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To cite this article: Yee Vern Yong BPharm & Asrul Akmal Shafie PhD (2016) Development, feasibility, and validity of a computer-based utility assessment tool for measuring asthma-specific health utilities in Malaysia using the standard gamble method, Journal of Asthma, 53:8, 835-842, DOI: [10.3109/02770903.2016.1156694](https://doi.org/10.3109/02770903.2016.1156694)

To link to this article: <http://dx.doi.org/10.3109/02770903.2016.1156694>



Accepted author version posted online: 06 Apr 2016.
Published online: 06 Apr 2016.



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ECONOMICS

Development, feasibility, and validity of a computer-based utility assessment tool for measuring asthma-specific health utilities in Malaysia using the standard gamble method

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Objectives: To develop and test the feasibility and validity of a computer-based utility assessment tool that used standard gamble (SG) method for measuring asthma-specific health utilities. **Methods:** A computer-based SG (CBSG) tool was developed using Microsoft® PowerPoint 2007 to value asthma-specific health states in Malaysia. Eight hypothetical health states were considered, including two anchor states (healthy and dead), three chronic (C) states and three temporary (T) states (each numbered 1 through 3, with increasing severity) in addition to the subject's current health state. Twenty adult asthma patients completed the CBSG tool in addition to paper-based Asthma Control Test, three health status measures (EQ-5D, EQ-VAS, and Mini Asthma Quality of Life Questionnaire (MiniAQLQ)), and VAS utility assessment tool. Patients and interviewers rated the difficulty of the VAS and CBSG tools. Correlations between current health state values derived from the various measures were determined. **Results:** The SG and the VAS received similar difficulty ratings. 17 patients completed the CBSG tool within 30 minutes. The mean utilities determined by the CBSG tool for the T1-T3 asthma health states met the expected logical order of 1>2>3, but those for the C1-C3 states did not. Correlation between current health state values derived from the CBSG tool and other measurement tools was poor. **Conclusion:** The CBSG tool developed for measuring utilities of asthma health states showed acceptable feasibility and overall validity.

Keywords

Visual analogue scale, MiniAQLQ, EQ-5D, EQ-VAS, utilities, standard gamble

History

Received 29 April 2015

Revised 27 December 2015

Accepted 15 February 2016

Introduction

Health-related quality of life (HRQoL) is an important outcome measure of asthma disease due to its association with history of respiratory symptoms such as shortness of breath. HRQoL measurement tools can be categorized based on the scope of their construct (generic vs. disease-specific), and how the construct is developed (non-preference vs. preference). Non-preference based tools such as SF-36 [1] and Mini Asthma Quality of Life Questionnaire (MiniAQLQ) [2] typically do not provide a single summary score of HRQoL (or valued HRQoL) that also meets the necessary requirements for use in cost-utility analysis, unlike the preference-based ones [3].

The values for preference-based tools are traditionally derived according to the Von Neumann-Morgenstern utility theory using the standard gamble (SG) method, which directly measures preferences in the decision making process under uncertainty [4]. Respondents are asked to choose between staying in a known health state or gambling on a change with a given probability of achieving a better health state or a worse health state. Another example of direct preference-based tool is the Visual Analogue Scale (VAS). This tool consists of a line

from 0 to 100 at either end [5]. Because SG is typically time-consuming and cognitively challenging, multi-attribute health status classification tools such as the EuroQol 5D (EQ-5D) [6] are more commonly used to derive valued HRQoL. These tools indirectly measure preferences by scoring the patient's descriptive responses using pre-determined weightage. Differences in preference weights between countries [7] emphasize the need to establish and use specific value sets for specific sub-populations.

