health state values that are calculated from either VAS data and/or TTO data, derived from general population samples. Value sets are then produced for the full set of health states. In Thailand, the value set for EQ-5D-3L health states was derived from a general population representative sample of 1,409 respondents that was taken in 2007, using TTO method[13]. The second highest score was 0.766 for state 11112 and the lowest score was -0.454 for state 33333[13].

A utility score for the Thai population can be converted from each EQ-5D-3L health state by subtracting the following from 1: constant terms, dimension-specific coefficients, and N3 terms. The constant term is used to correct for any dysfunction that is present, the dimension-specific coefficient is used to adjust for the level of problems presented in each dimension, and the N3 term is used to make adjustments if any dimension is given a rating of 3. The constant and coefficient values used to calculate the EQ-5D-3L value set for the Thai population are presented in Table 1, and example calculations for health state 11332 and 22222 is shown in Table 2.

In general, the EQ-5D-3L has good psychometric properties[14-17]. However, as there are only three levels of response categories, a substantial ceiling effect is usually observed[18,19], which makes it difficult to capture health improvement in respondents whose scores are very high. The EQ-5D-3L, therefore, while useful, is not very sensitive to measuring small changes, especially in mild conditions. To account for this limitation, the EuroQol group has recently launched

Table 1. Constant and coefficient values used to calculate the EQ-5D-3L value set (adapted from Tongsiri et al)[13]

Dimension	Level	Coefficient
Constant		0.202
Dimension 1 (mobility)		
	1	0
	2	0.121
	3	0.432
Dimension 2 (self-care)		
	1	0
	2	0.121
	3	0.242
Dimension 3 (usual activities)		
	1	0
	2	0.059
	3	0.118
Dimension 4 (pain/discomfort)		
	1	0
	2	0.072
	3	0.209
Dimension 5 (anxiety/depression)		
	1	0
	2	0.032
	3	0.11
If answer level 3 in at least 1 dimension (N3)		0.139

Table 2. Example of calculating utility for health states 11332 and 22222

Health state	11332	22222
Starting value	1	1
Constant	0.202	0.202
Dimension 1	0	0.121
Dimension 2	0	0.121
Dimension 3	0.118	0.059
Dimension 4	0.209	0.072
Dimension 5	0.032	0.032
N3	0.139	0
Utility value	0.3	0.393

the EQ-5D-5L, which has the same five dimensions as the original EQ-5D-3L, but with five levels on each dimension rather than three[20]. To date, 91 language versions of the EQ-5D-5L have been produced, including Thai[12].

The EQ-5D-5L has been validating in several groups of patients across six countries. It was found to have greater discriminative power than the EQ-5D-3L and to exhibit less ceiling effect. The EQ-5D-5L was also found to have higher convergent validity when compared to the EQ-5D-3L[21,22]. To date, no Thai value set derived from Thai population data has yet been produced for the EQ-5D-5L. However, Thailand's Health Intervention and Technology Assessment Program (HITAP) is currently undertaking research to establish value sets for the EQ-5D-5L using the EQ-VT protocol developed by the EuroQol group. The study is expected to be completed in 2014. In the meantime, the EuroQol group has developed crosswalk value sets for EQ-5D-5L in a number of countries, including Thailand, Denmark, France, Germany, Japan, the Netherlands, Spain, UK, US, and Zimbabwe. These crosswalk sets allow the value sets from the EQ-5D-3L to be used in EQ-5D-5L, and were developed using a response mapping approach[2,3]. As no value set derived from the Thai population exists, EQ-5D-3L is currently the preferred method used to measure utility.

Evaluation of health state differs according to whether patients or the general population are being surveyed. There is some debate as to whether it is more appropriate to survey the general population or patients living with the condition, when measuring utility for HTAs. In general, patients tend to give health states higher values than do the general population[24-27]. This is probably due to a number of factors, including adaptation to the health state and changes in perception resulting from living with a certain condition[28]. The general population may also focus disproportionately on the negative aspects of a given health state[29-31]. Moreover, patient value may be a more accurate measure, as patients know the reality of a given health state better than the general population, who have to imagine what it is like to live with the condition, rather than base their responses on genuine experience. Nevertheless, the Washington Panel on Cost-effectiveness in Health and Medicine as well as HTA guidelines from many countries[1,32] still recommended basing utility on values derived from the general population rather than a patient data set. The reason for this preference is two-fold–first, that tax-funded health care systems should be based on values that reflect the preferences of all taxpayers[33,34], and second that general population surveys generate more neutral values, as self-interest is less likely to influence their responses (the so-called "veil of ignorance" theory)[32]. As such, garnering utility data from general population samples, rather than patients, seems to be more appropriate for HTAs.

