# **User Guide**



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**How to obtain EQ-5D-5L:** To register your interest in using EQ-5D-5L, please complete the registration form on the **EuroQol website**. No license fee will be charged for non-commercial use of the instrument. For simple non-commercial studies, applicants are asked to agree to EuroQol's Terms of Use. For all other applications, the EuroQol Office will contact you by e-mail and inform you about the terms and conditions that apply to your use of the EQ-5D-5L, including licensing fees (if applicable).

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# 1. Introduction

This guide provides users with basic information on how to use the EQ-5D-5L questionnaire. Topics include administering the instrument, deriving a value for EQ-5D-5L health states, value sets, setting up a database for data collected using EQ-5D-5L, presentation of results, modes of administration and translations. The guide should be used in conjunction with the EuroQol website, which contains regularly updated, detailed information about EQ-5D-5L. Where appropriate, weblinks to relevant resources on the EuroQol website are provided in this guide. For further information or assistance regarding use of EQ-5D-5L, you can also contact the **EuroQol office** directly.

### 1.1 EuroQol

EuroQol\* consists of a Research Foundation and a Group Association. The EuroQol Research Foundation is a not-for-profit organisation that develops, makes available and supports the use of instruments with the widest possible applicability for the measurement and valuation of health.

The EuroQol Research Foundation is responsible for the development of EQ-5D, a preference-based measure of health-related quality of life (HRQoL) that is widely used around the world in clinical trials, population studies and real-world clinical settings. EQ-5D is recommended by several health technology assessment bodies internationally as a key component in the economic evaluation of health-care technologies.<sup>1</sup>

The EuroQol Research Foundation is a registered not-for-profit organisation that invests all income into research, education and user support.

The EuroQol Research Foundation is the single organisation that manages the distribution and licensing of the EuroQol family of instruments worldwide. The EuroQol Group invests its income into research, education and user support.

The EuroQol Group Association consists of a large global network of experts, from a wide range of academic disciplines and countries, who are committed to ongoing research on the EuroQol family of instruments.

The scientific expertise behind EuroQol is the EuroQol Group Association, an international

<sup>\*</sup> The organisational structure is provided on the **EuroQol website**.

network of multidisciplinary researchers dedicated to the measurement of health status. When established in 1987, the EuroQol Group Association originally consisted of researchers from Europe. Today, it is a global network of more than 120 members from Africa, Asia, Europe, North America, Oceania and South America.

For more than 30 years EuroQol has funded or co-funded research and development into standardised non-disease-specific instruments to describe and value HRQoL. Research areas include: the investigation and application of different valuation methodologies to obtain health state values for use in cost-utility analysis, development of value sets for health states, EQ-5D use in clinical studies and in

population surveys, experimentation with the EQ-5D descriptive system, computerised applications, interpretation of EQ-5D responses, the role of EQ-5D in measuring social inequalities in self-reported health, and the measurement and valuation of HRQoL in younger populations. The EuroQol Group Association has been holding annual scientific meetings since its inception in 1987.

The **EuroQol website** provides detailed information and updates on the EuroQol family of instruments, guidance for users, a list of available language versions and value sets by country/region, key references, frequently asked questions, details on how to register to use our instruments, information about the EuroQol Group organisation, and contact details.

# 1.2 The EQ-5D® family of instruments

EQ-5D is a standardised instrument developed by the EuroQol Group to provide a simple, generic measure of HRQoL for clinical and economic appraisal.2

The EQ-5D<sup>®</sup> family of instruments has been developed to describe and value HRQoL across a wide range of disease areas, settings, and populations. They are also frequently used in research into health in the general population.

There are four versions of the instrument: two for use in adults (EQ-5D-3L, EQ-5D-5L) and two for use in children and adolescents (EQ-5D-Y-3L, EQ-5D-Y-5L)\*. For over 30 years, EQ-5D instruments have been widely used in clinical trials, population studies and in real-world clinical settings. Given their use worldwide, they have been translated into numerous languages following a rigorous translation process (see Section 8).

EQ-5D instruments are cognitively undemanding and take only a few minutes to complete. Designed for self-completion by respondents and available in both paper and digital versions, the EQ-5D is ideally suited for use in online or postal surveys, in clinics and in interviews (face-to-face or telephone). Proxy versions are also available for populations in which self-completion is not possible (see Section 7.2). Instructions to respondents are included in the questionnaire.

Each EQ-5D instrument consists of two parts, a short descriptive system questionnaire and a visual analogue scale (EQ VAS). These are explained for the EQ-5D-5L in more detail in Section 1.3 while methods for assigning EQ-5D values (utilities, preference weights) to EQ-5D-5L health states are described in **Section 4**.

Other instruments currently in development, with experimental status, include the EQ-TIPS (Toddler and Infant Populations), a new instrument to measure and value health in children aged 0-3 years, and the EQ-HWB (Health and Well-being instrument) which assesses a broader range of dimensions than standard EQ-5D instruments and is intended for use in evaluating interventions in healthcare, public health, and social care.

# 1.3 EQ-5D-5L

## **Development History**

In 2005, a research programme was implemented to investigate methods to further improve the sensitivity of the original EQ-5D instrument, the EQ-5D-3L.3 After much deliberation, it was decided that there should be no change in the number of dimensions of health measured by the new version of EQ-5D. However, previously published studies by EuroQol Group members showed that experimental versions of EQ-5D that increased the number of question response levels from three to five could significantly increase reliability and sensitivity (discriminatory power) while maintaining feasibility and potentially reducing ceiling effects.<sup>4-7</sup> The Group therefore decided that the new version of the EQ-5D should include five levels of severity in each of the existing five EQ-5D dimensions and that it would be called EQ-5D-5L (Figure 1). In addition, the most severe label for the mobility dimension was changed from 'I am confined to bed' to 'I am unable to walk about', enhancing its applicability and increasing the sensitivity of the mobility dimension. The EQ VAS layout and instructions were also simplified in EQ-5D-5L, compared to EQ-5D-3L, making it easier to complete and score.\*

To make clear the differences between the instruments, the original EQ-5D was renamed EQ-5D-3L. The research underpinning the development and early testing of the EQ-5D-5L is summarised on the **EuroQol website**.8 EQ-5D-5L has been found to exhibit excellent psychometric properties across a broad range of populations, conditions and settings.9

#### **Instrument Characteristics**

The EQ-5D-5L consists of two parts, a descriptive system and the EQ VAS.

The descriptive system measures five dimensions of health: MOBILITY, SELF-CARE, USUAL ACTIVITIES, PAIN / DISCOMFORT and ANXIETY / DEPRESSION. Each dimension has five response levels: no problems, slight problems, moderate problems, severe problems, unable to/extreme problems. The respondent is asked to indicate his/her health state by checking the box next to the most appropriate response level for them in each of the five dimensions. Responses are coded as single-digit numbers expressing the severity level selected in each dimension. For instance, 'slight problems' (e.g. 'I have slight problems in walking about') is always coded as '2'. The digits for the five dimensions can be combined in a 5-digit code that describes the respondent's health state profile; for instance, 21111 means slight problems in the mobility dimension and no problems in any of the other dimensions (see **Section 2** for further information on how to score the descriptive system).

