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Evaluating the experiences and support needs of people living with chronic cancer: Development and initial validation of the Chronic Cancer Experiences Questionnaire (CCEQ)

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ABSTRACT

Background Many advanced cancers are managed as chronic diseases, yet there are currently no international guidelines for the support of patients living with chronic cancer. It is important to understand whether care and service arrangements meet the needs of this rapidly growing patient group. This study aimed to develop and validate a questionnaire to capture patients' experiences of living with chronic cancer and their views of clinical and support services.

Methods The research began 1 July 2010 and finished 21 February 2013. A conceptual framework and initial item-bank were derived from prior interviews with 56 chronic cancer patients. Items were reviewed by four oncologists and one clinical nurse specialist and during two focus groups with nine patients. Pilot questionnaires were completed by 416 patients across five cancer units. Item selection and scale reliability was explored using descriptive data, exploratory factor analysis, internal consistency analyses, multi-trait scaling analyses, and known-groups comparisons.

Results The final Chronic Cancer Experiences Questionnaire (CCEQ) includes 75 items. Sixty-two items contribute to 14 subscales with internal consistency between α0·68-0·88 and minimal scaling errors. Known-groups comparisons confirmed subscale utility in distinguishing between patient groups. Subscales were labelled: Managing Appointments, Co-ordination of Care, GP Involvement, Clinical Trials, Information and Questions, Making Treatment Decisions, Symptom Non-reporting, Keyworker, Limitations, Sustaining Normality, Financial Advice, Worries and Anxieties, Sharing Feelings With Others, and Accessing Support. Thirteen items assessing symptom experiences were retained as single items.

Conclusions The CCEQ has the potential to be used as a clinical instrument to assess patient experiences of chronic cancer or to screen for patient needs. It may also be used as an outcome measure for evaluating programmes and models of care and may identify areas for service development that could ultimately improve the care and support received by chronic cancer patients.

Keywords: Chronic cancer; advanced cancer; metastatic cancer; patient-reported outcome measures; experience of care.

Background

Approximately 50% of people diagnosed with cancer are predicted to survive their disease for at least ten years[1] and a substantial proportion will be living with advanced disease.[2] Chronic cancer is a unique phase of the advanced cancer trajectory and is defined as "a diagnosis of active, advanced or metastatic cancer that cannot be cured but can be managed through long-term continuous or cyclical treatment and/or on-going clinical observation".[3] A key finding from the 2014 National Cancer Patient Experiences Survey (NCPES)[4] was that patients who had a cancer recurrence were least likely to report that their care and treatment had been good and patients whose cancer was still present after treatment were least likely to be positive about their care. The report calls for a greater focus on

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understanding the different needs and concerns of patients with recurring cancer and those where treatment has not been effective.[4]

Improving patients' experiences of care requires a good understanding of the elements of care that matter most to patients.[5] Very little is known about patients' experiences of chronic cancer. For women with advanced breast cancer, research has shown that satisfaction with experience of care is poor, that care is predominantly in the hospital setting, and there is little evidence of involvement of general practitioners or palliative care services.[6] Prior research by the authors, interviewing 56 patients living with chronic cancer (breast, gynaecological, colorectal, renal, and prostate cancers), identified that patients experience a range problems, including: difficulty managing treatment schedules and frequent hospital appointments; a lack of integration between hospital and community/general practice services; difficulty coping with multiple and changing symptoms alongside the cyclical nature of chronic cancer; and difficulty dealing with uncertainty.[3]

To gain a better understanding of patients' experiences of living with chronic cancer, we wished to administer a survey across our region. We reviewed the content of existing validated instruments but concluded that no single instrument assessed the key areas important to patients living with chronic cancer. For example, the NCPES focuses on early diagnosis and treatment and predominantly inpatient care experiences. The Patient Assessment of Chronic Illness Care[7] assesses patients' self-management in a community setting and assumes that patient behaviour will influence their disease outcomes.[8] The EORTC outpatient Satisfaction with Care Questionnaire (OUT-PATSAT35)[9,10] is potentially useful but it is not yet validated. We felt there was an opportunity to gain insight into this area by translating the outcomes of our prior interview study into a new patient questionnaire. This article reports the development and preliminary validation of this new questionnaire, named the Chronic Cancer Experiences Questionnaire (CCEQ).

Methods

A mixed-methods approach to questionnaire development was undertaken through four phases: Phase 1 'Conceptual framework and item-bank' generated questionnaire structure and content based on previous patient interviews; Phase 2 'Face and content validity', clinicians and patients reviewed and suggest amendments to the item-bank; Phase 3 'Pilot testing' tested the clarity of items and feasibility of administration; and Phase 4 'Psychometric properties' administered the instrument across multiple cancer units and psychometric analysis determined subscale structures, internal consistency, and construct validity. The development stages of the questionnaire, summarised in Figure 1, align with best practice guidelines in questionnaire development.[11]

Phase 1: Conceptual framework and item-bank

Semi-structured interviews with 56 patients living with chronic cancer were reviewed to establish a conceptual framework for the questionnaire.[3] A framework approach[12] to thematic analysis was undertaken, which utilised *a priori* themes from the Department of Health Generic Choice Model for Long Term Conditions (GCM).[13] The GCM was used in the development of coding themes as it establishes universal factors that are hypothesised to be pertinent to all persons living with a long-term condition: self-care and self-management; clinical support; supporting independence; psychological support; and social and economic factors. These factors combined with emerging themes from the interviews to establish a broad theoretical framework for the questionnaire. The methods and outcomes of this analysis have been previously reported.[3]