Currently, there are few good asthma-specific preference based tools of HRQoL that are appropriate for the Malaysian population [8, 9], mostly due to lack of Malaysian value sets for asthma health states. To address this issue, we developed a computer-based visual tool to measure the utilities of different asthma health states using the SG method. We chose the SG approach because it measures the true utilities according to the Von Neumann-Morgenstern utility theory [4]. The computer-based SG (CBSG) tool was developed as a way to reduce the burden and complexity to the respondent. We also developed descriptions of asthma control and exacerbation health states. These states, together with the respondents' own health state, were valued using the CBSG tool and VAS.

This preliminary study aimed to test the feasibility and validity of the newly developed CBSG tool. To test the feasibility, respondents and interviewers were asked to rate the degree of difficulty for completing both VAS and CBSG tools. To test the validity, the utility of own health state measured by CBSG was

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compared with those measured by VAS, EQ-5D, MiniAQLQ and EQ-VAS.

Methods

Development of VAS and CBSG tools for valuing asthma health states

Nine asthma health states were defined based on recent international guidelines and literatures [10–12] for use in the VAS and CBSG tools: two anchor states (healthy and dead), three chronic states (C1–C3, corresponding to descending degrees of asthma control (well, partial, poor) and lasting for 10 years), three temporary states (T1–T3, corresponding to ascending degrees of asthma exacerbation (moderate, severe with urgent or Emergency Department visit, severe with hospitalization) and lasting for 3 months), and respondent's own health state over the past 2 weeks (O, lasting 10 years). The health states were made available in both the English and Malay languages. Full health states are described in [Appendix 1](#).

A vertical VAS with clearly defined endpoints of '0' as the least desired health state and '100' as the most desired health state was developed to value the health states. The CBSG tool was developed in Microsoft PowerPoint 2007 (Microsoft Corporation, United States of America), based on Gudex's description [13] ([Appendix 2](#)). The conventional SG method was used to value C1–C3, O, and the temporary state which had been initially valued as worst using the VAS. A chained SG procedure (worst state used in place of death) was used for the other two temporary health states.

Subjects

Verbally consenting and literate (in either the Malay or English language) adult asthma patients were consecutively enrolled cross-sectionally in Penang, Malaysia. The sample size required for the study is 20, based on the estimate of a linear regression test of $\rho = 0$ ($\alpha = 0.050$ two-sided) with one normally distributed covariate and 90% power to detect a ρ of 0.590 [14]. This sample size is also sufficient for non-parametric Mann–Whitney U-test and Wilcoxon Signed Ranks test to have approximately 95% of the parametric Student's *t*-test statistical power [15]. The Medical Research Ethics Committee of the Ministry of Health Malaysia approved this study conduct (NMRR-12-372-11920).

Study procedure

Two trained interviewers were assigned to one respondent at a time. The interviewers administered the study tools guided by a bilingual (English and Malay) interviewer script in a pre-determined order ([Figure 1](#)). Respondents were probed to justify the choice they made if the values were logically inconsistent, but were not asked to revise their preferences. Because lengthy interviews may indirectly cause cognitive bias, respondents were told that they could exit the interview at any point.

Data analysis

Logically inconsistent responses to the VAS defined as death ranked at 100 while all other health states were ranked worse

than death, and to the CBSG tool defined as choosing to live in the measured health state rather than a 100% probability of having perfect health, were excluded from the analysis. The utility for the EQ-5D health state was obtained using Malaysia's value sets [16]. The MiniAQLQ score was calculated by dividing the sum of the responses to each question by the total number of questions [2]. The VAS preference scores and utilities measured during conventional and chained SG for each health state were calculated as defined in [Appendix 3](#).

