# ORIGINAL ARTICLE Good validity of the international spinal cord injury quality of life basic data set

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Study design: Cross-sectional validation study.

**Objectives:** To examine the construct and concurrent validity of the International Spinal Cord Injury (SCI) Quality of Life (QoL) Basic Data Set.

**Setting:** Dutch community.

**Participants:** People 28–65 years of age, who obtained their SCI between 18 and 35 years of age, were at least 10 years post SCI and were wheelchair users in daily life.

**Measure(s):** The International SCI QoL Basic Data Set consists of three single items on satisfaction with life as a whole, physical health and psychological health (0=complete dissatisfaction; 10=complete satisfaction). Reference measures were the Mental Health Inventory-5 and three items of the World Health Organization Quality of Life measure.

**Results:** Data of 261 participants were available. Mean time after SCI was 24.1 years (s.d. 9.1); 90.4% had a traumatic SCI, 81.5% a motor complete SCI and 40% had tetraplegia. Mean age was 47.9 years (s.d. 8.8) and 73.2% were male. Mean scores were 6.9 (s.d. 1.9) for general QoL, 5.8 (s.d. 2.2) for physical health and 7.1 (s.d. 1.9) for psychological health. No floor or ceiling effects were found. Strong inter-correlations (0.48–0.71) were found between the items, and Cronbach's alpha of the scale was good (0.81). Correlations with the reference measures showed the strongest correlations between the WHOQOL general satisfaction item and general QoL (0.64), the WHOQOL health and daily activities items and physical health (0.69 and 0.60) and the Mental Health Inventory-5 and psychological health (0.70).

**Conclusions:** This first validity study of the International SCI QoL Basic Data Set shows that it appears valid for persons with SCI. *Spinal Cord* (2016) **54**, 314–318; doi:10.1038/sc.2015.99; published online 23 June 2015

## INTRODUCTION

Spinal cord injury (SCI), including a spinal cord lesion caused by a trauma or disease process, results in varying degrees of body impairment, activity limitations, participation restrictions and decreased quality of life (QoL).<sup>1</sup> Many researchers have investigated QoL following SCI, but results from published papers are difficult to compare because of variation in definitions of QoL, study designs, inclusion criteria and the measures used.<sup>2</sup> Unfortunately, there is as yet no single definition of QoL on which everyone agrees, in spite of the many efforts directed at clarifying or defining this concept.<sup>3,4,5</sup>

Without consensus on the definition of QoL, it is not surprising that there is no consensus either on how to measure QoL.<sup>2</sup> The development of new measures continues, and attempts to reach consensus on a standard QoL measure have been unsuccessful to date.<sup>6</sup> Considering that consensus on the definition and measurement of QoL is unlikely to emerge in the near future but that there is an urgent need to increase comparability between QoL studies in individuals with SCI, an International SCI QoL Basic Data Set (further: QoL Basic Data Set) was developed as part of the International SCI Data Sets Project.<sup>7</sup> The purpose of this QoL Basic Data Set, like all International SCI Basic Data Sets, is to standardize the collection and reporting of a minimal amount of information necessary to merge and compare results of published and unpublished studies on QoL in individuals with SCI. Similar to all International SCI Basic Data Sets, it was designed to include a minimal number of data elements, which together can be included in any SCI study and can be collected in routine clinical practice.<sup>7</sup>

The QoL Basic Data Set was developed by an international expert committee.<sup>8</sup> It is based on the definition of subjective QoL as reflecting an individual's overall perception of and satisfaction with how things are in his/her life.<sup>7</sup> To define 'what' to measure, QoL was considered as an umbrella term covering both health and well-being.<sup>4</sup> and it was considered useful to distinguish at least a physical health and a mental health domain.<sup>9</sup> Three items, one for each domain, were selected to provide clinicians and researchers information regarding an individual's satisfaction with their general QoL, physical health and psychological health. To define 'how' to measure, it was decided, following the above cited definition of QoL, to rate the individual's satisfaction with his/her situation on these three domains. Details on its conceptual basis and development have been described elsewhere.<sup>8</sup>

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The International SCI Data Sets were not developed to be used as measures; nevertheless they need to be valid and reliable. Content validity is always important, whereas construct and convergent validity are only relevant if a data set is used as a measure.<sup>10</sup> The QoL Basic Data Set is likely to be used as a measure, and therefore its psychometric properties have to be examined and this has not been done to date. The purpose of the current paper, therefore, is to examine the construct and convergent validity of the QoL Basic Data Set.