Questionnaire items were generated by grouping similar interview extracts and deriving composite statements. Statements were based on direct patient quotes, aiming to retain the "patient voice", such that items remained a true representation of the original data.[14,15] This method generated a large initial item-bank covering every aspect of patients' reported experiences. The item-bank was reviewed and iteratively refined by the research team until each item reflected a single

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experience or opinion as a brief statement. Each statement was operationalised to reflect a preference (e.g., "I would prefer to have fewer hospital appointments"), an experience (e.g., "Having cancer and treatment has caused me financial difficulty"), or question (e.g., "Do you get constipated?"). For each statement a five-point Likert-scale was devised to allow respondents to demonstrate their agreement with each statement (e.g., "Strongly Agree", "Agree", "Neither Agree nor Disagree", "Disagree", "Strongly Disagree"), the response option "Not Applicable" was included for most items. Items that addressed similar issues were grouped as discrete sections within the conceptual framework.

Phase 2: Face and content validity

Clinician review

The first-draft questionnaire was distributed in paper form to oncology practitioners, who had previously participated in interviews to discuss the definition of chronic cancer and patients' experiences. Practitioners reviewed the items and provided free-text feedback on content and phrasing. Feedback was reviewed and tabulated and items were refined accordingly.

Patient focus groups

Patients reviewed the second-draft questionnaire during two focus groups using discourse methods similar to cognitive interviews.[14] Eligible patients were: attending outpatient oncology clinics at a cancer unit for treatment, review, or follow-up assessments; had breast, colorectal/gastrointestinal, renal, prostate, or gynaecological disease that met the chronic cancer definition.[3] All were conversant and literate in English. All patients were initially approached by clinical staff and the research team provided study information and consented patients to the study. Leeds Central NHS Ethics Research Committee approved the particulars of this programme of research (reference: 10/H1313/28) and all patients provided written informed consent prior to participation. Focus groups were conducted in a private room at the cancer unit, were audio recorded, and lasted 120-minutes. Participants reviewed the questionnaire in groups of two or three and provided written and verbal feedback on each item and response option. Audio files were transcribed and comments were tabulated against individual items. Questionnaire items were refined where suggested amendments gained participants' consensus.

Phase 3: Pilot testing

For the third-draft questionnaire, free-text sections were added to allow respondents to provide additional comments on their symptoms, information preferences, or completing the questionnaire. Free-text feedback was used to verify the content of items (to ensure important content was not missing) and applicability of the questionnaire. The questionnaire was administered at a cancer unit on paper alongside a brief demographics questionnaire which included questions about social support (marital status, living arrangements), current employment, and educational attainment. Patients completed and returned the questionnaires during their hospital visit or from home via pre-paid postal return. Questionnaire responses were tabulated and feedback was reviewed. Ethical, governance, and eligibility criteria were as reported for the focus groups.

Phase 4: Psychometric properties

The fourth and final draft of the questionnaire (plus demographics questionnaire) was administered to patients attending one of five Cancer Units in District General Hospitals across the North of England. Ethical, governance, eligibility criteria, and recruitment procedures were as above with the addition that patients had not completed the pilot questionnaire and were attending one of five Cancer Units. Descriptive and psychometric analyses explored individual item performance and subscale reliability and validity. Positively phrased items were reverse scored so that a higher score

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represented a poorer/negative experience and response data was linearly transformed to a 0-100 scale. Items endorsed "Not Applicable" were classified as missing data for analysis purposes. Items were grouped according to the six domains of the conceptual framework and subjected to principal axis factoring (PAF) with promax rotation allowing for correlation between factors. Standard diagnostic tests were carried out to ensure suitability for PAF (Kaiser-Meyer-Olkin measure and Bartlett's test of sphericity). The number of factors extracted by the models was restricted to Kaiser's Eigen values >1. Factors were labelled according to item content, variance accounted for by each factor was recorded, and item loading values (>±0.3) were tabulated. Emergent factors were explored for optimal item reduction and internal consistency reliability (Cronbach's alpha correlation coefficients)[16] above $\alpha \geq 0.7$ was considered acceptable.[17] Multi-trait scaling analyses examined optimal item placement across subscales. Item-convergent validity was confirmed by a correlation of $r \geq 0.4$ between an item and its own scale, corrected for overlap.[18] Item-discriminant validity was confirmed by item-own scale correlations greater than item-other scale correlations and scaling errors were recorded.

Subscale scores were calculated as the mean of contributing items, where there was less than 50% missing data from subscale items. One-way analysis of variance (ANOVA) and independent samples t-tests examined the statistical significance of any group differences in subscales between: clinic group (breast, gastro-intestinal/colorectal, gynaecological, prostate, and renal); chronic disease duration (0-35, 36+ months); age (above and below mean age of sample: 41-67, 68-90 years); and education level (up to compulsory school level, beyond compulsory school level). Bonferroni corrections were applied to multiple post-hoc comparisons.[19]

Role of the funding source

Dimbleby Cancer Care, who funded this research, had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

The study was carried out between 1 July 2010 and 21 February 2013,

Phase 1: Conceptual framework and item-bank

The questionnaire's conceptual framework included six themes: clinical services; self-care and self-management; needs for independent living; work, finances, and benefits; psychological experiences; and support pathways.[3] Interview extracts were organised within each theme and the range and frequency of topics that patients discussed are shown in Table 1. Questionnaire items were derived by reducing patients' interview statements into succinct quotes, which resulted in an initial bank of 271 items that described the entire content of the interviews. The item-bank was reviewed by the research team and iteratively refined until 169 items summarised the content of the original data without exact duplication. Similar items were retained in an attempt to identify the best item phrasing.

