PATIENT-REPORTED OUTCOME MEASUREMENT GROUP, OXFORD

A STRUCTURED REVIEW OF PATIENT-REPORTED OUTCOME MEASURES (PROMs) FOR BREAST CANCER

Report to the Department of Health, 2009
A STRUCTURED REVIEW OF PATIENT-REPORTED OUTCOME MEASURES FOR WOMEN WITH BREAST CANCER

Nicola Davies
Elizabeth Gibbons
Anne Mackintosh
Ray Fitzpatrick

Patient-reported Outcome Measurement Group
Department of Public Health
University of Oxford

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Copies of this report can be obtained from:

Elizabeth Gibbons
Senior Research Officer
Patient-reported Outcome Measurement Group
tel: +44 (0)1865 289402
e-mail: elizabeth.gibbons@dphpc.ox.ac.uk
EXECUTIVE SUMMARY

Aims of the report
The aims of this report are to identify Patient-reported Outcome Measures (PROMs) which have been evaluated with patients with breast cancer and to provide a short-list of the most promising generic and cancer-specific instruments.

The methods of the review and the results of the search are described, including sources and search terms used to identify relevant published research. Details of this evidence are presented for generic PROMs, preference-based measures and cancer-specific instruments evaluated with patients with breast cancer. The report concludes with discussion and recommendations.

Results
Three generic instruments, which have been evaluated with breast cancer, were identified in this review:

1. Medical Outcomes Study 36-Item Health Survey (SF-36)
2. Medical Outcomes Study 8-Item Health Survey (SF-8)
3. Sickness Impact Profile (SIP)

One preference-based measure was identified:

1. European Quality of Life Questionnaire (EuroQol; EQ-5D)

Six cancer-specific instruments were identified in this review; two are specific to breast cancer (EORTC BR23, FACT-B):

1. Cancer Rehabilitation Evaluation System – Short-Form (CARES-SF)
2. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
3. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer module EORTC BR23
4. Functional Assessment of Cancer Therapy – General (FACT-G)
5. Functional Assessment of Cancer Therapy – Breast (FACT-B)
6. Functional Living Index – Cancer (FLIC)

Recommendations
Based on the volume of evaluations and good measurement and operational characteristics, the following are highlighted as promising PROMs for piloting in the NHS:

Generic:
SF-36

Preference-based:
EQ-5D

Cancer-specific:
1. EORTC QLQ-C30
2. FACT-B or FACT-G
Attention may need to be given to longer term issues of survivorship if the full spectrum of cancer in the population is to be included in surveys using PROMs although insufficient evidence was found to highlight measures for this review.
INTRODUCTION

Background
Patient-reported outcome measures (PROMs) offer enormous potential to improve the quality and results of health services. They provide validated evidence of health from the point of view of the user or patient. They may be used to assess levels of health and need in populations, and in users of services, and over time they can provide evidence of the outcomes of services for the purposes of audit, quality assurance and comparative performance evaluation. They may also improve the quality of interactions between health professionals and individual service users.

Lord Darzi’s Interim Report on the future of the NHS recommends that patient-reported outcome measures (PROMs) should have a greater role in the NHS (Darzi, 2007). The new Standard NHS Contract for Acute Services, introduced in April 2008, included a requirement to report from April 2009 on patient-reported outcome measures (PROMs) for patients undergoing Primary Unilateral Hip or Knee replacements, Groin Hernia surgery or Varicose Vein surgery. Furthermore, Lord Darzi’s report ‘High Quality Care for All’ (2008) outlines policy regarding payments to hospitals based on quality measures as well as volume. These measures include PROMs as a reflection of patients’ experiences and views. Guidance has now been issued regarding the routine collection of PROMs for the selected elective procedures (Department of Health, 2008) and since April 2009, the collection of PROMs for the selected elective procedures has been implemented and is ongoing.

In light of recent policy to include PROMs as an important quality indicator, the Department of Health now seeks guidance on PROMs which can be applied in patients with cancer and commissioned the Patient-reported Outcome Measurement Group, Oxford, to review the evidence of PROMs for selected cancers. It is proposed that the most common cancers, as identified via the Office for National Statistics, should be the subject of review in terms of most promising PROMS. Breast, lung, colorectal and prostate cancer are highlighted as being the four most common cancers, accounting for half of the 239,000 new cases of malignant cancer (excluding non-melanoma skin cancer) registered in England in 2005 (Figure 1). On scrutinising cumulative incidence data from the cancer registry of the Oxford region, findings support that these four cancers are the most common. According to the Department of Health’s Cancer Reform Strategy (2007), which aims to place the patient at the centre of cancer services, a ‘vision 2012’ has been created for each of these four cancer types, highlighting the progress that it is hoped will be made by 2012 in terms of the cancer pathway. Underlying this vision is the aim to achieve full implementation of improving outcomes guidance. In this context, PROMS are an important resource for monitoring cancer outcomes.
Breast cancer

Breast cancer is the most common cancer in England (Figure 1); one in nine women will develop breast cancer at some point in their lives. In 2004 there were around 36,900 new cases diagnosed, representing 32% of all cancers in women at a rate of 121 cases per 100,000. Four in five new cases are diagnosed in women aged 50 and over, peaking in the 55 to 64-year age-group. Incidence increased by 81% between 1971 and 2004, and by 13% in the ten years to 2004. Earlier detection and improved treatment have resulted in a rise in survival rates; five-year survival was 81% for women diagnosed in 1999-2003 in England. Survival from breast cancer is higher than that for cervical cancer and much higher than for the other major cancers in women - lung, colorectal and ovarian. For women diagnosed in 2001-03, 72% are likely to survive for at least ten years.

