#### Development of a patient-reported palliative care-specific health classification system: the POS-E

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Short title: Development of a palliative care-specific health classification system: the POS-E

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### Abstract

Background: Generic preference-based measures are commonly used to estimate Quality Adjusted Life Years (QALYs) to inform resource allocation decisions. However, concerns have been raised that generic measures may be inappropriate in palliative care.

Objective: To derive a health state classification system, which is amenable to valuation, from the 10-item Palliative Care Outcome Scale (POS); a widely used patient-reported outcome measure in palliative care.

Methods: The dimensional structure of the original POS was assessed using factor analysis. Item performance was assessed, using Rasch analysis and psychometric criteria, to enable the selection of items that represent the dimensions covered by the POS. Data from six studies of patients receiving palliative care were combined (N = 1011) and randomly split into two halves for development and validation. Analysis was undertaken on the development data and results were validated by repeating the analysis with the validation dataset.

Results: FollowingRasch and factor analyses, a classification system made of 7 items was derived. Each item had 2 ­– 3 levels. Rasch threshold map helped identify a set of 14 plausible health statesthat can be used for the valuation of the instrument, in order to derive of a preference-based index.

Conclusion: Combining factor analysis, and Rasch analysis with psychometric criteria, provides a valid method of constructing a classification system for a palliative care-specific preference-based measure. The next stage is to obtain preference weights so that the measure can be used in economic evaluations in palliative care.

Key Points for Decision Makers:

* We propose a new palliative care health state classification system termed POS-E.
* POS-E classifies palliative care states as a combination of seven dimensions.
* The dimensions are: pain; other symptoms; anxiety; depression; family anxiety; feeling good about oneself; and practical matters.

### Introduction

Economic evaluations are performed to inform the allocation of resources between competing health-care interventions. A commonly used method is cost-utility analysis, which compares interventions in terms of their cost per quality adjusted life years (QALYs) gained. The QALY combines life expectancy (in years) and quality of life (expressed in the form of “health state values”) into a single metric, based on people’s preferences.[1] The quality of life (QOL) portion is estimated by assigning a numerical value to each health state experienced by a person on a scale ranging from 1 (equivalent to full health), to 0 (dead).[2] A common way of estimating health-state values is to use a ‘‘generic’’ preference-based measure (PBM), such as the EuroQol five-dimensional questionnaire (EQ-5D),[3] Health Utilities Index Mark 3 (HUI3),[4] or Short-Form 6D (SF-6D)[5]. Each generic preference-based measure, e.g. EQ-5D, has a preference-based algorithm for assigning values to each health state. These preference weights are obtained by asking members of the general public to value the health states using a choice-based valuation technique such as standard gamble[6, 7] or time trade-off[6].   
These generic PBMs are deemed appropriate for all patients, irrespective of their medical condition, because they concentrate on broad aspects of health-related quality of life (HRQoL). However, the broad nature of these PBMs has led to debates around the degree to which they incorporate attributes of HRQoL that are particularly relevant to specific health conditions and health disciplines.[8] The estimation of QALYs in palliative care is one such case.

Palliative care is ‘*the active holistic care of patients with advanced progressive disease, aimed at achieving the best possible QoL for patients and families, through the management of pain and other symptoms, as well as provision of spiritual, psychological and social support; which may be initiated early in the course of treatment along with other curative treatments*’.[9] In the discipline of palliative care, there are concerns that generic PBMs do not incorporate many aspects of HRQoL important to palliative-care patients and rather are heavily focused on function (e.g. mobility, self-care and usual activities).[10-12] This has led to proposals for the development of a condition-specific preference based measure (CSPBM) that would be appropriate for palliative-care patients.[10, 13] Also, the likely dominant nature of palliative care needs in determining HRQoL arguably justifies the development and use of a CSPBM in palliative care. Presently, no such measure exists. The Palliative Care Outcome Scale (POS) has been suggested as suitable for this purpose.[10] The POS is validated palliative-care outcome measure[14] which has been used in many studies including RCTs and observational studies, as well as for service evaluation.[15-22] Given the dearth of economic evaluations in palliative care,[23] developing a CSPBM from a widely-accepted and commonly used instrument like the POS enables retrospective analysis of existing datasets and increases the likelihood that the measure will be used in future studies.[24]

The process of developing a preference-based measure from an existing condition-specific outcome measure involves three stages.[8] This paper reports on the first stage; the second and third stages will be addressed in a separate paper.

