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Reliability and Validity of EQ-5D in Malaysian Population

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Abstract This cross-sectional study, involving conveniently chosen respondents in the Klang Valley area, was designed to answer the question "Can EQ-5D be used as a QOL instrument in the National Health Morbidity Survey in Malaysia?". The chosen versions (Malay, Tamil, and Mandarin) of the translated EQ-5D were tested for their reliability and validity. After a written consent was obtained from each respondent, a standardized questionnaire for self-completion was given. It took an average of 10–15 min to complete the questionnaire. Each respondent who returned the completed questionnaire was approached again with an identical copy of the questionnaire to assess the test-retest reliability after a 2-week interval. Reliability was assessed by analyzing the study instrument's test-retest reliability, while a predictive validity was used to investigate the predictive strength of a composite index of the five factors of EQ-5D (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) on the overall perceived health (EQ VAS). An intraclass correlation (ICC), generated based on a single rate using the one way analysis of variance (ANOVA) model, was used to evaluate the test-retest reliability (Streiner and Norman 1995), while spearman rank correlation coefficient was used to quantify the predictive strength of a composite index of the five factors of EQ-5D on the overall perceived health (EQ VAS) (Elmes et al. 2006). It was surprising to note 1–2 folds increase in the reported cases for pain/discomfort and anxiety/depression, the same trend was observed across different versions of EQ-5D. The

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ICC values were found to be in the range of <0.01 to 0.92, while 0.61–0.86 were the range for the spearman rank correlation coefficient value. The findings in this study demonstrated the EQ-5D questionnaires translated by the EuroQOL Group had reasonable test-retest reliability and predictive validity results. With these results, it is hoped that these instruments will be incorporated into future National Health Morbidity Survey in Malaysia.

Keywords EQ-5D · Malaysia · Reliability · Quality of life

Introduction

In recent years, evidence based research has been encouraged in most countries especially in the area of health policy decision making. Among these, the quality of life research findings play an important role in the decision-making. Moreover, when the findings are truly the reflections of what the patients' perceive of their health status and to other non-medical aspects of their lives (Gill and Feinstein 1994).

QOL (Quality of Life) and HRQOL (Health-Related Quality of Life) are commonly used words in this type of research. It is important to differentiate QOL and HRQOL in the beginning of any study to avoid confusions at a later stage. HRQOL is a restricted definition of QOL, which is designed to exclude factors that, strictly speaking, lie outside the area of healthcare, such as housing, neighborhood and financial matters (Hamming and De Vries 2007). On the other hand, QOL refers to emotional, social, and physical well-being and their ability to function in the ordinary tasks of living that are non-health related, such as occupation, family, relationships, etc. These measures help to decide on the choice of treatment, inform patients' likely effects of treatments, monitors the success of treatments from the patient's perspective.

In QOL study, research tools used are known as instruments which is defined as the collection of items used for obtaining the desired data that may contain a single global question, such as "How are you?", or multiple items that may or may not be categorized into separate domains (Gill and Feinstein 1994). Broadly, the instruments are grouped as generic which is applicable to a wide variety of population covering the complete spectrum of function, disability and distress, while the specific instruments focus on specific aspects of health status and they are normally developed using disease specific measures, such as arthritis, and chronic lung disease (Guyatt et al. 1989).

During the development of a QOL instrument, accurate understanding of the individual's perspective must be considered in the methodology. For example, which dimensions of health are the most important, how the individual values his or her health status or functional status, and the ability of any instrument to accurately assess the individual's conceptual and developmental viewpoint of his or her quality of life (Jenney and Campbell 1997).

