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The effect of adding a 'sleep' dimension to EQ-5D

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Abstract: It has been recognized that the EQ-5D descriptive system may miss key dimensions of health such as sleep. Sleep has been shown in the past to have an important impact on quality of life. The objective of this study is to explore the effect of extending the current EQ-5D descriptive system by adding a sleep dimension. A new instrument, "EQ-5D+Sleep", is proposed by adding a sleep dimension to the EQ-5D descriptive system, with three levels. Based on an orthogonal design, 18 EQ-5D+Sleep states and 16 EQ-5D states were selected and a valuation study was undertaken interviewing 160 members of the generic public in South Yorkshire using the MVH protocol. Econometric models have been fitted to the data. Two null hypotheses were tested: 1).The coefficient for the sleep dimension is not significant; and 2).The inclusion of the sleep dimension has no impact on the way people value the other dimensions so that the coefficients of the original dimensions / levels remain unaffected. Results of modelling support acceptance of the two null hypotheses. This would seem to be no need to add a sleep dimension to the EQ-5D.

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Introduction:

The last few decades have witnessed the increasing interest in and practice of economic evaluation of health care technologies. One of reason is that there has been the increasing use of the 'off-the-Shelf 'generic preference-based health related quality of life (HRQoL) measures, such as the EQ-5D, HUI and SF-6D, etc.

The EQ-5D is one of the most widely used generic preference-based HRQoL measures. The developers of this instrument, known as the EuroQol Group aimed for a simple multi-attribute classification system covering the full health spectrum including physical, mental and social functioning, to ensure use across a wide range of health interventions. At the same time, the EuroQol Group recognized that the EQ-5D classification system could not claim to be a comprehensive measure of health status, (Brooks with the EuroQol Group, 1996), which leaves potential scope for expanding its descriptive system.

Empirical studies have been carried out to extend the EQ-5D descriptive system in two ways. One has been to improve its coverage by adding new health dimensions to the 5-dimensional EQ-5D system. The only published study has been done by Krabbe et al (1999), who added a cognitive dimension to the EQ-5D, which resulted in the so-called 'EQ-5D+C'. Researchers have also explored the possibility of adding disease-specific dimensions to the EQ-5D (Dowie, 2000) However, this comes into conflict with the generic nature of the measure and is seen by some within the Group as ad hoc and problematic. Another direction for development is to improve the ability of EQ-5D to capture changes in health by increasing the number of levels from three to four and five (Bonsel GJ et al, 1995; Selai C et al, 1996). This study belongs to the first approach, and explores the impact of adding to EQ-5D a generic, sixth dimension covering sleep.

It has been long observed that quantity and quality of sleep influence people's perception of health, productivity and performance in society. Sleep problems may include: difficulties falling asleep, waking during the night, waking early and being unable to go back to sleep again and waking in the morning feeling unrefreshed (Groger et al, 2004). Sleep problems are commonly associated with various types of medical conditions and treatments, which have been observed by clinicians. On the other hand, sleep problems are also common within the general population. Recent surveys (Groeger et al, 2004) showed that amongst a representative sample of 2000 adult Brittan's, 58% reported sleep problems on one or more nights in the previous week. The corresponding figures for 1010 Americans by gender are 63% for women and 54% for men (National Sleep Foundation, 2003).

A recent study conducted by our colleagues in Sheffield (personal communication, Paul Dolan and Yemi Oluboyede) explored the relationship between sleep and subjective well-being (SWB) using the British Household Panel Survey (BHPS). Their results firstly confirmed a high prevalence of sleep problems among the British general population (65.6% respondents have a sleep problem) and a significantly negative effect of poor sleep on SWB. Secondly, among the other significant attributes of SWB including unemployment, unable to walk for 10 minutes, limited in the amount and type of work that can be done, anxiety or depressed and general health status, poor sleep had the largest impact on SWB. An interesting finding in this study was that effect of sleep problems on SWB was independent from all the other attributes so that the sign and the size of the regression coefficients stay approximately the same after sleep was excluded from the regression. These results are in line with our assumption that effect of sleep on health matters in its own right. However, sleep is not covered by EQ-5D. On the other hand, some generic HRQoL measures such as 15D (Sintonen 1994) and AQoL (Hauthorne et al 1997; Richardson et al, 2004) and disease specific HRQoL measures such as Asthma Quality of Life Questionnaire (Juniper et al, 1993) and Overactive Bladder Questionnaire