Phase 2: Face and content validity

Clinician feedback

The 169 items were distributed to clinicians for review and feedback. Five oncologists and six clinical nurse specialists (CNS) were approached and four oncologists and one CNS provided feedback. Clinicians identified 67 items for removal: 36 were ambiguous and 31 duplicates. Alternative phrasing was suggested for five items to improve comprehension. Additional items relating to patients' symptom experiences and participating in clinical trials were requested. The research team drafted twelve new items. The revised item-bank contained 114 items.

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Patient focus groups

Forty-nine patients were approached about participation in the focus groups, of these 30 were interested and took study information. Once the session dates were booked 12 patients were unavailable and 4 did not feel well enough to participate. Of the 14 patients who agreed to participate, five subsequently dropped out; 2 due to changes in treatment schedule and 3 did not feel well enough to participate on the day. Nine patients participated in one of the two focus group sessions (renal (n=3), colorectal/gastrointestinal (n=3), gynaecological (n=2), and breast (n=1)). Of the 114 items, 81 were retained unchanged. Seven ambiguous items were deleted (e.g., "it has only been my insistence that has ensured I have received the right care"); 26 items were amended to improve clarity (e.g., "I would prefer to have fewer clinic appointments" was amended to "I would prefer to have fewer hospital appointments"); and 15 new items were suggested for clinical trials, finance and benefits, GP role in care, information and support needs.

Phase 3: Pilot testing

The third-draft questionnaire included 122 items plus three free-text sections. 103 patients completed the questionnaire from a sample of 127 (81% response rate). Patients self-reported marital, employment, and educational status. Clinical details (diagnosis, disease free duration, chronic phase duration, number of metastatic sites) were extracted from patients' clinical records. Patient clinical and demographic information are summarised in the second column (Phase 3) of Table 2. Reviewing patient questionnaire responses identified one potentially ambiguous item: "I would like to use support services / centres but I don't know if there is anything local to me". This item was simplified to: "I would like to use support services / centres". A new item was added to the clinical trials section "I have taken part in a clinical trial" with the response options "Yes", "No", and "Not Sure".

Phase 4: Psychometric properties

The fourth-draft questionnaire was administered to 342 patients across five cancer units and 313 patients returned completed questionnaires (92% response rate). As the questionnaires administered during phases 3 and 4 were very similar, response data was pooled to maximise sample size (N=416) for psychometric exploration of subscale structure and internal reliability. Missing data was low (item response rate range 91.59-99.76%). Demographic details of the phase 4 sample are summarised in the third column (Phase 4) of Table 2. Respondent-to-item ratios for Principal Axis Factoring (PAF) for each of the six questionnaire domains ranged from 9.7:1 (Clinical services, 43-items) to 69.5:1 (Finances and Benefits, 6-items).

Internal Scale Structure

Symptom items were not entered into PAF as they are typically 'causal' indicators of patient experiences[20,21] and we did not wish to develop symptom subscales. Thirteen subscales were identified from PAF that achieved acceptable internal consistency (Cronbach's alpha 0.71-0.88) and one subscale (Accessing Support) attained just below the threshold (α0.68). Item fit for all subscales was evaluated using multi-trait analyses (see Table 3). Two items from 'Managing Appointments' and one item from 'Accessing Support' subscales had item-convergent correlations below r=0.40 (r=0.35, r=0.39, and r=0.36 respectively), however none of these items correlated more strongly with any other subscale so were retained for further analysis. Sixty-one single items remained after analysis: 13 items assessing common side-effects of cancer treatments were deemed useful to the questionnaire and were retained, the remaining 48 items were removed.

Known-Groups

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Subscale scores 'Managing Appointments', 'Co-ordination of Care', 'GP Involvement', 'Keyworker', 'Worries and Anxieties', and 'Sharing Feelings With Others' were significantly different between clinic groups (P<0.05), with patients from breast clinics reporting the highest (poorest) scores (Table 4). Higher scores for 'GP Involvement' and 'Making Treatment Decisions' were reported by patients with chronic disease duration ≥36months compared to patients with chronic disease duration ≤35 months (P<0.05). Younger patients (41-67 years) reported higher scores for 'GP Involvement', 'Financial Advice', and 'Worries and Anxieties' compared to older patients (68-90 years) (P<0.01), whereas older patients reported higher scores than younger patients for 'Clinical Trials' (P<0.05). Patients who were not educated beyond compulsory school level reported higher scores for 'Clinical Trials', 'Limitations', 'Sustaining Normality', and 'Sharing Feelings With Others', and 'Accessing Services' (P<0.05). There were no differences between groups for subscale scores 'Information and Questions' and 'Symptom Non-reporting' (P>0.05). The final questionnaire items are presented in Table 5.

Discussion

This study developed a questionnaire to capture patients' experiences of living with chronic cancer and their views on clinical and support services. The rationale for developing the CCEQ was that existing instruments, particularly the NCPES[4], do not capture the range of experiences relevant to patients living with chronic cancer. The CCEQ is intended to support clinicians and researchers to develop a better understanding of this rapidly growing yet under-studied patient group.

Robust methods for developing psychometrically valid multidimensional patient experience instruments are yet to be established. The methods used in the current study combine two approaches taken from needs-based quality of life (NB-QoL)[22] and health-related quality of life (HRQL)[15] instrument development. Grounding the questionnaire in a conceptual framework based on patient-reported experience and deriving items directly from patient interview quotes is aligned with NB-QoL methods. NB-QoL instruments, however, are unidimensional measures of patients' quality of life needs. The CCEQ was designed to assess multidimensional components of patients' experiences and views on clinical services. Therefore HRQL methods such as exploratory factor analysis and classic psychometric methods were used to derive subscales and multi-trait scaling and known-groups analyses were used to validate the subscale constructs.