EQ-5D

EQ-5D, which is a QOL instrument selected for this study, is a generic measure of health status that provides a simple descriptive profile and a simple index value that can be used in the clinical and economical evaluation of health care and in

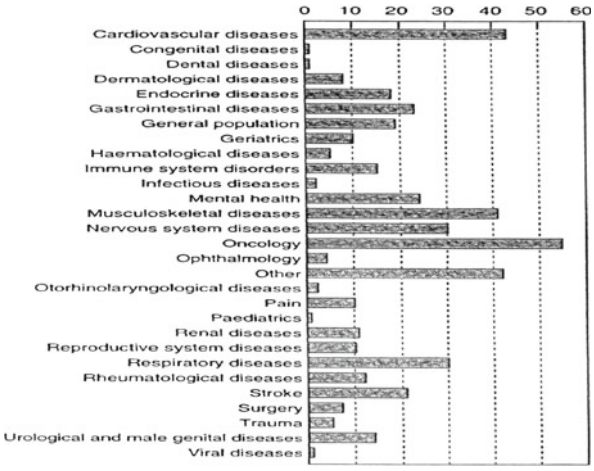
population health surveys (Rabin and de Charro 2001). The EuroQoL Group, which is a network of international multidisciplinary researchers, has developed an instrument called EQ-5D, and it is now widely used not only in clinical trials, but also in observational studies and other health surveys (Oppe et al. 2007).

The EQ5D questionnaire has been selected for the English national interview based health survey of about 16000 respondents and also for population surveys in Spain, Germany and Canada (Wee et al. 2007). Periodic reassessment of health could provide important data on the extent of any changes in the health of a population. For example, the extent to which the population is achieving national targets for health and when such standardized information is routinely collected, it would provide a simple indicator of evaluating the outcomes of patients' health care (Kind et al. 1998).

To date, there are approximately 500 registered studies in the EQ-5D database and Fig. 1 shows specifically the clinical areas that EQ-5D is used (Rabin and de Charro 2001). EQ-5D is mostly used in clinical observational studies and randomized control trials (RCTs). This strongly reflects on the growing enthusiasm of the pharmaceutical industry to include EQ-5D in their clinical research forms (CRFs) (Fig. 2) (Rabin and de Charro 2001).

EQ-5D is available in most major languages and cultural adaptations. The translation and adaptation processes are clearly stated in the translation guidelines developed by the EuroQoL Group, which involves a process of forward translation of the English version by two qualified translators, native in the target language, and back translation of the resulting consensus version by another two qualified translators, native in English but fluent in the target language (Rabin and de Charro 2001). The results are then tested on a sample of the target population in a cognitive debriefing exercise which is closely monitored by the EuroQoL Group members (Rabin and de Charro 2001).

The two pages of EQ-5D questionnaire consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS), a sample of this instrument can be



Source: Rabin & de Charro, 2001

Fig. 1 Clinical areas where EQ-5D is being used

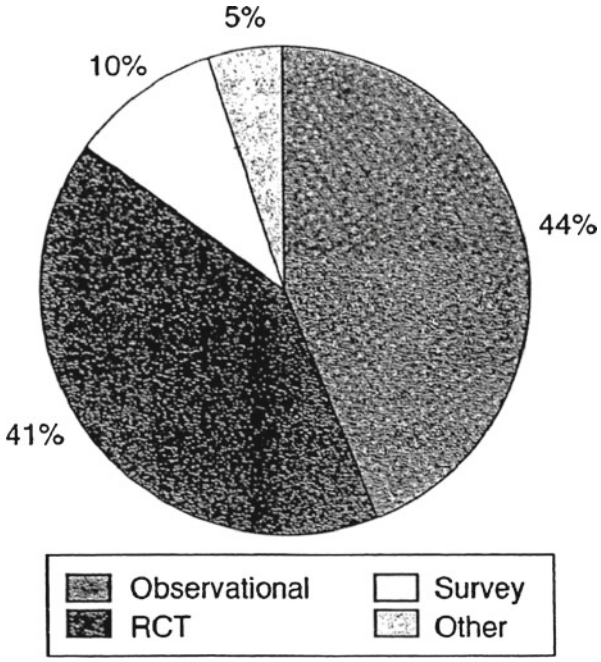


Fig. 2 Type of studies where EQ-5D is being used

Source: Rabin & de Charro, 2001

found in Fig. 3 (Rabin and de Charro 2001). The EQ-5D descriptive system comprises the following five domains or focus of attention (Gill and Feinstein 1994): mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain has three items: no problems, some problems, and severe problems. In totality, this will generate 243 health states ranging from 11111 (no problems in any

