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The Simplified Chinese Version of SF-6Dv2: Translation, Cross-Cultural Adaptation and Preliminary Psychometric Testing

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Abstract

Purpose: To translate, cross-culturally adapt and preliminarily test the Simplified Chinese version of SF-6Dv2 among the Chinese general population.

Methods: The translation followed the international guidelines. Face-to-face cognitive debriefing was carried out in a small sample of the Chinese general population, using both think-aloud and retrospective probing methods. Preliminary psychometric properties (including acceptability, ceiling/floor effect and known group validity) were investigated using a cross-sectional survey which was conducted in a representative sample of the general population in Tianjin, China.

Results: Translation was conducted by forward- and back-translation, followed by harmonization and expert review. Two minor modifications were made during cognitive debriefing. 509 respondents (54.4% males, aged 18-86 years) participated in the psychometric testing survey. The mean (standard deviation) duration of finishing SF-6Dv2 was 96.9 seconds (58.5 seconds). No respondents claimed difficulties on understanding/answering, and no ceiling/floor effect was found in the total summary score. Known-group validity verified that the questionnaire was able to distinguish between subgroups in terms of whether having chronic conditions.

Conclusions: The Simplified Chinese version of SF-6Dv2 is demonstrated to be conceptually equivalent with the original English version, also understandable and easy to finish amongst the Chinese general population.

Keywords: SF-6D; Translation; Cross-cultural adaption; Psychometric test; Health-related quality of life; China

Introduction

The Short Form Six-Dimension (SF-6D), derived from the SF-36 by Brazier et al. [1, 2], is one of the three most widely used preference-based health-related quality of life (HRQoL) instruments internationally [3]. The preference-based HRQoL instrument can be used to elicit a health utility score which is an essential component for the calculation of quality-adjusted life years (QALYs) for use in conducting economic evaluation, especially cost-utility analysis [4].

The preference-based HRQoL instrument comprises two main components: a health state classification system and a county-specific value set (or called "scoring algorithm"). A health state classification system normally consists of a set of standardized questions that measure HRQoL dimensions and their corresponding levels. The value set for an instrument represents the predetermined preference weights attached to each health status described based on the health state classification system; in particular, the health state utility score that is calculated using the value set lies on a 0-1 death-full health QALY scale [3, 4]. The health state classification system of the SF-6D, although not necessarily directly used in HRQoL data collection (which is done using mainly the SF-36), plays a vital role in developing the county-specific value set. Since its development, the SF-6D has been translated into more than 10 different languages [3], including the Traditional Chinese version which was developed in Hong Kong [5]. Along with the wide use of the SF-36 in Mainland China [6], there is a need to develop a Chinese-specific value set for the SF-6D to facilitate health economic evaluation.

Recently, the second version of the SF-6D (hereafter "SF-6Dv2") had been developed, which revisited the item selection from the SF-36 and modified the ambiguity between dimension levels and the inconsistency in wordings in the original version [3, 7]. In brief, 11 items from the SF-36 were originally used to generate the health state classification system of the SF-6Dv1, whilst 10 items from the SF-36 were used for the SF-6Dv2. Among the six dimensions, several modifications were made to address the ambiguity in the response levels of the physical functioning (between "moderate activities" and "bathing and dressing"), the

confusion of positive wording on the vitality item, and the crudeness due to using two SF-36 role limitation items. Detailed information was described elsewhere [3, 7].

The aims of this study were to translate and cross-culturally adapt the Simplified Chinese version of the SF-6Dv2 health state classification system among the Chinese general population, and to preliminarily test its psychometric properties. This study represents the first step to a Chinese-specific value set development.

Methods

Instrument

The SF-6Dv2 health state classification system has six dimensions: Physical functioning (PF), Role limitation (RL), Social functioning (SF), Pain (PN), Mental health (MH) and Vitality (VT). The PN-dimension has six response levels, while all others have five levels, with higher values representing more severe states [3, 7]. Overall the SF-6Dv2 descriptive system can define 18,750 (=5*5*5*6*5*5) health states.

Translation

The translation followed international guidelines [8, 9]: (1) two native Chinese-speaking translators experienced in translating HRQoL questionnaires independently translated the questionnaire forward into Chinese, then reconciled their translations into a single version; (2) an experienced native English-speaking translator, who was uninformed about the original English version of the SF-6Dv2, translated it back into English; (3) a manager approved a harmonized translation by discussing it with the three translators; (4) a professional analyst compared the original English version with the harmonized translation and approved; and (5) all authors reviewed and finalized the translation.

