

THE SF-6D BRAZIL QUESTIONNAIRE: GENERATION MODELS AND APPLICATIONS IN HEALTH ECONOMICS

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ABSTRACT

OBJECTIVE. Compare the preference measures derived from the SF-36, based on the two Brazilian versions of the Short Form 6 Dimensions questionnaire - Brazil (SF-6D Brazil).

METHODS. Observational and transversal study. The following quality of life assessment instruments were applied: HAQ, SF-36, EQ-5D and SF-6D (1998 and 2002 versions). Descriptive statistics and correlation coefficients were used for data analysis.

RESULTS. The study assessed 200 patients suffering from rheumatoid arthritis, with a mean age of 49.22 years, mean time with the disease of 11.16 years and mean HAQ score of 1.02. Preferences measured by the two versions of the SF-6D and by the EQ-5D showed significant correlations with one another, and Pearson coefficients ranged from 0.59 to 0.88 ($p < 0.01$).

CONCLUSION. The most current version of the SF-6D, based on the 2002 model, was found to be valid when compared to the version initially validated to Brazil and is a questionnaire alternative to assess preferences in economic analyses carried out in health care.

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INTRODUCTION

In the past few decades, the scientific community's growing interest for the field of quality of life and Health Economics has led to significant development in methods applied in the assessment of new technologies¹.

In that sense, two main approaches have been used to assess health-related quality of life: the use of descriptive measures and the preference-based measures. Descriptive approaches are those that use instruments with various domains, allowing for a broad description of the state of health. Approaches based on preference are those that seek to capture the value or usefulness, attributed by individuals, of a given health status, listing various possible scenarios and variables, from perfect health to death, in quantitative scales².

With a view for application in decision-making analyses and in health economics analyses, the second approach has been more valued because it has greater theoretical support and because it allows for a measure of quality-adjusted life years (QALYs)³.

The concept of QALYs was developed in the 1970s, based on the pioneer studies by Torrance⁴, in Canada, and Kaplan et al., in the United States⁵. The advantage of using

this measure is that it allows researchers to simultaneously capture gains with the reduction of morbidity (quality) and with the reduction of mortality (quantity), integrating both into a single score. Besides that, it enables adding the benefits obtained by different interventions in different health conditions⁶.

Application of the "QALY gain" measure can be better understood through some simple examples. We may consider an individual whose quality of life is reduced at a rate of 0.03 for 30 years due to the use of antihypertensive drugs in order to gain 10 years of life with a 0.9 level of quality. This individual's QALYs gain is $10 \times 0.9 - 30 \times 0.03 = 8.1$. Likewise, we could consider a program that extends the life expectancy of some individuals for two years at a 0.50 level of quality and that improves the quality of life of other individuals from 0.50 to 0.75 for two years. The QALYs gain for the group of individuals would be $2 \times 0.50 + 2 \times 0.25 = 1.5$.

The QALY model is the most widely used to assess outcomes in health care economic analyses, because it is intuitive, practical and easy to understand for clinicians and decision-makers⁷.

The generation of this measure is only possible, however, because quality of life can only be quantified by applying the

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concept of utility, based on the the theory of decision-making under uncertainty published in 1944 by John von Neumann and Oscar Morgenstern, based on which it is understood that individuals have preferences for different health states⁸⁻⁹.

Preference is a broad concept which expresses an individual's desire for a certain state, involving both the concept of utility as the concept of values. Utility is a specific type of preference, measured under uncertainty conditions, according to the paradigm founded by Von Neumann and Morgenstern. Values are preferences measured under certainty conditions, so as not to express subjective attitude when faced with risk, in the face of a decision¹⁰.

Based on this paradigm, various authors have looked for ways to generate QALYs through preferences taken from generic quality of life instrument Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)¹¹, once this is a widely evaluated questionnaire, applied for over 200 diseases and translated in 40 countries¹².

At the present time, six publications, with eight different algorithms, have detailed methods to derive utility from SF-36¹³. The practicality, validity and responsiveness of these algorithms for preferences derived from the SF-36 have been tested in groups of patients who had various diseases or had undergone various interventions: low back pain¹⁴, depression¹⁵, asthma¹⁴, lung transplant¹⁶, chronic renal failure¹⁷ and chronic hepatitis C¹⁸.

As a result of these investigation efforts, the questionnaire Short-Form 6 dimensions (SF-6D) was developed in the United Kingdom, to allow researchers to obtain preference measures in health care, based on items from the SF-36¹⁹⁻²⁰.

In Brazil, the first version of this questionnaire (made up of two generation models and developed in 1998) has already been translated and validated²¹. However, the comparison of this version with the new generation model of the SF-6D, developed in 2002, is not yet available.