### Methods

#### Design

A secondary analysis of baseline data from several studies of palliative care patients.   
A health-state classiﬁcation is a multidimensional framework that can be used to deﬁne health states. Such classiﬁcations deﬁne a set of health states by selecting one level from each dimension. The EQ-5D, for example, has ﬁve dimensions each comprising three levels of response and deﬁnes a total of 243 states (35). This presents a more manageable number to value (and even then only a sample of states were directly valued). The POS has ten items, eight of which have 5 levels while two items have 3 levels each. Given the number of items and their corresponding levels, the POS would define a practically unmanageable number of 3,515,625 health states (5×5×5×5×5×5×5×5×3×3). This would result in unreasonable cognitive demands on respondents to the valuation exercise required to estimate quality weights. Therefore, the first stage of deriving a health-state classiﬁcation that is amenable to valuation, from an existing measure, involves using Rasch analysis to reduce the size of the existing measure while minimizing the loss of descriptive information.[8] This classification system would be designed to capture the range of palliative care-related problems that can occur with different diagnosis with minimal loss of information and the ability to use the responses from the original instrument to map onto it. Although some studies have derived and valued health state classifications using standard methods (e.g. factorial and orthogonal block designs) which do not require a reduction in the size of the existing measure, such methods are inefficient because they treat items as independent (uncorrelated) statements and so are likely to result in deriving (and valuing) implausible health states. It is unlikely that the types of problems seen in palliative care are unrelated (as is implied in orthogonal and factorial designs). It makes no sense, for example to define a health state where a person feels “good about themselves always” but also feels “depressed always” as they are both likely to have the same primary cause. This approach of developing a health-state classification by using Rasch to reduce a larger instrument has been applied to numerous non-preference-based measures including SF-36,[25], SF-12,[26] menopausal health questionnaire,[27] atopic dermatitis,[28] King’s Health Questionnaire,[29], Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM),[30] and European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire 30 (EORTC QLQ-C30)[31].

This study used a four-stage process as recommended by Brazier et al[8] as follows:

1. Identify the most relevant dimensions of the POS for use in the POS-E, giving an initial descriptive system
2. Identify item response levels that could be removed from the new descriptive system
3. Identify item response levels that can be merged without loss of information
4. Validate the new instrument by repeating 1-3 above in a separate dataset

#### Data sets

We merged the following baseline POS data from six studies of palliative care patients.

1. a cancer mortality follow-back survey (N=596) from 2009 to 2010 in London (The QUALYCARE study);[32]
2. a study of Parkinson’s disease (longitudinal community study of predictive factors N=82);[33]
3. a randomised controlled trial on the effectiveness of an integrated palliative and respiratory care service for patients with advanced disease and refractory breathlessness in the UK (N=105), 2014;[12]
4. a longitudinal study on trajectories of illness of stage 5 chronic renal disease (N=74, UK)[34];
5. a cross-sectional study on symptom burden and palliative care needs in chronic obstructive pulmonary disease and cancer in Germany(N=109);[15]
6. a randomised phase II trial of dignity therapy (N=45, UK);[35]

Subsequently, we randomly split the data into a development data set (N=504) and a validation data set (N=508), providing suitable sample sizes for Rasch analysis. There is evidence that some Rasch fit statistics for polytomous instruments (e.g. POS) are sensitive to the sample size and larger samples can have a higher chance of type 1 errors.[36] The development dataset was used to develop the health classification and this was validated by repeating the analysis on the validation dataset. Table 8 (appendix) reports the descriptive statistics for each data set. All data sets were anonymized prior to analysis.

#### The Palliative Care Outcome Scale (POS)

The 10-item Palliative Care Outcome Scale (POS) is a short easy-to-use clinical outcome measure originally developed and validated in eight end of life and palliative care settings in the UK, including hospital, community, in-patient hospice, outpatient, day care and general practice.[14, 37] It was developed to measure domains that impact on the quality of life of palliative care patients. The questionnaire consists of ten items, each item scored on a 5-point Likert scale ranging from 0-4 except items 9 and 10 (‘time wasted ‘and ‘practical matters’) both of which are scored on a 3-point scale (0, 2 and 4) as shown in Online Resource 1. The POS has been well validated and is widely used in clinical practice and research regionally and nationally in the UK to evaluate and improve the quality of care, and has been culturally adapted for use in 20 European Union countries, and in Africa and other countries around the globe.[15-22] Two systematic reviews (in 2011 and 2015) on the use of the POS found that the POS was used in a total of 78 published studies of both cancer and non-cancer patients.[38, 39]

#### Analysis

The objective of the analysis was to derive a multi-dimensional health state classification system amenable to valuation by reducing the number of items and item-levels in the POS.