Cognitive debriefing

Following the published guidelines [9, 10], the cognitive debriefing interviews were conducted among a small sample (target N=6) of the general population with heterogeneous demographic characteristics (age, gender, education level, residence place and health condition) in Tianjin, China. Face-to-face interviews with both think-aloud (which encouraged respondents to verbalize anything they thinking about) and retrospective probing (which asked respondents further questions based on their feedback) methods were carried out [10, 11], in order to observe any difficulties in understanding, recalling and answering. Subsequently, an expert-review committee consisting of six Chinese experts (XF, LN, LSP, WHY, JXJ, GHJ), who have experience in quality of life and health utility measurement, reviewed the Simplified Chinese version of the SF-6Dv2, which was then sent to the original developers of the SF-6D for final approval.

Preliminary psychometric testing

A cross-sectional study was conducted in Tianjin city to determine the acceptability, ceiling/floor effect and known-group validity of the Simplified Chinese version of the SF-6Dv2. Tianjin is one of the four municipalities in China with 16 districts, and has more than 15 million permanent residents. A representative sample (target N=500) of the general population were recruited using multi-stage sampling in 11 districts in Tianjin, China. In each of the 11 selected district, 45-50 participants stratified by the distributions of age, gender and education level of the general population in Tianjin [12] were recruited. Recruiting was conducted in publicly accessible places such as streets, parks and campuses, as well as private places such as residences. Inclusion criteria were that respondents: (1) were ≥18 years; (2) were born in mainland China; (3) lived in mainland China during the last five years; (4) were literate and had no disease limiting cognitive function; and (5) gave informed consent.

All respondents were asked to finish the Simplified Chinese version of the SF-6Dv2 through face-to-face interviews. Two interviewers were involved during the interview with each respondent. According to the study protocol, one of the them operated the computer to show all of the questions to the respondent, and the other interviewer recorded problems and

difficulties encountered during the interview. Data including demographic characteristics (age, gender, marital status, household registration), socioeconomic status (education level, employment status, monthly income) and health-related indicators (smoking and alcohol consumption, presence of chronic conditions, health insurance coverage) were also collected.

Acceptability was assessed by the time spent finishing the questionnaire and self-reported difficulties on understanding/answering. Ceiling/floor effects of the total score (sum of each dimension level of SF-6Dv2) were considered present if more than 10% of respondents achieved the highest or lowest possible score [13]. Known-group validity was assessed by comparing the distributions of self-reported dimension levels on the SF-6Dv2 for respondents with and without self-reported chronic conditions, using a chi-squared test, and further assessed by using the ordered logit regression analyses (see Supplemental Material). The *p*-value <0.05 was considered statistically significant. All statistical analyses were conducted using STATA version 14.1 (StataCorp LP, College Station, Texas, USA).

Results

Translation

During the translation process, minor changes were made in wordings of examples given for the PF-dimension compared to the original English version. Specifically, "打高尔夫球 (playing golf)" was changed to "打太极拳 (playing Tai-Chi)", and "使用吸尘器 (pushing a vacuum cleaner)" was changed to "拖地板 (mopping the floor)", ensuring that it was representative of the daily life of the Chinese population (Table 1).

Cognitive debriefing

Cognitive debriefing was conducted with six respondents in Tianjin in October 2017. Respondents were aged 24-63 years, 50% were male, 50% had lived in a rural area, and 50% have had, or have taken care of patients with serious diseases. All respondents considered the

questionnaire to be understandable, and the response choices were appropriate and easy to choose.

Meanwhile, two semantic problems were raised by respondents, and corresponding modifications (Table 1) were proposed and reviewed by the expert committee. Firstly, the last sentence of the question in the RL-dimension was too long and may have caused ambiguity, so this was trimmed and rephrased accordingly. Second, the initial translation of the frequency words between the second level ("偶尔", "a little of the time") and the third level ("有时"," some of the time") in PF, RL, MH and VT dimensions was ambiguous in Chinese, so we changed the translation of the word in the second level from "偶尔" to "很少" ("很少" also means a little of the time, but it easier to distinguish from "有时"). Similar problems were presented between the forth level ("大部分时间", "most of the time") and the fifth level ("常常如此", "all of the time"), so we changed the translation of the word in the fifth level from "常常如此" to "一直如此". The modified Simplified Chinese version of the SF-6Dv2 was then finally approved by the original developers of the SF-6D.