Breast cancer is thus a priority on the government health agenda and has been for some time. ‘Improving Outcomes in Breast Cancer’ (1996, Department of Health) identified healthcare professionals’ roles in the treatment, management and care of women with breast cancer. Recommendations focused on how these services should be organised so that women with breast cancer across England and Wales receive high-quality healthcare. The National Institute of Health and Clinical Excellence has since published an updated version of this document (NICE, 2002). Collecting and using improved information on different aspects of cancer services and outcomes is central to delivering this strategy. Better information via patient-reported outcomes could enhance quality of care, inform commissioning, and promote patient choice. The following review provides current information available on PROMs used with breast cancer patients.
METHODS

Aims of the report

The aims of this report are to identify Patient-reported Outcome Measures (PROMs) which have been evaluated with patients with breast cancer and to provide a short-list of the most promising generic and cancer-specific instruments.

Structure of the report

The methods of the review and the results of the search are described, including sources and search terms used to identify relevant published research. Details of this evidence are presented for generic PROMs, preference-based measures and cancer-specific instruments evaluated with patients with breast cancer. The report concludes with discussion and recommendations.

Methods for the review

a) Inclusion criteria

Titles and abstracts of all articles were assessed for inclusion/exclusion by one reviewer and a sample was checked by another reviewer. Included articles were retrieved in full. Published articles were included if they provided evidence of measurement and/or practical properties (Fitzpatrick et al., 1998) for multi-item instruments assessing aspects of health status or quality of life in women with breast cancer.

- Selection by study design
  • studies where a principal PROM is being evaluated;
  • studies evaluating several PROMs concurrently;
  • applications of PROMs with sufficient reporting of methodological issues.

- Specific inclusion criteria for generic and disease-specific instruments
  • the instrument is patient-reported;
  • there is published evidence of measurement reliability, validity or responsiveness following completion in the specified patient population;
  • the instrument has been recommended for use with patients with breast cancer;
  • evidence is available from English language publications, and instrument evaluations conducted in populations within UK, North America, Australasia.

b) Exclusion criteria

• Clinician-assessed instruments

Comprehensive searches were conducted; articles retrieved were assessed for relevance and checked by another reviewer; and evidence of measurement performance and operational characteristics abstracted for each PROM identified.

c) Search terms and results: identification of articles

The searches were conducted using three main sources.

The primary source of evidence was the bibliographic database compiled by the PROM group in 2002 with funding from the Department of Health and hosted by the University of
Oxford. In 2005, it became the property of the NHS Information Centre for Health & Social Care. The most recent bibliographic update is current to December 2005. The PROM database comprises 16,054 records (up to December 2005) downloaded from several electronic databases using a comprehensive search strategy (Appendix A). These records had been assessed as eligible for inclusion in the bibliography and assigned keywords. The primary search strategy using the term ‘cancer’ in the keyword search generated 17,759 records, 272 of which were for breast cancer.

There are also 14,000+ additional records (2006/2007) held by the PROMs group. The primary search strategy using the terms ‘cancer’ and ‘breast’ or ‘breast cancer’ in the abstract and title search generated 402 records.

Supplementary searches which included hand searching of titles from 2006 to 2008 of the following key journals, and PubMed, generated 43 records:
- Cancer
- Journal of Clinical Oncology
- Health and Quality of Life Outcomes
- Medical Care
- Quality of Life Research

When assessed against the review inclusion criteria, 96 articles were included in the review..

**Table 1: Number of articles identified by the literature review**

<table>
<thead>
<tr>
<th>Sources</th>
<th>No. studies identified</th>
<th>No. studies included</th>
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<tr>
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<td>44</td>
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<tr>
<td>Supplementary searches</td>
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d) Data extraction
Data were extracted on the psychometric performance and operational characteristics of each PROM. Assessment and evaluation of the methodological quality of PROMs was performed independently by two reviewers adapting the London School of Hygiene appraisal criteria outlined in their review (Smith et al., 2005). These criteria were modified for our review (Appendix B).

The final short-listing of promising PROMs to formulate recommendations is based on these assessments and discussion between reviewers.
RESULTS: Generic PROMs evaluated with women with breast cancer

Three generic instruments were identified, which have been evaluated in breast cancer:

1. Medical Outcomes Study 36-Item Health Survey (SF-36)
2. Medical Outcomes Study 8-Item Health Survey (SF-8)
3. Sickness Impact Profile (SIP)

These instruments are briefly described in Appendix C.

1. Medical Outcome Short Form 36-Item Health Survey (SF-36)

A total of 24 articles evaluating the SF-36 with breast cancer patients were included.

High internal consistency of the eight SF-36 subscales is supported by a number of the included studies, with Cronbach’s alpha in the range of 0.68 to 0.94 (Bardwell et al., 2006; Byar et al., 2006; Wyatt et al., 2004; Figueiredo et al., 2004; Helgeson and Tomich, 2005; Alfano et al., 2006a & b; Doorenbos et al., 2006). Further support for the internal consistency of the SF-36 has been demonstrated for the MCS and PCS scores, alpha’s being 0.89 and 0.94, respectively (Golden-Kreutz et al., 2005). However, inter-item correlations failed to meet the accepted correlation of 0.35 or greater for 20 out of 82 comparisons in one study (Glick et al., 1998).

The SF-36 MCS demonstrated strong convergent validity with the Centre for Epidemiologic Studies Scale Screening Form in Bardwell et al. (2006) and scores discriminated cancer-related traumatic stress (Golden-Kreutz et al., 2005).