The EQ VAS records the respondent's overall current health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The EQ VAS provides a quantitative measure of the patient's perception of their overall health.

A sample paper version of EQ-5D-5L is shown in **Figure 1** and a sample digital version is provided in **Section 11**, accompanied by guidelines on how to represent EQ-5D-5L digitally.

**Note:** The instrument names (e.g. EQ-5D-5L, EQ-5D-Y-3L) are not abbreviations and are the correct terms to use in print or verbally.

As of 2018, the EQ VAS in all versions of the EQ-5D-3L has been updated to match the EQ VAS format used in the EQ-5D-5L.

#### SEVERITY LEVELS

for dimensions in the descriptive system

The numbers representing the five severity levels of a dimension are simply labels used in the numerical description of a health state (see <u>Section 2.1</u>). They have no arithmetic properties. For instance, one cannot assume that a state 21111 is better than 13111 and the numbers should <u>not</u> be added to derive a summary score. Summary scores for EQ-5D-5L health states can be derived through application of an appropriate 'value set' (see <u>Section 4</u>).

# PUBLICATIONS COMPARING the EQ-5D-3L and EQ-5D-5L

Considerable evidence is available on the comparative psychometric performance of the EQ-5D-3L and EQ-5D-5L descriptive systems. A good starting point for an overview of the differences in measurement properties is:

- A systematic review of studies comparing the two instruments by **Buchholz** and colleagues (2018). <sup>10</sup> The review concluded by supporting the use of the EQ-5D-3L and EQ-5D-5L in a broad range of patients, populations and countries/regions, while noting that the EQ-5D-5L showed better or at least similar measurement properties to the EQ-5D-3L.
- A head-to-head comparison of descriptive systems and value sets across seven countries (Canada, China, England/UK, Japan, Netherlands, South Korea and Spain) by Janssen and colleagues (2018).<sup>11</sup> The study found that the EQ-5D-5L is superior to the EQ-5D-3L with respect to various measurement properties, enabling improvements in sensitivity and precision in health status measurement. It recommends the EQ-5D-5L for use across applications, including economic evaluation, clinical studies, quality of care and in public health studies.

Please note that comparative performance across patient groups is driven by differences in the descriptive systems and the associated value sets. Since countries use different value sets, the differences between EQ-5D-3L and EQ-5D-5L can be country/region-specific.

# USE OF ACRONYMS with EQ-5D-5L

Please note that when reporting results using EQ-5D-5L, or in other contexts, researchers and others might prefer to use acronyms instead of writing out dimension headers in full. In this situation, the acronyms used should be as follows:

Mobility: MOBSelf-care: SC

Usual activities: UAPain/discomfort: PDAnxiety/depression: AD

■ EQ visual analog scale: EQ VAS

Note, these acronyms will be identical for the EQ-5D-3L but will not be the same for the youth (EQ-5D-Y-3L and -5L) instruments.

# Figure 1 / UK (English) EQ-5D-5L Paper Self-Complete

# (sample version, v1.3)

Under each heading, please choose the ONE answer that best describes your health TODAY.

MOBILITY	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	
I have slight problems doing my usual activities	
I have moderate problems doing my usual activities	
I have severe problems doing my usual activities	
I am unable to do my usual activities	
PAIN / DISCOMFORT	
I have no pain or discomfort	
I have slight pain or discomfort	
I have moderate pain or discomfort	
I have severe pain or discomfort	
I have extreme pain or discomfort	
ANXIETY / DEPRESSION	
I am not anxious or depressed	
I am slightly anxious or depressed	
I am moderately anxious or depressed	
I am severely anxious or depressed	
I am extremely anxious or depressed	

- - 40
- <del>-</del> 30

The worst health you can imagine

- We would like to know how good or bad your health is TODAY.
- This line is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
   0 means the <u>worst</u> health you can imagine.
- Please mark an X on the line to show how your health is TODAY.
- Now, write the number you marked on the line in the box below.

YOUR HEALTH TODAY =

# 2. Scoring the EQ-5D-5L descriptive system

This example shows how a health state is described using the EQ-5D-5L descriptive system in the paper self-complete version:

Under each heading, please choose the ONE answer th describes your health TODAY.	at best	Levels of perceived problems are coded as follows:
MOBILITY I have no problems in walking about I have slight problems in walking about I have moderate problems in walking about I have severe problems in walking about I am unable to walk about		Level 1 is coded as a '1'
SELF-CARE I have no problems washing or dressing myself I have slight problems washing or dressing myself I have moderate problems washing or dressing myself I have severe problems washing or dressing myself I am unable to wash or dress myself		Level 2 is coded as a '2'
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)  I have no problems doing my usual activities I have slight problems doing my usual activities I have moderate problems doing my usual activities I have severe problems doing my usual activities I am unable to do my usual activities		Level 3 is coded as a '3'
PAIN/DISCOMFORT I have no pain or discomfort I have slight pain or discomfort I have moderate pain or discomfort I have severe pain or discomfort I have extreme pain or discomfort		Level 4 is coded as a '4'
ANXIETY / DEPRESSION I am not anxious or depressed I am slightly anxious or depressed I am moderately anxious or depressed I am severely anxious or depressed I am extremely anxious or depressed		Level 5 is coded as a '5'

This example identifies the health state '12345'.

#### Notes:

- There should be only ONE response for each dimension.
- Missing values are preferably coded as '9'.
- Ambiguous values (e.g. two boxes ticked for a single dimension) should be treated as missing values.
- This example is for the EQ-5D-5L Paper Self-Complete. Instructions for the interview and proxy versions are provided with those instruments.

# 2.1 What is a health state?

Each of the five dimensions comprising the EQ-5D-5L descriptive system is divided into five levels of perceived problems:

LEVEL 1: no problem
LEVEL 2: slight problems
LEVEL 3: moderate problems
LEVEL 4: severe problems

**LEVEL 5:** unable to/extreme problems

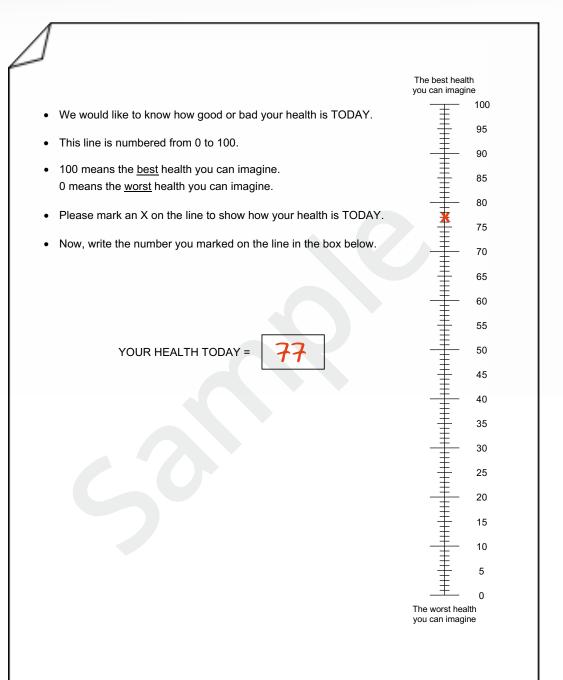
A unique health state is defined by combining one level from each of the five dimensions. A total of 3125 possible health states is defined in this way. Each state is referred to by a 5-digit code. For example, working clockwise from the top of the diagram, state 12345 indicates no problems with mobility, slight problems with washing or dressing, moderate problems with doing usual activities, severe pain or discomfort and extreme anxiety or depression, while state 11111 indicates no problems on any of the five dimensions.