#### Step 1: establishing dimensions

Principal component analysis (PCA) was used to assess the dimensions of the POS. PCA is commonly used in the development of new instruments to provide early indications of possible dimensions before Rasch analysis is attempted.[40] First, the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was used to assess the appropriateness of POS data for PCA (KMO value should be >0.5 if the data is appropriate).[41] In addition, Bartlett's test of sphericity was used to test whether the correlations between POS items were significant.[42] Significant factors (dimensions) were identified using Horn’s parallel analysis[43] incorporated into an online facility by Watkins[44]. Next, the rotated factor matrices were examined to assess correlations of every item with each of the main factors of the instrument. We used both orthogonal and oblique rotation methods and compared the results of both as has been recommended in the literature.[45] In all matrices, loadings with coefficients ≥ │0.400│were considered to reveal strong correlations between an item and a factor. Items loading on the same factor were considered to belong to the same underlying dimension captured by the POS.

#### Step 2: Eliminating items per dimension

Rasch analysis was used to reduce the POS to a simpler descriptive health-state classiﬁcation system by identifying POS items that did not fit the Rasch model and therefore were potentially unsuitable for inclusion in the classification system. Rasch analysis is a mathematical technique used to convert categorical data to continuous data.[46] Rasch methods can be used to assess the extent to which individual items represent the underlying construct that an instrument intends to measure, thus enabling the assessment of the appropriateness of items for a classification system.

The following criteria were considered for item exclusion, in line with recommendations for multidimensional measures [8]:

* Item level ordering (disordered thresholds): we examined threshold maps to identify items which had disordered thresholds. Ordered thresholds indicate for instance that a person with a high level of an attribute, such as pain, is more likely to endorse a high level on an item which measures pain than a person with less pain. Disordered thresholds suggest that respondents are unable to differentiate between adjacent item categories.[47] In such instances, adjacent response categories were merged to in order to obtain ordered thresholds. Items were excluded if their thresholds remained disordered despite merging of adjacent response categories. Further, if the only way to obtain an ordered threshold for an item was by merging adjacent response categories in a way that did not make clinical sense, then such an item was eliminated. For example, it was deemed clinically meaningless to merge response categories “moderately” and “severely” as these indicate significantly different levels of severity.
* Rasch goodness of fit: following threshold re-ordering, overall and item-specific fit statistics were inspected to assess the extent to which the entire instrument, as well as individual items, fit the Rasch model. Items were excluded if fit residuals were > 2.5 or < –2.5 and/or chi-squared statistics were significant at the 0.001 level after Bonferroni adjustment.[8]
* Differential-item functioning (DIF): items that demonstrate significant DIF are items with response patterns which vary according to specific patient factors such as diagnosis, age group, gender, or ethnicity. Such items were excluded from further consideration because DIF can be a source of misfit in the Rasch model, and because items forming a PBM should ideally express the same aspects of HRQoL across the whole patient population (and not to distinguish signiﬁcantly among sub-groups with different baseline characteristics).

#### Step 3: Item level reduction

Rasch analysis can identify response levels that may be merged without losing descriptive information, offering further means of simplifying the classification system.[8] We identified potential item categories for merging by examining Rasch category probability curves and response frequencies. Visual inspection of respective category probability curves determined which adjacent response categories to merge. We also sought expert opinion about the clinical and psychometric meaningfulness of the merged item-levels. These experts included a professor of Psychology (Dr R. Siegert; Auckland University of Technology New Zealand) and two palliative care clinicians (Dr P. Edmunds, King’s College Hospital London; and Dr P Kane, Beaumont Hospital, Dublin.   
Additionally, we assessed the unidimensionality of the new classification system by using the test proposed by Smith et al [48], which involves conducting paired t-tests of the final models. Unidimensionality is confirmed when 5% or less of the tests are significant at the P <0.05 level.[49] We also examined the person separation index (PSI) to assess how efficiently the final set of items was able to separate those people measured. PSI values range from 0.0 – 1, with higher values indicating better separation and a more precise measure.[49]

#### Step 4: validation of classification system

The health-state classification was validated by repeating steps 1-3 of the analysis using the validation data. We examined the examining overall and item fit statistics, DIF, unidimensionality and item–response combinations.  
RUMM2020 was used for all Rasch analysis and STATA version 12 for all other statistical analysis.