The CCEQ covers a broad range of experiences, which have been identified as important to patients living with chronic cancer.[3,6] The CCEQ assumes that patients with chronic cancer have an ongoing and predominantly outpatient relationship with hospital-based oncology services, with supplementary involvement from primary care and community or palliative care services, as described in previous research.[3,6] The importance of hospital-based outpatient services is reflected in the new instrument, which devotes 21 items (28% of questionnaire) to this area, including: managing frequent and lengthy hospital appointments ('Managing Appointments', 'Co-ordination of Care'); receiving information about prognosis and diagnosis and the opportunity to ask questions ('Information and Questions'); support for treatment decisions ('Making Treatment Decisions'); and participating in clinical trials ('Clinical Trials'). The remainder of the survey reflects that away from the cancer unit, patients predominantly 'self-manage' symptoms and side-effects ('Symptom Experiences') by deciding whether and when to seek additional support ('Symptom Non-reporting', 'Keyworker', 'Financial Advice', 'Accessing Support', and 'Sharing Feelings With Others') and develop strategies for managing their daily activities and social responsibilities around the effects of disease and treatment ('Limitations'; 'Sustaining Normality', 'Worries and Anxieties').

Given the lack of existing validated measures, the construct validity of the subscales was explored through 'known-groups' analysis, which compares subscale scores across demographic and clinical factors that are hypothesised to influence patients' experiences of care and services. We identified that patients attending breast cancer clinics had the highest scores (worse experiences) for 'Managing Appointments', 'Co-ordination of Care', 'GP Involvement', 'Keyworker', 'Worries and Anxieties', and

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'Sharing Feelings with Others', compared to patients attending other clinics. This finding is corroborated by broader literature which reports that breast cancer patients tend to report poorer quality of life and greater unmet psychological needs compared to patients from other cancer groups.[23-25] Patients with longer chronic disease duration reported poorer scores for 'GP Involvement' and 'Making Treatment Decisions', which potentially reflects increased dependence on cancer units but reduced treatment choices with advancing cancer. Interestingly, we identified that patients with lower educational attainment reported less interest in 'Clinical Trials', greater 'Limitations', greater difficulty 'Sustaining Normality', greater difficulty 'Sharing Feelings with Others' and greater difficulty 'Accessing Support' compared to patients with higher educational attainment. These findings make intuitive sense but contradict previous research which found no relationship between educational status and support needs in women with advanced breast cancer.[26] Two subscales did not vary by patient clinical or demographic factors, 'Information and Questions' and 'Symptom Non-reporting'. Scores for these subscales were comparatively low, showing that patients generally did not report problems in these areas. As such, the discriminative utility of these scales needs to be confirmed in future work. Overall, the data suggests that the 14 subscales are psychometrically valid and subscale mean scores should be derived rather than analysing individual item responses. Multi-item scales have the advantage over single items by reducing bias, misinterpretation, and measurement error in assessments[27] and verify the significance of the underlying constructs.[28]

The results of this study should be considered within the context of several limitations. The early-stage development of the instrument was carried out in a single cancer unit and only the final fourth-draft version of the survey was administered to patients attending different cancer units. Limiting the earlier stages of the work to one cancer unit may have introduced biases in the nature and range of experiences that were included in the questionnaire. It is important to recognise that this manuscript presents preliminary psychometric data. Further work is needed to determine the reproducibility or stability of scores over time (test-retest reliability) and the unidimensionality of the new subscales needs to be confirmed, for example using Rasch analysis.[29] Some of these limitations could be addressed by reviewing instrument performance following a trial period of use in clinical practice or through a clinical audit. Collecting data during routine practice may allow the inclusion of a more diverse patient sample than can be captured during research and would allow exploration of how useful the instrument may be in supporting the evaluation of services and identifying areas for improvement. Another issue that may be explored by use of the questionnaire in routine practice is acceptability of the instrument to patients. At 75 items, clinicians may be concerned that the questionnaire is overly long or burdensome to patients. The responses from patients during the development of this questionnaire suggests that the questionnaire would be well received. Patients commented that the questionnaire was simple and straightforward to complete and although there are a large number of questions, they felt the instrument positively reflects the complexity and far reaching consequences of living with chronic cancer. As such, we anticipate that the questionnaire will be acceptable to the majority of patients with chronic cancer, particularly if it is used sparingly such as part of an annual review or one off service evaluation.

Despite these limitations, the methodological approach undertaken in developing the instrument thus far has been robust, has been driven by the experiences of a large number of patients, and has resulted in a questionnaire that captures pertinent data about patients' experiences of living with chronic cancer and their perspective of clinical and support services. The CCEQ and scoring guidelines are freely available from the authors.

Conclusions

Improving patients' experiences of care requires a good understanding of the elements of care that matter most to patients. Very little research has examined the needs and experiences of patients living with chronic cancer. The CCEQ captures unique information about patients' experiences of this

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disease phase, it has the potential to be used as a clinical instrument to assess patient experiences or to screen for patient needs. It may also be used as an outcome measure for evaluating programmes and models of care and may help to identify areas for service development that could ultimately improve the care and support received by chronic cancer patients.