Preliminary psychometric testing

A total of 509 respondents (54.4% males) participated in this study in July 2018, with mean (SD) age of 45.4 (16.7) years, and ranged between 18-86 years. The distributions of characteristics of respondents were in close proximity to the Tianjin general population (Table 2).

The mean (SD) time spent on finishing the SF-6Dv2 was 96.9 seconds (58.5 seconds), and ranged from 27 to 214 seconds. No respondents claimed difficulties understanding/answering the questionnaire. The total summary scores of the questionnaire ranged from 6-27 (theoretical range: 6-31; Figure 1), and no floor or ceiling effects were found. As well 61.3% (N=312) of the respondents scored 7-12, representing a very mild health condition. Among the six dimensions (Figure 2), the proportion of respondents reporting problems in the VT-dimension was highest (N=405, 79.5%), whilst the proportion in SF-dimension was the lowest (N=185, 36.3%). Table 3 shows that having chronic conditions significantly

discriminated the distributions of all six dimensions of the SF-6Dv2, hence evidence of known-group validity. Further control for other socio-demographic characteristics, using the ordered logit regression results demonstrated that the conclusion remains robust (see Supplemental Table 1).

Discussion

The Simplified Chinese version of the SF-6Dv2 was developed. The conceptual and linguistic equivalence with the original English version was excellent, and only minor modifications were made during the cross-cultural adaptation. This study also provided empirical evidence for the adequate psychometric properties of the questionnaire.

The standardized and comprehensive methods of translation and cross-cultural adaption were employed. Instead of only using a probing method [14, 15], a think-aloud method, which has been demonstrated to work better for self-completion questionnaires, was also used in this study [9]. Additionally, we needed to ensure that the translation was easily and unambiguously understood in the Chinese language, whilst guaranteeing that it remained in line with the intended interpretation of the original version. The colloquial language such as "一直", "很少", were therefore selected because these are widely used phrases in daily conversation in China. Besides, speaking different dialects would not affect the understanding of the Simplified Chinese version of the SF-6Dv2 because different dialects have the same written Chinese (Mandarin). It is also worth noting that the ambiguity of descriptions with response levels in the original translation may have implications for translating HRQoL instruments into Simplified Chinese, such as the Chinese version of SF-36.

The acceptability of the questionnaire was well exhibited, based on it being well understood and having no burden to complete. Neither ceiling nor floor effects were observed among general population in this study suggest that the SF-6Dv2 may have better performance in terms of the ceiling/floor effects than the original SF-6D [16] or the EQ-5D-3L when using among the Chinese population [17]. The questionnaire also possessed good known-group validity. As expected, respondents with chronic conditions reported worse

health states [18]. Results of regression analyses were also in line with previous studies [17, 19, 20, 21].

Respondents were more likely to report problems in PN, MH, and most notably VT dimensions, which was consistent with studies in other countries [20-22], indicating respondents were more sensitive in these three dimensions when evaluating their own health status. On the other hand, this study showed that the Chinese population generally reported a lower proportion of problems in each SF-6Dv2 dimension than other countries such as Chile, Portugal and Australia [19, 20, 22]. This may be due to the cultural/racial/ethnic differences in an individual's perception of their HRQoL [23-25]. However, it should be noted that all of the previous studies adopted the SF-6Dv1, instead of the SF-6Dv2 used in this study.

Several limitations needed to be addressed. Firstly, the respondents were recruited in one city, which has limited representativeness of the total Chinese general population. Secondly, although the study sample were stratified to match the distributions of age, gender, and education level of the general population in Tianjin, this does not imply a random sample was recruited. Furthermore, since most of the respondents were recruited in publicly accessible places, this limited the chance to trace the same respondent to measure test-retest reliability. Thirdly, other generic instruments (e.g. EQ-5D) were not employed, which limits the ability to evaluate convergent or discriminant validity.

Conclusions

The translated and cross-culturally adapted Simplified Chinese version of the SF-6Dv2 is demonstrated to be understandable and interpreted as intended among the Chinese general population. The preliminary validation study supports its validity, and further studies are required to comprehensively evaluate its psychometric properties. This study presents the necessary step to the application of the SF-6Dv2 in China, and would further support the development of a Chinese-specific value set for SF-6Dv2 and its future applications in China.