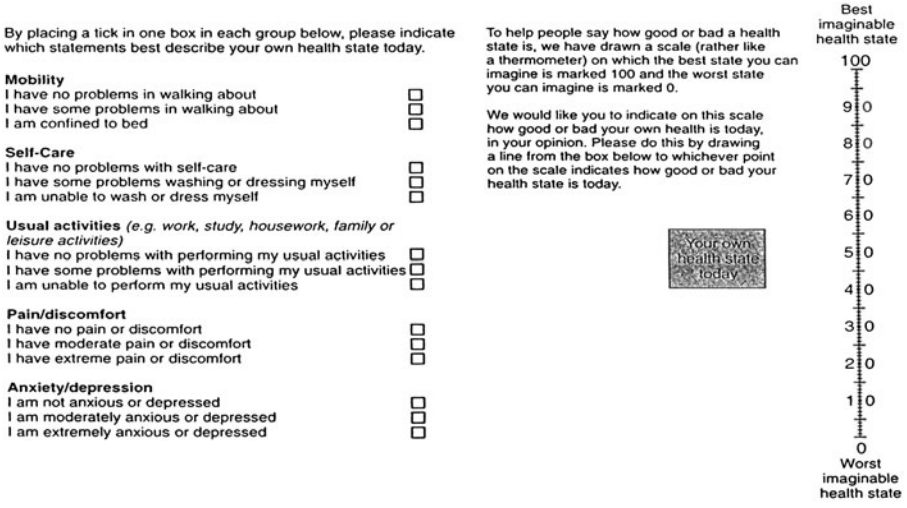


Fig. 3 EQ-5D self-classifier and visual analogue scale

domain) to 33333 (severe problems in all five domains) (Whynes 2008). The potential responses to this descriptive system can theoretically generate 243 (3^5) different health states (Petroua and Hockley 2005). On the other hand, the EQ-VAS is a 20-cm vertical, 0–100 points "thermometer", with 100 representing the "best imaginable health state" and 0 representing the "worst imaginable health state" (Wee et al. 2007). This self declare score is a reflection of the individual perception about the health state (Whynes 2008).

The performance of a QOL instrument is usually assessed by testing its practicality, validity and reliability. The validity, which seeks to measure health or health changed perceived by individuals, has three indirect ways of establishing, this can be obtained through content validity, face validity and construct validity (Petroua and Hockley 2005). While both the content and face validities are tested during the development of the instrument and repeated during the translation process of its original version, the construct validity can only be established by testing whether the underlying health status classification or descriptive system detects known or expected differences or changes in health (Petroua and Hockley 2005).

Generally, the team developing the instrument usually assesses the practicality and validity, the reliability is an important assessment ought to be conducted in individual studies as it determines the extent to which repeated administration of an instrument to a stable population yields the same results (Petroua and Hockley 2005).

Advantages of EQ-5D

The EQ-5D is an ideal QOL instrument for a survey study as it is cognitively undemanding, taking few minutes to complete and with regards to practicality, it is designed for self-completion by respondents and ideally suited for use in postal surveys, in clinics, and in face-to-face interviews. Furthermore, the global use of the EuroQoL instrument is manifest in the following ways: (i) the description and rating of own health state by the classification and thermometer approaches allow comparisons of reference groups (whether other patients or the general population), as well as comparisons for the same patients over time with or without health care intervention; (ii) any classified health state can be valued (with or without combining life years) using preferences elicited from a general population, and then used for similar comparisons. These data are readily available and do not have to be collected by researchers, although some may choose to do so; (iii) the descriptive information and/or the assigned valuations can be analyzed by background variables, such as age, sex, or education (Brooks and EuroQol Group 1996).