Moderate to strong convergent validity has been demonstrated with the Health Utilities Index (Lovrics et al., 2008). Moderate convergent validity has been demonstrated with the Impact of Cancer scale (Zebrack et al., 2006). Moderate to weak convergent validity has been demonstrated with the hormone-related symptoms subscale of the Breast Cancer Prevention Trial (BCPT) Symptom Checklist (Alfano et al., 2006a). Weak convergent validity was demonstrated with the Brief Cancer Impact Assessment (Alfano et al., 2006b), the FLIC (Wilson et al., 2005), and the EORTC QLQ-C30 (Glick et al., 1998).

Discriminant validity has been supported for the SF-36 with differences in scores for cancer type (Claus et al., 2006), breast cancer recurrence and disease-free status (Helgeson and Tomich, 2005), co-morbidities and treatment type (Byar et al., 2006; Bower et al., 2006; Figueiredo et al., 2004; Griggs et al., 2007; Purushotham et al., 2005; Muss et al., 2008). Patients’ scores on the SF-36 differed significantly for depressive status as measured via the CES-D (Bardwell et al., 2006; Doorenbos et al., 2006) and cancer-related fatigue (Byar et al., 2006; Andrykowski et al., 2005).

As predicted, the SF-36 Energy/Vitality subscale discriminated according to natural killer cell numbers in an Irish study (Garland et al., 2004). However, the SF-36 has demonstrated weak discriminative power with regard to emotional well-being, failing to demonstrate mental health differences between women with or without lymphoedema secondary to breast cancer (Wilson et al., 2005), as well as breast cancer patients and healthy post-menopausal women (Yost et al., 2005), breast cancer patients and USA normative data (Bardwell et al., 2004).
The SF-36 has demonstrated responsiveness in a number of intervention studies consistent with other outcome measures in the studies. These include evaluations of surgery (Lovrics et al., 2008), an educational support group intervention (Helgeson and Tomich, 2005), a self-efficacy enhancing intervention (Doorenbos et al., 2006), in-home nursing (Wyatt et al., 2004) and different drug therapies (Muss et al., 2008).

Further support for responsiveness to change has been demonstrated in the PCS and MCS scores at 4 and 12 months post-surgery (Golden-Kreutz et al., 2005).

Two studies reported no change in scores in women with unilateral breast cancer-associated lymphoedema of the arm receiving a massage intervention in patients (Wilburn et al., 2006) or specialist follow-up care (Grunfeld et al., 2006).

Seven of the included studies explicitly commented on patient acceptability of the SF-36, one reporting completion time as being less than 10 minutes (Byar et al., 2006) and the other six reporting response rates ranging from 54% to 100% (Zebrack et al., 2006; Bower et al., 2006; Lovrics et al., 2008; Muss et al., 2008; Alfano et al., 2006a & b).

2. Medical Outcome Short Form 8-Item Health Survey (SF-8)
One study evaluating the SF-8 with breast cancer patients was identified.

The SF-8 did not differentiate newly diagnosed breast cancer patients as a group from US norms (Hegel et al., 2006). However, both the PCS and MCS discriminated those who screened positive for depression and/or PTSD from those who did not (Hegel et al., 2006).

3. Sickness Impact Profile (SIP)
Two articles evaluating the SIP with breast cancer patients were identified.

The home management subscale and recreation and pastimes subscale have demonstrated good internal consistency at three time points, Cronbach’s alpha being in the range of 0.63-0.77 and 0.62-0.76, respectively (Allard, 2007).

The subscales measuring adverse impact of illness or its treatment on social activities and recreational activities only had a weak correlation with emotional distress as measured via the Affect Balance Scale in a study by Carver et al. (1998).

The home management and recreation and pastime subscale scores were responsive to change in women receiving an Attentional Focus and Symptom Management Intervention (AFSMI) intervention, whereby a significant time effect was identified between time 2 (one week following the first intervention session) and time 3 (one week following the second intervention session) (Allard, 2007).

A response rate of 79% was reported in one study utilising the SIP via telephone interview (Allard, 2007).
Preference-based measures
One measure was identified.

1. European Quality of Life Questionnaire (EuroQol; EQ-5D)
Three articles evaluating the EQ-5D with breast cancer patients were included in the review.

Convergent validity has been demonstrated with the FLIC and a VAS scale measuring perceived QoL (Conner-Spady et al., 2001).

The EQ-5D is responsive to change with significantly large change scores in patients receiving high dose chemotherapy (Conner-Spady et al., 2001) and to those receiving screening interventions (Jeruss et al., 2006).

One study has interpreted EQ-5D scores via conventional interpretations of effect size of small (0.2), medium (0.5), and large (0.8) (Conner-Spady et al., 2001), whilst another has used ECOG Performance Status as an anchor (Pickard et al., 2007). In the latter study, minimal important differences (MIDs) for the overall cohort (n=534), which included breast cancer patients, were 0.10 to 0.12 for EQ-5D dimensions and 7 to 10 for VAS scores (Pickard et al., 2007).

Ceiling effects have been reported in stage II and III breast cancer patients (n=40) undergoing high dose chemotherapy (Conner-Spady et al., 2001), but not in a cohort of mixed cancer patients, 50 of whom had breast cancer (Pickard et al., 2007).
RESULTS: Cancer-specific PROMs

Six cancer-specific instruments were identified in this review; two are specific to breast cancer (EORTC BR23, FACT-B):

1. Cancer Rehabilitation Evaluation System – Short-Form (CARES-SF)
2. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
3. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer module EORTC BR23
4. Functional Assessment of Cancer Therapy – General (FACT-G)
5. Functional Assessment of Cancer Therapy – Breast (FACT-B)
6. Functional Living Index – Cancer (FLIC)

These instruments are briefly described in Appendix D.