# Guide ( BC-5D-51

# 3. Scoring the EQ VAS

This example from the EQ-5D-5L Paper Self-Complete version shows how the EQ VAS is scored.



## **Notes:**

Missing values should be coded as '999'.

# 4. Assigning EQ-5D values (utilities, preference weights) to EQ-5D-5L health states

# 4.1 Deriving EQ-5D values for EQ-5D-5L health states

EQ-5D-5L health states can be summarised using the 5-digit code (see Section 2.1) or represented by a single summary number (EQ-5D value)\*, which reflects how good or bad a health state is according to the preferences of the general population of a country/region. EQ-5D values are a major feature of the EQ-5D-5L instrument, facilitating the calculation of quality-adjusted life years (QALYs) that are used to inform economic evaluations of healthcare interventions. The preferences of the general population of a country/region for different health states represent the societal perspective which, in general, is considered the preferred perspective in health economic analysis.<sup>12-14</sup>

EQ-5D values for health states are derived by applying a formula that attaches values (weights) to each of the levels in each dimension. The EQ-5D value is calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111). The collection of EQ-5D values (weights) for all possible EQ-5D-5L health states is called a value set. Most EQ-5D-5L value sets have been obtained from a standardised valuation exercise, in which a representative sample of the general population in a country/ region is asked to place a value on EQ-5D-5L health states. The standardised valuation study protocol, **EQ-VT**, was developed by the EuroQol Group to create standard value sets for the EQ-5D-5L.\*\* This protocol is based on the use of the composite time trade-off (cTTO) valuation technique, supplemented by a discrete-choice experiment (DCE). Using value sets produced with the EuroQol Group's standardised valuation technology, EQ-VT ensures that results are derived using the most state-of-the-art valuation techniques while also facilitating international comparability.

**Note:** It is advisable to contact the appropriate local, regional, or national authorities about current value set requirements.

<sup>\*</sup> An EQ-5D value is also sometimes referred to as an index, score, utility, preference weight, preference-based value, or QALY weight.

<sup>\*\*</sup> Further information about the EQ-VT protocol is provided in Chapter 2 of the book, *Value Sets for EQ-5D-5L* (Springer, 2022).<sup>16</sup>

# Jser Guide 今 EQ-5D-5L

# 4.2 Standard EQ-5D-5L value sets

At the time of publication, EQ-5D-5L valuation research using EQ-VT has been undertaken in more than 35 countries around the world. An updated list of available value sets, including publication references and links to value set STATA files (for some countries), can be found on the **EuroQol website**. Note, to obtain a value set, if not available via our website, please contact the valuation study authors.

If a standard EQ-5D-5L value set is not available for your country, an option may be to select an EQ-5D-5L value set for a country/region that most closely approximates yours. Alternatively, if an EQ-5D-3L value set is available, you can choose to use a so-called 'crosswalk' value set — see section 4.3 below.

## 4.3 Crosswalk value sets

If an EQ-5D-5L value set is not available for your country/region of interest but a value set for an EQ-5D-3L version is available, then a "crosswalk" mapping function can be used to 'translate' responses on EQ-5D-5L to a value for a corresponding EQ-5D-3L health state. Lists of

available EQ-5D-3L value sets are provided on the **EuroQol website**. For further information about the mapping methodology behind the crosswalk, see the publication by Van Hout and colleagues (2012).<sup>15</sup>

#### **FURTHER INFORMATION ON VALUE SETS**

- An essential guide to standard value sets for EQ-5D-5L has been published in *Value Sets for EQ-5D-5L* (Springer, 2022).<sup>16</sup> This book provides a structured summary of each EQ-5D-5L value set, as well as a comparative review of their characteristics. The book also includes a user guide, providing clear guidance to researchers on how to choose a value set, and for what purpose. The book can be accessed via the EuroQol website.
- Documents containing the scoring algorithms, information on the valuation studies, tables of values for all 3125 health states and syntax files<sup>a</sup> may be requested from the EuroQol office.
- A syntax file is a computer program that can be run using statistical software to automatically calculate the values for the EQ-5D health states stored in a database.



Data collected using EQ-5D-5L can be entered in a database, as illustrated in the example below:

VARIABLE NAME	סו	SEX	AGE	EDU	COUNTRY	YEAR	MOBILITY
Variable description	Patient ID number	1 = Male 2 = Female 9 = Missing value	999 = Missing value	1 = Low 2 = Medium 3 = High 9 = Missing value	Country where data was collected	Year in which data was collected	1 = No problems 2 = Slight problems 3 = Moderate problems 4 = Severe problems 5 = Unable to 9 = Missing value
Data row 1	1001	1	43	1	UK	2011	4
Data row 2	1002	2	24	2	UK	2011	2

VARIABLE NAME	SELF-CARE	ACTIVITY	PAIN	ANXIETY	HEALTH STATE	EQ_VAS
Variable description	1 = No problems 2 = Slight     problems 3 = Moderate     problems 4 = Severe     problems 5 = Unable to 9 = Missing value	1 = No problems 2 = Slight problems 3 = Moderate problems 4 = Severe problems 5 = Unable to 9 = Missing value	1 = No PD 2 = Slight PD 3 = Moderate PD 4 = Severe PD 5 = Extreme PD 9 = Missing value	1 = Not anxious 2 = Slightly AD 3 = Moderately AD 4 = Severely AD 5 = Extremely AD 9 = Missing value	5-digit code for EQ-5D-5L	999 = Missing value
Data row 1	1	3	2	5	41325	63
Data row 2	1	1	1	1	21111	90

#### Notes:

- The variable names are just examples. However, the variables for the five dimensions of the EQ-5D descriptive system should be named 'mobility', 'self-care', 'activity', 'pain' and 'anxiety'.
- A respondent's rating on EQ VAS is to the nearest whole number.
- PD, pain or discomfort; AD, anxious or depressed.

# 6. Presenting EQ-5D-5L results

Data collected using EQ-5D-5L can be presented in various ways. A basic subdivision can be made according to the structure of the EQ-5D-5L:

- 1. Presenting results from the EQ-5D-5L descriptive system as a health profile
- 2. Presenting results of the EQ VAS as a measure of overall self-rated health status
- 3. Presenting results for EQ-5D-5L values.

The way results can be presented is determined both by the data and by what message you, as a researcher, wish to convey. The following subsection illustrates some of the basic ways of presenting EQ-5D-5L data. A comprehensive methodological guide to analysing and reporting EQ-5D data by Devlin and colleagues is also available.<sup>17</sup>

# 6.1 Health profiles

Reporting descriptive statistics on patient-reported outcomes (PRO) data can be very insightful. In patient samples, it can identify which dimensions of health are most affected by a given condition or treatment; in population health surveys, it can provide an overview of the frequency of problems across dimensions and, in repeated surveys, show their evolution over time.