Malaysia

The Department of Statistics Malaysia has reported a population of 28.25 million with a GDP of 5.3% as of December 2010. It has also reported a live birth of 246.6 million female and 264.2 million male with a life expectancy at birth of 76.6 and 71.7 respectively (Department of Statistics, Malaysia 2010). There is a diverse ethnic groups in Malaysia with the main groups comprising Malay, Chinese and Indian. Although Malay is the national language in Malaysia, majority of the

population are able to speak and/or write at least two other languages mainly English, Chinese and Tamil.

The Ministry of Health Malaysia conducts a National Health and Morbidity Survey once in every 10 years. The general objective of this survey is to collect health related community based data and information for the Ministry of Health Malaysia to review health priorities, program strategies as well as activities in planning and allocating the resources (Institute of Public Health 2008, p. 2).

The 2006 National Health and Morbidity Survey reported a prevalence of 15.5% chronic illness (asthma, cancer, diabetes mellitus, cardiovascular diseases and mental illness) in Malaysia (Institute of Public Health 2008, p. 258). In the same survey, 77.8% male and 83.8% female respondents reported having chronic pain interfering their work, study and daily activities (Institute of Public Health 2008, p. 272–273). Correlation of chronic pain prevalence with the psychiatric morbidity showed that psychiatric morbidity [measured by a General Health Questionnaire 28 (GHQ 28)] was present in 18.5% of those with chronic pain (Institute of Public Health 2008, p. 808). Other psychiatric conditions, such as insomnia, suicidal ideation both acute and chronic, had similar high prevalence of 20.0%, 29.1% and 8.3% respectively with chronic pain (Institute of Public Health 2008, p. 808).

Improving the mental health of a population is an important indicator to improve the productivity of a country. With this thought, the purpose of this study was to investigate the reliability and validity of the translated EQ-5D instruments in Malaysian population. The ultimate goal of this research is to recommend to the Ministry of Health Malaysia to incorporate this instrument into future National Health Morbidity Survey in collecting a valid measure of health for clinical and economical appraisal for Malaysian population.

Method

Translated Instrument

The translated instruments were obtained from the EuroQoL group with permission. The EuroQoL Group's website (www.euroqol.org) contains detailed information about EQ-5D, guidance for users, a list of available language versions, EQ-5D references and contact details. This study was approved by the Medical Review and Ethics Committee (MREC), Ministry of Health Malaysia.

Sample Size Justification

According to Walter et al. (Walter et al. 1998), with two replicates per respondent, the expected inter-rate reliability of at least 0.8 (H_1: $\rho_1=0.8$), the reliability of 0.7 (H_0: $\rho_0=0.7$) or higher would be acceptable, $\alpha=0.05$ and $\beta=0.2$ (corresponds to 80% power), then, a total number of 118 respondents are required. Assume 27% non-response rate, then, a total number of 150 respondents are needed for each version of EQ5D. Since this study involved four different languages, therefore, with a sample size of 150 respondents for each language, the total sample size was approximated to be 600 respondents.

Study Design and Data Collection Method

This was a cross-sectional study, involving conveniently chosen respondents in the Klang Valley area. As the chosen versions (Malay, Tamil, and Mandarin) of EQ-5D had been translated and pre-tested by the EuroQoL group earlier, this study started with the field-testing of the instruments in Malaysian population.

Klang valley is an area adjoining the state of Selangor in Malaysia and comprises Kuala Lumpur and its suburbs.

The distribution of population in Kuala Lumpur is approximately 1,627,172 with an average annual population growth rate of 1.85% in just an area of 243 km^2. (Department of Statistics, Malaysia 2010)

A total of 600 subjects were enrolled from various conveniently chosen sites, such as universities and offices, in the Klang Valley area. Each language had 150 subjects respectively.