In the UK, the National Institute of Health and Clinical Excellence (NICE)[35] recommends that "For the reference case, the measurement of changes in HRQL should be reported directly from patients, and the value of changes in patients' HRQL (that is, utilities) should be based on public preferences, using a choice-based method. The EQ-5D is the preferred measure of HRQL in adults. The methods to elicit EQ-5D utility values should be fully described. When EQ-5D data are not available or are inappropriate for the condition or effects of treatment, the valuation methods should be fully described and comparable to those used for the EQ-5D. Data collected using condition-specific, preference-based measures may be presented in separate analyses. The use of utility estimates from published literature must be supported by evidence that demonstrates that they have been identified and selected systematically".

The Australian guidelines of the Pharmaceutical Benefits Advisory Committee (PBAC)[36] recommend indirect method including the Health Utilities Index (HUI2 or HUI3), the EQ-5D, SF-6D, or the Assessment of Quality of Life (AQoL). However, none of these is singled out as the optimum measurement, as all have their own strength and weakness. The use of any other instruments should be justified.

Guidelines for pharmacoeconomic research in the Netherlands[37] recommend that, in the case of empirical studies, EQ-5D or HUI2/3 that are completed by patients or by proxy can be used. In the case of modelling, two approaches are recommended. The most appropriate approach is to value health states by conducting a representative sample survey from the population, using one of the following methods: standard gamble, time trade-off, or visual analogue scale. If this approach is not possible, or not deemed appropriate, the next recommended approach is to take utilities from published studies. Where different utilities are taken from different sources, the method of assessment, type of assessor, and context of the assessment task should be similar.

Canadian guidelines for HTA assessment[38] stipulate that both indirect and direct methods can be used to measure utility. However, the method should be justified fully, and a detailed explanation of its validity and reliability should be provided. When treatment has significant impact on the patient's caregiver, the quality of life of the caregiver should also be measured. However, this should be reported separately in the analysis and excluded when calculating the Incremental Cost Effectiveness Ratio (ICER).

According to NICE guidelines[35], the EQ-5D is the recommended instrument for measuring utility in adults. However, measuring utility among children is more complex and challenging due to the lack of appropriate instruments for use in children, especially those who are younger than 5 years old[39,40]. The direct method, for instance, is unsuitable for use in children due to their undeveloped cognitive abilities[41,42]. At present, a few instruments that use the indirect method have been developed for use in children. The EQ-5D, the recommended instrument in adults, is suitable for children aged 12 years old or older and the EQ-5D-Y was developed for use in children aged between 7 to 12 years old. However, no current value sets for the EQ-5D-Y have yet been developed. The HUI2, which NICE recommends as an instrument for measuring utility in children, also requires the use of some form of proxy for very young children (5 to 8 years old)[44]. In addition, a specific value set for HUI2 has been developed for the UK population but not for the Thai population yet.

A number of studies have revealed the significant variety in the range of utility values used in HTA. For instance, one review of the utility values used in a cost effectiveness model of treatment for osteoporosis patients ranged from 0.28 to 0.72 for hip fractures and from 0.31 to 0.8 for vertebral fractures[45]. This wide range may be due to the large number of instruments that are available, as well as differences in the age, social background, and nationality of those surveyed and the severity of their condition[46]. As a result, when utility values are derived from published literature, clear justification for the use of the data should be provided, especially in terms of similarity of source population and appropriateness of the instruments. In their 2005 study, Cooper et al. [47] proposed a hierarchy of data sources that can be used to derive utility. In their studies[47], either 1) direct utility assessment for the specific study from a sample either a) of the general population, b) with knowledge of the disease(s) of interest, and c) of patients with the disease(s) of interest or 2) indirect utility assessment from specific study from patient sample with disease(s) of interest, using a tool validated for the patient population were at the top of the hierarchy. On the other hand, expert opinion was at the lowest of the hierarchy.

Guidelines for Health Technology Assessment in Thailand (second edition): Recommendations for measuring utility value

1. A set of utility values should be derived from general population data.

2. The EQ-5D-3L is the preferred instrument for deriving utility value, due to the validity, reliability, responsiveness, feasibility and availability of the established value set for Thai population. Primary data collection in patients with similar characteristics should be conducted, using the EQ-5D-3L value set derived from the Thai general population. Appropriate sample sizes should also be determined.