The categorical ratings of difficulty for VAS and CBSG in both English and Malay were compared using the Chi-Square test to assess the feasibility of the CBSG. The calculated preference scores from the VAS and SG for each health state were compared using the Wilcoxon Signed Ranks test, since the data were not normally distributed. The face and content validity of the health state descriptions were assessed by logical consistency, i.e., whether the order of the utilities and values corresponded to the levels of severity associated with each health state. Hence, responses that did not follow the hypothesized order were not excluded from the analysis. Linguistic validity was assessed by comparing the preference scores between the Malay and English language (used during the interview) using the Mann–Whitney U-Test and logical consistency. We hypothesized that the utilities would rank in this order: C1 > C2 > C3 and T1 > T2 > T3. The correlation between the values of EQ-5D, EQ-VAS, MiniAQLQ, VAS (O), and SG (O) was analyzed using a Spearman correlation because the distribution of data was not normal. Correlation results were used to assess construct validity of the CBSG tool.

Results

Twenty-five adults were approached for this study but only 20 participated in the study (response rate 80%; [Table 1](#)). Then, 65% ($N = 13$) of the respondents completed the entire interview within an hour, and half of them answered in English. All respondents indicated that they understood the SG exercise on the first attempt. The mean time for CBSG completion was 24 ± 10.2 minutes; 85% ($N = 17$) of the respondents completed the CBSG tool within 30 minutes. The overall difficulty ratings for the VAS and CBSG tools were similar (no significant differences), according to both the respondents and interviewers ([Table 2](#)) and between those who answered in English and Malay.

The mean values of the study subjects' current health status as measured by EQ-5D, EQ-VAS, MiniAQLQ, VAS (O) and SG (O) are shown in [Table 3](#). The mean values for the C1–3 and T1–3 asthma health states as measured by the VAS and CBSG tool are presented in [Figure 2](#). Logically inconsistent cases (one for VAS, eleven for SG) were excluded from the calculation of mean values. The logical inconsistencies were attributed to respondents who felt that the health states were not severe enough to warrant treatment, and living in the measured temporary health state was equivalent to recovering from the worst state.

The order of the VAS values for both the chronic and temporary states was logically consistent, fulfilling the hypothesis that the rankings would be ordered C1 > C2 > C3 and T1 > T2 > T3. 90% of respondents ranked T3 as the worst temporary health state in the VAS. The VAS values for a given