Footnotes

Contributors: CH and GV developed the protocol for the study. SP, AD, and LK collected and managed study data. CH, SP, and GV analysed and interpreted the study data. CH, GV, SP, and AD contributed to drafting the report. All authors have seen and approved the final version of the report.
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Competing interests: All authors have completed the ICMJE uniform disclosure form atwww.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work other than those acknowledged above; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.
Ethical Approval: The study was approved by Leeds Central Research Ethics Committee (reference number 10/H1313/28).
Data sharing: Details of how to obtain additional data from the study (for example, raw questionnaire data) are available from the corresponding author at c.harley@leeds.ac.uk
Transparency declaration: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.
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Figure 1. Study profile showing the development phases of the Chronic Cancer Experiences Questionnaire

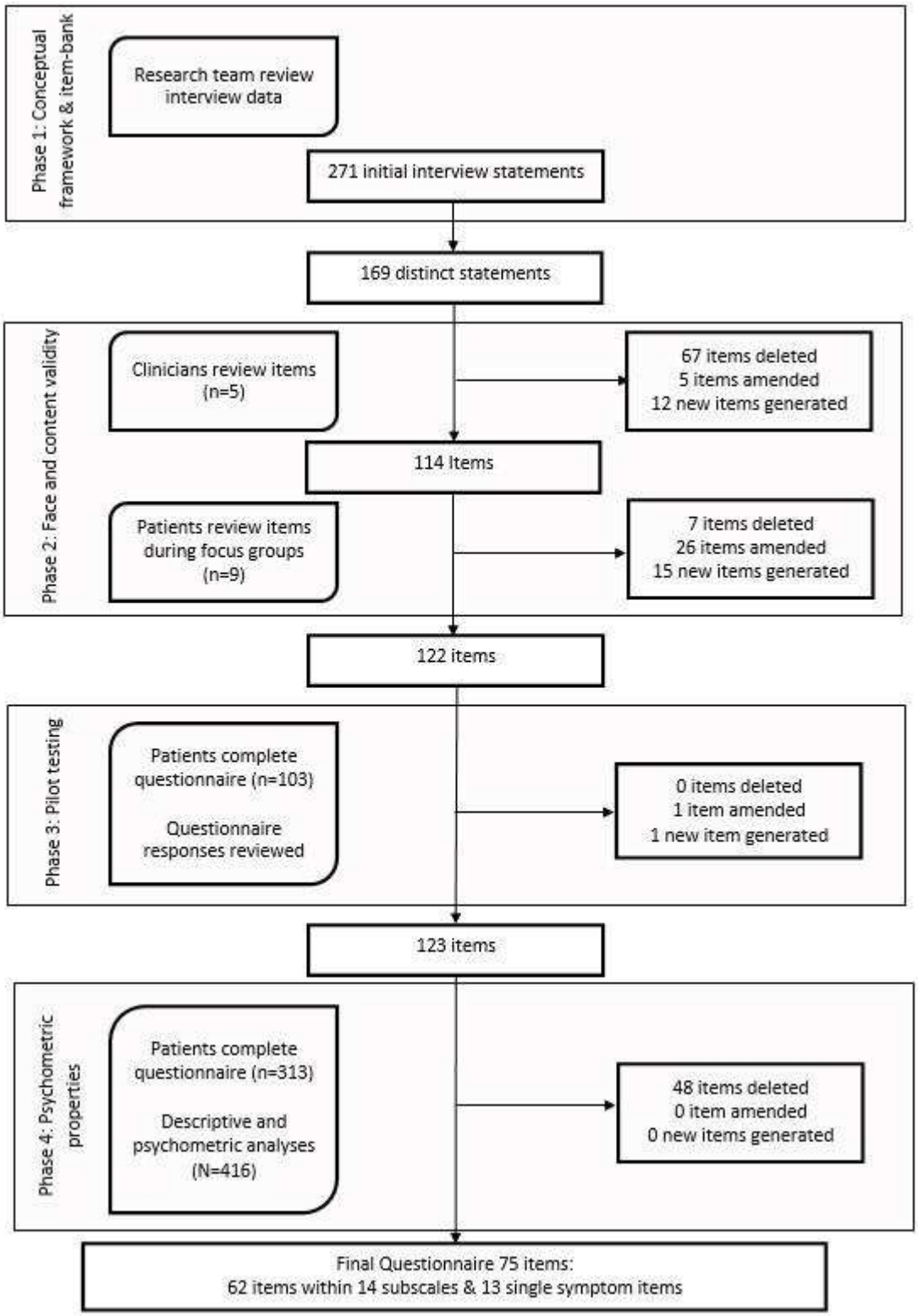

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Table 1. Patient interview coding framework, summarising the thematic content of the interviews and the frequency by which each issue was raised by patients per clinic group.

	Renal (n=11)	Breast (n=11)	Gynaecological (n=12)	Prostate (n=10)	Colorectal (n=12)	Total (N=56)
Clinical services						
Hospital appointments	26	32	18	46	19	**141**
Nurse role (keyworker)	24	29	36	27	20	**136**
Continuity between care providers	44	13	19	11	16	**103**
GP role	14	30	15	22	19	**100**
Regular care provider	20	25	3	9	8	**65**
Multiple care providers	18	31	8	3	4	**64**
Co-morbidities	13	4	8	6	15	**46**
Oncologist role	8	6	3	1	4	**22**
Out of hours contact	13	0	4	0	0	**17**
Contacting services	2	8	3	0	4	**17**
Self-care and self-management						
Side-effects	82	66	62	49	63	**322**
Side-effect management	34	36	24	20	25	**139**
Prognosis information	5	11	6	13	22	**57**
Change in side-effects	36	1	11	4	4	**56**
Asking questions	10	12	9	11	10	**52**
Treatment expectations	10	12	5	12	8	**47**
Treatment options	14	8	2	10	8	**42**
Clinical trials	5	5	19	6	7	**42**
Treatment type	8	19	1	4	2	**34**
Diagnosis information	5	7	8	5	8	**33**
Treatment cycle	11	7	3	2	6	**29**
Patient's role in managing medicines	9	5	9	0	3	**26**
Access to information	1	11	0	1	7	**20**
Treatment breaks	9	0	0	5	4	**18**
Patient tenacity	1	8	4	0	2	**15**
Treatment dosages	9	0	1	1	2	**13**
Patient as information carrier	4	1	4	1	0	**10**
Needs for Independent Living						
Limited activities	41	51	37	32	46	**207**
Supportive networks	34	34	43	12	43	**166**
Social activities	17	19	11	14	17	**78**
Need for independence	15	13	13	8	11	**60**
Planning activities	11	7	13	1	6	**38**
Work, Finances, Benefits						
Benefits	27	40	29	12	29	**137**
Work	22	15	22	7	19	**85**
Getting advice	34	19	16	4	8	**81**
Getting by financially	8	25	13	14	21	**81**
Future planning	5	5	0	0	9	**19**