2.1 In some conditions, where the use of EQ-5D-3L is considered inappropriate, alternative methods may be used to measure utility. Direct methods that may be suitable include SG, TTO, and VAS in the general population. Indirect methods that may be appropriate include standardised and acceptable preference-based questionnaires, such as the HUI, SF-6D, or QWB. However, in all cases where the EQ-5D is not used, full justification of the method choice should be provided, and the selected method should be described in full.

2.2 When EQ-5D data is not available, the utility data that is derived from other Health Related Quality of Life (HRQOL) instruments can be used and mapped onto the EQ-5D instrument. In all cases, full justification should be provided and the mapping function should be validated and fully described.

2.3 For children, the recommendations are as follows:

- For children aged 12 years or older, the EQ-5D-3L is the preferred instrument for measuring utility. Where the EQ-5D-3L is used with children aged 12 years or older, all changes in HRQOL data should be derived from the direct reports of the children, and the value of the change in the children's quality of life (utility) should be based on general population preference, derived from the Thai EQ-5D-3L value set.

- For children aged between 8 and 12 years old, the EQ-5D-3L can also be used. Where the EQ-5D-3L is used with children aged between 8 and 12 years old, change in HRQOL should be reported by proxy, and the value of the change in the children's quality of life (utility) should be based on general population preference, derived from the Thai EQ-5D-3L value set. Alternatively, any HUI2 data that is derived from direct reports of children can be used in conjunction with the UK value set. Justification should be provided.

- For children aged 8 years old or younger, the EQ-5D-3L can also be used. Where the EQ-5D-3L is used with children aged 8 years or younger, change in HRQOL should be reported by proxy, and the value of the change in the children's quality of life (utility) should be based on general population preference, derived from the Thai EQ-5D-3L value set. Alternatively, any HUI2 data that are derived from direct reports of children can be used in conjunction the UK value set. Justification should be provided.

2.4 Where utility values are obtained from the published literature, the methods that have been used to garner the data should be systematic and transparent. Utility values should be derived from the Thai population or a population that has similar characteristics to the Thai population. The method used to measure utility should comply with the strictures outlined in the Thai's HTA guidelines and should be described in full.

2.5 Reliance on expert opinion should be avoided.

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Potential conflicts of interest

None.

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การวัดอรรถประโยชน์

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ปีสุขภาวะ (QALY) เป็นผลลัพธ์ทางสุขภาพที่ได้รับการแนะนำให้ใช้ในการประเมินทางเศรษฐศาสตร์อย่างกว้างขวางที่สุด โดยปีสุขภาวะเป็นการวัดผลกระทบของมาตรการทางสุขภาพทั้งในเชิงปริมาณและในเชิงคุณภาพ ปีสุขภาวะสามารถคำนวณได้โดยการนำเอาระยะเวลาที่ใช้ในสถานะสุขภาพนั้น ๆ คิดเป็นปีคูณกับค่าอรรถประโยชน์ ซึ่งเป็นค่าถ่วงน้ำหนักด้านคุณภาพชีวิต ทั้งนี้ค่าอรรถประโยชน์จะมีค่าตั้งแต่ 0 (สภาวะสุขภาพที่แย่ที่สุดหรือเทียบเท่ากับการเสียชีวิต) ถึง 1 (สภาวะสุขภาพที่ดีที่สุดหรือแข็งแรงสมบูรณ์ที่สุด) บทความนี้จะอธิบายวิธีการต่าง ๆ ที่ใช้ในการวัดค่าอรรถประโยชน์โดยย่อ ตลอดจนสรุปข้อแนะนำสำหรับการวัดอรรถประโยชน์ตามที่ระบุไว้ในคู่มือการประเมินเทคโนโลยีด้านสุขภาพสำหรับประเทศไทย ฉบับที่ 2 ซึ่งมีข้อแนะนำมีดังต่อไปนี้ เมื่อเป็นไปได้ควรทำการเก็บข้อมูลปฐมภูมิในผู้ป่วยโดยใช้ EQ-5D-3L และใช้ตารางคะแนนอรรถประโยชน์ที่พัฒนาขึ้นจากประชากรไทยในการแปลงค่าคุณภาพชีวิตที่วัดจากผู้ป่วยให้เป็นค่าอรรถประโยชน์ ในบางกรณีที่การใช้ EQ-5D-3L ไม่เหมาะสมก็สามารถใช้วิธีการอื่น ๆ เช่น Standard gamble (SG), Time-trade-off (TTO), Visual analogue scale (VAS), Health Utilities Index (HUI), SF-6D หรือ Quality of Well Being (QWB) ได้ อย่างไรก็ตามควรแสดงเหตุผลตลอดจนรายละเอียดของเครื่องมือดังกล่าวอย่างครบถ้วน