1. **Cancer Rehabilitation Evaluation System – Short Form (CARES-SF)**

A total of six articles evaluating the CARES-SF are included in the review.

Test-retest reliability has been demonstrated in one study, with 86% agreement between test and retest at one, seven, and 13 months post-diagnosis (Schag et al., 1991).

The CARES-SF has acceptable internal consistency, supported by three studies (Schag et al., 1991; Dausch et al., 2004; Shelby et al., 2006), with alphas for subscales ranging between 0.61 and 0.85.

Convergent validity with the long-form CARES was high, correlations ranging from 0.90 to 0.98 on the global score and five sub-scores (Schag et al., 1991). The CARES-SF global and five subscale scores had strong correlations with the Functional Living Index – Cancer (FLIC) in two studies of newly diagnosed breast cancer patients (Ganz et al., 1990; Schag et al., 1991). Further evidence of convergent validity was demonstrated with all CARES scores significantly correlating with the clinician-rated Karnofsky Performance Status. As was expected, the physical CARES summary scale showed the strongest correlation with this instrument.

The CARES-SF has demonstrated discriminative validity in a number of studies, with scores discriminating between women (n=216) receiving various types of treatment, including chemotherapy, hormone therapy and systematic adjuvant therapy (Casso et al., 2004). The instrument scores have also demonstrated discriminant validity for women reporting physical problems and women reporting difficulty communicating with friends and relatives (Shelby et al., 2006). However, discriminative validity has been lacking in terms of self-reported psychological problems (Shelby et al., 2006) and depression (Dausch et al., 2004) in women with breast cancer.

The CARES-SF has demonstrated responsiveness over time, with the Global CARES-SF scores significantly improving from 1 month to 7 months, 1 month to 13 months, and 7 months to 13 months post-surgery (Schag et al., 1991). Further support for the responsiveness of the CARES-SF has been demonstrated in a weight training intervention, with significant
changes on the physical and psychosocial subscale scores at 6 months post intervention (Ohira et al., 2006).

High response rates of 75% for a postal survey including the CARES-SF were reported in one study (Casso et al., 2004).

2. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
A total of 14 articles evaluating the QLQ-C30 are included in the review.

The QLQ-C30 has demonstrated acceptable internal consistency with Cronbach’s alpha levels above 0.70 for all domains except role function and cognitive function (Osoba et al., 1994). Further evidence is reported for item level analysis with item-total correlations being above 0.35 on all but three of the comparisons made (Glick et al., 1998). In terms of item discrimination, overlaps are evident between the social function and cognitive function scales, the emotional function and cognitive function scales, and the physical function, role function, and social function scales, alphas for combined scales ranging from 0.51 to 0.87. Except for the relatively low correlation between item 5 (whether the responder needed ‘help with eating, dressing, washing yourself or using the toilet’) and the physical function domain, the correlations for all other items were much higher within their own domain than with any other domain (ranging from -0.65 to 0.95) (Osoba et al., 1994). The QLQ-C30 has met accepted internal consistency and item discrimination standards, above that of the generic SF-36 (Glick et al., 1998).

Using principal components factor analysis, two factors were found from the 12 psychosocial items, namely, emotional distress and functional ability (McLachlan et al., 1999). Analysis of the factor structure via an orthogonal varimax transformation showed reasonably good agreement with the postulated factor structure (Osoba et al., 1994). The main difference was that items 1 and 5 pertaining to physical function did not load with the other items (2, 3 and 4) on this factor at baseline, pre-chemotherapy (McLachlan et al., 1999).

Convergent validity has been reported for the QLQ-C30 with a number of similar conceptually analogous PROMs. The QLQ-C30 has demonstrated reasonable convergent validity with the FACT-G (Glick et al., 1998) and the Supportive Care Needs Survey (Snyder et al., 2008). Further support for convergent validity is reported for the psychosocial subscale with several subscales from other PROMs (Psychosocial Adjustment to Illness Scale [PAIS], the Profile of Mood States [POMS], the Mental Adjustment to Cancer [MAC] scale, and the Impact of Events Scale [IES]), with correlations ranging from 0.52 (PAIS) to 0.74 (POMS) (McLachlan et al., 1998). There were weak to moderate correlations between QLQ-C30 emotional function and MAC fighting spirit, hopeless/helpless and anxious preoccupation. Furthermore, QLQ-C30 social function did not relate substantially to MAC coping style.

With the IES, the only quantitatively significant correlation occurred between QLQ-C30 emotional function and IES intrusion. Agreement was highest for the QLQ-C30 with the POMS and the PAIS, but moderate with the IES, and lowest for the MAC (McLachlan et al., 1998).

The QLQ-C30 global health/QoL, role function, and social function subscales show evidence of discriminant validity between known groups identified via the clinician-rated Eastern Cooperative Oncology Group (ECOG) Performance Status, but the emotional, cognitive, and
psychosocial function subscales did not demonstrate discriminant ability with reference to all anticipated clinical parameters (McLachlan et al., 1998). The QLQ-C30 has also demonstrated discriminant validity in terms of cancer type (including breast cancer), disease severity (Osoba et al., 1994), DSM-IV depression status, age (Grabsch et al., 2006), widowed status (Hack et al., 2006), and supportive care needs (Snyder et al., 2008). The instrument has also demonstrated discriminative ability to disease progression (Lemieux et al., 2007).

Evidence of responsiveness of the QLQ-C30 is reported in a longitudinal study of chemotherapy, where the only domain that did not change significantly between pre- and post-treatment was pain (Osoba et al., 1994).

Minimally Important Differences (MIDs) have been reported for the QLQ-C30 (Osoba et al., 1998). Effect sizes corresponding to a small improvement were between 0.09 and 0.51 for subscales (Osoba et al., 1998). The MID using 0.5 SD was confirmed by Lemieux et al., (2007) in metastasized breast cancer (n=133).