When reporting data, it is important to begin by describing the number and percentage of patients reporting each level of problem on each dimension of the EQ-5D-5L. For example, Table 2 shows EQ-5D-5L data from a recent survey of 6800 individuals who were representative of the Lombardy (Italy) general adult population for

age, gender and geographic distribution.<sup>18</sup> The study authors also reported the proportion of patients with a full health state of 11111 (38.0%), as well as stratifying the results by age and gender (data not presented here). Tables can also be broken down for other relevant subgroups — for example, by treatment arm, age group or sex — and/or by study visit, e.g. before/after treatment.

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Table 2 / EQ-5D-5L frequencies and proportions reported by dimension and level<sup>18</sup>

	MOBILITY n (%)	SELF-CARE n (%)	USUAL ACTIVITIES n (%)	PAIN / DISCOMFORT n (%)	ANXIETY / DEPRESSION n (%)
Level 1 (No problems)	5727 (84.2)	6406 (94.2)	5770 (84.9)	3592 (52.8)	4196 (61.7)
Level 2 (Slight problems)	614 (9.0)	214 (3.1)	626 (9.2)	2046 (30.1)	1747 (25.7)
Level 3 (Moderate problems)	353 (5.2)	132 (1.9)	311 (4.6)	1018 (15.0)	757 (11.1)
Level 4 (Severe problems)	86 (1.3)	31 (0.5)	65 (1.0)	123 (1.8)	56 (0.8)
Level 5 (Extreme problems/ unable to do)	20 (0.3)	17 (0.3)	28 (0.4)	21 (0.3)	44 (0.6)
Total	6800 (100)	6800 (100)	6800 (100)	6800 (100)	6800 (100)

**Note:** Sometimes it is more convenient to dichotomise the EQ-5D levels into 'no problems' (level 1) and 'any problems' (levels 2, 3, 4 and 5), thereby changing the profile into frequencies of reported problems.

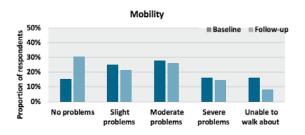
Data can also be presented to show changes in health over time. For example, in a single-centre observational longitudinal cohort study of patients (n=112) with stroke in Poland, the EQ-5D-5L was administered on two separate occasions.<sup>19</sup> The initial survey took place during index hospitalisation, before discharge. The second survey was conducted after an initial post-stroke recovery phase about

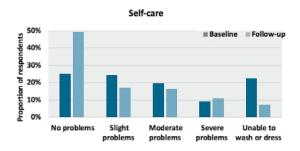
4 months later, in outpatient clinics, neurological rehabilitation departments or the patients' own homes. Table 3 shows significant differences in the distribution of responses to the self-care and usual activities dimensions of the EQ-5D-5L (p<0.001 and 0.001, respectively). It can also be helpful to report this information graphically (Figure 2).

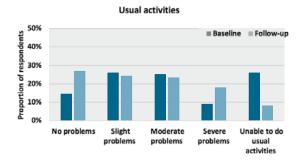
Table 3 / Distribution of EQ-5D-5L dimension responses at baseline and at follow-up  $^{19}$ 

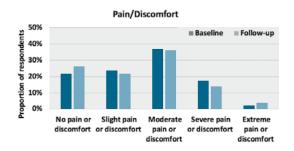
DIMENSION	BASELINE n (%)	FOLLOW-UP n (%)	P VALUE
MOBILITY			
No problems	17 (15.2)	34 (30.4)	0.057
Slight problems	28 (25.0)	24 (21.4)	
Moderate problems	31 (27.7)	29 (25.9)	
Severe problems	18 (16.1)	16 (14.3)	
Unable to walk about	18 (16.1)	9 (8.0)	
SELF-CARE			
No problems	28 (25.0)	55 (49.1)	< 0.001
Slight problems	27 (24.1)	19 (17.0)	
Moderate problems	22 (19.62)	18 (16.1)	
Severe problems	10 (8.9)	12 (10.7)	
Unable to wash or dress	25 (22.3)	8 (7.1)	
USUAL ACTIVITIES			
No problems	16 (14.3)	30 (26.8)	0.001
Slight problems	29 (25.9)	27 (24.1)	
Moderate problems	28 (25.0)	26 (23.2)	
Severe problems	10 (8.9)	20 (17.9)	
Unable to do usual activities	29 (25.9)	9 (8.0)	
PAIN/DISCOMFORT			
No pain/discomfort	24 (15.2)	29 (25.9)	NS
Slight pain/discomfort	26 (23.2)	24 (21.4)	
Moderate pain/discomfort	41 (36.6)	40 (35.7)	
Severe pain/discomfort	19 (17.0)	15 (13.4)	
Extreme pain/discomfort	2 (1.8)	4 (3.6)	
ANXIETY/DREPRESSION			
Not anxious/depressed	20 (17.9)	26 (23.2)	NS
Slightly anxious/depressed	36 (32.1)	44 (39.3)	
Moderately anxious/depressed	33 (29.5)	31 (27.7)	
Severely anxious/depressed	20 (17.9)	9 (8.0)	
Extremely anxious/depressed	3 (2.7)	2 (1.8)	

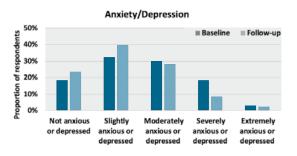
Figure 2 / Proportion of responses by level of severity for EQ-5D-5L dimensions at baseline and at follow-up<sup>19</sup>











Although very useful information is contained in tables like Table 3, they can be hard to read; an overall summary is sometimes helpful. One way of simplifying the information is based on the principles of a Pareto improvement in Welfare Economics — the Pareto Classification of Health Change.<sup>20</sup> With this approach, an EQ-5D-5L health state is deemed to be 'better' than another if it is better on at least one dimension and is no worse in any other dimension. An EQ-5D-5L health state is deemed to be 'worse' than another if it is worse in at least one dimension and is no better in

any other dimension. Using that principle to compare a patient's EQ-5D-5L health states between any two time periods, there are only four possibilities:

- Their health state is better
- Their heath state is worse
- Their health state is exactly the same
- The changes in health are 'mixed': better on one dimension, but worse on another.

### **6.2 EQ VAS**

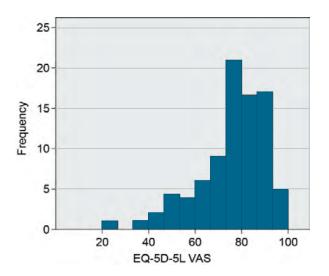
As described earlier, the EQ VAS is a 0-100 scale where respondents are asked to indicate their overall health on the day they complete the questionnaire. EQ VAS scores are conceptually different to EQ-5D-5L values, or Index scores, which are described in the next section. EQ VAS scores represent the individual respondent's perception of their current overall health, while EQ values represent the value (or utility) which a society attaches to a given EQ-5D-5L health state. Whether to use one or the other, or both, when presenting study results depends on the aim of the study. EQ VAS data may be more relevant in clinic settings, or population studies and surveys, when self-reported descriptive data are required, whereas EQ-5D-5L values may be more relevant in economic assessments of health care, when perceived benefits at a societal level are relevant.