Inclusion Criteria

The inclusion criterion for this study was that each respondent should be able to read and understand any one of the languages (English, Malay, Tamil, and Mandarin) and were cognitively able to answer questionnaire independently. Respondents who had cognitive impairment, severe psychosis and those who had problems understanding the language were excluded from the sample.

Field Testing of EQ-5D (Fig. 4)

The chosen versions (Malay, Tamil, and Mandarin) of EQ-5D were tested for their reliability and validity. This study was conducted in public surroundings like in universities and offices, and 150 respondents were enrolled in each language with a total of 600 respondents.

After a written consent was obtained from each respondent, a standardized questionnaire for self-completion was given. Respondents were also requested to provide demographic information, such as age, sex, nationality, ethnicity, religion, marital status, academic qualifications and occupational status. It took an average of 10–15 min for respondents to complete the questionnaire.

Each respondent who returned a completed questionnaire was approached again with an identical copy of the questionnaire to assess the test-retest reliability after a 2-week interval. The time interval was determined in order to avoid any possibility of a respondent to remember how he/she answered in the previous questionnaire and yet was short enough to minimize the possibility that the complaints had changed in between the tests.

Reliability Analysis

The test-retest reliability was used to examine the reliability of the EQ-5D after a 2-week interval (Chen 2009). An intraclass correlation (ICC), generated based on a single rate using the one way analysis of variance (ANOVA) model, was used to evaluate the test-retest reliability (Streiner and Norman 1995). By convention, ICC values of 0.70 are

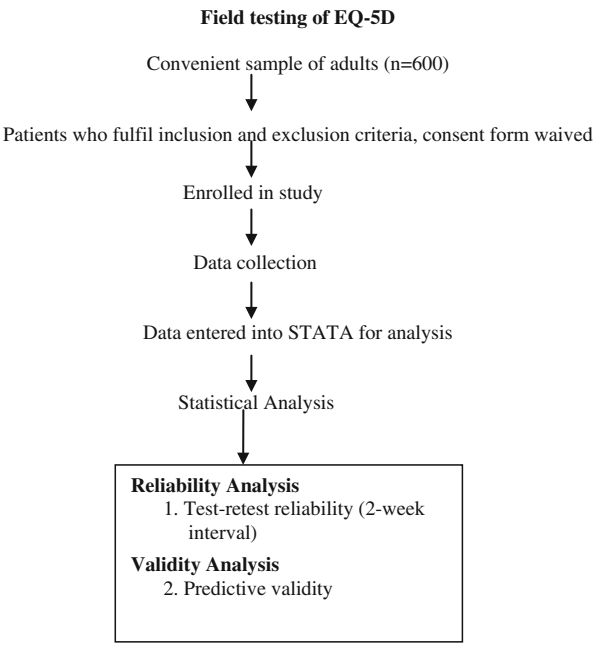


Fig. 4 Statistical analyses for EQ-5D

considered to be an acceptable reliability coefficient (Maurice et al. 1998, Nunnally and Bernstien 1994).

Validity Analysis

Predictive validity relates one measure of behaviour to another, and correlation coefficient is commonly used to quantify the degree of predictive validity (Elmes et al. 2006). Previous study has indicated the EQ VAS scores were predictable from the EQ-5D health state classification (Whynes 2008). Therefore, correlation coefficient was used to investigate the predictive strength of the composite index of the five factors of EQ-5D (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) on the overall perceived health (EQ VAS score).

A STATA software version 9.0 was used to perform the analyses, and statistical significance was set at 5% level. All missing data were imputed by using mean value.

Results

Response Rate

Since all recruited respondents answered the questionnaires completely, therefore, the response rate was 100%.