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Psychological Experiences						
Attitude towards illness	21	48	39	23	50	**181**
Worries	25	32	16	21	16	**110**
Emotions	12	26	22	7	24	**91**
Acceptance	8	16	11	14	25	**74**
Individual perspective	11	23	7	13	18	**72**
Burdening others	6	19	9	6	21	**61**
Faith and trust	3	24	9	10	12	**58**
Experiences	8	16	8	1	11	**44**
Coping strategies	8	18	12	3	2	**43**
Sustaining normality	5	5	4	13	4	**31**
Uncertainty	7	4	6	7	5	**29**
Support Pathways						
Support from services	31	47	30	17	24	**149**
Attitude to services	19	21	14	2	11	**67**
Hospice	1	32	8	7	6	**54**
Patient peer support	6	10	11	8	7	**42**
Domestic support/services	11	8	6	4	6	**35**
Patient as carer	2	14	2	4	9	**31**
Access/barriers to services	3	10	10	0	4	**27**
Transport	9	4	1	9	1	**24**
Suggestions for services	4	14	0	2	2	**22**
Social network	4	13	0	0	4	**21**
Drug delivery + prescriptions	9	5	1	0	3	**18**
Self-care support	10	3	0	1	2	**16**
Nutritionist	2	2	0	0	0	**4**
Faith healer	0	1	2	0	0	**3**

The frequency of an issue reported in this table reflects the number of times that each issue was recorded as a 'unit of meaning' across all interviews. A unit of meaning may have been derived from a few words, a sentence, or a paragraph. The frequencies indicate the number of times that each issue was raised across all interviewees and may include repetition of an issue by participants.

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Table 2. Patient Demographic and Clinical Data

	Phase 3 N=103	Phase 4 N=313
Age in years mean (range)	65 (41-90)	67 (41-88)
Gender, n (%)		
Male	50 (48.5)	157 (50)
Disease free duration in months*, mean (range)	33.2 (0-377)	31.4 (0-307)
Chronic phase duration in months, mean (range)	41.4 (2-191)	35.0 (0-178)
Number of metastatic sites, mode (range)	1 (0-4)	2 (1-5)
Clinical Groups, n (%)		
Breast	25 (24.5)	73 (23.2)
Colorectal/Gastrointestinal	19 (18.5)	53 (16.9)
Gynaecological	18 (17.5)	61 (19.4)
Prostate	19 (18.5)	98 (31.2)
Renal	22 (21.5)	29 (9.2)
Marital Status, n (%)		
Married	70 (68)	221 (72.7)
Cohabiting	6 (5.8)	17 (5.6)
Widowed	16 (15.5)	26 (8.6)
Separated/divorced	5 (4.8)	25 (8.2)
Single	3 (2.9)	15 (4.9)
Missing	3 (2.9)	10 (3.2)
Employment Status, n (%)		
Retired	70 (68)	206 (69.6)
Working full time	10 (9.7)	19 (6.4)
Working part time	7 (6.8)	21 (7.1)
Unable to work due to illness	8 (7.8)	37 (12.5)
At home and not looking for work	3 (2.9)	9 (3.0)
Other	2 (1.9)	4 (1.4)
Missing	3 (2.9)	18 (5.7)
Education level, n (%)		
Continued education after school	47 (45.6)	139 (47.9)
Degree or professional qualification	33 (32)	90 (31.8)

*Disease free duration calculated as time between date of primary diagnosis and date of advanced diagnosis in months

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Table 3. Subscale internal reliability, item-convergent validity, item-discriminant validity, and validity scaling errors

Subscale label	Number of items	α	ICV	IDV	Number of scaling errors
Clinical Services					
1. Managing Appointments	7	0.71	0.35 - 0.58	-0.08 - 0.36	2
2. Coordination of Care	2	0.88	0.79	-0.02 - 0.20	0
3. GP Involvement	4	0.78	0.41 - 0.72	-0.11 - 0.20	0
4. Information and Questions	5	0.77	0.44 - 0.64	-0.07 - 0.43	0
5. Making Treatment Decisions	3	0.82	0.61 - 0.72	-0.02 - 0.45	0
6. Clinical Trials	3	0.80	0.63 - 0.68	-0.11 - 0.22	0
Self-care and Self-management					
7. Symptom Non-reporting	2	0.71	0.56	-0.01 - 0.33	0
8. Key Worker	4	0.78	0.49 - 0.71	-0.03 - 0.36	0
Needs for Independent Living					
9. Limitations	4	0.88	0.60 - 0.84	-0.17 - 0.56	0
10. Sustaining Normality	4	0.77	0.46 - 0.69	-0.10 - 0.62	0
Work, Finances, and Benefits					
11. Financial Advice	5	0.79	0.44 - 0.70	-0.07 - 0.31	0
Psychological Experiences					
12. Worries and Anxieties	7	0.83	0.47 - 0.69	-0.07 - 0.58	0
13. Sharing Feelings With Others	6	0.81	0.46 - 0.67	-0.06 - 0.54	0
Support and Services					
14. Accessing Support	5	0.68	0.36 – 0.50	-0.14 – 0.27	1

α Cronbach's alpha correlation coefficient
ICV Item-convergent validity, item to own scale correlation corrected for overlap
IDV Item-divergent validity, item to other scale correlation

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Table 4. Differences in subscale scores by clinic group, chronic disease duration, age group, and education level.