EQ VAS data should be presented using a measure of central tendency and a measure of dispersion. This could be the mean value and the standard deviation (SD) or, if the data are skewed, the median values and the interquartile range (IQR). A couple of examples are provided here:

- In a large (n=1296) EQ-5D-5L valuation study in China, the mean (SD) EQ VAS was reported as 86.0 (11.4).<sup>21</sup>
- In an e-survey of patients (n=337) across 30 countries with tenosynovial giant cell tumour, it was reported that the median (IQR) EQ VAS was 75 (65–85) for localised and 75 (56.5-85) for diffuse type tumours.<sup>22</sup>

EQ VAS data can also be presented graphically, such as in frequency charts (Figure 3).

Figure 3 / EQ-5D-5L VAS frequency distribution (hypothetical data)



## 6.3 EQ-5D values

Information about EQ-5D values, derived using a value set, can be presented in much the same way as the EQ VAS data, i.e. using measures of central tendency and dispersion, such as mean values and the SD (or standard error). If the data are skewed, the median values and the 25th and 75th percentiles could be presented. Note, when reporting EQ-5D values, a maximum of three decimal places is usually sufficient.

Table 4 provides an example where EQ-5D-5L values are reported for a representative sample of the Spanish general population (n=21,007) using data from the Spanish National Health Survey 2011–2012.<sup>23</sup> The EQ-5D-5L values are reported by various sociodemographic factors and clinical characteristics in the paper.

Table 4 / Selected study sample characteristics, EQ-5D-5L male and female population norms<sup>23</sup>

	EQ-5D-5	EQ-5D-5L VALUES					
	MEAN	SD					
Overall	0.897	0.212					
GENDER							
Female	0.867	0.238					
Male	0.931	0.171					
AGE GROUP							
15-17	0.983	0.115					
18-29	0.978	0.101					
30-39	0.971	0.110					
40-49	0.959	0.111					
50-59	0.930	0.166					
60-69	0.922	0.172					
70-79	0.871	0.214					
80-89	0.744	0.315					
≥90	0.645	0.304					
MARIT	AL STATUS						
Single	0.952	0.150					
Married	0.928	0.174					
Divorced/separated	0.930	0.165					
Widowed	0.836	0.239					
SMOKI	NG STATUS						
Yes	0.903	0.199					
No	0.991	0.050					
NET MONTHLY INC	OME OF HOUSE	HOLD (€)					
<550	0.897	0.209					
551-1300	0.903	0.195					
1301–2250	0.947	0.151					
2251-3450	0.961	0.146					
≥3451	0.972	0.093					

Table 5 gives a hypothetical example of how to present results for EQ-5D values for an intervention study. The improvement in health state utility associated with treatment with Drug A versus Drug B was 0.08 (p<0.05) at Week 12.

Data can also be presented graphically; a hypothetical example is presented in Figure 4 where the group highest mean health status, using EQ-5D-5L values, is subgroup 3. Subgroup 1 reported the worst health.

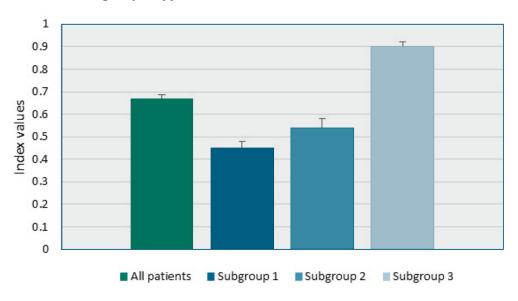
The differences between all subgroups were statistically significant (p<0.05).

Table 5 / Impact of treatment on EQ-5D-5L values (hypothetical data)

\!! **	DRL	JG A	DRI	JG B	P-VALUE <sup>a</sup>			
VISIT	N	Mean (SD)	N	Mean (SD)				
Baseline	229	0.59 (0.30)	227	0.60 (0.28)	0.6345			
Week 12	194	0.57 (0.32)	186	0.65 (0.29)	0.0149			

<sup>&</sup>lt;sup>a</sup> Using *t*-test.

Figure 4 / Mean EQ-5D-5L values and 95% confidence intervals for the total patient population and three subgroups (hypothetical data)



#### **ANALYSIS OF UTILITY DATA FOR ECONOMIC EVALUATION**

When analysing data to inform an economic evaluation, the approach will generally need to be different from an analysis that has been undertaken for regulatory purposes – i.e. which reports a comparison between treatment arms. Typically, EQ-5D-5L data will be analysed to estimate the difference between health states (defined in an economic model) or the effect of specific events (e.g. a stroke, exacerbation or relapse). Such an analysis should also control for the effect of treatment arm, but the treatment arm may not be the primary focus of the analysis. For further insight on this topic, please refer to the ISPOR Good Research Practices Task Force report on 'Estimating Health-State Utility for Economic Models in Clinical Studies' by Wolowacz et al, 2016.<sup>24</sup>

# EXAMPLE TEXT FOR DESCRIBING EQ-5D-5L AND REPORTING AND ANALYSING EQ-5D-5L DATA FOR STUDY PROTOCOLS / PROPOSALS

Study protocols and project proposals often require information to be included describing the EQ-5D-5L instrument and how the results will be reported and analysed. Below is an example of the kind of information that could be provided on EQ-5D-5L for an intervention study.

#### About the EQ-5D-5L

• The EQ-5D-5L<sup>1</sup> is a widely used generic measure of health status consisting of two parts. The first part (the descriptive system) assesses health in five dimensions (MOBILITY, SELF-CARE, USUAL ACTIVITIES, PAIN/DISCOMFORT, ANXIETY/DEPRESSION), each of which has five levels of response (no problems, slight problems, moderate problems, severe problems, extreme problems/unable to). This part of the EQ-5D-5L questionnaire provides a descriptive profile that can be used to generate a health state profile. For example, a patient in health state 12345 would have no problems with mobility, slight problems with self-care (washing or dressing), moderate problems with doing usual activities, severe pain or discomfort and extreme anxiety or depression. Each health state can potentially be assigned a summary EQ-5D-5L value based on societal preference weights for the health state. These weights, sometimes referred to as 'utilities', are often used to compute QALYs for use in health economic analyses. Health state EQ-5D values generally range from less than 0 (where 0 is the value of a health state equivalent to dead; negative values representing values as worse than dead) to 1 (the value of full health), with higher scores indicating higher health utility. The health state preferences often represent national or regional values and can therefore differ between countries/regions. The second part of the questionnaire consists of a visual analogue scale (VAS) on which the patient rates his/her perceived health from 0 (the worst imaginable health) to 100 (the best imaginable health). The EQ-5D-5L questionnaire is cognitively undemanding, taking only a few minutes to complete. Instructions to patients are included in the questionnaire.

#### Reporting and analysis of results

- A health profile will be generated by visit and by treatment. Summary statistics will be derived, including numbers of patients and proportions of categorical responses for the five EQ-5D-5L dimensions.
- If relevant (i.e. if results are to be used in an economic evaluation of the intevention[s] under investigation), a health state EQ-5D value will be calculated from individual health profiles using [insert country/region specific value set and reference here where a value set is not available for your country/region, it may be possible to use a value set for a country/region that most closely approximates yours or use a crosswalk value set<sup>a</sup>]. Mean, standard deviation (SD), minimum, median, and maximum scores will be provided for the study population by visit and by treatment.
- The EQ VAS score (between 0 and 100) will be summarised using mean, SD, minimum, median and maximum scores by visit and by treatment.
- For the health state EQ-5D value and EQ VAS scores, mean, SD, minimum, median and maximum will be provided for change from baseline to [enter questionnaire assessment time points here, e.g. Week 12, Week 24] and [final study assessment, e.g. Week 52].
- The type of model used and the covariates and fixed effects will be study-dependent. As an example, an ANCOVA model could be conducted for the changes from baseline to [assessment time points], with country and treatment as fixed effects and baseline as a covariate. In this example, significance of change within each treatment group and significance of the difference between the treatment groups would be reported.