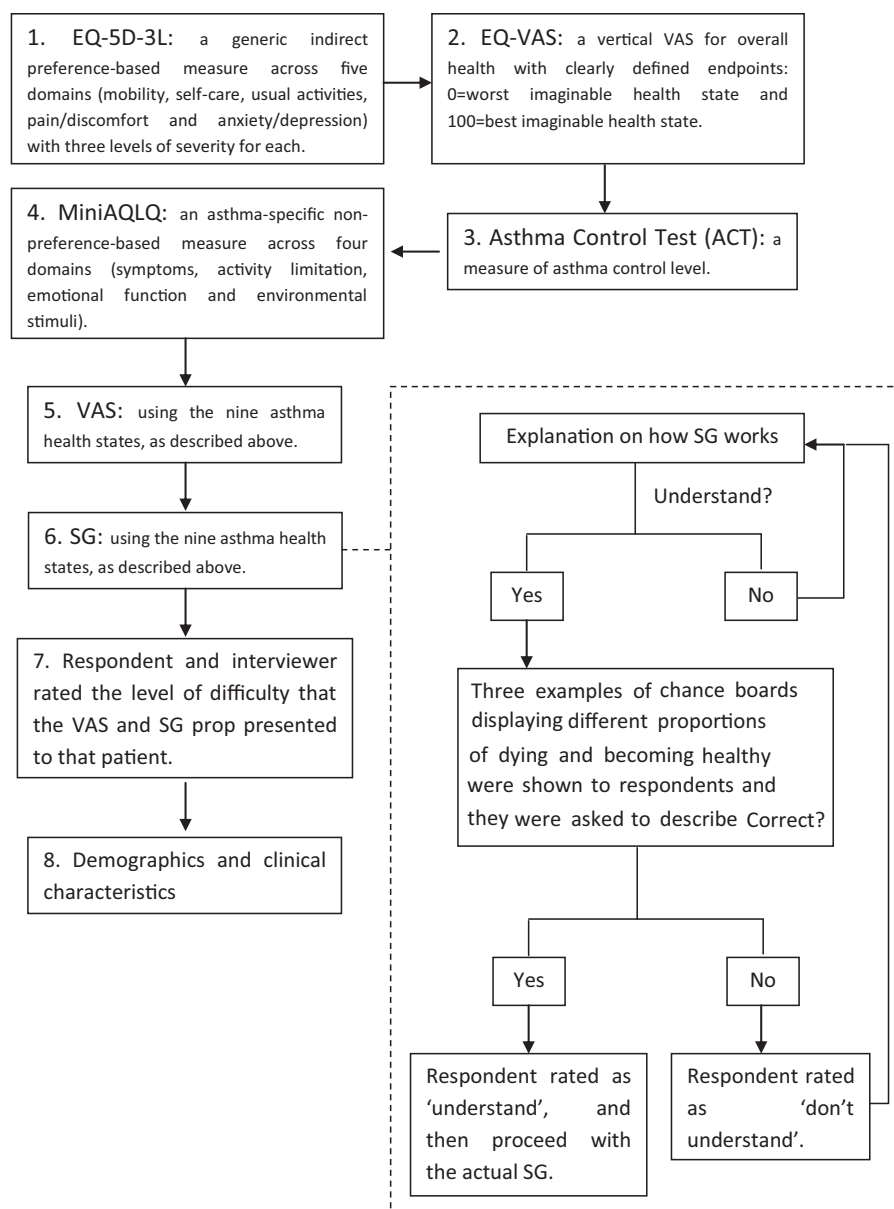


Figure 1. The flow chart of the study procedure. The interview was conducted according to the numeric order.

asthma health state were significantly different from the values for the neighboring states, except for C2 vs C3. The order of the CBSG tool utilities was logically consistent for the temporary asthma health states, although the difference between T1 and T2 utilities was not significant. However, the order of the CBSG tool utilities for the chronic states was not logically consistent, and the differences were not statistically significant. Thus, the temporary health state descriptions had good face and content validity, but the chronic health state descriptions did not. Nevertheless, the bilingual descriptions had good linguistic validity because whilst the logical consistencies were identical, the preference scores between the two languages used were not significantly different from each other.

There was a strong relationship between 1) EQ-5D and MiniAQLQ ($r = 0.77$) and 2) VAS and MiniAQLQ ($r = 0.55$), and a medium relationship between 1) EQ-VAS and MiniAQLQ ($r = 0.43$) and 2) EQ-5D and VAS ($r = 0.45$) (Table 4). The own health state value derived from the CBSG did not correlate well with any of the other tools.

Discussion

This preliminary study evaluated a newly developed CBSG tool for feasibility and validity in valuing asthma health states. Outcomes from the SG were compared with those from VAS, and from three other established health status measurement tools. The overall validity of a preference-based measure can be assessed in three ways [17]: (1) descriptive validity of its health state description; (2) the theoretical soundness of its valuing preference method; and, through empirical validity.

Descriptive validity comprises 'content and face' and construct validity. CBSG was found to have valid 'content and face' description, but with poor construct validity based on the weak correlations with other preference measures. The weak correlation between CBSG and other tools was similar to the findings from Juniper et al. [11] study. However, no fair comparison can be made between these two studies because the sample size differs by a half. Notwithstanding that this result implied a poor construct validity of SG as a tool to measure HRQoL in asthma, SG technique is itself considered valid

Table 1. Demographic and clinical characteristics of study subjects.

		n (%)
Age (years)	21 – 30	7 (36.8)
	31 – 40	6 (31.6)
	41 – 50	4 (21.1)
	51 – 60	1 (5.3)
	61 – 70	1 (5.3)
Gender	Male	3 (15)
	Female	17 (85)
Ethnicity	Malay	13 (65)
	Chinese	3 (15)
	Indian	4 (20)
Employment	Working	11 (55)
	Student	6 (30)
	Housewife	1 (5)
	Retired	2 (10)
Smoking status	Never smoked	18 (90)
	Ex – smoker	1 (5)
	Refused to answer	1 (5)
Asthma duration (years)	<2	2 (10.5)
	≥2	17 (89.5)
Last asthma symptoms (days)	<60	9 (47.4)
	≥60	10 (52.6)
Asthma control	Poor ^a	8 (40)
	Partial ^b	9 (45)
	Full ^c	3 (15)

Missing data (where $n < 20$) was due to respondents' refusal to answer.

