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# Cross-cultural development of the EORTC QLQ-SWB36: A stand-alone measure of spiritual wellbeing for palliative care patients with cancer

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**Bella Vivat** *School of Health Sciences and Social Care, Brunel University, UK*

**Teresa Young** *Mount Vernon Cancer Centre, Northwood, UK*

**Fabio Efficace** *Health Outcomes Research Unit, Italian Group for Adult Hematologic Diseases (GIMEMA), Italy*

**Valgerður Sigurðadóttir** *Palliative Care Unit, National University Hospital, Iceland*

**Juan Ignacio Arraras** *Oncology Departments, Hospital de Navarra, Spain*

**Guðlaug Helga Ásgeirsdóttir** *Palliative Care Unit, National University Hospital, Iceland*

**Anne Brédart** *Psycho-Oncology Unit, Institut Curie, France*

**Anna Costantini** *Psycho-Oncology Unit, Sant'Andrea Hospital, 2nd Faculty of Medicine, Sapienza University of Rome, Italy*

**Kunihiko Kobayashi** *Department of Respiratory Medicine, Saitama International Medical Centre, Japan*

**Susanne Singer** *Medical Psychology and Medical Sociology, University of Leipzig, Germany*

on behalf of the EORTC Quality of Life Group

## Abstract

**Background:** No existing stand-alone measures of spiritual wellbeing have been developed in cross-cultural and multiple linguistic contexts.

**Aim:** Cross-cultural development of a stand-alone European Organisation for Research and Treatment of Cancer (EORTC) measure of spiritual wellbeing for palliative care patients with cancer.

**Design:** Broadly following EORTC Quality of Life Group (QLG) guidelines for developing questionnaires, the study comprised three phases. Phase I identified relevant issues and obtained the views of palliative care patients and professionals about those issues. Phase II operationalised issues into items. Phase III pilot-tested those items with palliative care patients. Amendments to the guidelines included an intermediate Phase IIIa, and debriefing questions specific to the measure.

**Setting/participants:** Phase III pilot-testing recruited 113 people with incurable cancer from hospitals and hospices in six European countries and Japan.

**Results:** A provisional 36-item measure ready for Phase IV field-testing, the EORTC QLQ-SWB36, has been developed. Careful attention to translation and simultaneous development in multiple languages means items are acceptable and consistent between different countries and languages. Phase III data from 113 patients in seven countries show that the items are comprehensible across languages and cultures. Phase III patient participants in several countries used the measure as a starting point for discussing the issues it addresses.

**Conclusion:** The EORTC QLG's rigorous cross-cultural development process ensures that the EORTC QLQ-SWB36 identifies key issues for spiritual wellbeing in multiple cultural contexts, and that items are comprehensible and consistent across languages. Some cross-cultural differences were observed, but data were insufficient to enable generalisation. Phase IV field-testing will investigate these differences further.

## Keywords

Cancer, cross-cultural comparison, palliative care, quality of life, questionnaire, spirituality, spiritual wellbeing

## Corresponding author:

Bella Vivat, School of Health Sciences and Social Care, Brunel University, Uxbridge, Middlesex UB8 3PH, UK.  
Email: bella.vivat@brunel.ac.uk

## Introduction

Palliative care seeks to address patients' spiritual needs<sup>1,2</sup> and it is argued that spiritual concerns contribute to how people assess their quality of life.<sup>3-5</sup> Spiritual wellbeing (SWB) may alter towards the end of life<sup>6</sup> and identifying the spiritual concerns of people with advanced/incurable disease has been recognised as important for end-of-life care and supportive care.<sup>7</sup> Research increasingly focuses on spiritual care,<sup>8,9</sup> with some researchers stating that patients' spiritual needs should be assessed<sup>10</sup> or calling for validated measures to investigate the effects of spiritual care.<sup>11,12</sup> To date most research in this area has focused on people living with advanced cancer.<sup>6,13</sup> Their spiritual needs may differ from those of people with other life-limiting conditions, but little research has explored this. This study therefore focused specifically on cancer patients in order not to introduce any confounding factors.