Floor effects for items 5 (help with eating, dressing, washing yourself or using the toilet), 14 (nausea), 15 (vomiting) and 17 (diarrhoea) are reported in Osoba et al. (1994), indicating lower functioning and poorer HRQoL for patients pre-chemotherapy. No floor or ceiling effects are reported for items 14 and 15 post-chemotherapy. Ceiling effects were evident for all five psychosocial subscales in one study (McLachlan et al., 1998).

Acceptability of the QLQ-C30 is demonstrated in a number of studies reporting high response rates and low levels of missing data in both the pencil and pen response format (Aranda et al., 2005; Osoba et al., 1994) and a computerised response format (Taenzer et al., 1997). The average time required to complete the instrument is approximately 11 minutes, with most patients requiring no assistance (Aaronson et al., 1993).

The feasibility of using the QLQ-C30 to collect QoL data was supported by two of the studies reviewed (Coates et al., 1992), one utilising a computerised response format (Taenzer et al., 1997).

3. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer module (EORTC BR23)

Very little evidence is reported for this module. One recent study used it to evaluate HRQoL in women following breast reconstruction surgery. The authors report that the EORTC BR23 and the FACT-B were not sensitive to detecting change in this population (Potter et al., 2009).

A total of 12 articles evaluating the FACT-G are included in the review.

Evidence of acceptable reproducibility has been reported in a mixed sample of cancer patients (n=60) with ICC ranges from 0.82 to 0.92 with a test-retest period of 3 to 7 days (Cella et al., 1993).

Cronbach’s alpha for the total FACT-G have been reported between 0.89 (Cella et al., 1993) and 0.94 (Romero et al., 2006), with the four subscales ranging from 0.65-0.87 (Cella et al., 1993; Smith et al., 2007; Davies et al., 2008a; Davies et al., 2008b). However, in a study
demonstrating internal consistency via inter-item correlations, failure to meet the accepted 0.35 was evident on 31 of the 68 comparisons. The FACT-G fared better than the generic SF-36, but worse than the EORTC QLQ-C30 (Glick et al., 1998).

Factor analysis revealed five subscales to the FACT-G, namely, physical, social, emotional, and functional well-being, and relationship with doctor (Cella et al., 1993). A four-factor structure of the FACT-G was obtained in a UK study, these factors corresponding to version 4 subscales of physical, social, emotional, and functional well-being (Smith et al., 2007). However, in this same study, the social well-being subscale was identified as being multidimensional, suggesting a two-factor scale of family concerns and close personal relationships.

Convergent validity has been demonstrated with strong correlation between the FACT-G and the Functional Living Index – Cancer (FLIC) and measures of mood distress (Taylor Manifest Anxiety Scale, Brief Profile of Mood States) (Cella et al., 1993). Moderate correlations are reported between the FACT-G and the Eastern Cooperative Oncology Group (ECOG) Performance Status Rating self-report (Cella et al., 1993) and Quality of Life in Cancer Survivors (QOL-CS) (Ferrell et al., 1995); reasonable correlations are reported with the EORTC QLQ-C30 and SF-36 (Glick et al., 1998). Subscale outcomes have also been found to correlate with personal measures of health status, as assessed via the Health Baseline Comparison Questionnaire (Davies et al., 2008b) and information satisfaction, as assessed via the Information Satisfaction Questionnaire (Davies et al., 2008a). Divergent validity has been supported by low correlations with the shortened Marlowe-Crowne Social Desirability Scale (Cella et al., 1993).

The FACT-G has demonstrated discriminant validity in terms of different stages of disease in a study by Cella et al. (1993) and chemotherapy patients and healthy controls (Mar Fan et al., 2005).

However, evidence has emerged in terms of differential item functioning (DIF), whereby items have been found to perform differently for different groups (i.e. race, ethnicity, education, language, self- vs. interviewer-administered) in a study by Crane et al. (2006).

The FACT-G has demonstrated responsiveness to change in scores from a group of patients receiving chemotherapy (Cella et al., 1993) as well showing time-dependent improvements post-chemotherapy at one and two year follow-up (Mar Fan et al., 2005). However, there were non-significant changes in FACT-G scores in patients receiving an exercise rehabilitation programme, as measured at baseline and at 12-weeks (Campbell et al., 2005).

Distribution-based and anchor-based methods are available for identifying clinically meaningful differences. Normative data are available for the interpretation of FACT-G scores (Brucker et al., 2005) and the ECOG Performance Status is commonly used as an anchor for FACT-G interpretation (Cella et al., 2002).

Patient burden is minimal and the reading level of the questionnaire is 4th grade. Acceptability is supported in a longitudinal study (Mar Fan et al., 2005) and postal methodology (Ferrell et al., 1995), response rates being high in both cases.

Ease of administration and scoring has been supported during questionnaire development (Cella et al., 1993).
5. Functional Assessment of Cancer Therapy – Breast (FACT-B)
A total of 15 articles evaluating the FACT-B are included in the review.

Evidence of acceptable reproducibility has been reported for subscales and aggregate scores with ICC ranges of 0.88 to 0.85 for the breast cancer subscale and FACT-B total score, respectively, using a test-retest period of 3 to 7 days (Brady et al., 1997). The arm morbidity subscale FACT-B+4 has also demonstrated stability, with a test-retest reliability of 0.97 in the initial validation study (Coster et al., 2001).