(Coyne, 2002) contain 'sleep' dimension in their descriptive systems Given the impact of sleep on people's SWB, it is worthwhile to explore the effect of extending the current EQ-5D descriptive system by adding a sleep dimension.

The paper present a valuation survey to compare values derived for EQ-5D and the newly proposed "EQ-5D+sleep" instrument respectively. Econometric models were estimated for valuations elicited and the modelled coefficients for EQ-5D and the EQ-5D+Sleep instrument were compared to test two null hypotheses:

--- The coefficients for the sleep dimension is not significant, and
--- The inclusion of the sleep dimension has no impact on the way people value the other dimensions so that the coefficients of the original dimensions / levels remain unaffected.

Methods:
In overview, the study was a small-scale valuation study of the EQ-5D+Sleep instrument using the MVH protocol and conventional econometric modelling. To facilitate within-study comparison of the modelled preferences, a subgroup of respondents were asked to value the standard EQ-5D instrument without the sleep dimension.

The instruments and the selection of states
EQ-5D+Sleep, as an extension of the standard EQ-5D descriptive system was proposed. The additional sleep dimension consists of the following three levels to ensure wording consistency with the standard EQ-5D dimensions:
--- I have no problems with sleep
--- I have some problems with sleep
--- I have extreme problems with sleep

An orthogonal design using SPSS indicates that for a symmetric 6-dimensional 3-level instrument, an additive model can be estimated based on valuations of 18

states. The corresponding number of states for a symmetric 5-dimensional 3-level instrument is 16. According to those calculations, 18 EQ-5D+Sleep states and 16 EQ-5D states were selected for valuation. Eighteen EQ-5D + sleep states were stratified into severity groups based on their total level score, or the city block count, across the dimensions and then randomly allocated into 2 blocks with each block containing 9 states. The 16 EQ-5D states were allocated in the same way into 2 blocks with each block containing 8 states.

There are 6 'matched health state pairs' across the 16 EQ-5D states and the 18 EQ-5D+Sleep states, where a matched pair contains a EQ-5D state and a corresponding EQ-5D+sleep state consisting of the same EQ-5D profile plus any given level of the extra sleep dimension. The 6 matched health state pairs consist of: 11233 vs. 112331, 22232 vs. 222321, 12312 vs. 123122, 33132 vs. 331322, 31211 vs. 312113, and 33333 vs. 333333.

The interviews

The main part of the study consisted of a valuation study of selected EQ-5D+Sleep states and EQ-5D states by members of the public in South Yorkshire, UK. The method for sampling the population was to use the electoral register as the sampling frame. A random sample of names was sent letters inviting them to take part in the study. Those who agreed were visited and interviewed in their home. The interviews were carried out by three professional interviewers. Given the budget constraint, a total sample size of 160 individuals were decided to be included in the valuation survey, with 80 each for EQ-5D+Sleep and EQ-5D states. In the valuation survey, the respondents were randomly broken up into 4 groups with 40 each: those in the first 2 groups valued one block of EQ-5D+Sleep states each, and those in the other 2 groups valued one block of EQ-5D states each. In this way, each state was valued 40 times, which is reasonable compared to the average of 15 times per state for the SF-6D valuation study (Brazier et al, 2002) or the average of 24 times for the UK HUI survey (McCabe et al 2005). This sample size implies a power of 0.6 to test a mean difference of

0.1 between health state values at the 0.05 significance level with a standard deviation of 0.3 (Dolan, 1997; Brazier et al 2002). The "pits" states --- 33333 for EQ-5D and 333333 for the EQ-5D+Sleep --- were valued by all respondents within each group and therefore both pits states have been valued 80 times. The interviews were based largely on the MVH valuation protocol (Dolan, 1997), and included self-reported health using the respective descriptive systems, ranking of hypothetical states, and a valuation exercise of the states using Time Trade Off (Gudex, 1994), followed by personal background questions. For those respondents who valued EQ-5D states, an extra question related to their sleep status was asked in their background using the sleep dimension of the EQ-5D+Sleep instrument. A VAS of the states was not included in the interview to reduce response burden.