# MATERIALS AND METHODS

# Design

This study is a secondary analysis of data from the Active LifestyLe Rehabilitation Interventions in aging Spinal Cord injury (ALLRISC) study.<sup>11</sup> This is a time-since-SCI-stratified cross-sectional study among individuals with longterm SCI who use a wheelchair for daily transportation in the Netherlands. Strata of time since SCI were 10–19, 20–29 and 30 years or more.

## Participants

Eligible participants were identified from the medical files of all eight centers, with specialty in SCI rehabilitation in the Netherlands. The inclusion criteria of the ALLRISC study were as follows: having traumatic or non-traumatic SCI; age at injury between 18 and 35 years; time since SCI at least 10 years, current age between 28 and 65 years; and using a wheelchair in daily life for longer distances (>500 m). Exclusion criterion was insufficient mastery of the Dutch language.

From this database, participants with complete QoL Basic Data Set data were selected for the current study.

## Procedure

The measurement protocol included an aftercare check-up by the local SCI rehabilitation physician and physical tests by a trained research assistant, and participants were asked to complete a self-report questionnaire before their visit to the center either in digital or in paper and pencil form. The study protocol has been approved by the Medical Ethics Committee of the University Medical Centre Utrecht and all local review boards. Written or oral, in case the participants was not able to write, informed consent was obtained from all participants.

#### Instruments

The QoL Basic Data Set consists of three items on satisfaction with life as a whole, satisfaction with physical health and satisfaction with psychological

#### Table 1 Sample characteristics (N = 261)

	% or mean (s.d.)
Age at the interview (mean; s.d.; range)	47.9 (8.8); 28–66
Time since SCI (mean; s.d.)	24.1 (9.1); 10-47
10–19 years	37.2
20–29 years	34.1
30 years or more	28.7
Gender (% male)	73.2
Level of education (% college/university)	56.9
Relationship (% married/stable relationship)	62.4
Employment (% having paid work $\geq 1$ h per week)	8.3
Traumatic SCI (%)	90.4
Tetraplegia (%)	40
Motor complete SCI (%)	81.5
Total score SCIM (mean; s.d.; range)	56.7 (18.3); 14–94
Total score MHI-5 (mean; s.d.; range)	74.8 (15.9); 12–100
Total score WHOQOL-5 (mean; s.d.; range)	17.9 (3.5); 8–25

Abbreviations: MHI, Mental Health Inventory; SCI, spinal cord injury; SCIM, Spinal Cord Independence Measure; WHOQOL, World Health Organization Quality of Life measure.

health during the past 4 weeks.<sup>8</sup> Each item is answered on a 0–10 numerical rating scale with markers 'complete dissatisfaction' and 'complete satisfaction'. It was independently translated into Dutch by two experts in SCI rehabilitation and QoL measurement. Differences were discussed and consensus was reached. As the literal translation of the term psychological health ('psychologische gezondheid') would easily be associated with psychiatric illness, it was described as mental health, emotions and mood ('mentale gezondheid, emoties en stemming') to ensure conceptual equivalence.<sup>10</sup> The final translation was reviewed and approved by a panel of eight physician specialists in SCI rehabilitation.

Demographic data included the following: age, gender, marital status, ethnicity, having children, education, work and living situation.

Impairment was classified according to the International Standards for the Neurological Classification of SCI.<sup>12</sup> Assessment was performed by the rehabilitation physician.

Functional independence was measured using the Spinal Cord Independence Measure III.<sup>13</sup> The Spinal Cord Independence Measure III was administered by the research assistant as part of an oral interview.

Mental health was measured with the Mental Health Inventory-5, which is identical to the Mental Health subscale of the Medical Outcome Studies Short-Form-36 (SF-36), a measure that has extensive use in SCI research.<sup>14</sup> The Mental Health Inventory-5 consists of five questions on mood over the last 4 weeks and has shown construct validity and convergent validity in individuals with SCI.<sup>15</sup>

Satisfaction with overall QoL, physical health and the ability to perform daily activities was measured with three items from the abbreviated World Health Organization Quality of Life measure.<sup>16</sup> Each item is scored on a 5-point Verbal Rating Scale. These three items showed construct validity and cross-cultural validity in individuals with SCL.<sup>17</sup>