^aAsthma Control Test score ≤19.

^bAsthma Control Test score 20–24.

^cAsthma Control Test score 25.

to measure utilities, since it conforms to the axioms of the Von Neumann–Morgenstern utility theory [18]. Further studies, particularly in larger sample size (because magnitude of correlation is unstable in small sample size [19]) should be conducted to accumulate more evidence and confirm the validity of SG method in asthma.

In the second validation, SG is a technique that itself is valid to measure utilities because it is a choice-based method that follows the axioms of the Von Neumann–Morgenstern utility theory [18]. Furthermore, the utilities were elicited from asthma patients themselves. And the feasibility data shows that CBSG can be used (at least, on literate patients) to elicit utilities that reflect the patients' preferences. Despite the general perception that SG method is more taxing for respondents than the VAS method, the difficulty ratings for the newly developed CBSG tool and VAS were similar. This might be caused by the design of the tool (bright colors, pie charts, computer administration) that helped respondents to understand how SG works, and/or clear explanations of the SG process by the interviewers. Given

Table 2. Difficulty ratings for VAS and SG measurement tools.

Level of Difficulty	VAS n (%)	SG n (%)
Respondent		
Easy	3 (16.7)	6 (30)
Neither easy or difficult	9 (50)	8 (40)
Difficult	6 (33.3)	4 (20)
Very difficult	0	2 (10)
Interviewer		
Very Easy	2 (10)	1 (5)
Easy	7 (35)	6 (30)
Neither easy or difficult	7 (35)	7 (35)
Difficult	4 (20)	4 (20)
Very Difficult	0	2 (10)

Table 3. Mean values of health state measurements.

Outcome Measure	n	Maximum value	Mean (SD)
EQ-5D-3L	20	1	0.84 (0.09)
EQ-VAS	20	100	76.95 (16.83)
MiniAQLQ	20	7	4.84 (1.06)
VAS (O)	19	1	0.44 (0.36)
SG (O)	18	1	0.49 (0.33)

SD: standard deviation.

O: own health state over past 2 weeks.

that the CBSG tool was not rated more difficult than VAS, it should be considered feasible.

For the third, empirical validity looks at whether or not the measured utilities do indeed reflect patients' preferences in real-life practice. One method is by comparing the measured utilities against hypothesized preferences, similar to what this study has done. As the results implied, the chronic health states were not empirically valid unlike the temporary health states. The utilities of the temporary states as measured by the CBSG can be considered valid since they conform to the logical order, with significant differences between the values. However, the utilities of the chronic states as measured by this CBSG tool could not be considered valid because C2 was valued as worse than C3 and the differences among the three mean utilities were not significant.

This was unlikely due to misunderstanding of interviewers' words / directions, because this situation did not arise for the temporary health states; the directions (except the duration spent) supplied in the interviewer script were the same for all health states. Language barriers are unlikely to have played a role in this situation because in addition to the non-significant differences in the difficulty ratings between English and Malay language, respondents were strictly selected in this aspect, and their comprehension and literacy were indirectly assessed during self-administration of questionnaires. Instead, we believed that the C2 and C3 health state descriptions were worded almost identically, except for the qualifiers "any of the following" for C2 vs. "any three of the following" for C3, which may have contributed to the apparently illogical ordering of the values.