### Results

#### Step 1: factor analysis

The KMO measure of sampling adequacy reached 0.79, suggesting that factoring of data was appropriate and meaningful. Bartlett’s test of sphericity demonstrated the statistical significance of the findings (p<0.0001). Although the analysis identified 3 factors with eigenvalues above 1 which explained 52% of the total variance (see Table 7 in appendix for details), Horn’s parallel analysis indicated 2 significant factors (Table 1). The scree plot appears to support a two factor solution as the slope of the line flattens after the second factor (fig.1).

Table 1 significant components of the POS identified by PCA in [N504]. Comparison of components with eigenvalues >1 with significant components identified by Horn’s parallel analysis

| **Component** | **PCA: Initial Eigenvalues** | | | **Horn’s parallel analysis: Significant mean eigenvalues (SD)** | |
| --- | --- | --- | --- | --- | --- |
| **Total** | **% of Variance** | **Cumulative %** |
| 1 | **2.908** | 29.080 | 32.807 | **1.2609** | (0. 0359) |
| 2 | **1.269** | 12.693 | 41.773 | **1.1833** | (0. 0355) |
| 3 | 1.013 | 10.128 | 51.901 | **1.1134** | (0 .0242) |
|  |  |  |  |  |  |

Significant eigenvalue levels identified using each approach are provided in bold; SD = standard deviation

**Fig.1 Scree plot of Principal Component Analysis in [N=504]**

In line with results of parallel analysis, a two factor solution was extracted for rotation. Table 2 shows two rotated factors, one comprising six items – primarily about psychological and physical wellbeing – and the other comprising three items (two relating to the standard of care and one relating to psychological wellbeing). One item (time wasted) did not load above 0.40 on either of the two factors. Results were very similar between the two methods of rotation (orthogonal vs oblique), with all the items loading on the same components.

|  |  |  |  |
| --- | --- | --- | --- |
| Table 2 Rotated 2 Component Matrix (Orthogonal; N=504) | | | |
|  | Component | | **Conceptual domain of item** |
| 1 | 2 |
| anxiety | **.772** |  | Psychological wellbeing |
| depression | **.658** | .230 | Psychological wellbeing |
| family anxiety | **.644** | -.226 | Psychological wellbeing |
| pain | **.585** | .292 | Physical |
| symptoms | **.575** | .244 | Physical |
| feeling good | **.567** | .368 | Psychological wellbeing |
| time wasted | .260 |  | Quality of care |
| information |  | **.737** | Quality of care |
| practical matters |  | **.640** | Quality of care |
| share feelings |  | **.525** | Psychological wellbeing |

Principal Component Analysis; Rotation: Varimax with Kaiser Normalization; Loadings ≥ │0.400│are shown in bold;

The results of PCA indicated that the POS consists of two domains which are moderately correlated. These domains do not appear to be consistent with predefined conceptual domains of the POS. Our findings suggest that the POS comprises a measure with no clear multidimensionality. Thus, it was deemed necessary to conduct Rasch analysis on the whole instrument – rather than on any specific domain – in the next stage of the analysis.

#### Steps 2 and 3: use of Rasch analysis and expert opinion to merge categories, eliminate items and develop a unidimensional scale

##### Item-level ordering

A total of nine items (items 1, 2, 4, 5, 6, 7, 8, 9, and 10) were disordered in the initial Rasch model. For two of the nine disordered items (pain – item 1; and other symptoms – item 2), “slightly” and “moderately” were collapsed into a single category, as were “severely” and “overwhelmingly”, resulting in three categories per item. Similarly, family anxiety, shared feelings, depression, feeling good (items 4, 6, 7 and 8 respectively) were converted to 3-level items by merging “occasionally” and “sometimes” into a single category, and also “most of the time” and “always”. Wasted time (item 9) and practical matters (item 10), which have three levels in the original questionnaire, were converted to two-level items by merging “half a day” with “more than half a day” (item 9), and “practical problems being addressed” with “ no practical problems” (item 10). The threshold probability curves for item 5 (information) suggested that this item would only work with two categories. And so “full information”, “information given but hard to understand”, “information given on request”, and “very little information given” were collapsed into a single category. However, because this merging was not deemed to be clinically meaningful, item 5 was eliminated from further analysis.