Internal consistency has been supported by a number of studies, with Cronbach’s alphas for the entire FACT-B ranging from 0.82 to 0.91 (Hack et al., 2003; Wyatt et al., 2004) and subscales being in the range of 0.63-0.90 (Manning-Walsh, 2005a; Hack et al., 2003; Cella et al., 1993). In the initial validation study for the arm morbidity subscale FACT-B+4, subscale items demonstrated good internal consistency, with Cronbach’s alphas ranging from 0.62 to 0.88 (Coster et al., 2001).

The FACT-B general subscales retain the same content validity as the FACT-G (Cella et al., 1993). The total FACT-B was developed with an emphasis on patients’ values, firstly being tested longitudinally (n=47) and then with a larger sample (n=295), supporting its use in oncology clinical trials as well as in clinical practice (Brady et al., 1997). The FACT-B+4 was developed in consultation with breast cancer health professionals and breast cancer patients, supporting content validity of this supplementary scale (Coster et al., 2001).

Evidence of convergent validity is demonstrated with significant correlations with conceptually similar measures, such as the FLIC (Brady et al., 1997). Further support of convergent validity is evident with hypothesised correlations between FACT-B well-being subscales and the POMS subscales (Depression/Tension/Anger, Vigour, and Fatigue) (Brady et al., 1997). Weak correlations have been reported between the FACT-B and the Marlowe-Crowne Social Desirability Scale, indicating the expected lack of relationship between these differing concepts (Brady et al., 1997).

Discriminant validity has been demonstrated with scores differing in patient- and clinician-reported ECOG Performance Status (Brady et al., 1997) and according to chemotherapy status (Shilling and Jenkins, 2007) and use of herbal remedies (Zick et al., 2006). No discriminant validity was established between types of nursing care received (Wyatt et al., 2004). The ability of the FACT-B to discriminate according to demographic variables is mixed. In one study, the questionnaire discriminated by age, disease severity, and socioeconomic status (Zick et al., 2006) whilst in another it did not discriminate in terms of age, time since diagnosis, or socioeconomic or marital status (Manning-Walsh, 2005b). The latter study is not necessarily generalisable since it was an Internet-based study. The FACT-B+4 discriminated between patient groups in the initial validation study (Coster et al., 2001).

The FACT-B has demonstrated responsiveness to change with significant improvement in scores in a number of intervention studies, including complete decongestive therapy for upper extremity lymphoedema (Mondry et al., 2004), in-home nursing (Wyatt et al., 2004), a dance and movement class at 13 and 26 weeks post-intervention (Sandel et al., 2005), an eight-month self-efficacy counselling intervention at four and eight months (Lev and Owen, 2000), and a 12-week support-group intervention (Targ and Levine, 2002). Nevertheless, in the latter study, the significant score change was in terms of functional and emotional well-being
domains, with no responsiveness from the social well-being domain, as would have been expected (Targ and Levine, 2002). FACT-B+4 scores showed responsiveness to change, with a significant decline in scores in the immediate post-operative period, and later score increases (improvement) as arm morbidity problems resolved (Coster et al., 2001).

By combining the results of distribution- and anchor-based methods, MID estimates have been obtained, these being 2-3 points for the breast cancer module, and 7-8 points for the total FACT-B (Eton et al., 2004).

Patient burden is minimal and the reading level of the questionnaire is 4th grade. Acceptability is supported by high response rates in a number of the reviewed studies (Brady et al., 1997; Manning-Walsh, 2005a & b; Gordon et al., 2005). In the validation study for the FACT-B+4, patients appeared to find the scale quick and easy to complete, with good completion rates for all items within the questionnaire (Coster et al., 2001).

Ease of administration and item brevity has been reported in the development of the FACT-B, as has the appropriateness of the instrument in clinical settings (Brady et al., 1997).

6. Functional Living Index – Cancer (FLIC)
A total of seven articles evaluating the FLIC are included in the review.

One study reports a Cronbach’s alpha of 0.89 (Clinch, 1996), demonstrating good internal consistency.

Strong convergent validity has been reported between the FLIC and the FACT-G (Brady et al., 1997), ECOG Performance Status (Elliott et al., 2004), CARES (Ganz et al, 1990), and EQ-5D (Conner-Spayd et al., 2001), but weak convergent validity with the generic SF-36 (Wilson et al., 2005).

The FLIC has failed to demonstrate discriminant validity for nodal status, receipt of chemotherapy, and type of surgery (Ganz et al., 1990) and the presence of other health conditions (Elliott et al., 2004.) However, it has demonstrated discriminant validity in terms of concurrent illness, ECOG Performance Status (Elliott et al., 2004) and lymphoedema status (Wilson et al., 2005).

FLIC scores have been found to be responsive to change in patients receiving high dose chemotherapy (Conner-Spayd et al., 2001).

To the best of our knowledge and that of other researchers (Wilson et al., 2005), minimally clinically important differences have not been published for the FLIC.

Reported patient acceptability of the FLIC is mixed, with one study reporting a high response rate of 94% (n=405) (Elliott et al., 2004) and another reporting poor compliance rates (Finkelstein et al., 1988).
Results: Other condition-specific PROMs in breast cancer

Several additional cancer-specific PROMs were identified by the search strategy, but there was insufficient evidence to include them in this review. These PROMs are listed in Table 2.