Compliance with ethical standards

The protocol of this study was approved by the Institutional Review Board of School of Pharmaceutical Science and Technology, Tianjin University (No. 20180615). Informed consent was obtained from all individual participants included in the study.

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Conflict of interest

The authors declare that they have no conflict of interest.

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Table 1 The comparison of original English version and translated Simplified Chinese version of SF-6Dv2 (Physical Functioning and Role Limitation dimensions)

	The original English version of SF-6Dv2	The initial translation of Simplified Chinese version of SF-6Dv2	The final Simplified Chinese version of SF-6Dv2
Physical Functioning	**Does your health now limit you in your daily physical activities?** • Not limited at all in vigorous activities (such as running, lifting heavy objects, participating in strenuous sports) • Limited a little in vigorous activities (such as running, lifting heavy objects, participating in strenuous sports) • Limited a little in moderate activities (such as moving a table, pushing a vacuum cleaner, bowling, or playing golf) • Limited a lot in moderate activities (such as moving a table, pushing a vacuum cleaner, bowling, or playing golf) • Limited a lot in bathing and dressing	**您的健康现在限制了您的日常身体活动吗？** • 高强度活动（如跑步、抬起重物、参加剧烈运动）完全没有限制 • 高强度活动（如跑步、抬起重物、参加剧烈运动）受到一点限制 • 中等强度活动（如搬桌子、拖地板、打保龄球或打太极拳）受到一点限制 • 中等强度活动（如搬桌子、拖地板、打保龄球或打太极拳）受到很大限制 • 洗澡和穿衣受到很大限制	
Role Limitation	**During the past 4 weeks, how much of the time have you accomplished less than you would like at work or during other regular daily activities as a result of your physical health or emotional problems?** • None of the time • A little of the time • Some of the time • Most of the time • All of the time	**在过去 4 个星期中，您在工作或其它日常活动中，有多少时候会由于身体健康或情绪问题而未全部完成预期想要完成的工作？** • 从来没有 • 偶尔 • 有时 • 大部分时间 • 常常如此	**在过去 4 个星期中，您有多少时候会由于身体健康或情绪问题，而导致实际完成的工作或其他日常活动比想要完成的少？** • 从来没有 • 很少 • 有时 • 大部分时间 • 一直如此

The examples changed during the translation are underlined using dots.

The modified sentence and response levels through cognitive debriefing interviews were underlined.

Table 2 Characteristics of respondents for the cross-sectional survey

Characteristics	Total sample (N=509) N (%)	Tianjin statistics [a] (%)
Gender [b]		
Male	275 (54.0%)	54.4%
Female	234 (46.0%)	45.6%
Age (mean [SD])	45.4 (16.7)	NA
Age group (y) [b]		
18-29	103 (20.2%)	20.0%
30-39	104 (2.4%)	19.9%
40-49	88 (17.3%)	17.7%
50-59	94 (18.5%)	18.8%
≥ 60	120 (23.6%)	23.6%
Education [b]		
Primary or lower	94 (18.5%)	19.2%
Junior high school	170 (33.4%)	34.6%
Senior high school	117 (23.0%)	22.2%
College or higher	128 (25.1%)	24.0%
Ethnic group		
Han Chinese	485 (95.3%)	97.4%
Other	24 (4.7%)	2.6%
Household registration		
Urban	348 (68.4%)	70.0%
Rural	161 (31.6%)	30.0%
Marital status		
Unmarried	111 (21.8%)	17.1%
Married	358 (70.3%)	75.8%
Divorced	15 (3.0%)	2.0%
Widowed	25 (4.9%)	5.1%
Health insurance		
Urban employee	316 (62.1%)	NA
Urban and rural resident	184 (36.1%)	NA
Commercial	93 (18.3%)	NA
Other	5 (1.0%)	NA
No	5 (1.0%)	NA
Employment status		
Employed	299 (58.7%)	NA
Retired	127 (25.0%)	NA
Student	49 (9.6%)	NA
Unemployed	34 (6.7%)	NA
Monthly income (RMB)		
< 2000	108 (21.2%)	NA
2000-5000	294 (57.8%)	NA
5000-10000	81 (15.9%)	NA

>10000	26 (5.1%)	NA
Smoking status		
Never	334 (65.6%)	NA
Former smoker	54 (10.6%)	NA
Still	121 (23.8%)	NA
Alcohol consumption		
Never	282 (55.4%)	NA
Former drinker	54 (10.6%)	NA
Still	173 (34.0%)	NA
Number of chronic conditions [c]		
0	297 (58.3%)	NA
1	125 (24.6%)	NA
2	46 (9.0%)	NA
3	25 (4.9%)	NA
4 or more	16 (3.2%)	NA

[a] All of the data were based on the Tianjin permanent population. The data of ethnic group was collected from the *Sixth National Census (2010)*[11], and other data were collected from *Tianjin Statistical Yearbook 2017*[12]; N/A indicates that a direct data was not included in the Statistical Yearbook.