Respondents might have missed that difference during the SG while paying more attention to the death outcome or probabilities. The VAS values, although based on the same health state descriptions, did comply with the validity tests. The utilities measured by the CBSG tool might be improved if the health state descriptions, particularly for C2 and C3, were revised. Further studies should be done to assess this possibility.

Given these mixed outcomes, the authors concluded that the CBSG tool has an acceptable overall validity. It would be unfair to conclude that the overall validity of the CBSG tool is poor just because of the weak construct validity and the utilities for chronic health states did not follow the hypothesized order.

The major limitation of this study is its lengthy interview. However, none of the respondents took the option of leaving the interview early. Even though there were no formal translations of the health state descriptions, non-rejection of utility and difficulty difference hypothesis between those who responded to either language showed that the bilingual descriptions were equivalent as a function of language. It may be argued that the linguistic validity results were compromised by the small sample size of this study. However, the use of Mann–Whitney U-test is justifiable because our sample size ($N = 20$) exceeded

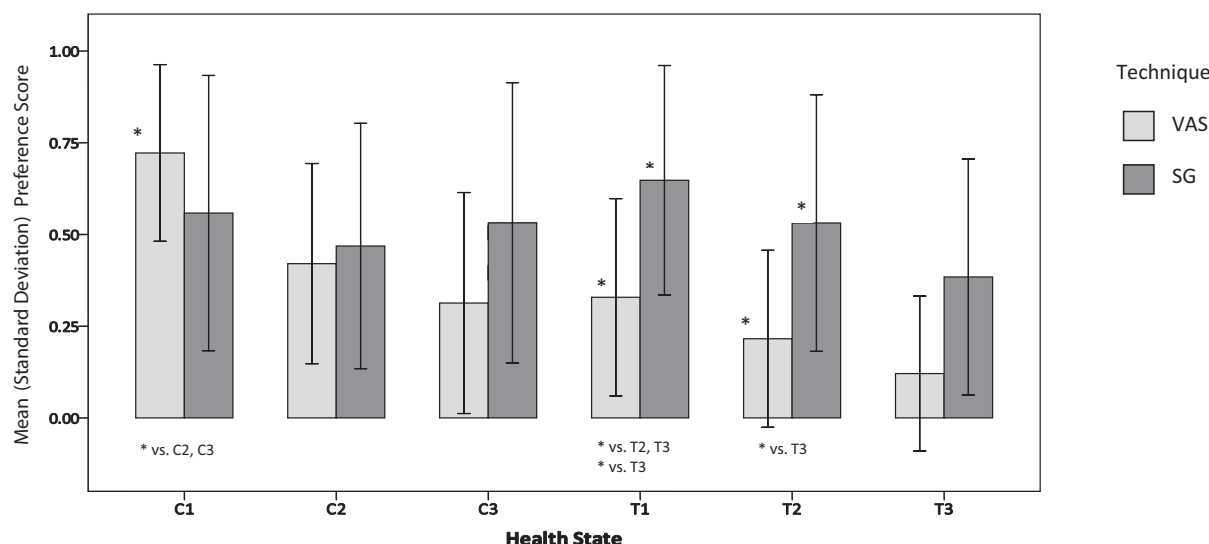


Figure 2. Mean (standard deviation represented by the error bar) preference scores of the hypothetical health states as measured by VAS and SG. For each health state, logical inconsistent responses were excluded from the calculation of the mean. For the VAS, $n=19$. For the SG, n 's are as follows: C1: 18; C2: 19; C3: 19; T1: 18; T2: 18; T3: 19. * $p < 0.05$.

Table 4. Correlation coefficients between outcome measure values.

Outcome measure	EQ-VAS	MiniAQLQ	VAS(O)	SG(O)
EQ-5D-3L	0.45*	0.77*	0.13	-0.09
EQ-VAS		0.43	0.26	0.06
MiniAQLQ			0.55*	-0.22
VAS(O)				-0.16

* $p < 0.05$.