# User Guide 🗬 EQ-5D-5L

# 7. EQ-5D-5L translations and modes of administration

# 7.1 EQ-5D-5L translations

The EQ-5D-5L (Paper Self-Complete version) is available in more than 150 languages. Please check the **EuroQol website** for the latest list of available language versions. All translations / adaptations of EQ-5D-5L are produced using a standardised translation protocol that conforms to internationally recognised guidelines. The translation process itself is based on forward and back translation, and in-depth cognitive debriefing.<sup>25</sup> New translations can be produced on request by submitting a new registration on the **EuroQol website**.

The EuroQol office manages the production of new translations and in general, translation costs are covered by the client requesting a translation.

For more information on the EQ-5D-5L translation process, consult the **EuroQol** website or contact the **EuroQol** office.

# 7.2 Modes of administration

The EQ-5D-5L is available in several modes of administration including:

- Self-complete versions (paper, digital and digital survey platforms)
- Proxy versions (paper, digital and digital survey platforms)
- Interviewer-administered versions (paper, digital, proxy, and digital survey platform versions)

Please see Table 6 in the section below for a summary of the different modes of administration and check the **EuroQol website** for a list of all currently available versions.

**Note:** You can also check whether the language version you need is available by completing the EQ-5D registration form on the EuroQol website. If it is not available, please select the unavailable language versions you would like to receive in the availability matrix. You will be provided with a quote and timelines for producing the translations.

# 8. Other EQ-5D products

## 8.1 EQ-5D-3L

The EQ-5D-3L has a descriptive system that comprises the same five health dimensions as in the EQ-5D-5L, but each dimension has three levels: no problems, some problems, extreme problems. The EQ-5D-3L preceded the 5L version of the EQ-5D and was introduced in 1990. The EQ-5D-3L has been proven to be valid, reliable and responsive in numerous conditions and populations.<sup>26</sup>

The EQ-5D-3L is still one of the most widely used instruments for measuring health status; it is currently available in more than 180 different language versions (for the self-complete versions), across several modes of administration (Table 6). Please check the EuroQol website for the latest list of available language versions and modes of administration.

# 8.2 EQ-5D-Y-3L (formerly EQ-5D-Y)

The EQ-5D-Y-3L was the first child-friendly version of the EQ-5D-3L questionnaire that was developed specifically for children and adolescents (Table 7). The EQ-5D-Y-3L (Paper Self-Complete version) is available in more than 100 language versions for use in over 60 countries. EQ-5D-Y-3L is available in several modes of administration (Table 6). Please check the EuroQol website for the latest list

of available language versions and modes of administration. A valuation protocol is now available for the EQ-5D-Y-3L for use by research teams to generate value sets. A number of EQ-5D-Y-3L value sets have already been published, with more in development around the world. For a list of available EQ-5D-Y-3L value sets, please see the **EuroQol website**.

# 8.3 EQ-5D-Y-5L

The EQ-5D-Y-5L has been developed to provide child and adolescent respondents with a wider range of options to describe their health. (<u>Table 7</u>) This newer youth version of EQ-5D includes five response levels in each of the five EQ-5D-Y

dimensions of the descriptive system. A number of EQ-5D-Y-5L language versions are available in several modes of administration (Table 6), with more in development. Please check the EuroQol website for the latest list of available versions.

At present, value sets for the EQ-5D-Y-5L are not available. The EuroQol Group is currently working on a protocol for the valuation of EQ-5D-Y-5L health states as well as a crosswalk function to link EQ-5D-Y-5L health states and existing EQ-5D-Y-3L value sets. Users are recommended

not to use adult EQ-5D-5L value sets to generate values for EQ-5D-Y-5L health states, as societal preferences for adult (5L) health states may differ considerably from societal preferences for child/adolescent (Y) health states.

Table 6 / Available EQ-5D modes of administration

		l l		l l
MODES OF ADMINISTRATION	EQ-5D-3L	EQ-5D-5L	EQ-5D-Y-3L	EQ-5D-Y-5L
SELF-COMPLETE VERSIONS				
Paper Self-Complete	<b>✓</b>	<b>~</b>	<b>~</b>	<b>~</b>
Digital Self-Complete	<b>V</b>	~	~	~
• Digital supported platforms <sup>a</sup>	V	<b>V</b>	~	
<ul> <li>British Sign Language version (for use in REDCap)</li> </ul>		~		
PROXY VERSIONS				
Paper Proxy 1	<b>~</b>	~	<b>~</b>	~
Digital Proxy 1	V	V	~	~
Digital supprted platforms <sup>a</sup> , Proxy 1		~	~	
INTERVIEWER-ADMINISTERED VERSIONS				
Paper Interviewer Administration	V	~	~	~
Digital Interviewer Administration	<b>V</b>	~	~	~
Paper Proxy 1 Interviewer Administration	V	~	~	~
Digital Proxy1 Interviewer Administration	V	V	~	~
<ul> <li>Digital supprted platforms<sup>a</sup>, Interviewer Administration &amp; Proxy Interviewer Administration</li> </ul>	V	<b>v</b>	V	

<sup>&</sup>lt;sup>a</sup> Digital supported platforms include REDCap, Qualtrics and LimeSurvey. More information is available on the **EuroQol website**.

## **Note: Digital Supported Platforms**

The ready-to-use modules for the digital supported platforms are for non-commercial use only. If a commercial user would like to use one of these platforms, they will receive the regular Digital version and should arrange their own permissions to use the platform and create their own reproduction on the platform.

Information about available versions of these digital supported platforms can be found on the **EuroQol website**.

Table 7 / Broad guidance on use of EQ-5D versions by age range<sup>a</sup>

AGE RANGE	RECOMMENDATION
0-3 years	■ There are no versions of EQ-5D currently available for this age range. <sup>b</sup>
4-7 years	• For children aged 4-7, researchers should consider using an <i>interviewer-administered</i> or <i>proxy</i> version of the EQ-5D-Y-3L or EQ-5D-Y-5L.
8-11 years	Use EQ-5D-Y-3L or EQ-5D-Y-5L The self-complete version is recommended in this age group. If a child or children in a study are expected to have difficulty responding to the self-complete version, researchers should consider using an interviewer-administered or proxy version.
12-15 years	Both the youth (EQ-5D-Y-3L or EQ-5D-Y-5L) and adult EQ-5D versions can be used An overlapping area. Generally, EQ-5D youth versions are recommended in this age group. However, depending on study design, it might be preferable to use one of the EQ-5D adult versions. For example, if a study includes a mix of adult respondents and respondents between the ages of 12 and 15 it may be preferable to use an adult version of EQ-5D (EQ-5D-3L or EQ-5D-5L) for all respondents, for the sake of consistency, ease of adminstration and analysis.
16 years and older	• Adult version (EQ-5D-3L or EQ-5D-5L) may be preferred Although it is generally recommended to use an adult version of EQ-5D in respondents aged 16 and over, in studies where all respondents are 18 or under it may be preferable to only use a youth EQ-5D version for the sake of consistency and ease of administration and analysis.