	Clinic group						Chronic disease duration			Age group			Educated beyond compulsory school level		
	Breast	CR/GI	Gynae	Prostate	Renal		0-35 months	36+ months		41-67 years	68-90 years		no	Yes	
	n=98	n=72	n=78	n=117	n=51		n=271	n=145		n=211	n=205		n=202	n=186	
Subscale Label	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	*P*	Mean (SD)	Mean (SD)	*P*	Mean (SD)	Mean (SD)	*P*	Mean (SD)	Mean (SD)	*P*
Managing Appointments	**20.45 (14.60**)	**15.81 (10.49)**	**14.21 (11.81)**	**16.09 (10.58)**	16.12 (12.95)	**0.013**	16.06 (11.89)	17.90 (12.93)	0.154	17.03 (13.37)	16.35 (12.19)	0.583	16.49 (13.17)	16.94 (11.58)	0.728
Coordination of Care	**65.32 (28.50)**	**65.67 (24.17)**	**66.28 (27.92)**	**59.93 (27.03)**	**48.25 (26.61)***	**0.001**	60.71 (28.33)	64.26 (25.88)	0.225	64.01 (28.18)	59.63 (26.68)	0.114	62.57 (27.91)	61.36 (27.20)	0.677
Information and Questions	18.30 (14.54)	14.33 (13.17)	14.47 (10.75)	15.81 (11.52)	16.96 (9.86)	0.181	15.22 (11.90)	17.56 (12.96)	0.065	15.32 (12.25)	16.79 (12.37)	0.223	15.83 (12.79)	16.32 (11.96)	0.697
Making Treatment Decisions	15.26 (20.36)	13.15 (20.16)	9.04 (15.39)	13.80 (19.89)	9.64 (13.14)	0.159	**10.97 (17.07)**	**15.74 (20.94)**	**0.021**	10.93 (18.04)	14.40 (19.08)	0.061	13.51 (19.56)	11.64 (17.80)	0.328
GP Involvement	60.59 (25.06)	56.31 (25.20)	**66.22 (24.82)**	**51.94 (26.19)**	56.09 (22.51)	**0.003**	**55.88 (25.82)**	**61.55 (24.39)**	**0.031**	**61.74 (23.43)**	**53.87 (26.84)**	**0.002**	56.56 (25.85)	58.97 (24.89)	0.355
Clinical Trials	41.30 (30.82)	37.31 (28.88)	38.49 (31.94)	31.82 (28.16)	45.07 (29.70)	0.070	37.06 (30.07)	39.27 (29.99)	0.483	**34.60 (29.21)**	**41.40 (30.57)**	**0.024**	**41.34 (30.51)**	**33.20 (28.62)**	**0.008**
Symptom Non-reporting	28.55 (23.25)	23.35 (22.12)	25.73 (20.21)	23.47 (19.80)	25.53 (17.67)	0.446	23.96 (20.82)	28.03 (21.01)	0.070	26.30 (22.49)	24.32 (19.11)	0.354	25.81 (20.90)	24.64 (20.97)	0.598
Key Worker	**32.95 (24.41)***	**29.46 (17.69)***	**19.26 (17.66)**	**22.47 (14.88)**	**16.05 (16.06)**	**0.000**	23.65 (18.08)	26.62 (21.67)	0.145	24.56 (20.12)	24.83 (18.74)	0.891	24.96 (18.84)	23.50 (20.00)	0.467
Limitations	56.10 (26.14)	50.35 (26.01)	54.11 (27.04)	46.99 (30.17)	56.41 (25.75)	0.098	53.59 (27.48)	49.67 (27.57)	0.174	54.53 (27.48)	49.83 (27.47)	0.086	**55.75 (27.90)**	**47.88 (27.12)**	**0.006**
Sustaining Normality	25.19 (17.99)	23.93 (16.02)	22.18 (16.91)	23.47 (19.00)	29.98 (16.76)	0.144	25.24 (18.21)	23.19 (16.63)	0.262	23.10 (17.32)	26.01 (17.96)	0.094	**27.05 (18.01)**	**21.77 (17.45)**	**0.004**
Financial Advice	42.14 (22.15)	39.03 (20.94)	40.89 (21.31)	36.93 (21.19)	37.85 (21.40)	0.564	38.76 (21.32)	40.09 (21.58)	0.584	**42.88 (21.58)**	**35.18 (20.50)**	**0.001**	40.89 (21.79)	37.13 (20.80)	0.111
Worries and Anxieties	**65.83 (17.63)***	**53.62 (19.40)**	**63.17 (21.28)***	**50.14 (19.63)**	**54.97 (20.90)**	**0.000**	58.56 (20.22)	55.37 (21.08)	0.136	**61.63 (21.24)**	**53.06 (18.88)**	**0.000**	57.18 (20.00)	57.73 (20.95)	0.791
Sharing Feelings With Others	**50.38 (21.08)**	40.24 (19.85)	47.29 (20.39)	**39.92 (21.26)**	43.35 (18.25)	**0.001**	44.70 (20.79)	44.17 (20.91)	0.807	46.06 (21.29)	42.88 (20.21)	0.123	**47.15 (19.81)**	**41.15 (21.30)**	**0.005**
Accessing Support	49.98 (23.08)	55.05 (18.34)	45.27 (19.39)	48.60 (19.26)	49.64 (17.48)	0.092	**47.41 (20.36)**	**54.38 (18.59)**	**0.003**	48.59 (21.08)	50.86 (18.75)	0.305	**51.55 (19.16)**	**47.13 (20.71)**	**0.050**

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Table 5. Wording of the final 75 items organised according to the six themes of the theoretical framework.

