
Patient Reported Outcome Measures (PROMs)

Standards

K “Complete” PROMs questionnaires

- (a) Both the Q1 and Q2 PROMs questionnaires could comprise multiple health status measures (PROMs), including:
 - (i) A generic instrument (PROM) comprised of a set of 5 questions (the EQ-5D measure);
 - (ii) A generic Visual Analogue Scale (VAS);
 - (iii) A condition-specific instrument (PROM);
- (b) It is inevitable that some Patients will miss out or fail to respond to questions when completing the Q1 and/or Q2 questionnaires. For all of the Q1 and Q2 questions a missing or ambiguous response must be treated as “missing” data and coded appropriately in the submission to the HSCIC Clearing House in accordance with the PROMs Data Interface Specification Standard.
- (c) Some degree of missing responses will be tolerated within the programme. A relatively small number of missing responses can be imputed using statistical methods. On the other hand, some missing responses will render the returned questionnaire invalid, as the data will not be useful for subsequent analyses. The HSCIC Clearing House will apply standard imputation rules as and where appropriate.
- (d) For the generic set of 5 questions element of the questionnaires (the EQ-5D), the responses will be considered to be “complete” provided no more than 20% of the questions (1 question) have missing responses on each questionnaire. Otherwise, the responses will be considered “incomplete”. Further detail on the treatment of missing responses is provided in the EQ-5D user guide, which can be downloaded from the EuroQol Group’s website (<http://www.euroqol.org/>).
- (e) For the generic VAS element of the questionnaires, the responses will be considered “complete”, provided the response is not missing, on each questionnaire. Otherwise, the responses will be considered “incomplete”. Further detail on the treatment of missing responses for the VAS is provided in the EQ-5D user guide, which can be downloaded from the EuroQol Group’s website (<http://www.euroqol.org/>).
- (f) For the condition-specific element of the questionnaires, the responses will be considered to be “complete” or otherwise based on bespoke rules for each condition-specific measure. For example, for the Oxford Hip and Knee scores which are included in the Hip and Knee questionnaires respectively, provided no more than 20% of the questions have missing responses on each questionnaire they will be considered to be “complete”. Otherwise, the responses will be considered to be “incomplete”. Further detail on the treatment of missing data from the Oxford scores is available from the University of Oxford website (see Guides to scoring,

http://phi.uhce.ox.ac.uk/ox_scores.php). Further details of the scoring system for the Aberdeen Varicose Vein Questionnaire (AVVQ) are available upon request to the Authority. Where the AVVQ asks Patients to draw in their varicose veins, no markings constitutes a missing response for the Q1 questionnaire only.

- (g) A Q1 or Q2 questionnaire, as a whole, will be considered to be incomplete for the purposes of the PROMs programme if:
- The Patient has withdrawn their consent to participate prior of submission of records to the Clearing House. Under these circumstances, as set out in the *Data Processing Standard*, the records should not be submitted to the HSCIC Clearing House. Where a patient has withdrawn their consent and the record is submitted to the Clearing House, the record in question will be rejected.
 - The responses to the generic set of five (5) questions, the VAS and the condition-specific instrument are all incomplete, where these have been included in the PROMs questionnaires.
 - The responses to the generic set of five (5) questions and the VAS are both incomplete, where there is no condition-specific instrument included in the questionnaire, and where these components have been included in the PROMs questionnaires.
- (h) Furthermore, Q2 questionnaires will be considered incomplete if the linked Q1 questionnaire was incomplete.
- (i) For the avoidance of doubt, a questionnaire will be considered complete if one of: (a) the generic set of five (5) questions, or (b) the VAS, or (c) the condition-specific instrument are complete. Provided the Patient has given their consent, and, for Q2s, that the Q1 questionnaire was also complete.
- (j) All questionnaires, where patient consent has not been withdrawn, should be submitted to the HSCIC Clearing House irrespective of whether the Supplier considers them to be incomplete.
- (k) Payment would be made on the basis of valid, complete records.