Table 2: Other cancer-specific PROMs not reviewed

<table>
<thead>
<tr>
<th>Instrument Name</th>
<th>No. records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer Chemotherapy Questionnaire (BCQ)</td>
<td>2</td>
</tr>
<tr>
<td>Breast Cancer Prevention Trial (BCPT) Symptom Scales/BCPT Symptom Checklist</td>
<td>4</td>
</tr>
<tr>
<td>Brief Cancer Impact Assessment (BCIA)</td>
<td>3</td>
</tr>
<tr>
<td>Cancer Behaviour Inventory (CBI)</td>
<td>1</td>
</tr>
<tr>
<td>Concerns about Recurrence Scale (CARS)</td>
<td>1</td>
</tr>
<tr>
<td>Experience of Breast Cancer Questionnaire (EBCQ)</td>
<td>1</td>
</tr>
<tr>
<td>Ferrans and Powers QoL Index – Cancer Version (QLI-CV)</td>
<td>1</td>
</tr>
<tr>
<td>Functional Assessment of Cancer Therapy – Breast Symptom Index (FBSI)</td>
<td>1</td>
</tr>
<tr>
<td>Impact of Cancer (IOC)</td>
<td>1</td>
</tr>
<tr>
<td>Linear Analogue Self-Assessment (LASA)</td>
<td>3</td>
</tr>
<tr>
<td>Lymphoedema and Breast Cancer Questionnaire</td>
<td>1</td>
</tr>
<tr>
<td>Quality of Life Breast Cancer Version (QOL-BC)</td>
<td>2</td>
</tr>
<tr>
<td>Quality of Life – Cancer Survivors (QOL-CS)</td>
<td>3</td>
</tr>
<tr>
<td>Supportive Care Needs Survey (SCNS)</td>
<td>2</td>
</tr>
</tbody>
</table>
SUMMARY OF EVIDENCE

Generic PROMs
Table 3 summarises the evidence of measurement and operational performance applying the adapted appraisal criteria of the generic PROMs identified in this review. Based on the volume and quality of evidence, the SF-36 is clearly the most promising generic health measure. The EQ-5D and SIP both have some evidence of good performance in women with breast cancer although the SIP may be more burdensome due to the large number of items. The EQ-5D has the advantage of generating a utility score.

The SF-36, although popular for measuring health status, does have limitations when utilised with breast cancer patients. Support for the psychometric properties of the SF-36 in this cohort is evident, but the evidence also makes it clear that this instrument is not sensitive enough to measure breast cancer-specific health status data. If used with breast cancer patients, it is recommended that an instrument specific to breast cancer is administered alongside the SF-36.

There is very little evidence supporting the psychometric properties of the SF-8 with breast cancer patients.

Cancer-specific PROMs
Table 4 summarises the evidence of measurement and operational performance applying the adapted appraisal criteria to the PROMs identified in these reviews.

The CARES-SF has been evaluated mainly with newly diagnosed breast cancer patients. Rehabilitation needs are likely to vary across age, disease severity, treatment type, and many more generic and disease-specific variables. Therefore, the CARES-SF needs ideally to be utilised across a more heterogeneous sample before its full potential can be accurately assessed.

The EORTC QLQ-C30 has been evaluated mainly with advanced and metastatic breast cancer patients. Furthermore, it is worth noting that site-specific modules can be added to the QLQ-C30 to gain insight into site-specific QoL. In the case of breast cancer, the appropriate module is BR23 although little evidence is reported to date.

The FACT-G has been utilised at different stages of disease and treatment as well as in a variety of interventional studies. With respect to breast cancer, a site-specific module can be added to the FACT-G, namely, the FACT-B. A further adjunct, the arm morbidity subscale FACT-B+4, can be used to capture the experience of patients affected by specific post-operative problems.

The FACT-B has also been utilised at different stages of disease and treatment as well as in a variety of interventional studies, proving itself to be especially appropriate within clinical settings due to its ease of administration and completion.

The FLIC was designed specifically for cancer patients undergoing treatment and is functionally oriented. Therefore, it might be most useful in clinical practice with patients who are expected to experience functioning difficulties, or in the monitoring of rehabilitation interventions.
The instruments included in this review have been used with recently diagnosed patients or patients undergoing treatment, principally to evaluate the effectiveness of interventions. However, as more patients are living longer following treatment, there is increasing interest in measuring quality of life among long-term survivors of cancer. In this context, our recommendations regarding generic instruments will likely remain appropriate, but the content of condition-specific instruments may lose face validity as the predicament of survivorship is different from that of undergoing treatment. There is evidence that the experiences of individuals who have survived cancer for some time are not completely captured by instruments focused on experiences surrounding diagnosis and treatment (Gotay and Muraoka, 1998). Pearce et al. (2008) identified and appraised several instruments which have been specifically developed for long-term survivors of cancer some of which have been evaluated with women with breast cancer. Currently, from a psychometric perspective, survivorship instruments are deemed to be limited. Avis and Foley (2006) found some positive evidence of responsiveness for a cancer survivor outcome measure, the Quality of Life in Adult Cancer Survivors (QLACS) Scale. Further consideration would be necessary if the health and well-being of the long-term survivors is to be measured routinely.

RECOMMENDATIONS
There are three main approaches to the measurement of patient-reported outcomes in people with cancer. The generic approach to health status measurement allows for comparison across health conditions; generic cancer measures are more focused on dimensions relevant to people with cancer; add-on modules focus on domains specific to the particular type of cancer. These three approaches are illustrated in the evidence found in this review.