- a It is important to note that this table only provides general recommendations and that various factors need to be taken into account when deciding which version (self-complete, interviewer-administered, proxy) of the youth or adult EQ-5D to use, including children's literacy level, age range for inclusion, disease characteristics, etc.
- b A new instrument, **EQ-TIPS**, is in development to measure and value health in children aged 0-3 years.

- The EuroQol Research Foundation is a registered charity in the Netherlands and serves as the single point of distribution for the EuroQol family of instruments.
- If you would like to use EQ-5D-5L in your study/trial/project, you must first complete the
  registration form on the <u>EuroQol website</u>. Registering does not commit you to purchasing
  a license.
- After your registration to use EQ-5D-5L has been approved, it can be used free of charge for academic, educational, public health, and other non-commercial purposes.
- Commercial users are charged a license fee, which is calculated by the EuroQol office based on the user information provided in the registration form. Fees charged are used to fund the activities of the EuroQol Research Foundation in line with its vision and mission.
- The <u>EQ-5D licensing policy</u> and standard timelines for licensing and receiving the instrument are available on the <u>EuroQol website</u>.
- Additional information on how to obtain EQ-5D-5L is available on the **EuroQol website**.

# 10. Additional resources on the EuroQol website

Throughout this User Guide, weblinks to relevant resources on the EuroQol website have been provided. Here is a selection of additional web resources that the reader may find useful:

- Answers to frequently asked questions
- EQ-5D terms explained
- Key EQ-5D-5L references
- EQ-5D books
- EQ-5D working papers
- Explanation of EQ-5D version numbering and quality control
- Educational material (animations, presentations and infographics)
- Further information and support

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# 11. Digital versions of EQ-5D-5L

#### Digital representation guidelines 11.1

The digital format of EQ-5D-5L can be used on any digital device. A library of EQ-5D-5L Representations is available from the customer portal, consisting of example approved screenshots of digital EQ-5D-5L versions for every requested language. These enable customers and vendors to check that their digital implementation of EQ-5D-5L conforms to EuroQol's Digital Representation Design Guidelines. In summary, the Design Guidelines require that:

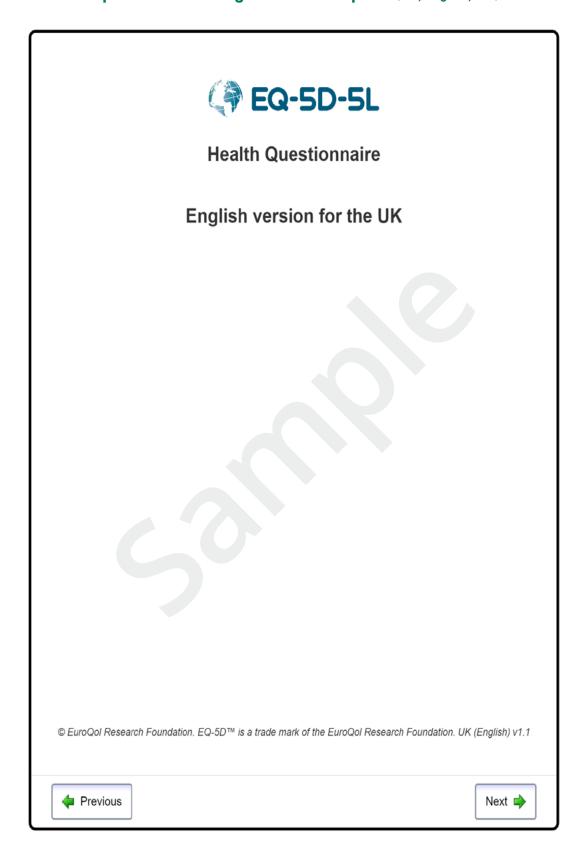
- The digital reproduction of EQ-5D-5L digital format should be responsive and should not require scrolling at any point during the completion of the EQ-5D-5L.
- Every dimension of the EQ-5D-5L should be displayed on a separate screen with the instruction above the dimension and the levels listed below each other.
- The copyright line should be displayed on every screen.
- The VAS should be vertical with the VAS instructions next to the scale.

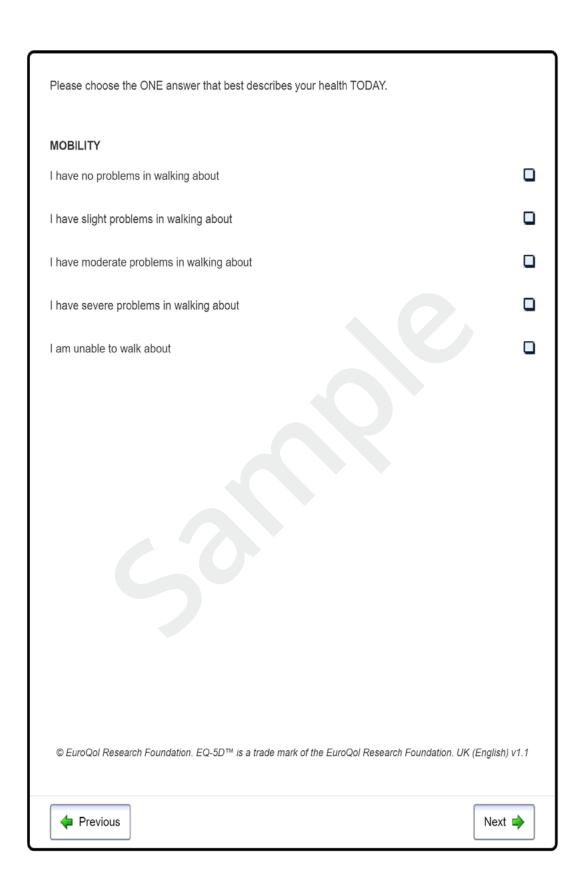
Please note, the user is responsible for implementing the EQ-5D-5L digital format on the platform of choice based on the Digital Representation Design Guidelines and the EuroQol Office Representations. Any deviation from these Design Guidelines and the Representations is at user's own risk.