Cross-cultural development of measures is essential if measures are to contain concepts suitable for the cultures where the measures will be used, because certain concepts and/or distinctions between concepts may exist in one language but not in others.<sup>9,14</sup> This is especially pertinent for measures relating to spiritual wellbeing, which may contain highly culturally specific concepts.<sup>9</sup> A number of SWB measures for cancer patients receiving palliative care have been developed, but no stand-alone functional measures of SWB for palliative cancer patients have been developed cross-culturally.<sup>9</sup> Most such measures have been developed in the US<sup>9,15</sup> and two of these cover all relevant issues. However, one is too lengthy to be suitable for a palliative care population, and both contain vague and/or inappropriate items.<sup>9</sup> Some existing measures have been validated in more than one cultural context,<sup>9,16</sup> but validating measures developed in mono-cultural contexts is not ideal for producing universally acceptable measures.<sup>14</sup>

The Quality of Life Group (QLG) of the European Organisation for Research and Treatment of Cancer (EORTC) constructs quality of life (QoL) questionnaires following a systematic cross-cultural approach.<sup>17,18</sup> Its modular system comprises a core questionnaire, the EORTC QLQ-C30, covering generic QoL issues for cancer patients,<sup>19</sup> plus additional questionnaires ('modules') for specific diseases, symptoms and/or treatment issues. The QLG supported the development of a measure of SWB for palliative cancer patients. This paper presents the development of this measure to a version suitable for international field-testing.

## Participants and methods

QLG guidelines for module development comprise four phases.<sup>17</sup> The first three phases of the study broadly followed these guidelines, although with some modifications

(Table 1), since the guidelines were developed for symptom-related modules, so were not always suitable for the SWB measure.

Eligible patients for the study were people with cancer receiving palliative care, defined as care/treatment with no curative intent. This broad definition was chosen to address cultural variations in interpreting 'palliative', to enable inclusion of patients who could not have been recruited if the definition had excluded all anti-cancer treatment. Patients were recruited from hospital and hospice inpatients and hospice day care units. Ethical approval was gained in each site (further details at end of paper) and informed consent obtained from all participants. Socio-demographic and clinical data were recorded.

From the outset it was recognised that measurement/assessment of SWB cannot be clearly separated from intervention because (as has also been argued in relation to QoL assessments<sup>20</sup>) raising issues related to SWB can be considered as initiating an intervention.<sup>4,9</sup> Particular ethical considerations therefore applied throughout measure development, and all collaborators identified an appropriate professional for further discussion with patients following interviews, if needed.

### Phase I: identifying relevant issues

**Literature review.** Phase I began with a literature review identifying relevant issues,<sup>9</sup> framed by a working definition of spirituality developed from key sources<sup>3,10,21-23</sup> and agreed amongst collaborators. A key decision made during this review was for the measure to be functional (exploring how respondents' beliefs function in their lives), rather than substantive (exploring the specific content of those beliefs),<sup>9,24</sup> so addressing spiritual wellbeing rather than spirituality. Three hypothesised dimensions for SWB were developed: personal relationships with self and others; existential issues; and religious/spiritual beliefs and practices.<sup>9</sup> Issues identified in the literature review were assigned to the appropriate dimension.

**Interviews.** Following EORTC QLG translation guidelines,<sup>25</sup> including two forward and back translations, collaborators translated issues from English into their own languages. Suitable patients and health/social care professionals were interviewed. Collaborators aimed to interview experienced palliative care professionals, including at least one religious professional in each country, and patients with a variety of religious beliefs, including none.

Interviewees' feedback was collected with a structured interview script, based on QLG guidelines,<sup>17</sup> but with some modifications (Table 1). A key modification concerned issue phrasing. Interviewees in QLG module development are usually asked whether particular issues arise for them,<sup>17</sup> for example, 'cough' for the lung cancer module.<sup>26</sup>

**Table 1.** EORTC Quality of Life Group module development process, aims and guidelines, and variations for this study.

	Aim	Guidelines	Variations for development of EORTC QLQ-SWB36 and rationale
<b>QLG module development process</b>	To develop modules that cover relevant areas of quality of life that are not (sufficiently) covered by the core questionnaire (EORTC QLQ-C30).	One week time frame for all items. Use with the EORTC QLQ-C30.	One week time frame inappropriate for some concepts, e.g. 'My beliefs have changed since I have felt less well'. The EORTC QLQ-SWB36 is being developed as a stand-alone measure because the issues covered are distinct from those in the EORTC QLQ-C30; in particular, are not symptom focused.
<b>Phase I: issue generation</b>	To compile an exhaustive list of relevant issues utilising existing measures, a literature review, and interviews with patients and health/social care professionals.	Establish relevance by direct questioning of patients/HCPs about their experience. Establish importance by asking patients and HCPs to choose a subset of 5–10 questions for inclusion.	As the issues did not relate to symptoms, participants were asked for their 'thoughts and/or feelings' in case they had not experienced the issue, e.g. 'thoughts and/or feelings about being lonely'. Participants were asked to indicate for each issue in the issues list whether they thought it should or should not be included in the final measure, and to identify a subset of the 25–30 issues they thought most important across all three dimensions, selecting a minimum of five from each dimension. Similarities between issues were explored and the preferred options of those issues thought similar were identified. During the study it was decided that 90 items were too many to pilot-test in Phase III and that some issues should therefore be deleted at the end of Phase I. At least one patient and one professional considered every issue important. An 'importance' score, combining responses concerning relevance and inclusion, was therefore derived to help identify issues for deletion. Separate scores were derived for patients and HCPs, and patient scores were prioritised.
<b>Phase II: operationalisation</b>	To operationalise issues into a set of items.	Items should fit the format of the EORTC QLQ-C30 response scale	Upon rephrasing, some issues generated poor questions, e.g. 'Do you live one day at a time?' A statement format was therefore chosen, with respondents identifying the relevance of each statement using the standard response scale for all the items, other than the last item, for which respondents rate their spiritual wellbeing on a seven-point scale.