##### Rasch model goodness of fit

After all thresholds were ordered, we assessed goodness of fit by examining overall and individual item statistics. Initial overall fit statistics of the items indicated poor fit to the Rasch model, with items 3, 5 and 6 showing misfit (a fit residual beyond ± 2.5 and a chi-square probability significant at the 0.001 level). Also, items 5 and 9 exhibited DIF. Results of the initial analysis on all items are shown in Table 3. Based on the results of Rasch analysis, a number of items were consecutively excluded from further analysis according to our exclusion criteria, until a good model fit was achieved.

Table 3 Results of initial Rasch analysis of POS-E (all items included)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Item | Threshold |  | Statistics after threshold re-ordering | | | |
|  |  |  | Residuala | *X*-square | P-valueb | DIF |
| 1. Pain | **Disordered** |  | -0.574 | 8.352 | 0.499 | No |
| 2. Other symptoms | **Disordered** |  | -1.410 | 21.811 | 0.010 | No |
| 3. Anxiety | Ordered |  | **-3.254** | 40.843 | **0.000** | No |
| 4. Family anxiety | **Disordered** |  | -0.046 | 10.655 | 0.300 | No |
| 5. Information | **Disordered** |  | **3.442** | 46.423 | **0.000** | **Yes** |
| 6. Shared feelings | **Disordered** |  | **3.758** | 34.484 | **0.000** | No |
| 7. Depression | **Disordered** |  | -1.237 | 9.849 | 0.363 | No |
| 8. Feeling good | **Disordered** |  | -1.048 | 8.598 | 0.475 | No |
| 9. Time wasted | **Disordered** |  | 2.177 | 25.787 | 0.002 | **Yes** |
| 10. Practical matters | **Disordered** |  | 1.118 | 11.222 | 0.261 | No |
|  |  |  |  |  |  |  |
| Overall model statistics after |  | **Total item *X-square = 218.025; P = 0.0000*** | | | | |
| threshold re-ordering |  | Person-separation index: 0.657 | | | | |

1. Residuals >2.5 or < −2.5 are considered high; b) P<0.01 indicates items that do not meet Rasch item fit criteria. All statistics showing item misfit into the Rasch model are illustrated in bold

Successive Rasch analyses led to the exclusion of items 5, 6 and 9 as they persistently had a poor fit to the Rasch model. For example, item 5 (information) had the poorest fit when compared with other items, it exhibited DIF, and its thresholds could only be ordered by combining adjacent levels in a way that was neither cognitively nor clinically meaningful. Items were excluded one at a time and Rasch statistics as well as the person separation index were constantly checked. This resulted in final a scale consisting of seven items (1, 2, 3, 4, 7, 8 and 10). With the exception of item 10, all other items had three response levels (for example, “not at all”, “occasionally or sometimes”, and “most of the times or always”). Item 10 (which originally had three levels to start with) was collapsed to two levels – “no problems or problems resolved” and “problems in the process of being resolved or problems exist” (Table 4). The scale demonstrated a good model fit (*X2*probaility 0.047). All items had a reasonable fit, as shown in Table 5, and no DIF was observed. The person separation index reached a reasonable level of 0.678.

Table 4 Items and levels in final POS-E scale

|  |  |  |
| --- | --- | --- |
| Item | Categories | Score |
| Family anxiety | No, not at all | 0 |
|  | Occasionally/sometimes | 1 |
|  | Most of the time/always | 2 |
| Other symptoms | No, not at all | 0 |
|  | slightly/moderately | 1 |
|  | severely/overwhelmingly | 2 |
| Pain | No, not at all | 0 |
|  | slightly/moderately | 1 |
|  | severely/overwhelmingly | 2 |
| Depression | No, not at all | 0 |
|  | Occasionally/sometimes | 1 |
|  | Most of the time/always | 2 |
| Anxiety | No, not at all | 0 |
|  | slightly/moderately | 1 |
|  | severely/overwhelming | 2 |
| Practical matters | Addressed | 0 |
|  | Not addressed | 1 |
| Feeling good | Always/most of the time | 0 |
|  | Occasionally/sometimes | 1 |
|  | Not at all | 2 |