The analysis

Background characteristics of the two groups of respondents who valued the EQ-5D+Sleep and the EQ-5D descriptive system respectively were summarized. X square test was performed to examine whether there was any difference between those two samples in terms of age, gender, self-reported health status. TTO valuations derived for health states defined by the two descriptive systems were computed using the MVH transformation method (Dolan, 1997) which ensures all health states values are bound between (-1) and (+1). The number of observations, mean TTO and standard deviation, maximum and minimum values are reported for the two instruments. T-tests were performed to test for significant differences between the 6 matched health states across the two instruments.

The next stage was modelling health state values of the EQ-5D and the EQ-5D+Sleep. The main purpose of modelling is to compare the coefficients between the two EQ-5D systems to test the 2 hypotheses. The models have an additive specification with the 'dis_TTO value' (defined as 1 – TTO) as the dependent variable and each level of each domain entered as a dummy variable with the least severity levels acting as baseline. Random effects models using individual

level data (Brazier, et al, 2002) were estimated for the 2 descriptive systems. Personal characteristics such as age, gender and any self-reported EQ-5D dimension that were different across the 2 samples were introduced into subsequent models to examine and control their potential effects between the samples.

After the model estimation, the coefficients for the EQ-5D model and the EQ-5D+ Sleep model were compared to test the 2 null hypotheses presented above. The first hypothesis was quite straightforward, while the second hypothesis was examined by a within-study comparison of the modelled coefficients for the 5 original EQ-5D dimensions between models for EQ-5D and EQ-5D+Sleep using z-tests with a 0.10 significance level (Paternoster P, et al, 1998; Clogg et al, 1995)

$$z = \frac{\text{Coefficient of EQ-5D+Sleep} - \text{coefficients of EQ-5D}}{\sqrt{SE^2(\text{EQ-5D+Sleep coefficient}) + SE^2(\text{EQ-5D coefficient})}}$$

(SE: Standard Error)

Results

Sample background characteristics

A total of 161 respondents were interviewed The personal characteristics of the two samples who valued EQ-5D+Sleep and the EQ-5D are summarized in table 1. In general, the 2 samples were comparable in terms of age, gender, education, social-economic status. The 2 samples of respondents had similar health status described by the EQ-5D mobility, usual activity, self-care, pain and anxiety dimensions, but more respondents (n=33) in the EQ-5D sample suffered from moderate sleep problem than the EQ-5D+Sleep sample (n=20). The results of X square suggested that there was no significant difference between the two samples in terms of age, gender, health status at 0.05 level. However, personal characteristics which are commonly thought may affect people's values (i.e. gender and age) and relatively differ from the two sample (such as self-report pain and sleep) were still introduced into model estimation to test their effects.

Health states TTO value descriptions

A total of 1512 TTO values were elicited by 161 respondents in the interview survey with 770 values for the 16 health states of the EQ-5D and 742 values for the 18 states of EQ-5D+Sleep. The descriptive statistics of for those values are summarized in table 2. All intermediate health states were valued about 40 times while the 2 'pits' states (the worst states defined) were valued 80 times each.

For all the health states valued, the individual TTO values ranged from a minimum value of -0.98 to a maximum value of 1.00. In terms of mean TTO values, EQ-5D states ranged from -0.227 (state 33333) to 0.609 (state 12312) while EQ-5D+Sleep states ranged from -0.233 (state 333333) to 0.764 (state 211223). The standard deviations of EQ-5D states ranged from 0.35 to 0.63 with an average of 0.52, while for the EQ-5D+Sleep states the standard deviation ranged from 0.3 to 0.5 with an average of 0.43. These are larger than the standard deviation of 0.3 found in previous studies (Brazier, 2002; Dolan, 1997). Across the two instruments, less severe health states with larger TTO values tend to have smaller standard deviations.