L. Electronic Representations Standard

Approvals

- (a) Electronic representations of the PROMs questionnaires are permitted provided that Supplier fully complies with this Electronic Representations Standard.
- (b) Unless agreed otherwise in writing, Supplier is explicitly not entitled to translate, modify, distribute, abridge, convert, alter, amend, or make available in whatever way the PROMs questionnairesIntellectual Property embodied in the PROMs questionnaires, including but not limited to any minor or significant change in wording or organization of the PROMs questionnairesIntellectual Property embodied in the PROMs questionnaires, without the prior written consent of the Authority.
- (c) Suppliers must be granted approval in writing by the Authority to use any electronic representations of the PROMs questionnaires in advance of their use within the PROMs Services. The Authority will determine if the representations are consistent with the Licences it holds for use of Intellectual Property embodied in the PROMs questionnaires. Suppliers will seek approval by submitting to the Authority a url (weblink) for the software used to field the proposed electronic representations to devices. The Supplier will also provide details of the intended device(s) upon which the electronic representations will be used.
- (d) For the avoidance of doubt, the Authority will be the final arbiter of whether or not the electronic representations are compliant with this Standard. In cases where there is some doubt over the compliance or otherwise of the electronic representations with the relevant Licences held by the Authority, the Authority will refer the electronic representations to the Licensors of the Intellectual Property comprised within the questionnaires. In these circumstances, the Licensors will be the final arbiters and the Authority and the Supplier will be bound by Licensor's decision.

Rendering

- (e) PROMs questionnaires may be rendered electronically by devices including tablet computers, other touchscreen devices or other computers, provided that the screen of the device is no less than 9.6" on the diagonal. For web representations it should not be possible to view and complete the electronic representation of the questionnaires on any web-enabled device with a screen size of less than 9.6" on the diagonal.
- (f) All devices used to administer PROMs questionnaires should display the questionnaire on a portrait display with the facility to switch the display to landscape disabled;

- (g) All PROMs questionnaires must be displayed using a contrast ratio of at least 7:1. This value is used to account for the loss in contrast that can result from low visual acuity, congenital or acquired colour deficiencies, or the loss of contrast sensitivity that typically accompanies aging.
- (h) All electronic representations of the PROMs questionnaires must retain the same **look and feel** as the paper and pen versions of the questionnaires. This means:
 - a. Unless otherwise specified in this Standard, the layout, format, font, font size, ordering, presentation of questionnaire items and response boxes should be equivalent to that of the paper and pen questionnaire format,
 - b. All branding, colour (including NHS pantones) and styles employed should be equivalent to those used on the paper and pen versions of the questionnaires,
 - c. All supplementary items included on the paper and pen questionnaires should be reflected in the electronic versions,
 - d. Electronic versions should replicate and include trademark and copyright statements in an equivalent format to that used for the paper and pen versions of the questionnaires,
- (i) Fonts used for displaying the PROMs questionnaires should be sans serif, and specifically use the NHS Frutiger font in line with NHS branding guidelines.

Navigation

- (j) The User (patient completing the PROMs questionnaire) is **not** required to complete each item of the PROMs questionnaires before being permitted to advance to a subsequent item or question. The User must be permitted to decline to complete any individual item,
- (k) The User must be permitted to revisit items and to change their responses. This should be possible during completion of the instrument and prior to the final confirmation step,
- (l) The User should not be required to make use of scrolling at any point during the completion of the PROMs questionnaire.
- (m) No default response should be selected for any item in the PROMs questionnaires.

Layout of the EQ-5D-3L

- (n) The EQ-5D-3L element of the PROMs questionnaires should be laid out on one page. For avoidance of doubt, this means that the five questions (dimensions) and for each, the three response categories should appear on one page,

- (o) The standard Tablet instruction text for the EQ-5D-3L should read: “Under each heading, please tap (tablet/touchscreen) /click (web) the ONE box that best describes your health TODAY”.
- (p) A guide for the layout of the EQ-5D-3L is provided as figure 1 below,

Layout of the EQ-VAS

- (q) The instructions for the VAS should read:

“We would like to know how good or bad your health is TODAY.
 This scale is numbered from 0 to 100.
 100 means the best health you can imagine.
 0 means the worst health you can imagine.
 Please tap (tablet/touchscreen) / click (web) on the scale to indicate how your health is TODAY.”
- (r) The VAS should be presented vertically in-line with all other recognised versions of the EQ-5D.
- (s) The VAS should include the anchors of ‘The best health you can imagine’ and ‘The worst health you can imagine’.
- (t) The VAS should be presented with the maximum length realistically possible whilst accommodating the other constraints (anchors, navigation icons etc).
- (u) The VAS should feature hash marks at each integer. Each decile should be numbered (0, 10, 20,..., 100).
- (v) The VAS should permit a user to select any value between 0 and 100, including these bounds.
- (w) The value box should appear to the left of the scale aligned so that its middle is approximately level with a value of 50 on the VAS.
- (x) The value box text reads: “YOUR HEALTH TODAY”. No default value for the VAS exercise should be displayed. Once the User has selected a value on the VAS this should remain displayed unless the User subsequently selects a different value at which point it should be updated.
- (y) A guide for the layout of the VAS is provided as figure 2, below.