(Continued)

Table 1. (Continued)

Aim	Guidelines	Delete item if any two of the criteria below apply	Include item if at least three of the criteria below apply	Variations for development of EORTC QLQ-SWB36 and rationale
<b>Phase III: pilot-testing</b> To test items for potential problems with phrasing/translation and sequencing.	Delete item if any two of the criteria below apply	Delete item if any two of the criteria below apply	Include item if at least three of the criteria below apply	Phase IIIa – pre-pilot-testing phase (unique to this study) Aims: 1. To further reduce the number of items for testing in Phase IIIb. 2. To justify deleting any item identified as a possible candidate for deletion.
To assess acceptability of items.	Mean Score	<1.5	≥1.5	Deletion criteria: 1. Items meeting any of the following criteria to be considered for deletion: • Mean score < 1.5 • Prevalence < 25% • Missing data > 25% • Correlation/s with similar item/s • Low importance score (taken from Phase I) • Potential problems with translation into common European languages
To check for additional items or redundant items.	Prevalence Range Importance (Phase I) Patient comments should be considered and can override other considerations.	<30% All responses in 1 category <33%	≥30% Responses in 2 or more categories ≥33%	2. Items which meet the deletion criteria to be retained if their Phase I importance scores are high, and/or if patient comments suggest they are valuable.
				Phase IIIb – broadly equivalent to usual Phase III
				Inclusion criteria: • Mean ≤ 1.5 • Range: ○ Less than 50% of responses in categories 1 or 4 AND ○ Responses in at least three categories for each country
				Deletion criteria • Data missing from at least 4 patients AND • Significant negative comments from patients AND • Item highly correlated (Rho > 0.75) with another, less problematic item or items.
				Patient comments and Phase I importance score to be taken into account for decisions regarding both inclusion and deletion of items.

HCP: health care professional.

Commonly experienced issues are operationalised into items. However, when developing issues pertinent to SWB, the concern is whether issues matter to respondents, which their personal experiences may not necessarily indicate. So the issue of 'loneliness' cannot be presented as: 'Have you felt lonely?' since a response of 'not at all' only means that the respondent has not experienced loneliness, not that they do not think it important. Issues were therefore presented as: 'having thoughts and/or feelings about feeling lonely'. This phraseology was also less abrupt for issues which were potentially sensitive.

Phase I interviewees assigned relevance to each issue and indicated whether they thought it should or should not be included. They chose 25–30 issues they thought most important, including at least five from each dimension. Interviewees also suggested any issues they felt were missing and should be added.

Another guideline modification was a question asking whether interviewees thought any issues were similar and, if so, which issue they preferred. This explored whether slight distinctions between issues (for example, the distinction in English between gaining comfort, strength or support from one's spiritual or religious beliefs) were meaningful to all respondents, and across all languages.<sup>14</sup>

### Phase II: operationalisation

QLG guidelines discourage early deletion of issues.<sup>17</sup> However, there were too many issues to test them all with patients who might be fatigued. Another modification was therefore defining complementary criteria for exclusion/inclusion: exclude those issues which no interviewee said should be included, and include those which no interviewee said should be excluded (Table 1).

Each issue was assigned an 'importance' score: 2 × number of interviewees selecting the issue for inclusion + number saying it was 'very relevant'. Discrepancies in patient/professional responses were evident, as is often noted in this area.<sup>6,27</sup> Separate scores were therefore derived and issues ranked according to patient scores, although responses from all interviewees were considered when making final decisions.

Once issues for inclusion were identified, the two principal investigators (PIs) independently operationalised them into items. The PIs compared their items, agreed provisional constructions and, following discussion with collaborators, final versions were agreed.

The QLG Module Development Committee and two external reviewers reviewed an internal report on Phases I and II. They recommended additional pre-pilot-testing to reduce the length of the measure further, considering that patients might still find it tiring.