There are a total of 6 matched health state pairs across EQ-5D and EQ-5D+Sleep states chosen for valuation. Significant difference between paired EQ-5D and EQ-5D+Sleep was found only for health states pair 11233 vs. 112331 ($p = 0.01$) where a 'no problem' sleep level was added to a generally moderate EQ-5D state. However, no statistically significant differences (at $p = 0.05$) were found for the other pairs, namely, 22232 vs. 222321, 12312 vs. 123122, 33132 vs. 331322, 31211 vs. 312113, 33333 vs. 333333, where various sleep levels were added to relatively moderate or severe EQ-5E states. The implication here seems to be that, in most cases adding an extra sleep dimension to the EQ-5D system does not change people's values significantly, which was further examined using econometric modelling technique as reported below.

Health states modelling

The results of modelling are presented in table 3 where models (1) and (2) are main-effect models estimated for EQ-5D and EQ-5D+Sleep respectively, and models (3) and (4) introduce respondents personal characteristics into model estimation. In the two EQ-5D+Sleep models (models 2 and 4), the coefficients of the sleep dimension were not significant and the figures were very small, which implied that adding the sleep dimension has not significantly affected the TTO values of EQ-5D+Sleep health states. Thus the first null hypothesis cannot be rejected.

Comparing models 1 and 2, 5 coefficients of the EQ-5D model were significant at 0.05 level while 8 coefficients were significant for the model of EQ-5D+Sleep. Within each descriptive system, the regression coefficients were logically ordered. In other words, the coefficients for level 3 indicated a larger health loss than the coefficients for level 2 of the same dimension, implying that the predicted health state values would satisfy logical consistency. Both models agreed that the mobility dimension contributed the largest magnitude between the least and most severe levels (level 1 vs. level 3). In terms of the least magnitude between level 1 and level 3, this was the usual activity dimension for EQ-5D model but anxiety/depression dimension for EQ-5D+Sleep. The EQ-5D model showed a severe ceiling problem with a constant term of 0.281 while the EQ-5D+Sleep model had a smaller constant term of 0.146.

Generally, the coefficients of the both model were generally comparable as their differences were as minor as 0.01 (i.e. 0.315 vs.0.307 for mobility dimension), except the self-care dimension with difference more than 0.1 level (0.122 vs.0.259). The results of z-tests between corresponding coefficients of the 2 models quantitatively supported this conclusion. Only the 2 coefficients of the self-care dimension were statistically significantly different between the 2 models while other coefficients were not significantly different. The implication seems to be that the inclusion of the sleep dimension has no impact on the way people value the 4 other dimensions (mobility, usual activity, pain and anxiety) so that

the coefficients these dimensions / levels remain unaffected. However, the inclusion of the sleep dimension has an impact on the way people value the self-care dimension so the coefficient of the self-care coefficient has changed significantly.

Respndents' age, gender, self-reported pain and sleep were introduced into the EQ-5D and the EQ-5D+Sleep models (model 3 and 4) in order to control for possible differences between the 2 samples. The youngest age group (age 18 – 25), males, and the least severe levels of self-report pain and sleep served as baselines. The results show that none of these coefficients were significant in the 2 models, and they rarely changed the coefficients of the original models without the covariates, except the constant term of the EQ-5D+Sleep model.

Discussion and conclusion

As widely-used tools for economic evaluation between competing health interventions, the standardized preference-based instruments of HRQoL have attracted considerable interest. The theoretical debates have tended to focus on the best method to value health states, i.e. Standard Gamble, VAS, TTO and DCE (Dolan, 1996; Parkin, 2006). Little empirical works has explored the role of descriptive system in the value people give to the health states of the generic instruments. This paper attempted to examine the role of the descriptive system on valuation using EQ-5D.