Table 5 Rasch statistics of the POS-E measure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Item |  | Rasch analysis statistics | | |
|  |  | Residual | *X*-square | P-value |
| 1. Pain |  | 0.452 | 5.586 | 0.694 |
| 2. Other symptoms | | -0.424 | 11.073 | 0.198 |
| 3. Anxiety | | -2.090 | 20.088 | 0.010 |
| 4. Family anxiety | | 1.221 | 11.423 | 0.179 |
| 7. Depression | | 0.247 | 10.893 | 0.208 |
| 8. Feeling good | | 1.084 | 6.422 | 0.600 |
| 10. Practical matters | | 2.951 | 9.339 | 0.315 |
| Overall model statistics | | Total item X-square = 74.825; P = 0.0472 | | |
|  |  | Person-separation index: 0.678 | | |

Figure 2 below shows the threshold map with items arranged in order of increasing difficulty from top to bottom, and with severity levels increasing from left to right.

Fig.2 threshold map illustrating plausible health states obtained by Rasch analysis

As shown in Figure 3 below, the item map demonstrates that the new instrument is well targeted to the study population as it is able to capture the whole range of severity of palliative-care symptoms, with minimal floor or ceiling effects and good spread of items across the full range of respondents’ scores.

Fig.3 Item map of the POS-E showing the distribution of items across respondents

##### Deriving plausible health states from the POS-E for utility measurement

The threshold map (Fig.2) was used to derive plausible health states. This map illustrates the most likely combinations of item responses expected to be obtained by the study population at various levels (locations) of symptom severity. Items have been ordered from the easiest (item 4: family anxiety) to the most difficult (item 8: feeling good), as indicated by their average location in the Rasch model. Shaded areas 0 (blue), 1 (red) and 2 (green) correspond to the 3 levels “not at all”, “occasionally or sometimes”, and “most of the times or always”, respectively, with the exception of item 10, which has 2 levels – 0; “no problem s or problems resolved”, and 1; “problems in the process of being resolved or problems exist”. The threshold map allows prediction of the most likely responses at various levels of severity. For example, a person whose symptom severity corresponds to location 0 on the logit scale is expected to most likely respond 001112 (to items 4, 2, 1, 7, 3, 10 and 8, respectively).

Each combination of item responses represents a plausible health state, likely to be observed in people with common palliative care problems. As illustrated in table 6, fourteen distinct health states can be identified.

The results of the test for unidimensionality proposed by Smith [48] showed that the proportion of independent t-tests that were significant at the 0.05 level was 1.52% (well below the 5% level), thus supporting the unidimensionality of the classification system.

Table 6: Health states (and coverage) of the POS-E as identified by the threshold map

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Item | Health states (N=504) | | | | | | | | | | | | | |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| 4. Family anxiety | 0 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 2. Other symptoms | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 |
| 1. Pain | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 |
| 7. Depression | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| 3. Anxiety | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| 10.Practical matters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 8. Feeling good | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 2 | 2 | 2 |
| Coverage (N) | 40 | 79 | 13 | 49 | 17 | 8 | 128 | 35 | 14 | 13 | 27 | 14 | 21 | 46 |

#### Step 4: validation of the classification system

The POS-E was validated on the validation sample [N=508]: the scale had satisfactory overall and item fit statistics and no DIF was observed. The post hoc unidimensionality test verified the scale’s unidimensionality in this sample, too, and the threshold map indicated the same most likely item response combinations (reflecting plausible health states) with those demonstrated by the analyses on the estimation sample. In total the POS-E describes 1,458 health states.

### Discussion

We describe the first stage in developing a health-state classiﬁcation for palliative care – the POS-E. Based on rigorous research methods,[8] we have derived the POS-E classification system from an existing palliative care measure, the POS. The next stage of the research will involve preference elicitation and related regression-based statistical modelling to derive preference weights for all health states described by the POS-E. This will result in a CSPBM that is capable of generating QALYs for use in economic evaluations in palliative care.

POS-E is a unidimensional 7-item scale, able to capture the full range of severity of palliative care needs. Six of the items have three levels each while one item (measuring practical matters), has two levels. The person-separation index of this scale was approximately 0.68, which is somewhat lower than the 0.70 value that is generally considered acceptable for group comparison [50]. Nevertheless, the 0.68 figure was deemed adequate for our purpose, considering that the ability of the scale to discriminate amongst different respondent groups needed to be traded off with its conciseness and convenience in a valuation survey, where respondents need to process a combination of individual statements rather than a summated scale score.