### Phase III: testing the provisional measure

**Phase IIIa: pre-pilot-testing.** For the pre-pilot-testing, Italian and Icelandic collaborators translated provisional items. Icelandic, Italian and UK patients completed the measure, and those in Iceland and the UK completed a debriefing interview. Criteria for deletion were missing data and low prevalence (Table 1). Participants' comments and correlations with other items were examined for items identified for possible deletion. Collaborators in seven countries completed a translation questionnaire, and data from this were also considered.

All collaborators agreed a final, shorter measure. Following peer-review of the Phase IIIa report, the new measure was translated into all collaborators' languages through the EORTC Quality of Life Department and began Phase IIIb.

**Phase IIIb: pilot-testing.** Collaborators sought to recruit palliative cancer patients with a range of religions (including none) and socio-demographic characteristics, and where possible, from multiple ethnicities within countries. Participants completed the measure unaided and then participated in a debriefing interview. Specific questions were asked about items previously identified as possibly ambiguous. The time for completing the measure and whether participants needed any help completing it were recorded.

Most items had four response categories: 'not at all', 'a little', 'quite a bit', and 'very much'. The exceptions were two items concerning changes in beliefs and one item rating SWB (see notes to Table 2). Inclusion criteria related to mean scores and range of responses (table A). Items were considered for deletion if respondents had made negative comments and if response data were missing. Correlations between these items and all other items in the measure were investigated, and those which strongly correlated were considered for deletion. The PIs analysed the data; findings were circulated and discussed amongst the collaborators.

## Results

### Phase I: identifying relevant issues

**Literature review.** The focused literature review for September 1996–September 2001<sup>9</sup> identified 84 issues: 64 from existing measures and 20 from qualitative papers. Twenty-nine of these 84 issues were assigned to dimension P (personal relationships with self and others), 24 to dimension Q (existential) and 31 to dimension R (religious and/or spiritual beliefs and practices). A repeated literature review in 2007 identified no new issues,<sup>9</sup> nor did a specific examination of all published measures in 2010.

**Table 2.** Item numbers and phrasing in EORTC QLQ-SWB38 with amendments made for QLC-SWB36.

SWB38 item no.	QLQ-SWB38 item phrasing	Amendments for QLQ-SWB36
1	I have felt able to deal with problems	
2	I have felt at peace with myself	
3	I have felt able to forgive myself for things I have done	
4	I have felt troubled	
5	I have worried about the future of people who are important to me	
6	I have felt lonely	
7	I have felt able to share thoughts about life with people who are close to me	
8	I have felt loved by those who are important to me	
9	I have felt that I have someone to talk to about my feelings	
10	I have felt dependent on others	
11	I have felt able to trust others	
12	I have felt able to forgive others for things they have done	
13	I have felt that I am valued as a person	
14	I have been able to find things I enjoy doing	
15	I have wondered whether anything can be done for me	
16	I have felt that it is unfair that I am ill	
17	I have felt that my life is fulfilling	
18	I have felt that my life is worthwhile	
19	I have felt that my life is meaningful	DELETED
20	I have felt able to plan for the future	
21	I have had worries and/or concerns about the future	
22	I have had time for quietness, prayer or meditation	
23	I have felt that it is important that other people pray for me	
24	I believe in God or the gods or a supreme being or a higher power	COMBINED WITH ITEMS 27 + 29 & REPHRASED: '...God or someone or something greater than myself' NEW ITEM CONSTRUCTED: 'I have always believed in God or someone or something...'
25	I feel connected to a being greater than myself	REPHRASED: 'I feel connected to God or someone or something greater than myself'
26	I trust in God or the gods or a supreme being or a higher power	REPHRASED: 'I trust in God or someone or something greater than myself'
27	I have spiritual beliefs	REMOVED (COMBINED WITH 24)
28	In the last few weeks my spiritual beliefs have become...	COMBINED WITH 30 & REPHRASED: 'My beliefs have changed in the last few weeks' RELOCATED TO FOLLOW ITEM 24. NEW ITEM CONSTRUCTED: 'My beliefs have changed since I have felt less well'
29	I have religious beliefs	REMOVED (COMBINED WITH 24)
30	In the last few weeks my religious beliefs have become...	REMOVED (COMBINED WITH 28)
31	What I think is important about life has changed in the last few months	DELETED
32	My feelings about life have changed in the last few months	REPHRASED: 'My feelings about life have changed in the last few weeks' NEW ITEM CONSTRUCTED: 'My feelings about life have changed since I have felt less well'
33	I believe in life after death	
34	I feel that there is more to life than we can perceive directly	
35	I feel that I will live on through my words, deeds and/or influence on other people	
36	I live one day at a time	
37	I have spiritual wellbeing	
38	How would you rate your overall spiritual wellbeing?	