[b] The quota sampling was used in which three quotas, i.e., gender, age and education status, were pre-defined on the basis of their distribution in the Tianjin permanent population.

[c] The chronic conditions include: Hypertension, dyslipidemia, diabetes or high blood sugar, cancer or malignant tumor, chronic lung disease, liver disease, heart disease, stroke, kidney disease, stomach or other digestive disease, emotional or psychiatric problems, memory-related disease, arthritis or rheumatism, asthma, or other respondent-reported chronic conditions.

Table 3 Comparison of reported problems on SF-6Dv2 among respondents with and without chronic conditions for the known group validity

	Physical Functioning		Role Limitation		Social Functioning		Pain		Mental Health		Vitality	
	Chronic condition*** [b]		Chronic condition***		Chronic condition***		Chronic condition***		Chronic condition*		Chronic condition**	
	No (N=297)	Yes (N=212)	No (N=297)	Yes (N=212)	No (N=297)	Yes (N=212)	No (N=297)	Yes (N=212)	No (N=297)	Yes (N=212)	No (N=297)	Yes (N=212)
Level												
1	186 (62.6%)	72 (34%)	166 (55.9%)	94 (44.3%)	202 (68%)	122 (57.5%)	166 (55.9%)	83 (39.2%)	120 (40.4%)	87 (41%)	62 (20.9%)	42 (19.8%)
2	86 (29%)	77 (36.3%)	87 (29.3%)	51 (24.1%)	68 (22.9%)	37 (17.5%)	43 (14.5%)	22 (10.4%)	106 (35.7%)	60 (28.3%)	82 (27.6%)	47 (22.2%)
3	21 (7.1%)	49 (23.1%)	38 (12.8%)	51 (24.1%)	23 (7.7%)	36 (17%)	72 (24.2%)	62 (29.2%)	64 (21.5%)	49 (23.1%)	125 (42.1%)	79 (37.3%)
4	4 (1.3%)	11 (5.2%)	5 (1.7%)	13 (6.1%)	4 (1.3%)	15 (7.1%)	12 (4%)	32 (15.1%)	3 (1%)	11 (5.2%)	23 (7.7%)	31 (14.6%)
5	0 (0%)	3 (1.4%)	1 (0.3%)	3 (1.4%)	0 (0%)	2 (0.9%)	4 (1.3%)	8 (3.8%)	4 (1.3%)	5 (2.4%)	5 (1.7%)	13 (6.1%)
6 [a]	--	--	--	--	--	--	0 (0%)	5 (2.4%)	--	--	--	--

[a] There are 6 levels in Pain dimension, and 5 levels in other dimensions in SF-6Dv2 descriptive system.

[b] *** p <0.001, ** p <0.01, * p <0.05. The comparison of distributions of dimensions levels between respondents with and without self-reported chronic conditions was evaluated by chi^2 test.

The chronic conditions considered include hypertension, dyslipidemia, diabetes or high blood sugar, cancer or malignant tumor, chronic lung disease, liver disease, heart disease, stroke, kidney disease, stomach or other digestive disease, emotional or psychiatric problems, memory-related disease, arthritis or rheumatism, asthma, or other respondent-reported chronic conditions.