One limitation of our approach, similar to the methodology proposed by Sugar et al. [51], is that the number of generated health states is limited and does not capture the whole range of plausible combinations of responses. Despite generating a limited number of health states, application of this approach allows for the valuation of all potential health states described by POS-E: an advantage of Rasch analysis over the clustering-based approach is that it assigns all potential health states (i.e. all combinations of item responses including those not illustrated in threshold maps) to different locations along the scale according to their level of severity. The relationship between the health states’ location across the latent variable and the respective utility values obtained in a valuation exercise can be estimated and used to generate utility values for all patients completing POS-E. This solution has been explored, using regression techniques, in a subsequent application of this approach on the Flushing questionnaire [52]. The findings of this latter study show that it is possible to assign appropriate utility values to all potential health states of a measure based on their location along the latent variable as estimated by Rasch analysis. However, it is conceivable that the Rasch approach we used would be best suited to a unidimensional instrument.

Developing a CSPBM from an existing palliative care measure has numerous advantages. Adapting a widely-accepted and commonly used instrument, like the POS, enables retrospective analysis of existing datasets and increases the likelihood that the measure will be used in future studies.[24]

However, a major disadvantage of CSPBMs is that they may be prone to focusing effects where the effect of the condition is overrated because respondents to the valuation survey focus solely on the areas of health included in the classification system rather than viewing them in a broader perspective. Another disadvantage CSPBMs is the correlation between perfect health and the best possible state described by a classification system. It is conceivable that a person could endorse the best possible health state based on a specific instrument, but yet have other problems not covered by its classification system. Thus, it becomes challenging to compare results between different PBMs because “best possible” health states are instrument specific.[8]

Nevertheless, these disadvantages are perhaps less crucial when the condition of interest is the overriding factor in determining HRQoL, as is likely to be the case for palliative-care and end-of-life care patients. Furthermore, because advanced life-limiting conditions affect people’s HRQoL in a wide variety of ways, the POS-E classification system covers a wider range of dimensions than many other CSPBMs do. The decision on whether to use a CSPBM or a generic PBM will always involve a trade-off between the pros and cons of CSPBMs relative to the condition of interest.[8] In the case of palliative and end-of-life care, the potential limitation of existing generic measures[13], the wide range of the POS-E classification system, and the likely dominant nature of palliative care needs in determining HRQoL all favour the development and use of a CSPBM. The argument in favour of CSPBMs for palliative care is further strengthened by research around the role of capabilities and wellbeing in end of life care which highlights that the objectives of end of life care do not always focus solely on health but may also include impact on wellbeing.[53] This is particularly evident in the development work for the ICECAP Supportive Care Measure (ICECAP-SCM)[54] – a CSPBM which measures capability at the end of life for use in economic evaluations. The POS-E relates to the ICECAP-SCM in that both instruments seek to incorporate important aspects of palliative and end-life care into economic evaluations. Standard economic instruments have been criticised for failing to do this.[11, 10] But, there are important differences between the two instruments which arise mainly due to conceptual differences in their respective evaluative frameworks. While the POS-E measures impact on health (or utility); the ICECAP-SCM gives more attention to broader impacts on capability and wellbeing, and is particularly important where health outcomes are not the focus of evaluation such as social care interventions[55]. Nevertheless, because palliative and end of life care include both aspects of health (e.g. pain) and aspects of wellbeing (e.g. availability of social support) among other things, the POS-E and ICECAP-SCM can be regarded as complimentary rather than mutually exclusive. Our analysis is based on pooled data from six studies; this was necessary in order to obtain a large enough sample to produce reliable and representative estimates. However, because the data were from different types of cancer and non-cancer patients, it is perhaps a reasonable reflection of the diverse diagnoses of palliative care patients and therefore is arguably more generalizable.

### Conclusion

This study has shown that reducing the POS to a health state classification system for palliative care (POS-E) is possible, and that the results are robust. The POS-E classifies palliative care states as a combination of seven items: pain; other symptoms; anxiety; depression; family anxiety; feeling good about oneself; and practical matters. We have also identified 14 plausible health states that can be used to value the HRQoL of palliative care patients.