Demographic Data

The detailed characteristics of all respondents were summarized in Table 1. About 150 respondents were recruited for each language with age ranged from 18 to 73 years old. The highest average age observed was 37.5 years in the Tamil version, followed by 34.4 years, 33.1 years and 33 years in the English, Malay and Mandarin versions respectively. Predominantly of the respondents were females (67% for Malay version, 63% for English version, 50% for Mandarin version and 65% for the Tamil version). Majority of the respondents who participated in Malay and Tamil EQ-5Ds were married (62% and 58% respectively) and government employees (76% and 41% respectively). In additions, more than half of the respondents for Malay EQ-5D possessed tertiary academic qualification (53%). Slightly more than one third of the respondents from the English EQ-5D were government employees (37%).

Among the five dimensions, majority of the respondents claimed they did not encounter any "problems" in all the dimensions except for both pain/discomfort and anxiety/depression. For example, in Malay version of EQ-5D, 4 (3%) respondents reported encountering "problem" with mobility. It was surprising to note 1–2 folds increase in the reported cases for pain/discomfort and anxiety/depression, the result was 13 (9%) and 11 (7%) respectively. The same trend was observed across different versions of EQ-5D (Table 1).

Table 1 Sample characteristics

	EQ-5D Questionnaire Language			
	Malay (*N*=150)	English (*N*=150)	Mandarin (*N*=151)	Tamil (*N*=150)
Age (years)				
Mean (SD)	33.1 (9.5)	34.4 (13.0)	33.0 (13.1)	37.5 (12.2)
Female – n (%)	101 (67)	94 (63)	75 (50)	97 (65)
Married – n (%)	93 (62)	55 (37)	53 (35)	87 (58)
Government Employee – n (%)	114 (76)	55 (37)	26 (17)	61 (41)
Tertiary Academic Qualification – n (%)	79 (53)	124 (82)	101 (67)	59 (39)
Reported Problems for EQ-5D Items – n (%)				
Mobility	4 (3)	3 (2)	2 (1)	12 (8)
Self-Care	1 (1)	1 (1)	1 (1)	1 (1)
Usual Activity	3 (2)	3 (2)	3 (2)	16 (11)
Pain/Discomfort	13 (9)	28 (19)	36 (24)	57 (38)
Anxiety/Depression	11 (7)	22 (15)	55 (36)	40 (27)
VAS Score				
Median (IQR)	90 (50, 100)	85 (45, 100)	80 (40, 100)	90 (50, 100)
Mean (SD)	85.9 (11.9)	83.7 (11.8)	76.6 (13.4)	85.8 (10.4)

IQR Interquartile Range; *SD* Standard Deviation

Reliability of EQ-5D

The values of ICC were summarized in Table 2, these values can ultimately be interpreted as the magnitude of consistency for respondents in answering the questionnaires after 2-week interval. Ideally, one would expect the value to be at least 0.70 (Maurice et al. 1998). ICC value was the highest for usual activities dimension for English EQ-5D, followed by mobility, self-care, anxiety/depression and pain/discomfort. With regard to the Mandarin EQ-5D, anxiety/depression dimension scored the highest ICC, followed by pain/discomfort, usual activities, mobility and self-care. On the other hand, the ICC for mobility dimension in Tamil EQ-5D was the highest, followed by pain/discomfort, usual activities, anxiety/depression and self-care.

Validity of EQ-5D

Spearman rank correlation coefficient was used to quantify the predictive strength due to the skewedness of the data. The correlation coefficient values summarized in Table 3 indicated the predictive strength of the composite index of the five factors on the overall perceived health (EQ VAS) to be at least moderate, the values ranged from 0.61 to 0.86.