#### Statistics

Statistical analyses were performed using SPSS version 19.0 for Windows.(IBM Corporation, Armonk, NY, USA) Floor and ceiling effects were considered to be present if >15% of the respondents achieved the lowest or highest possible score, respectively.<sup>18</sup> Skewness was considered to be present if the corresponding statistic was below - 1.0 or above 1.0. Internal consistency was considered acceptable if Cronbach's alpha coefficient was at least 0.70 and corrected item-total correlations were larger than 0.30.18 Convergent validity was assessed using Spearman's correlations. To establish convergent validity, positive correlations of 0.60 or higher were expected between the general QoL item and the World Health Organization Quality of Life measure satisfaction with overall QoL item, between the physical health item and the physical health and daily activities items of the World Health Organization Quality of Life measure and between the psychological health item and the Mental Health Inventory-5 score, because these items/instruments measure similar constructs.<sup>2,19</sup> Spearman's correlations between 0.30 and 0.59 were expected for the other associations with the QoL Basic Data Set items because all scores reflect different but related constructs.<sup>19</sup> Finally, correlations with demographic variables were calculated. Nonparametric Spearman's correlations were used in all analyses because of partly skewed score distributions. Correlations below 0.30 were interpreted as weak, and correlations of 0.50 or higher were interpreted as strong.20

# RESULTS

A total of 282 participants were tested of whom 261 had complete data on the QoL Basic Data Set and were included in the current study. Four participants missed all Data Set items and three more did not complete the psychological health item. The characteristics of the sample are described in Table 1. The level of education in the study group is high compared with that of the general Dutch population.

The three items showed generally strong inter-correlations: 0.48 between satisfaction with physical health and satisfaction with mental health, 0.55 between satisfaction with life as a whole and satisfaction with physical health and 0.71 between satisfaction with life as a

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Table 2 Descriptive statistics of the l	nternational Spinal Co	ord Injury QoL Basic	Data Set ( $N = 261$ )
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QoL basic data set scores (range 0–10)	Mean (s.d.)	Median (IQR)	Skewness	Kurtosis	Minimum score (%)	Maximum score (%)
Satisfaction with life as a whole	6.9 (1.9)	7 (6–8)	-1.1	1.6	1.1	4.2
Satisfaction with physical health	5.8 (2.2)	6 (4–7)	-0.5	-0.2	1.5	3.1
Satisfaction with psychological health	7.1 (1.9)	7 (6–8)	-0.9	1.1	0.8	7.3
Total QoL Basic Data Set score	6.6 (1.7)	6 (5.7–7.7)	-0.8	0.9	0.4	1.5

Abbreviations: IQR, interquartile range; QoL, quality of life.



Figure 1 (a–d) Frequency distributions of the single items and the total score of the International QoL Basic Data Set. A full color version of this figure is available at the Spinal Cord journal online.

whole and satisfaction with mental health. Because of these strong inter-correlations, computing a total QoL Basic Data Set score was considered. This total score showed good internal consistency (alpha = 0.81; item-rest correlations 0.57-0.74).

Table 2 and Figure 1a and d show the frequency distributions of the three items and the total QoL Basic Data Set score. One of the three item scores showed a skewed distribution. The Skewness of the total QoL Basic Data Set score was within limits.

Table 3 shows the correlations between the three items and the QoL Basic Data Set score with the reference measures. Each time, the expected strong correlation was found and was stronger than the expected weak to moderate correlations. The correlations between the total QoL Basic Data Set and each of the reference measures were of approximately the same size. Table 4 shows the QoL Basic Data Set scores in subgroups defined by various demographic and SCI characteristics. Differences between subgroups were generally small, and only one of all the statistical tests was significant.

# DISCUSSION

The analyses in this study provide support for the construct and convergent validity of the International SCI QoL Basic Data Set<sup>8</sup> to provide minimum data on QoL in individuals with SCI. With only three items, this QoL Basic Data Set is easy to apply as an added measure in every SCI study, on its own or as add-on to a more extensive QoL measurement.

The time needed to administer the QoL Basic Data Set was not recorded as it was part of a larger questionnaire but is expected to be

## Table 3 Convergent validity of the International Spinal Cord Injury QoL Basic Data Set (N=261)

WHOQOL General QoL	WHOQOL health	WHOQOL daily activities	MHI-5
0.64	0.45	0.53	0.61
0.46	0.69	0.60	0.42
0.49	0.39	0.41	0.70
0.61	0.62	0.62	0.66
	WHOQOL General QoL 0.64 0.46 0.49 0.61	WHOQOL General QoL WHOQOL health   0.64 0.45   0.46 0.69   0.49 0.39   0.61 0.62	WHOQOL General QoL WHOQOL health WHOQOL daily activities   0.64 0.45 0.53   0.46 0.69 0.60   0.49 0.39 0.41   0.61 0.62 0.62

Abbreviations: MHI-5: Mental Health Index-5; QoL, quality of life; WHOQOL, World Health Organization Quality of Life. Expected correlations ≥0.60 in bold.