### Further research

The next step for this study is to undertake a valuation survey in order to attach appropriate utility values to all health states of POS-E and thus convert it into a preference-based index. The aim is that the new PBM will be suitable for cost-utility analyses of palliative care interventions, where the use of generic PBMs such as EQ-5D has been shown to be problematic.[56-58] Since this measure has been derived from the POS, an instrument routinely used for outcome monitoring in palliative care patients in the United Kingdom and beyond, it is expected that this study will enable wider assessment of healthcare interventions for managing palliative care patients in the form of cost-utility analysis.

### Compliance with Ethical Standards

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**Ethical approval**: For this type of study formal consent is not required.

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### Appendix

Table 7 Rotated 3 Component Matrixa (N=504)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Component** | | | **Conceptual domain of item** |
| 1 | 2 | 3 |
| anxiety | **.764** |  |  | Psychological wellbeing |
| depression | **.707** |  |  | Psychological wellbeing |
| feeling good | **.645** | .207 | -.265 | Psychological wellbeing |
| family anxiety | **.625** | -.305 |  | Psychological wellbeing |
| pain | **.600** | .259 |  | Physical |
| symptoms | **.543** | .309 | .327 | Physical |
| information |  | **.755** |  | Quality of care |
| practical matters | .211 | **.697** |  | Quality of care |
| share feelings | .240 | .283 | **-.667** | Psychological wellbeing |
| time wasted |  |  | **.602** | Quality of care |
| Extraction Method: Principal Component Analysis; Rotation Method: Varimax with Kaiser Normalization; Loadings ≥ │0.400│are shown in bold;   1. Rotation converged in 5 iterations. | | | | |

Table 8 Descriptive statistics for development and validation data sets

|  |  |  |
| --- | --- | --- |
| Characteristic | Development (N=504) | Validation (N=508) |
|  |  |  |
| Female | 53% | 52% |
| Male | 47% | 48% |
| Age <60 y | 16% | 12% |
| Age > 60 y | 84% | 88% |
| Cancer | 79% | 77% |
| Non- cancer | 21% | 23% |
| Mean total POS score | 13.03 | 13.14 |

Descriptive statistics of datasets

Dataset 1: a cancer mortality follow-back survey (N=596) from 2009 to 2010 in London (The QUALYCARE study)

Dataset 2: a cross-sectional study on symptom burden and palliative care needs in chronic obstructive pulmonary disease and cancer in Germany (N=109)

Dataset 3: a study of Parkinson’s disease (longitudinal community study of predictive factors (N=82)

Dataset 4: a randomised phase II trial of dignity therapy (N=45, UK)

Dataset 5: a longitudinal study on trajectories of illness of stage 5 chronic renal disease (N=74, UK)

Dataset 6: a randomised controlled trial on the effectiveness of an integrated palliative and respiratory care service for patients with advanced disease and refractory breathlessness in the UK (N=105), 2014

Table 9: Descriptive statistics of datasets according study

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Dataset 1** | **Dataset 2** | **Dataset 3** | **Dataset 4** | **Dataset 5** | **Dataset 6** |
| N | 596 | 109 | 82 | 45 | 74 | 105 |
| Age(Mean, SD) | 74 (12.8) | 65 (9.56) | 67 (8.82) | 67 (16.73) | 80 (6.74) | 67 (9.87) |
| Female (%) | 49 | 52 | 37 | 51 | 49 | 42 |
| Ethnicity (%) |  |  |  |  |  |  |
| White | 92 | 95 | 80.4 | 84.4 | 68.9 | 77.1 |
| Black | 2.8 | 1 | 3.7 | 13.2 | 16.2 | 14.3 |
| South Asian | 1.7 | 2 | 4.8 | 2.4 | 8.1 | 1.7 |
| Chinese | 0.5 | 0 | 1.2 | 0 | 2.5 | 0 |
| Other | 2.6 | 2 | 6.1 | 0 | 4.3 | 5.7 |
| Diagnosis (%) |  |  |  |  |  |  |
| Cancer | 100 | 45 | 0 | 100 | 0 | 20 |
| Non-cancer | 0 | 55 | 100 | 0 | 100 | 80 |
|  |  |  |  |  |  |  |
| POS Total score (Mean, SD) | 13.5 (6.72) | 10.3 ( 5.9) | 13.9 ( 6.2) | 11.7 (6.7) | 11.2 (7.1) | 15.0 (6.6) |