The growing application of preference measures and the QALYs model for economic analysis of new interventions in health makes it essential to improve these measurement techniques.

The present study aims to compare the two generation models for the SF-6D (1998 version) with the new model for this questionnaire (2002 version), developed by Brazier et al.

METHODS

Participants

The sample was selected at the Rheumatology outpatient clinic of Universidade Federal de São Paulo, from April 2005 to April 2006.

The study included patients with a diagnosis of rheumatoid arthritis, according to the American College of Rheumatology criteria – (ACR)²², undergoing follow-up at the service, and who signed a written consent form. This population was selected because it has been previously evaluated for the translation, cultural adaptation and validation of the SF-36 questionnaire for Brazil.

Patients who has been diagnosed and/or undergoing treatment for other, associated rheumatic diseases, psychiatric condition or fibromyalgia were excluded. Patients with

severe cognitive deficit that made it impossible for them to understand the research instruments were also excluded.

All participants signed the written consent form approved by the Universidade Federal de São Paulo Research Ethics Committee.

Evaluation Instruments

The Short Form 6 Dimension (SF-6D Brazil) questionnaire

Brazier et al. restructured the SF-36 into a health index called SF-6D, based on scenarios built with questions from that questionnaire and measured by the Standard Gamble (SG) and Visual Analogue Scale (VAS). The SF-36 questionnaire was reduced by combining two domains (role physical and role emotional) and eliminating the general health domain¹⁹. The classification system obtained was, therefore, structured in six domains, with the capacity to describe 9,000 health states based on the developed questionnaire²¹.

After this, a group of 59 health states described by the classification system was tested on a convenience sample, made up of 165 individuals, including health care professionals, students and patients. Each respondent was asked to assign preferences to the 12 health states described, using the VAS and SG techniques. Finally, the health states described by the classification system were mapped and associated with the direct preference measures (VAS and SG), by means of two multiple regression¹⁹.

In 2002, Brazier et al. reviewed the SF-36, establishing a new classification of health states into six domains. A total of 249 states defined by the SF-6D was valued in a representative sample of 611 members of the United Kingdom population, using the SG technique²⁰. A health state can therefore be defined by the SF-6D by selecting one item in each of the six dimensions or domains that make up the instrument, beginning by the physical function and ending by vitality. A total of 18,000 health states can be defined in this manner, based on the structured questionnaire (Annex). All the answers in the original SF-36 questionnaire can be used to build the SF-6D as long as the 10 items used to build the SF-6D have been completed.

The SF-36 items used for the construction of the SF-6D (2002 version) were as follows: functional capacity (items 1, 2 and 10); global limitation (item 3 from physical aspects and item 2 from emotional aspects); social aspects (item 2); pain (all items); mental health (item 1); and vitality (item 2).

The SF-6D unique score, which varies from 0 to 1, represents the strength of an individual's preference for a given health state, in a scale in which 0 is equal to the worst health state and 1 is equal to the best health state¹⁹⁻²⁰.

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)

The SF-36 is a generic quality of life questionnaire made up of 36 items (questions), distributed among eight domains and summarized into one physical component and one mental component. The score for each of the eight domains varies from 0 (worst health state) to 100 (best health state). The Brazilian version of the questionnaire can already be found in the scientific literature and was used for this study²³.

Annex 1 - SF-6D adapted to Brazilian Portuguese - Brazil (2002 version)

Instructions: This information will let us know how you feel and how much you are capable of going through your daily activities. Please mark the item that is closest to how you feel for each question. If you have doubts about how to answer, try to answer as accurately as possible.

Physical functioning

1. Your health does not limit you in vigorous activities
2. Your health limits you a little in vigorous activities
3. Your health limits you a little in moderate activities
4. Your health limits you a lot in moderate activities
5. Your health limits you a little in bathing and dressing
6. Your health limits you a lot in bathing and dressing

Role limitation

1. You have no problems with your work or other regular daily activities as a result of your physical health or any emotional problems
2. You are limited in the kind of work or other activities as a result of your physical health
3. You accomplish less than you would like as a result of emotional problems
4. You are limited in the kind of work or other activities as a result of your physical health and accomplish less than you would like as a result of emotional problems

Social functioning

1. Your health limits your social activities none of the time
2. Your health limits your social activities a little of the time
3. Your health limits your social activities some of the time
4. Your health limits your social activities most of the time
5. Your health limits your social activities all of the time

Pain

1. You have no pain
2. You have pain, but it does not interfere with your normal work (both outside the home and housework)
3. You have pain that interferes with your normal work (both outside the home and housework) a little bit
4. You have pain that interferes with your normal work (both outside the home and housework) moderately
5. You have pain that interferes with your normal work (both outside the home and housework) quite a bit
6. You have pain that interferes with your normal work (both outside the home and housework) extremely