Notes: Items 1–37 had standard EORTC response categories Not at all (1), A little (2), Quite a bit (3), Very much (4), except for items 28 and 30, which had response categories Much weaker (1), Weaker (2), Stronger (3), Much stronger (4) OR Have not changed (0). Item 38 had a seven-point rating scale: Very poor (1) – Excellent (7) OR Don't know/Can't answer (0).

**Phase I interviews.** Twenty-two patients and 22 professionals in Austria, Belgium, Croatia, Iceland, Italy, the Netherlands and the UK were interviewed (clinical and socio-demographic details in Tables 3 and 4).

### Phase II: operationalisation

At least one patient and at least one professional selected each of the 84 issues for inclusion, so none met the exclusion criterion. The complementary inclusion criterion of not being identified for exclusion was met by 38 issues: 9/29 issues in dimension P, 13/24 issues in Q and 16/31 in R.

The majority of patient interviewees considered 55 of the 84 issues very relevant and wanted to include them, and few or no interviewees wanted to exclude these 55 issues. They were therefore retained. Thirteen issues had low patient 'importance' scores and were excluded. The remaining 16 issues were not initially clear candidates for inclusion or exclusion, but, following further analysis and discussion with collaborators, 10 were excluded and six retained.

Thus, 61 issues from the 84 in the issues list were operationalised into items, with one being operationalised into two items. Interviewees suggested six new issues, which were operationalised into seven new items. The provisional measure (EORTC QLQ-SWB69) therefore had 69 items (Figure 1).

### Phase III: testing the provisional measure

**Phase IIIa: pre-pilot-testing.** Seventeen patients in the UK, Iceland and Italy participated in pre-pilot-testing (clinical

and socio-demographic details in Table 3). Thirty-five of the 69 items were deleted on the basis of missing data, prevalence, correlations and participants' comments. Of the 34 retained items, one religious/spiritual item was divided to form two items. Three new items were added, including a global question rating overall SWB. The 69-item measure thus became a 38-item measure (Figure 2). The translation questionnaire was completed for French, German, Icelandic, Italian, Norwegian and Spanish, and two items consequently rephrased. Appropriate timeframes were assigned to items. The revised measure (EORTC QLQ-SWB38) then began Phase IIIb.

**Phase IIIb: pilot-testing.** The EORTC QLQ-SWB38 was pilot-tested with 113 patients from seven countries: France, Germany, Iceland, Italy, Japan, Spain and the UK (clinical and socio-demographic details in Table 3). Ethnic differences were predominantly between, rather than within, countries. Forty-five (40%) of respondents were male. Respondents' ages ranged from 32 to 88 years, median 67. Fifty-nine respondents (52%) were Christian, 22 (19%) stated that they had no religion and 17 (15%) that they were unsure. Religious data were missing from 11 respondents; the other four followed religions other than Christianity. Respondents had a variety of cancers, and prognoses ranged from less than one month to over 12 months. Most (34) (30%) participants' prognoses were 6–12 months.

Three participants (one German and two Japanese) needed help with understanding items and nine needed practical help. Forty-two participants (37%) expressed

**Table 3.** Sociodemographic and medical data of patient participants.

		Phase I N=22	Phase IIIa N=17	Phase IIIb N=113
Birth country	Austria	3	–	–
	Belgium	3	–	–
	Croatia	3	–	–
	Denmark	–	–	1 <sup>a</sup>
	France	–	–	11
	Germany	–	–	4
	Iceland	4	2	29
	Italy	3	5	21
	Japan	–	–	15
	Kenya	1 <sup>b</sup>	–	–
	Netherlands	3	–	–
	Spain	–	–	16
	UK	2	10	16 <sup>c</sup>
	Gender	Male	8	7
Female		14	10	68
Age	Mean	53	58	64
	Median	50	55	67