While comparing the 5-dimension 3-level descriptive system of EQ-5D with other similar measures such as SF-6D, 15D and AQoL, EQ-5D seems to have too few severity levels to fully describe patients' current health states or sensitively capture health changes over time. Also, EQ-5D could be criticized that it may miss several core dimensions of general health, such as 'cognition' and 'vitality' and 'sleep'. Krabbe and his colleagues examined the effect of adding a cognition dimension to the EQ-5D classification system and concluded that the EQ-5D state values were affected by impaired cognition. However, the generalisability of the results may be problematic as their respondents were university faculty

members who may consistently give a higher value to health states without cognition problem compared to members of the general public due to their academic background.

Recognising the importance of sleep for people's quality of life, the current study attempted to examine the effect of adding a sleep dimension to the original EQ-5D descriptive system using general public's preference value and conventional econometric modelling. The study employed an orthogonal design to select health states for valuation in both the EQ-5D and its plus sleep version proposed. This is different from the UK MVH study which selected 43 health states out of a total 243 for valuation covering minor, moderate and severe states; and also different from the Krabbe's study which selected states based on prevalence of states from a population survey.

Among the health states chosen by the orthogonal design, there were 6 matched health state pairs which could be used to test whether significant differences exist between an EQ-5D state and its corresponding version with an extra sleep dimension. In most cases, adding a sleep dimension did not change the EQ-5D values significantly. The only exception was the health states 11233 vs. 112331 where adding a 'no sleep problem' dimension resulted in health state value significantly increased from 0.179 (11233) to 0.486 (112331). People seem to value highly the ability to sleep well under extreme pain and anxiety. However, when no sleep problems was added to EQ-5D state 22232 to form EQ-5D+sleep state 222321, the 2 states were not statistically significantly different from each other.

The results of modelling health state values suggest that adding a sleep dimension to the original EQ-5D descriptive system has no obvious influence on valuations of the original EQ-5D health states. Models show that not only the coefficients of the sleep dimension are not significant but also most coefficients

of the other dimensions of EQ-5D remained the same. The same conclusion remained robust after personal characteristics of respondents were introduced in to the models. However, there was an exception of the self-care dimension with significantly changed coefficients after the inclusion of the sleep dimension, which is difficult to explain. This study was a small-scale exploratory study, and further larger scale studies are needed.

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TABLE1 Personal characteristics of the respondents

		EQ-5D (N=81)	EQ-5D+Sleep (N=80)
Gender**	Male	21	28
	Female	58	52
Age**	18-35	20	19
	36-55	33	29
	56-	26	31
Self reported ** EQ mobility	No problems	64	66
	Moderate problems	17	14
Self reported ** EQ self care	No problems	80	76
	Moderate problems	1	4
Self reported ** EQ usual activities	No problems	68	67
	Moderate problems	12	12
	Extreme problems	1	1
Self reported ** EQ pain/discomfort	No problems	49	51
	Moderate problems	29	23
	Extreme problems	3	5
Self reported ** EQ anxiety/depression	No problems	66	66
	Moderate problems	14	12
	Extreme problems	1	1
Self-reported EQ sleep***	No problems	41*	56
	Moderate problems	33*	20
	Extreme problems	3*	3
Education after minimum school leaving age**	Yes	46	50
	No	35	30
Home ownership**	Own home outright or with mortgage	60	58
	Rent from a local authority	14	17
	Rent from the private sector	7	5

*: Note that for those respondents who valued the EQ-5D, they reported their own health using the EQ-5D and the self-reported sleep question was put in the personal characteristics section at the end of the interview. Those who valued the EQ-5D+Sleep, they reported their own health using the EQ-5D+Sleep.
**: $P > 0.10$
***: $0.05 < P < 0.1$