Mental health

1. You feel tense or downhearted and low none of the time
2. You feel tense or downhearted and low a little of the time
3. You feel tense or downhearted and low some of the time
4. You feel tense or downhearted and low most of the time
5. You feel tense or downhearted and low all of the time

Vitality

1. You have a lot of energy all of the time
2. You have a lot of energy most of the time
3. You have a lot of energy some of the time
4. You have a lot of energy a little of the time
5. You have a lot of energy none of the time

Health Assessment Questionnaire (HAQ)

The Health Assessment Questionnaire (HAQ) is a specific quality of life instrument developed to enable the assessment of health state parameters in therapeutic tests involving patients with rheumatoid arthritis²⁴. The scale includes a total of 20 items, grouped into eight categories, with two or three questions, according to the daily life activities to which they refer. The score for each category varies from 0, assigned to the absence of difficulty, to three, for the inability to perform a given activity. Based on the category scores, the final score of the instrument can be obtained, which ranges from 0 to 3.

Euroqol-5D (EQ-5D)

The Euroqol-5D (EQ-5D) is an instrument developed in Europe for indirect measure of preferences for health states, validated in our field and widely used in health economics analyses. The tool is made up of five assessment domains, whose scale ranges from -0,594 to 1,000, and by a visual analogue scale of 20 cm, ranging from 0 (worst possible health state) to 100 (best possible health state)²⁵. The EQ-5D score was obtained by means of York tariffs for the English population²⁶.

Statistical analysis

Data for this transversal study were collected by means of applying the instruments through an interview.

The focus of analysis is comparing the measures derived from the three generation models of the SF-6D (two from the 1998 version and one from the 2002 version) with one another and with the EQ-5D.

All analyses were performed using computer application SPSS® version 11.0 for Windows®. Descriptive statistics was employed to characterize the sample, through a socio-demographic questionnaire. Correlations between the preferences measured by the SF-6D models and those obtained with the EQ-5D were determined using the Pearson correlation coefficient. For this study, we adopted $p < 0.05$ (alpha = 5%) for statistically significant values.

RESULTS

A total of 200 patients who met the ACR criteria for rheumatoid arthritis and had agreed to take part in the study were evaluated. From the 200 individuals evaluated, 200 completed SF- 6D and EQ-5D, and 199 completed the HAQ.

The mean age of participants was 49.22 years (SD = 10), and 78% were female. Most individuals identified their skin color as white (41%) and brown (56.5%). Most were married (56.5%) and inactive in the job market (62%). Mean education was 6.38 years (SD = 4.1); mean family income per capita was R\$ 366.88 (DP = 367.6) and mean number of residents per home was 3.80 residents (SD = 1.8).

Mean time with the disease was 11.16 years (SD = 8.4), and most participants belonged to the I and II functional categories (33% and 38.5%, respectively) and presented a mean HAQ of 1.02; 74% of individuals did not present extra-articular manifestation and 73% presented articular deformities. At the time of the assessment, the mean number of painful articulations was 5.56 e and the number of

edematized articulations was 7.35. The self-assessment of pain and general state by VAS had a mean 41.42 mm (SD = 25.1) and 67.30 mm (SD = 20.7), respectively, for the participants in the study.

Table 1 presents the mean of domains and summaries obtained from the SF-36.

Table 2 presents the mean obtained for the preference measures obtained from the generation models of the SF-6D and from the EQ-5D.

Table 3 shows significant correlations ($p < 0.01$) between the algorithms of preferences derived from the SF-6D and

from the EQ-5D with correlation coefficients ranging from 0.59 to 0.88.

DISCUSSION

Over the years, the preference assessment systems based in questionnaires played an important role in disseminating the application of preference measures in developing countries because they were less influenced by the cognitive state and socioeconomic conditions of the evaluated individuals¹⁰.

Table 1 - Mean of domains and summary components of the SF-36 for 200 patients with rheumatoid arthritis

Domain ¹	Mean	SD	Minimum	Maximum
Physical functioning	47.97	25.6	0.00	100
Role limitation due to physical problem	43.62	43.5	0.00	100
Bodily pain	51.28	22.8	0.00	100
General health perceptions	52.03	17.2	5.00	92
Vitality	55.00	19.9	5.00	100
Social functioning	71.46	25.9	13.00	100
Role limitation due to emotional problem	61.33	44.4	0.00	100
Mental health	63.74	20.4	12.00	100
Summary component²				
Physical	36.20	11.1	14.27	61.82
Mental	48.12	9.7	21.15	68.04