Table 2 Intraclass correlation

Version of EQ-5D	Item	Intraclass correlation
Malay EQ-5D	Mobility	0.29
	Self-care	<0.01
	Usual activity	0.76
	Pain/Discomfort	0.81
	Anxiety/Depression	0.57
English EQ-5D	Mobility	0.58
	Self-care	0.40
	Usual activity	0.62
	Pain/Discomfort	0.25
	Anxiety/Depression	0.34
Mandarin EQ-5D	Mobility	0.25
	Self-care	<0.01
	Usual activity	0.50
	Pain/Discomfort	0.88
	Anxiety/Depression	0.92
Tamil EQ-5D	Mobility	0.68
	Self-care	<0.01
	Usual activity	0.11
	Pain/Discomfort	0.47
	Anxiety/Depression	0.06

Discussions

The sample characteristics of this sample were compared against the Malaysian population data for generalizability purposes. According to the latest statistics in Malaysia, majority of the population were in the age group of 17–64, the composition of male and female was about the same, and approximately 1/3 of the population remain single while slightly more than half of the population were married (Department of Statistics, Malaysia 2002; Department of Statistics, Malaysia 2010). Although the usage of convenience sampling could potentially lead to higher female composition than male in the sample, it will not have significant impact on the findings of the study. Another source of statistics in Malaysia revealed majority of the Malaysians were found to be in the services sector (Department of Statistics, Malaysia 2009). Table 1 showed majority of the respondents were found to be government employees, these results can further be reclassified into services sector.

Although majority of the respondents rated "no problem" as their health state on the day this study was conducted (Table 1), the younger respondents had observed "problem" in dimension such as pain/discomfort and anxiety/depression. This observation was consistent across different languages. It is alarming to note the younger respondents showing a persistent "problem" with anxiety/depression, as in the previous study (Uncommon Knowledge LLP 2001–2010). Increasing amount of stress and pressure from family and society could indirectly contribute to this outcome (Uncommon Knowledge LLP 2001–2010; Weissman and Klerman, 1978). This outcome is similarly noted from the observation of increasing prevalence in depression among the younger generation in the United States (Cross-National Collaborative Group 1992). On the other hand, it will be interesting to study the reasons why the younger respondents encounter "problem" with their pain/discomfort.

Majority of the test-retest reliabilities were below 0.70 (Table 2). An ICC of less than 0.25 indicated a relatively small variation between respondents. In other words, a measure of equity had been achieved whereby most of the respondents responded in an approximately the same manner (Foy 2001).

Moderate predictive strength was found between the composite index of the five factors (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) on the overall perceived health (EQ VAS). This outcome was consistent with a previous study (Whynes 2008).

Table 3 Spearman rank correlation coefficients

	Spearman rank correlation coefficients
Malay EQ-5D	0.61
English EQ-5D	0.63
Mandarin EQ-5D	0.69
Tamil EQ-5D	0.86

Limitations

There are some limitations in this study. Firstly, our respondents generally reported good health status. This could be due to the fact that majority of the respondents were younger than 30 years old. Therefore, this group of respondents was less likely to report any problem with their health status. Hence, this outcome could potentially reduce the ability of the study to report the true health status of the Malaysian population.

Secondly, since this study was conducted only in the Klang Valley area, therefore, the generalizability of the results may applicable to the urban areas. Further studies are suggested to investigate whether the same results are applicable for the rural areas in Malaysia.

Thirdly, this study did not present the EQ-5D index score due to the unavailability of the Malaysian utility function as of this moment. Previous studies reported the utility function differs between countries and it was suggested a country's own social value set is necessary to be established (Maurice et al. 1998; Tsuchiya et al. 2002). Therefore, it is important to conduct a pilot study in establishing the utility function for Malaysia (Kim et al. 2005).

Conclusions

In conclusion, our findings demonstrated the EQ-5D questionnaires translated by the EuroQOL Group had reasonable test-retest reliability results and predictive validity results. Therefore, it would be appropriate to suggest to the Ministry of Health Malaysia to incorporate these instruments into future National Health and Morbidity Survey. The evaluation of psychometric property specifically for the Malay version of the EQ-5D using Malaysian population had been published (Varatharajan et al. 2010). With these instruments, it is hoped that clinicians in Malaysia can assess the health status of patients with diverse cultural and ethnicity background in undergoing treatments and procedures for various diseases in a more effective manner.

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