TABLE 2 Description of health states' TTO values of EQ-5D and EQ-5D+Sleep

	Health state	N	Mean	Std. Deviation	Minimum	Maximum
EQ-5D	**33333**	81	-0.227	0.521	-0.975	0.985
	32323	41	0.028	0.613	-0.975	1
	33132	40	0.093	0.561	-0.975	1
	11233*	41	0.179	0.600	-0.875	1
	21331	41	0.238	0.573	-0.875	0.992
	31112	41	0.290	0.632	-0.975	1
	32221	40	0.316	0.578	-0.925	1
	31211	41	0.375	0.610	-0.975	1
	23222	41	0.397	0.507	-0.975	1
	13213	40	0.399	0.508	-0.875	1
	23311	41	0.425	0.519	-0.875	1
	22232	40	0.440	0.509	-0.875	1
	22113	41	0.461	0.529	-0.925	1
	13121	40	0.541	0.467	-0.925	1
	21123	40	0.574	0.423	-0.725	1
	12131	40	0.578	0.412	-0.875	1
	11322	40	0.595	0.423	-0.975	1
	12312	41	0.609	0.352	-0.875	1
	Total	770	0.320	0.575	-0.975	1
EQ-5D+Sleep	**333333**	78	-0.233	0.445	-0.975	0.625
	331322	40	0.171	0.493	-0.925	0.992
	322232	38	0.232	0.465	-0.975	1
	223313	38	0.282	0.481	-0.925	1
	222321	39	0.310	0.499	-0.925	1
	321111	38	0.385	0.432	-0.925	1
	231131	38	0.385	0.479	-0.975	1
	312113	38	0.393	0.473	-0.925	1
	313221	40	0.395	0.455	-0.825	1
	232212	39	0.402	0.496	-0.875	1
	121233	38	0.442	0.423	-0.975	1
	133211	40	0.459	0.449	-0.725	1
	112331*	40	0.486	0.471	-0.825	1
	132123	40	0.546	0.452	-0.625	1
	123122	38	0.591	0.298	-0.475	1
	213132	40	0.597	0.305	-0.525	1
	111312	40	0.721	0.304	-0.375	1
	211223	40	0.764	0.318	-0.475	1
	Total	742	0.375	0.501	-0.975	1

Note: 1. Matched health states are bold.

* Significant difference between the matched health states in 0.10 level according to t test

TABLE 3 Random effects models for EQ-5D and EQ-5D+Sleep health states

Dimensions & levels	Main effects model			Main effects model with covariants	
	EQ-5D	EQ-5D+Sleep	Z score	EQ-5D	EQ-5D+Sleep
	(1)	(2)	(1) vs.(2)	(3)	(4)
Constant	**0.281**	**0.146**	1.659	**0.284**	**0.314**
Mobility					
2	0.034	**0.065**	-0.674	0.027	**0.058**
3	**0.315**	**0.307**	0.185	**0.292**	**0.298**
Self-care					
2	-0.017	**0.141**	-3.038*	-0.011	**0.143**
3	**0.122**	**0.259**	-3.172*	**0.132**	**0.265**
Usual activity					
2	0.057	**0.073**	-0.364	**0.065**	**0.074**
3	**0.108**	**0.137**	-0.658	**0.098**	**0.134**
Pain/uncomfort					
2	0.059	0.042	0.368	**0.072**	0.042
3	**0.242**	**0.208**	0.761	**0.257**	**0.202**
Anxiety/depression					
2	0.008	-0.005	0.292	0.017	-0.004
3	**0.168**	**0.130**	0.910	**0.177**	**0.124**
Sleep					
2	-	-0.049		-	-0.051
3	-	0.036		-	0.036
Gender					
Female	-	-		0.056	-0.105
Age					
36 - 55	-	-		-0.073	-0.189
56 -	-	-		0.062	-0.004
Self-report pain/uncomfort					
2	-	-		0.026	0.051
3	-	-		-0.397	-0.185
Self-report sleep					
2	-	-		-0.104	-0.036
3	-			-0.162	-0.092

1. Dependent variable dis_tto = 1 – tto.
2. Bold coefficients are statistically significant at 0.05 level.
3. * z scores indicate difference between coefficients are statistically significant at 0.05 level.