## Table 4 QoL Basic Data Set scores in subgroups defined by demographic and SCI characteristics

	Satisfaction with life as a whole	Satisfaction with physical health	Satisfaction with psychological health	Total QoL Basic Data Set score
Age				
<50 (158)	6.9 (1.9)	5.8 (2.3)	7.1 (1.9)	6.6 (1.7)
50 or above (103)	6.8 (1.8)	5.8 (2.1)	7.0 (1.9)	6.6 (1.7)
Gender				
Male (191)	6.7 (2.0)	5.7 (2.2)	7.0 (2.0)	6.5 (1.8)
Female (70)	7.4 (1.4)	6.0 (2.0)	7.2 (1.8)	6.9 (1.4)
Education <sup>a</sup>				
Low (103)	6.7 (2.1)	5.5 (2.2)	7.0 (1.9)	6.4 (1.7)
High (136)	7.1 (1.8)	5.9 (2.1)	7.1 (1.9)	6.7 (1.7)
Time since SCI				
10–19 years	6.9 (2.0)	6.0 (2.3)	6.7 (2.1)	6.6 (1.9)
20–29 years	6.8 (2.0)	5.6 (2.2)	7.3 (1.8)	6.5 (1.6)
30 or more	6.9 (1.9)	5.9 (2.0)	7.1 (1.8)	6.1 (1,6)
Level of SCI				
Tetraplegia (104)	6.6 (1.9)	5.8 (2.3)	7.1 (1.9)	6.5 (1.8)
Paraplegia (156)	7.0 (1.9)	5.9 (2.0)	7.1 (1.9)	6.6 (1.6)
Completeness of SCI				
Complete (212)	6.9 (1.9)	5.8 (2.2)	7.1 (1.9)	6.6 (1.7)
Incomplete (48)	6.9 (1.9)	6.0 (1.9)	7.1 (2.1)	6.7 (1.6)

<sup>a</sup>Unable to classify education in 22 cases.

no > 1-3 min. No special training is needed to administer the QoL Basic Data Set. The few missing values indicate that the items are acceptable for individuals with SCI and feasible to complete. However, most participants completed the questionnaire online, and administration by paper/pencil might have revealed a higher proportion of missing values.

Convergent validity of the three items and the total score were in the range of 0.64 for the satisfaction with life as a whole item up to 0.70 for the satisfaction with psychological health item. This is in the range of the values indicating convergent validity of at least 0.60.<sup>19</sup>

Taken together, the three items make up a scale with good internal consistency. According to the classical test theory, this means that the items can be considered to measure the same concept (QoL) and a total score can be computed. Item-response theory ('Rasch') analysis to assess the construct validity of this scale was considered but deemed not applicable, as there is no reason to hypothesize a hierarchy between the three items.

## Limitations of this study

Use was made of an ongoing cross-sectional study. Consequently, important psychometric characteristics as test–retest reliability and sensitivity to change could not be established. An ongoing project in the Netherlands will provide information on the reliability of most International SCI Basic Data Sets, among which is the QoL Basic Data Set (Post, forthcoming). Second, because of the inclusion criteria of the ALLRISC study the sample consisted of mainly middle-aged individuals with complete SCI and living with SCI for a long time. It is therefore possible that the results of this study do not apply to recently injured individuals or individuals with incomplete SCI who do not use a wheelchair. Third, no information was collected on the participants' understanding of the QoL Basic Data Set items, and it is possible that these were less well understood or well-received than would have been assumed. Finally, the results of this study apply to the Dutch translation of this QoL Basic Data Set. We feel confident about the quality of our translation, as it followed the recommendations for translation of the International SCI Data Sets.<sup>10</sup> In addition, as many previous translations of QoL measures used a similar terminology, the independent translations did not reveal major problems, and the final version was approved by an expert panel.

## Implications

The results of this study show that the QoL Basic Data Set can be used to collect information on QoL in SCI research and clinical practice. The QoL Basic Data Set might also be useful as a screening measure to identify individuals with SCI with possible adjustment problems, for whom targeted assessments with well-validated measures are indicated, but this should be confirmed by a future study. Having a standard way to consistently assess QoL across different settings, cultures and environments will allow comparison of research results and clinical data worldwide. In the context of the continuing debate on the conceptualization and measurement of QoL, the QoL Basic Data Set is a significant step toward unifying our ability to record and report this important information.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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