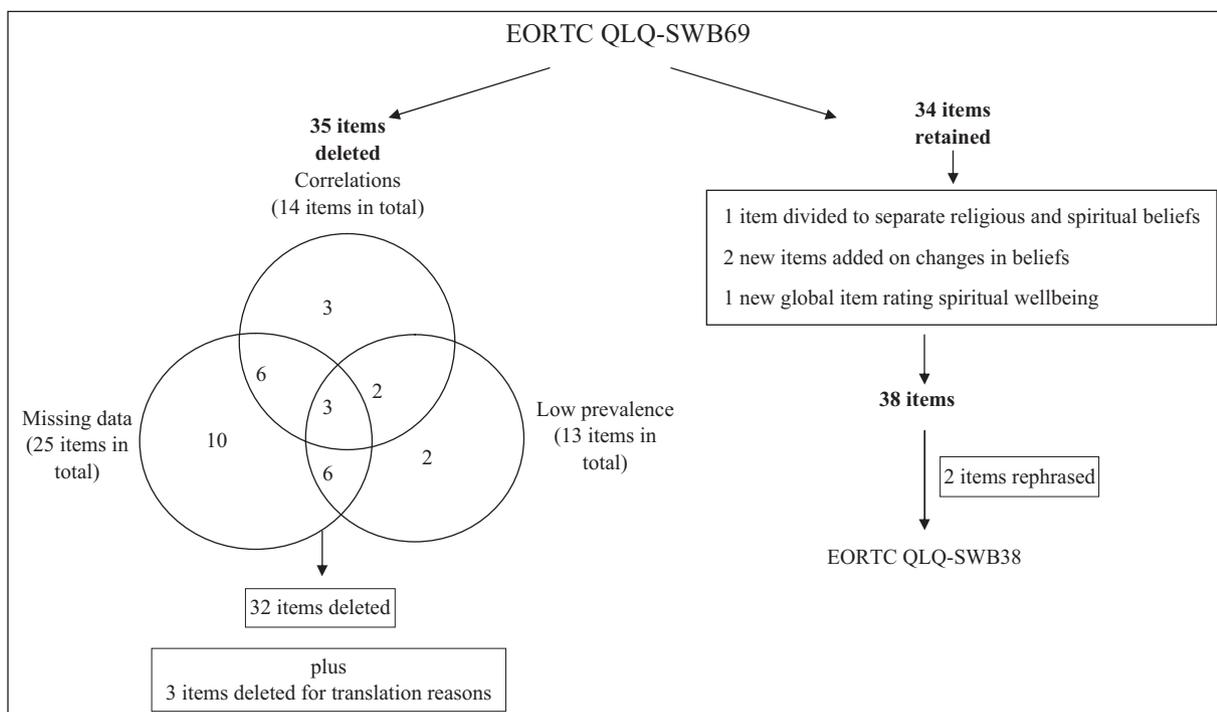
(Continued)

Table 3. (Continued)

		Phase I N=22	Phase IIIa N=17	Phase IIIb N=113
	Range	41–81	46–79	32–88
Religion	Catholic	5	5	16
	Lutheran	4	2	25
	Other Christian	8	6	18
	Buddhist	0	0	2
	Hindu	0	1	1
	Jewish	0	0	1
	None	5	2	22
	Unsure	0	1	17
	Missing	0	0	11
Education	Less than compulsory	0	0	17
	Compulsory	6	8	36
	Post comp. below university	10	3	38
	University	3	5	18
	Postgraduate	3	1	1
	Missing	0	0	3
Marital	Single	4	0	8
	Married/with partner	14	13	69
	Separated/divorced	2	0	12
	Widowed	2	4	24
	Missing	0	0	11
Tumour site	Breast	5	5	20
	Colorectal	6	1	13
	Gynaecological	4	0	6
	Lung	1	2	29
	Upper GI	1	1	9
	Urology	4	4	14
	Other	1	2	20
	Missing	0	2	2
Metastases	Yes	16	9	97
	No	1	5	10
	Missing	5	3	6
WHO status	0 Fully active	5	2	12
	1 Restricted	3	11	27
	2 Ambulatory	6	1	29
	3 Limited	7	1	33
	4 Disabled	1	1	8
	Missing	0	1	4
Prognosis	<1 month	0	0	3
	1–3 months	6	2	15
	3–6 months	6	5	23
	6–12 months	3	7	34
	12+ months	3	0	31
	Missing	4	3	7
Current treatment <sup>d</sup>	Yes	–	–	75
	No	–	–	33
	Missing	–	–	5

<sup>a</sup>Recruited in Iceland.<sup>b</sup>Ethnically Indian, born in Kenya, recruited in UK.<sup>c</sup>One patient ethnically Indian, born and recruited in UK.<sup>d</sup>Data not collected in Phase I or Phase IIIa.





**Figure 2.** Phase IIIa: development of EORTC QLQ-SWB38 from EORTC QLQ-SWB69.

appreciation of the opportunity to discuss their responses. This was particularly noted in France, Iceland, Spain and the UK.<sup>28</sup>

Ten items met both inclusion criteria in all countries and another 15 did so in every country except Germany (there were only four German participants, so their responses did not always cover all response categories). More than 50% of participants responded 'not at all' to an item concerning feeling lonely, or 'very much' to an item concerning feeling loved.