Additional resources are available on the EuroQol website:

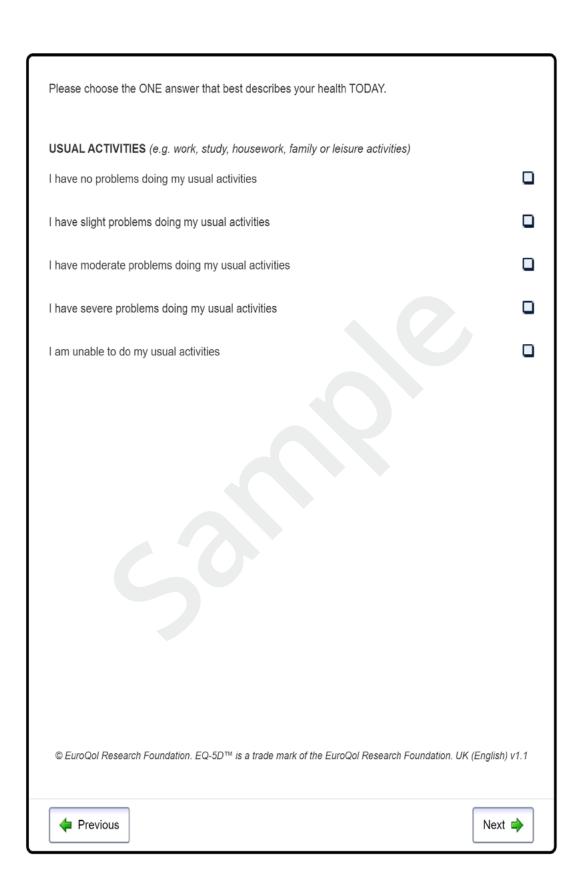
- **Digital data collection requirements**
- **Digital Representation Design Guidelines**
- **EQ-5D sample demos**

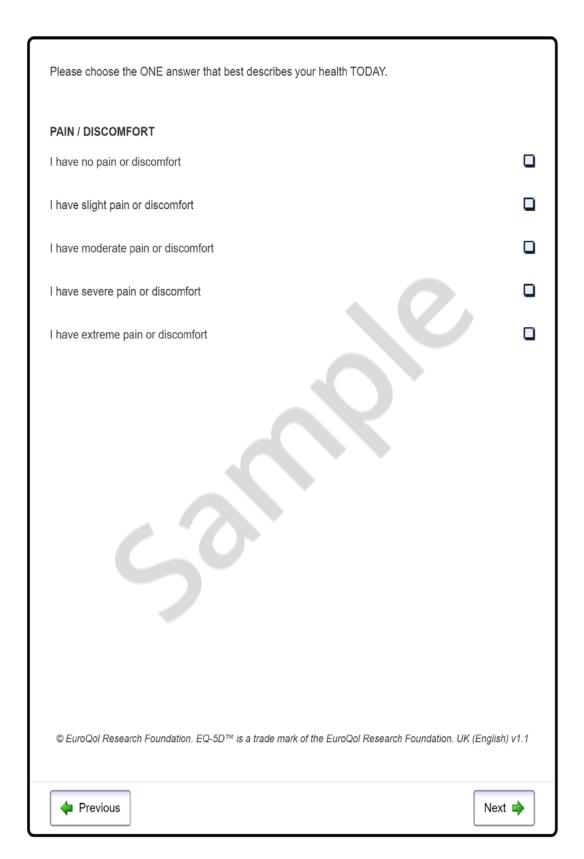
# 11.2 Sample EQ-5D-5L digital self-complete (UK, English, v1.1)

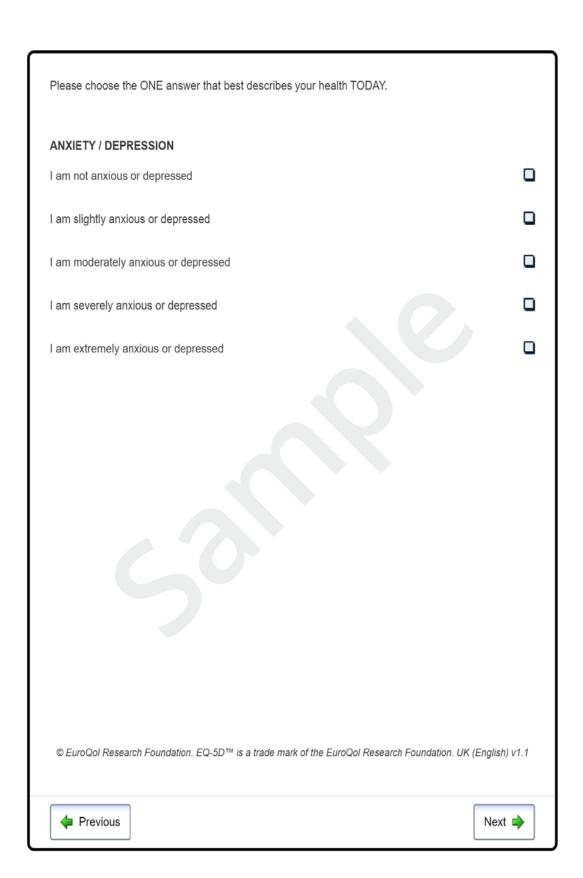


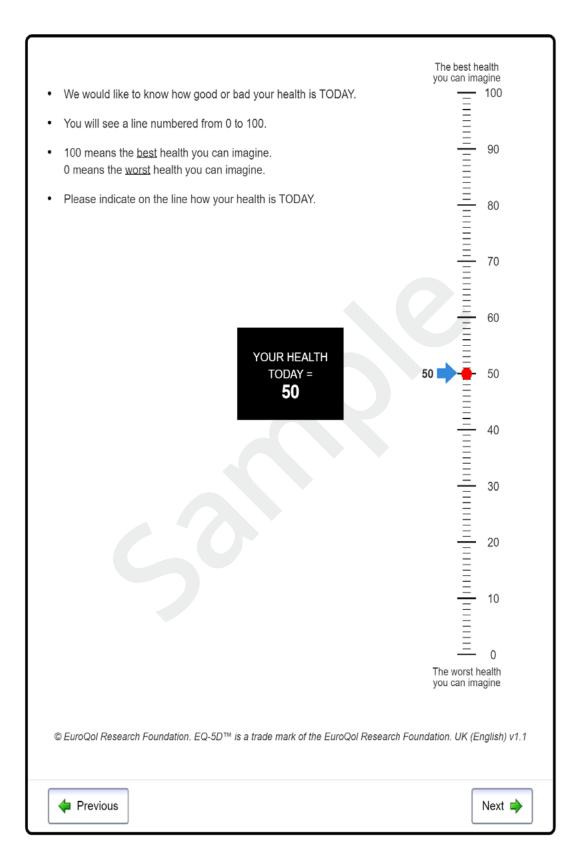


Please choose the ONE answer that best describes your health TODAY.	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	0
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
© EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation. UK (Eng	
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# User Guide 今 EQ-5D-5L

# 12. References

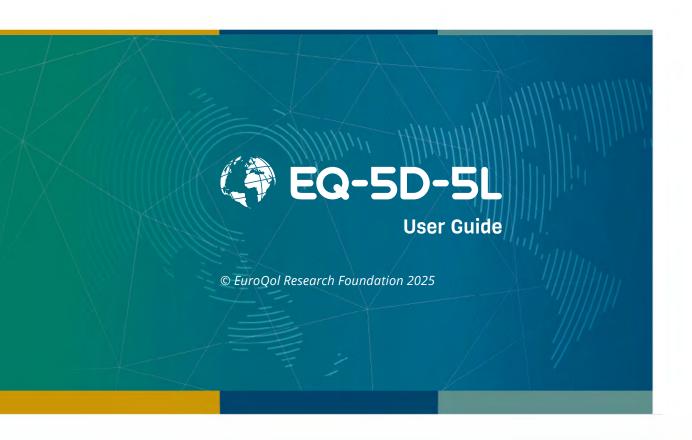
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