Theme 1: Clinical Service	
Managing Appointments	
1.	I find it reassuring to have regular hospital appointments
2.	I would prefer to have fewer hospital appointments
3.	My hospital appointments are straightforward and easy to manage
4.	My hospital appointments interfere with my work / domestic duties
5.	The number of appointments I have causes problems for my family / carer
6.	I find getting around the hospital difficult
7.	I get annoyed by how much waiting around there is at the hospital
Co-ordination of Care	
8.	I want to choose which doctor I see in clinic
9.	I would rather wait to see my preferred doctor than see the next available doctor in clinic
Information and Questions	
10.	The staff at the hospital are friendly and make me feel at ease
11.	I feel there is enough time to ask questions when I come to clinic
12.	The doctors are very open and will tell you anything you need to know
13.	I am content with the information I have received about my diagnosis
14.	I am content with the information I have received about my prognosis
Making Treatment Decisions	
15.	I am given the opportunity to discuss my treatment plan with the doctors
16.	My decisions about care and treatment are respected by the doctors and nurses
17.	If I have questions about new treatments my doctor is happy to discuss these with me
GP Involvement	
18.	My GP is involved in my cancer care
19.	My GP doesn't know enough about cancer to support me during treatment
20.	My GP organises my referrals to other specialists (i.e. hospice, psychologist, community nurse)
21.	If I have a cancer or treatment-related problem I contact the GP before getting in touch with the hospital
Clinical Trials	
22.	I have taken part in a clinical trial
23.	I would consider taking part in a clinical trial even if it did not benefit me directly
24.	I would consider travelling to another hospital to take part in a clinical trial
25.	I would like to be kept informed about clinical trials for which I may be eligible
Theme 2: Self-care and Self-management	
Symptom Experiences	
26.	Do you feel sick (nauseous)?
27.	Do you vomit (sick)?
28.	Do you have trouble breathing (feel breathless, short of breath)?
29.	Do you have pain?
30.	Do you feel fatigued or tired (or have weak or heavy arms or legs)?
31.	Do you have trouble sleeping (falling asleep, staying asleep, waking early)?
32.	Do you get constipated?
33.	Do you have difficulty concentrating?
34.	Do you have difficulty remembering things?
35.	Do you lack appetite (don't feel hungry)?
36.	Do you have diarrhoea (loose watery stools)?
37.	Do you have skin problems (such as areas of dry skin, sore skin, sore hands/feet, rashes, skin infections)?
38.	Do you have a sore mouth/tongue?
Symptom Non-Reporting	
39.	I don't always tell the doctors the full extent of my symptoms as I am concerned that they will stop treatment
40.	I don't tell the doctors the full extent of my pain because I do not want to take pain medication
Keyworker	
41.	I know who my keyworker is (e.g. specialist nurse)
42.	I know who to contact if I have questions about my symptoms
43.	I don't know who to contact for advice between treatments
44.	At times I have felt abandoned by the medical staff
Theme 3: Needs for Independent Living	

Limitations	
45.	The cancer / treatment limits what I can do physically
46.	The cancer / treatment limits my ability to do social activities / hobbies
47.	I get frustrated by not being able to do what I used to do
48.	I can't plan because I don't know how I'm going to feel from one day to the next
Sustaining Normality	
49.	I feel that I lead a pretty normal life
50.	I get out and about most days
51.	I try to live today like I have every other day of my life
52.	I find keeping active and busy is a good way to cope
Theme 4: Work, finances, and Benefits	
Financial Advice	
53.	Having cancer and treatment has caused me financial difficulty
54.	I'd like to talk to someone about my finances
55.	I don't know who to go to for financial advice
56.	I would like advice about my entitlement to benefits (social security) or grants
57.	I am worried about paying bills or getting into debt
Theme 5: Psychological Experiences	
Worries and Anxieties	
58.	The uncertainty of what's going to happen is the hardest part
59.	I don't think about my illness that much
60.	I worry about how my family will cope in the future
61.	I often feel anxious or worried
62.	I find waiting for test / scan results a very difficult time
63.	If I get an ache or pain I think it is the cancer growing
64.	I am scared of dying
Sharing Feelings with Others	
65.	I don't cope that well, I just bury my head in the sand
66.	There are times when I feel isolated and alone
67.	I have lost confidence in social situations
68.	I don't always tell those close to me how bad I am feeling as I don't want to worry them
69.	I worry that I am burdening people if I ask for help
70.	I tend to bottle up my emotions
Theme 6: Support Pathways	
Accessing Support	
71.	I have been given information about how I can access recommended support services (e.g. home care, Macmillan, or hospice)
72.	Things would have to get really bad before I got involved with support services / centres
73.	Macmillan are only for people who are very ill or near end of life
74.	I am in regular contact with a community nurse (e.g. palliative, Macmillan or Sue Ryder nurse)
75.	I get support from my local hospice