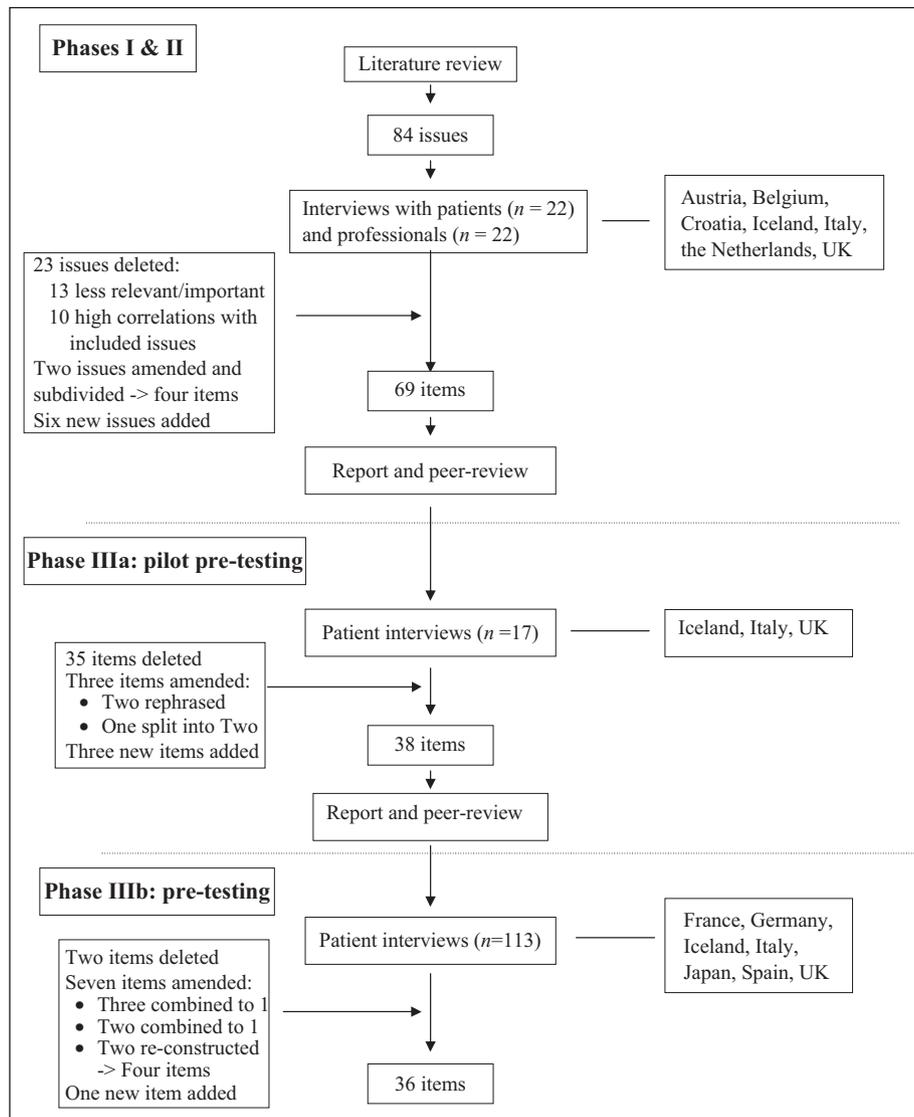
For the item concerning feeling loved, 87 participants (77%) responded 'very much'. Only one participant (in the UK) responded 'not at all' to this item and only three (one Japanese and two British) responded 'a little'. However, it was important that this particular item received any such responses at all, so it was retained for further exploration in field-testing. Similarly, although 64 of the 113 participants (57%) responded 'not at all' to the item concerning feeling lonely, and all 16 Spanish participants responded either 'not at all' or 'a little' to this item, eight participants (7%) (four Italian, two British, one German and one Icelandic) responded 'very much', with comments indicating that they found this issue very important. It was therefore also retained for further investigation.

Response ranges for some nationalities to two other items were noteworthy. All 15 Japanese participants responded either 'a little' or 'quite a bit' to an item concerning being at peace with oneself. All 16 Spanish participants

responded either 'quite a bit' or 'very much' to an item concerning life being fulfilling. On examination of responses to these items by other participants, they were also retained and identified for specific attention during field-testing.

The most marked difference between nationalities was in European and Japanese participants' responses to religious items. European participants' responses to these items spanned the range of categories, with no notable differences between nationalities. However, Japanese participants had some negative comments about these items, and all 15 Japanese participants responded either 'not at all' or 'a little' to items concerning God or a being greater than themselves. Four Japanese participants provided no response at all to two items concerning spiritual or religious beliefs, while the 11 Japanese participants who did respond to these two items all responded either 'not at all' or 'a little'. The religious items were adapted accordingly; some were rephrased, and five items were combined to form two items (Table 2, items 24–30).