¹0 = worst health state and 100 = best health state

²mean for American population = 50, SD = 10

Table 2 - Mean preference measures by health states of patients with rheumatoid arthritis according to the SF-6D versions and the EQ-5D

Preference Measure	N	Mean	SD	Minimum	Maximum
SF-6D (2002) ¹	200	0.81	0.1	0.41	0.99
SF-6D (EVA) ²	200	0.45	0.2	0.12	0.92
SF-6D (SG) ³	200	0.80	0.1	0.47	0.99
EQ-5D ⁴	200	0.65	0.3	-0.48	1.00

¹SF-6D 2002 Version

²SF-6D 1998 Version built through VAS technique

³SF-6D 1998 Version built through SG technique

⁴EQ-5D = The Euroqol index of health-related quality of life

Table 3 - Correlation between the preferences measured by the SF-6D versions and by the EQ-5D in 200 patients with rheumatoid arthritis

Preference Measure	SF-6D (2002) ¹	SF-6D (EVA) ²	SF-6D (SG) ³	EQ-5D
SF-6D (2002) ¹	1.00			
SF-6D (EVA) ²	0.80**	1.00		
SF-6D (SG) ³	0.88**	0.83**	1.00	
EQ-5D ⁴	0.66**	0.59**	0.62**	1.00

** $p < 0,01$

¹SF-6D 2002 Version

²SF-6D 1998 Version built through VAS technique

³SF-6D 1998 Version built through SG technique

⁴EQ-5D = The Euroqol index of health-related quality of life

The methods developed by Brazier in 1998 and 2002 derive direct preference measures (VAS and SG), having been built on valuations of hypothetical scenarios generated through the SF-36 in a sample of the British population¹⁹⁻²⁰, which was then included in the SF-6D.

Despite the differences generated, which may harm the comparison of studies that use different methods, the algorithms developed for the SF-6D presented correlations ranging from mild to strong with one another, which initially suggests that they are measuring the same construct. Similar findings are confirmed by studies that have used different methods to derive preference from the SF-36 in various populations^{13, 14, 16, 18}.

When we compared the study by Kaplan et al. with our data, we observed very similar correlations between the preferences obtained by the tested algorithms and those of the EQ-5D²⁷. In the studies that have evaluated other diseases, we also observed good correlations between different indirect measures of preference when compared to measures derived from the SF-36^{28, 29, 30}.

Generally, the methods presented very similar behaviors when compared with one another and with the EQ-5D, which suggests the good validity of the construct. According to another study conducted previously in our field, the SF-6D (1998 version) also presented significant correlation with the clinical parameters of the population evaluated and with the direct measures of preference (Standard Gamble, Time Trade-Off and Visual Analogue Scale), which are seen as the gold standard for the measurement of preferences for health states²¹.

Some characteristics of the methods proposed by Brazier et al. deserve to be brought out in order to make the selection and comparison with other methods of deriving preferences from the SF-36. The Brazier method is the only one that estimates the SG (which is regarded as theoretically more consistent, in terms of health decision analysis), and also the only one to use hypothetical scenarios in valuation; that is, individuals do not assess their own health state. The literature highlights a tendency to obtain higher values when hypothetical scenarios are used³¹. On the other hand, the Cost-Effectiveness Panel in Health and Medicine has been standing up for the use of values obtained from the community and not from patients, when conducting economic analyses³². The Brazier method has been more commonly used in recent studies, especially the most up-to-date version, from 2002, which may, in the future, contribute to improve the assessment of the SF-6D validity³³⁻³⁷.

It is also interesting to highlight that both the methods that use the SF-36 questionnaire and those that use the SF-6D questionnaire present strong correlations with one another^{14-18, 21, 27}. This behavior suggests that, regardless of using the SF-6D questionnaires, the measures derived from the SF-36 presented similar values. Therefore, studies that used the SF-36 could obtain preference measures in a practical way, simply by deriving preferences with the proposed algorithms, including Brazier's itself.

Some limitations of this study must be highlighted. First of all, the sample selected from a reference center may not

be a good representation of the universe of patients with rheumatoid arthritis. Secondly, this study did not assess the responsiveness of the SF-6D to changes in the clinical picture of the disease over time. However, the study by Kaplan et al. has shown good responsiveness of the Fryback, Nichol and Brazier algorithms²⁷.

CONCLUSION

The different generation models of the SF-6D present moderate to strong correlations with one another and with the preferences measured by the EQ-5D. This behavior suggests that the application of these different models are valid sources of preference measures for application in economic health analyses.

The most current version of the SF-6D, based on the 2002 model, was found to be valid when compared to the version initially validated to Brazil and is a questionnaire alternative to assess preferences in economic analyses carried out in health care.

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