Layout of the Aberdeen Varicose Vein Questionnaire

- (z) The Aberdeen Varicose Vein Questionnaire (AVVQ) contains an item which requires patients to draw their varicose veins onto a diagrammatic representation. This is

typically scored by overlaying a grid (figure 3, below) and counting the number of boxes selected. For electronic representations of Varicose Vein questionnaire, the grid should be overlaid over the diagram and the User should be invited to complete the diagram by selecting (web) or tapping (tablet/touchscreen) the boxes in which they have varicose veins.

- (aa) The AVVQ item should be shown as large as possible on screen.

Layout of other questionnaire items

- (bb) Other questionnaire items should be laid out in a manner consistent with the paper versions of the questionnaires and with the rest of this Standard wherever possible.

EQ-5D-3L Health Questionnaire

Under each heading, please tap the ONE box that best describes your health TODAY

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐

I have some 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 with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

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Figure 1: Layout of the EQ-5D-3L

EQ-5D-3L Health Questionnaire

- We would like to know how good or bad your health is TODAY
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Please tap on the scale to indicate how your health is TODAY.

YOUR HEALTH TODAY
61

The best health you can imagine
100
90
80
70
60
50
40
30
20
10
0
The worst health you can imagine

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Figure 2: Layout of the VAS

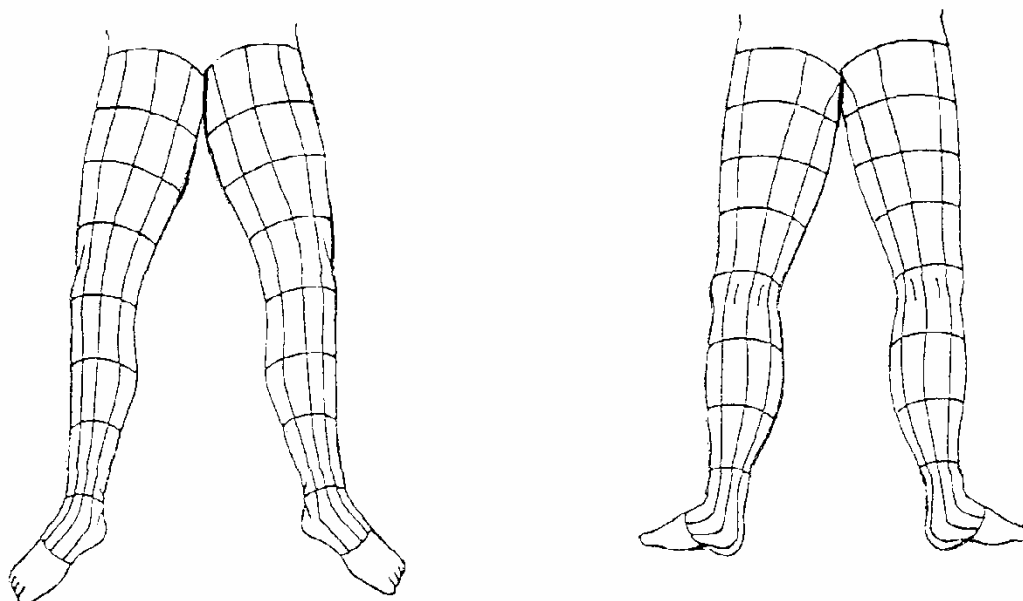


Figure 3: AVVQ scoring grid

M Scanning and scoring standard

- (a) The majority of fields on PROMs questionnaires should normally be completed either by the selection of pre-coded boxes (as indicated on the PROMs questionnaires) or by the direct entry of text or numbers into designated fields. These data items will either be captured directly (electronic data capture) or indirectly (scanned from paper).
- (b) A minority of fields on the PROMs questionnaires will be require alternative data entry, for example by drawing in or marking areas of the body affected by a condition or disease or by marking on visual scales a particular value.
- (c) For the EuroQol Visual Analogue Scale (EQ-VAS), instructions on how to score the scale are available at: <http://www.euroqol.org/eq-5d/what-is-eq-5d/how-to-use-eq-5d.html>
- (d) For the Aberdeen Varicose Vein Questionnaire (AVVQ), the vein diagram question is completed by overlaying a scoring grid (set out as figure 1, below) over the completed diagram (varicose veins marked on legs) and counting the number of squares covered by varicose veins.

Figure 1: AVVQ scoring grid.