Two other items were deleted owing to missing data, negative comments from participants and strong correlations with other items (Table 2, items 19 and 31). Two items were developed into two items each (Table 2, items 28 and 32) and one new item was added. Thus a 36-item measure, the EORTC QLQ-SWB36, was agreed for field-testing (see Table 2 for the changes made to the EORTC QLQ-SWB38 items). Figure 3 presents a summary of the whole of Phases I–III.



**Figure 3.** Overall summary of development of the EORTC QLQ-SWB36.

## Discussion

The EORTC QLQ-SWB36 has been developed on the basis of relevant literature, expert opinion and interviews with palliative cancer patients in 10 European countries and Japan. The rigorous development process ensures that the measure covers important issues and is manageable by palliative patients; that item wording is comprehensible; and that, owing to careful attention to translations and simultaneous development in multiple linguistic and cultural contexts, items are consistent across languages, and the measure acceptable in all countries which have participated in its development.

No published stand-alone functional measures of SWB for people receiving palliative care for cancer have been developed cross-culturally,<sup>9,13</sup> and validation studies have identified some cultural issues with existing measures.<sup>16</sup>

The current study is distinct in that the development of the measure has been from the outset in multiple cultural and linguistic contexts. Cross-cultural development helps ensure that items are appropriate in all participating cultures and contexts, and the pilot-testing of the EORTC QLQ-SWB36 has especially highlighted the importance of this for religious items. The measure needs to include concepts addressing religious issues, which are clearly important for the SWB of people with religious beliefs. However, most Japanese participants found religious items problematic, making Japanese involvement in the pilot-testing particularly valuable. Strategies were found to address the difficulties with these items, while still retaining the concepts, and the Phase IV field study will test the solutions devised.

Items exploring relational and existential issues seem more applicable across countries, although response ranges

for a few items varied between countries. The number of participants in pilot-testing was insufficient for generalisation, however, so these findings will be explored further in Phase IV.

The pilot-testing aimed to develop the measure, not conduct an intervention. Nevertheless, over a third of the respondents (37%) used participation as an opening for discussing the issues the measure addresses and expressed their appreciation of being able to talk about these matters. This illustrates the measure's potential to function as both a quantitative assessment and a qualitative intervention tool, which suggests possible benefits for practice. This aspect of the measure will be explored further in field-testing.

The study included participants from a range of nationalities, but minority ethnic groups within countries were under-represented. This was a recruitment issue, and it is recognised that minority ethnic communities are under-represented in palliative care services, partly because proportionately fewer older people from minority ethnic communities currently live in European countries,<sup>29</sup> but also for reasons of actual or perceived discrimination.<sup>29-31</sup> Phase IV field-testing is being conducted in a broader international context and will seek participants with a wider range of religious beliefs and from more varied ethnic backgrounds within, as well as between, countries.

The field-testing will explore the reliability and validity of the EORTC QLQ-SWB36, evaluate its clinical and psychometric properties and investigate its hypothesised scale structure. At least 400 patients with advanced cancer will be recruited, with collaborators currently in 14 participating countries, across Europe, and also in the Middle East, Japan, Australasia, Latin America and the US. A subsidiary study with patients with conditions other than cancer will run concurrently. Researchers interested in using the measure may seek permission from the PIs through the EORTC Quality of Life Department: <http://groups.eortc.be/qol/>

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## Ethical approval

In the UK national ethics approval was given by Hertfordshire REC, reference 05/Q0201/39. In Iceland the study also received national ethics approval from The National Bioethics Committee, reference VSN 06-078-S1, and The Data Protection Authority, reference 2006/385. In Spain the study was approved, together with several other EORTC Quality of Life Group projects, by a regional ethics committee: El Comité Etico de Investigación Clínica de Navarra (ethics committee for clinical research in Navarra; no reference number allocated to the study.) In the other collaborating countries, ethical approval was granted, following confirmation of UK NRES approval, by local hospital ethics committees, as follows: France: the ethics committee of the Institut Curie, Paris (no reference number allocated to the study); Germany: Ethik-Kommission an der Medizinischen Fakultät der Universität Leipzig (ethics committee of the medical faculty of Leipzig University; no reference number allocated to the study); Italy: The Local Ethical Committee of Sant'Andrea Hospital, Rome (reference number: Prot CE n 1239/2006); Japan: The Review Board of Saitama International Medical Centre, Hidakacity (reference number: 08-020).

## Conflict of interest

The authors declare that there is no conflict of interest.

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