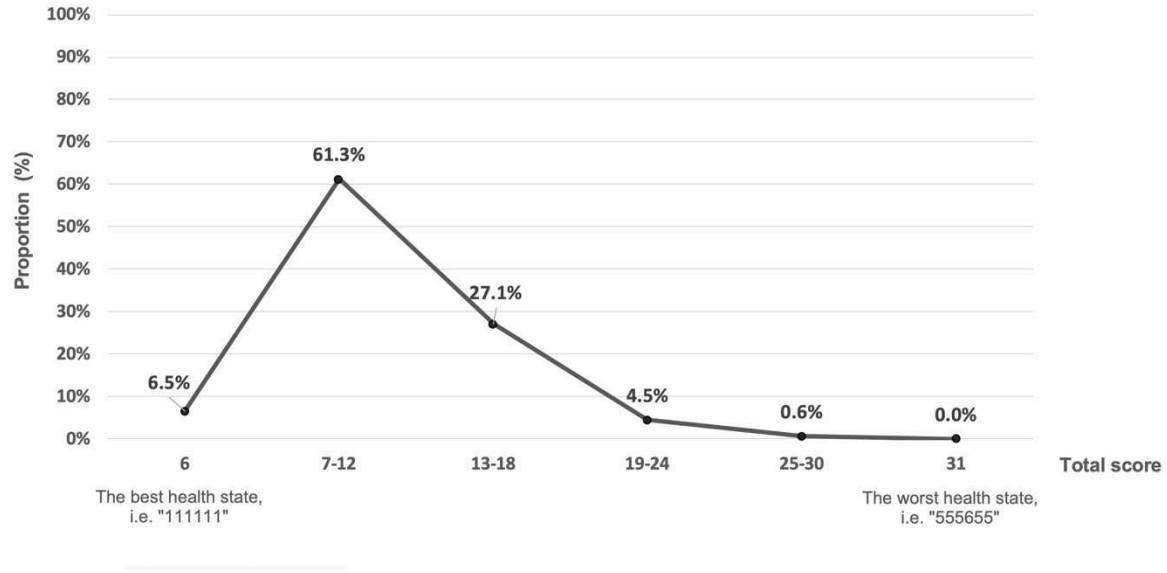

Fig 1 The distribution of SF-6Dv2 total score of respondents (N=509).

Note: The total score was calculated by the sum of each dimension level of SF-6Dv2.

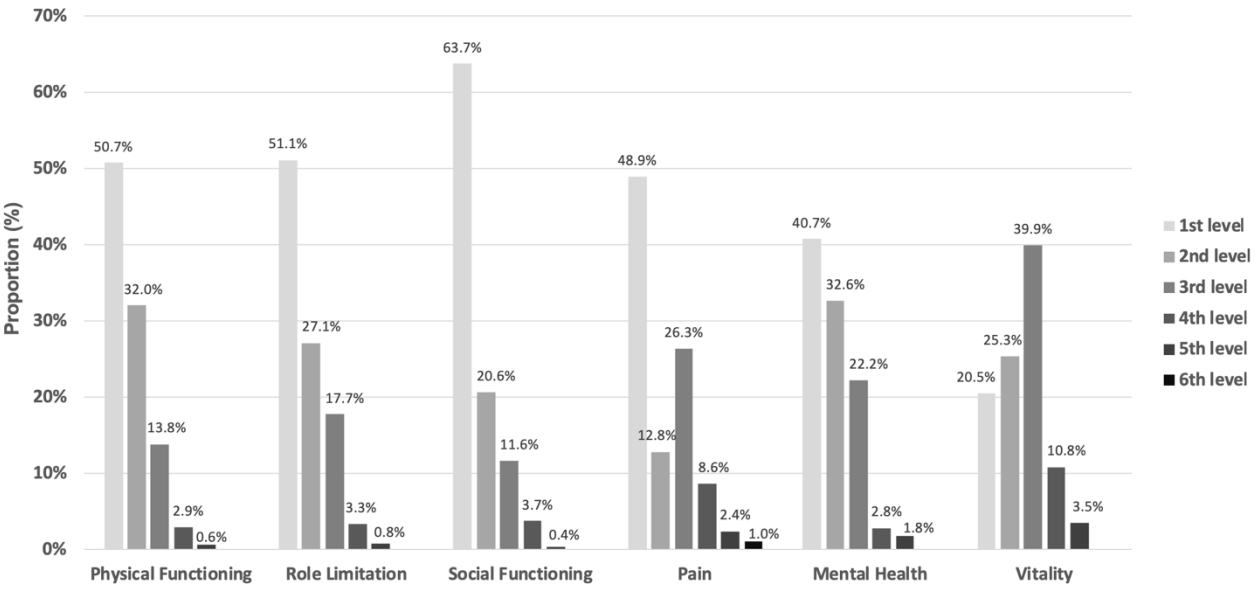

Fig 2 The distribution of SF-6Dv2 specific-dimension scores of respondents (N=509).

Note: There are 6 levels in Pain dimension, and 5 levels in other dimensions in SF-6Dv2 descriptive system.