O: own health state over past 2 weeks.

the minimum (7 or less) that is needed by the test to detect a difference [20] between Malay and English-language group.

In terms of the values measured by VAS, these were exposed to a) context bias: the score for a health state depends on the number and type of other states presented at the same time, i.e., if a state is among other worse states, its preference score is inflated [4] and b) end-aversion bias: on average, respondents tend to place a health state 1.78 times away from the healthy end – they tend to shy away from the near ends of the scale [5]. Given that existing correction methods are not yet well established [5], these likely biased values were not corrected prior to comparison with other measured values.

Due to the small sample size and the health state descriptions of chronic health states which could have affected the construct and empirical validity of CBSG respectively, future studies with larger sample size and better health state descriptions are necessary to improve the current state of construct and empirical validity. Another limitation of this study is that the reliability of utilities (in repeated measure) measured by the CBSG tool was not examined in this preliminary study.

Conclusion

The CBSG tool developed for measuring utilities of asthma health states showed acceptable feasibility and overall validity. However, due to the weak construct and empirical validity of the chronic health states utilities, the current CBSG tool is

more appropriate to be used to measure or elicit utilities that reflect patients' preferences for temporary health states.

Acknowledgements

The authors would like to thank the Director General of Health Malaysia for permission to publish this article. The authors would also like to thank Professor David Price and Dr. Simon van Rysewyk for their generous contributions in providing comments and suggestions to this article. The authors would like to thank Dr Irhan Ali for granting permission to interview his patients in his clinic at Hospital Pulau Pinang.

Declaration of interest

The corresponding author is currently employed by the Ministry of Health Malaysia. However, the authors alone are responsible for the content and writing of the article.

Funding

This study was supported by the Ministry of Health Malaysia (warrant number 01426).

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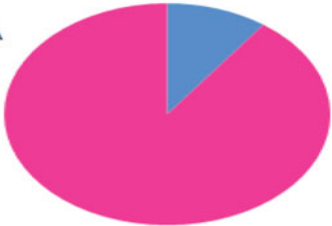
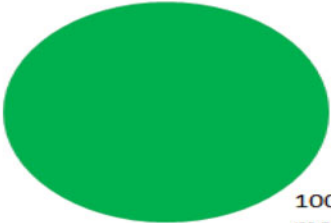
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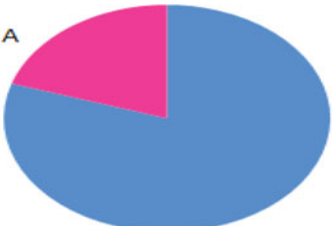
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Appendix 1. Health states description [1–3].

-
- C1: You have asthma with all of these following features: You have asthma but it affects your life a little or none at all. You may experience asthma symptoms such as shortness of breath or wheeze twice or less in a week. You can do as much daily activities as you wish. You also sleep well through the night. You use your blue inhaler twice or less in a week.
- C2: You have asthma with any of these following features: You have asthma and it affects your life moderately. During daytime, you experience asthma symptoms such as shortness of breath or wheeze more than twice a week. You find it difficult to do your daily activities. You are awake from your night sleep due to asthma symptoms. You use your blue inhaler more than twice a week.
- C3: You have asthma with three or more of these following features: You have asthma and it affects your life moderately. During daytime, you experience asthma symptoms such as shortness of breath or wheeze more than twice a week. You find it difficult to do your daily activities. You are awake from your night sleep due to asthma symptoms. You use your blue inhaler more than twice a week.
- T1: You are breathless even when talking. At this time, you prefer to sit and rest. You can only talk in short phrases. You start to increase the use your blue inhaler gradually until you don't feel breathless anymore. You may also be sent to the Accident & Emergency department for the medication through the mask to make you able to breathe better, but the pharmacy does not supply any five to seven-day duration of small white tablets.
- T2: You are breathless even when resting. At this time, your body lurches forward and wheezes loudly. You can only talk in few words. You start to increase the use your blue inhaler gradually. The pharmacy supplies five to seven-day small white tablets, regardless being sent to the Accident & Emergency department for the medication through the mask to make you able to breathe better.
- T3: You are breathless even when resting. At this time, your body lurches forward and wheezes loudly. You can only talk in few words. You start to increase the use your blue inhaler gradually. But the situation becomes worse that you are admitted to the ward, requiring medications such as the small white tablets or injections.
- O: Think about how your asthma has bothered you during the last two weeks. Try to remember whether your asthma made you wheeze or feel short of breath and whether it limited you in your activities such as work, sports, social activities or hobbies. Think about whether you were bothered by such things as cigarette smoke, dust or pollution. Remember whether your asthma woke up at night. Consider whether asthma has made you feel frustrated or afraid.
-

Appendix 2. An example of the conventional (top) and chained (bottom) SG prop, and a brief description on how these work [4].

CHOICE A  90% chance of becoming healthy 10% chance of dying immediately	Would you prefer Choice A or Choice B now? (Please click either one, then click arrow beside) CHOICE A  CHOICE B  Does not matter 
CHOICE B  100% chance of maintaining in green health state	

CHOICE A  20% chance of becoming healthy 80% chance of being in the worst (blue) health state	Would you prefer Choice A or Choice B now? (Please click either one, then click arrow beside) CHOICE A  CHOICE B  Does not matter 
CHOICE B  100% chance of maintaining in green health state	

Respondents were asked to choose between two alternatives: to accept treatment or not. If they are not willing to accept treatment, then they will remain in a certain health state for a specified duration. However, if they choose to accept treatment for that certain health state, then they will face risk of either dying ($X\%$) or becoming healthy again ($100-X\%$). In chained SG procedure, they will instead face risk of either worsening ($Y\%$) or becoming healthy again ($100-Y\%$). In this study, the worst state is the worst among the three temporary health states as ranked in VAS. The risks were changed by 10%, oscillating between the high and low ends of the scale in a “ping-pong” fashion, until 1) the indifference point was reached where keeping the previous choice on a better health state at a given probability were valued equally by the respondent or 2) the respondent kept his previous choice when the probability was changed. The SG exercise also considered situations that were worse than death and the worst state. These situations arise when the respondent chooses to accept the treatment even though that choice carries a 100% probability of dying or declining into the worst state.

Appendix 3. Calculation of preference scores

VAS

The VAS preference scores for each health state were initially transformed to a 0-to-1 scale and then the final values were calculated as follows:

$$\text{VAS score} = (x - d)/(1 - d) \text{ [4]}$$

where x was the scale score of the health state in question and d was that of the death state.

Conventional SG

Taking p as the probability of becoming healthy after treatment, the utilities (h_i) measured during the conventional SG for situations better than death were

- 1) the p at the point of indifference [4] or
- 2) the sum of p at that point when the previous choice was kept and one half of the increment [5] (i.e., one half of 10%, or 5%).

For situations worse than death, the h_i were

- 1) $-p / (1 - p)$ at the point of indifference [4] or
- 2) $-(p + 5\%) / (1 - (p + 5\%))$ at that point when the previous choice was kept.

The h_i for this situation was further transformed to a -1-to-0 scale by

$$U' = h_i / (1 - h_i) \text{ [6]}$$

where U' was the transformed utility. This transformation was essential for reducing the effect of distribution skewness for an equal distance from death when compared to situations better than death (0-to-1 scale).

Chained SG

The utilities in the chained SG for situations better than the worst state were calculated as follows:

$$h_Q = p + (1 - p) * h_A \text{ [4,7]}$$

where h_Q was the utility of the measured health state and h_A was the utility of the worst temporary health state. In situations worse than the worst state, the utility of the measured health state was calculated as follows:

$$h_Q = (h_A - p)/(1 - p) \text{ [7,8]}$$

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