The EORTC QLQ-C30 and FACT-G or FACT-B are shortlisted as promising cancer-specific PROMs for piloting in the NHS. The more generic FACT-G may be sufficient where the focus is on outcomes for individuals with a broad range of types of cancer, including cancer of the breast. The SF-36 and EQ-5D are recommended as generic measures, the EQ-5D particularly when a utility score is required. Attention may need to be given to longer term issues of survivorship if the full spectrum of cancer in the population is to be included in surveys using PROMs, although insufficient evidence was found to highlight specific measures for this review.
Table 3: Appraisal of psychometric and operational performance of generic PROMs for breast cancer

<table>
<thead>
<tr>
<th>Instrument (n studies)</th>
<th>SF-36 (35)</th>
<th>SF-8 (1)</th>
<th>SIP (2)</th>
<th>EQ-5D (3)</th>
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<tbody>
<tr>
<td>Reproducibility</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Internal consistency</td>
<td>++</td>
<td>0</td>
<td>+</td>
<td>n/a</td>
</tr>
<tr>
<td>Validity: Content</td>
<td>+++</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Construct</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>++</td>
<td>0</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Interpretability</td>
<td>+++</td>
<td>+++</td>
<td>0</td>
<td>+</td>
</tr>
<tr>
<td>Floor/ceiling/precision</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>+/-</td>
</tr>
<tr>
<td>Acceptability</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Feasibility</td>
<td>++</td>
<td>+</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Psychometric and operational criteria
0 not reported
— no evidence in favour
+ some limited evidence in favour
++ some good evidence in favour
+++ good evidence in favour
Table 4: Appraisal of psychometric and operational performance of condition-specific PROMs for breast cancer

<table>
<thead>
<tr>
<th>Instrument (n studies)</th>
<th>CARES-SF (6)</th>
<th>EORTC QLQ-C30 (16)</th>
<th>FACT-G (13)</th>
<th>FACT-B (21)</th>
<th>FLIC (8)</th>
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</thead>
<tbody>
<tr>
<td>Reproducibility</td>
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<td>0</td>
<td>+</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Internal consistency</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Validity: Content</td>
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<td>+++</td>
<td>+++</td>
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<td>+</td>
</tr>
<tr>
<td>Construct</td>
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<td>+++</td>
<td>+++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Interpretability</td>
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<td>++</td>
<td>++</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Floor/ceiling/precision</td>
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<td>0</td>
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<tr>
<td>Acceptability</td>
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</tr>
<tr>
<td>Feasibility</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>0</td>
</tr>
</tbody>
</table>

**Psychometric and operational criteria**

0  not reported
—  no evidence in favour
+  some limited evidence in favour
++ some good evidence in favour
+++ good evidence in favour
APPENDIX A: sources for PROM bibliography

1. AMED: Allied and Complementary Medicine Database
2. Biological Abstracts (BioAbs)
3. BNI: British Nursing Index Database, incorporating the RCN (Royal College of Nursing) Journals Database
4. CINAHL: Cumulative Index to Nursing and Allied Health Literature
5. Econlit - produced by the American Economic Association
6. EMBASE - produced by the scientific publishers Elsevier
7. MEDLINE - produced by the US National Library of Medicine
8. PAIS: Public Affairs Information Service
9. PsycINFO (formerly PsychLit) - produced by the American Psychological Association
10. SIGLE: System for Information on Grey Literature in Europe
11. Sociofile: Cambridge Scientific Abstracts Sociological Abstracts Database
12. In addition, all records from the journal ‘Quality of Life Research’ are downloaded via Medline.
PROM Bibliography search strategy\(^1\)

\textit{a. records to December 2005 (downloads 1-12)}

\((\text{acceptability or appropriateness or (component$ analysis) or comprehensibility or (effect size$) or (factor analys$) or (factor loading$) or (focus group$) or (item selection) or interpretability or (item response theory) or (latent trait theory) or (measurement propert$) or methodol$ or (multi attribute) or multiattribute or precision or preference$ or proxy or psychometric$ or qualitative or (rasch analysis) or reliabilit$ or replicability or repeatability or reproducibility or responsiveness or scaling or sensitivity or (standard gamble) or (summary score$) or (time trade off) or usefulness$ or (utility estimate) or valid$ or valuation or weighting$)}\)

\textit{and}

\((\text{(COOP or (functional status) or (health index) or (health profile) or (health status) or HRQL or HRQoL or QALYS$ or QL or QoL or (qualit$ of life) or (quality adjusted life year$) or SF-12 or SF-20 or SF?36 or SF-6) or ((disability or function or subjective or utilit$ or (well?being)) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire$ or profile$ or scale$ or score$ or status or survey$))) or (\text{(bibliograph$ or interview$ or overview or review) adj5 ((COOP or (functional status) or (health index) or (health profile) or (health status) or HRQL or HRQoL or QALYS$ or QL or QoL or (qualit$ of life) or (quality adjusted life year$) or SF-12 or SF-20 or SF?36 or SF-6) or ((disability or function or subjective or utilit$ or (well?being)) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire$ or profile$ or scale$ or score$ or status or survey$))))\)}

\textit{or}

\((\text{HRQL or HRQoL or QL or QoL or qualit$ of life or quality adjusted life year$ or QALYS$ or disability adjusted life year$ or DALYS$ or COOP or SF-12 or SF-20 or SF-36 or SF-6 or standard gamble or summary score$ or time trade off or health index or health profile or health status or ((patient or self$) adj (rated or reported or based or assessed)) or ((disability or function$ or subjective or utilit$ or well?being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire$ or profile$ or scale$ or score$ or status or survey$))))\)

\textit{b. records from January 2006 (download 13)}

\((\text{((acceptability or appropriateness or component$ analysis or comprehensibility or effect size$ or factor analys$ or factor loading$ or feasibility or focus group$ or item selection or interpretability or item response theory or latent trait theory or measurement propert$ or methodol$ or multi attribute or multiattribute or precision or preference$ or proxy or psychometric$ or qualitative or rasch analysis or reliabilit$ or replicability or repeatability or reproducibility or responsiveness or scaling or sensitivity or valid$ or valuation or weighting$)}\)

\textit{and}

\((\text{HRQL or HRQoL or QL or QoL or qualit$ of life or quality adjusted life year$ or QALYS$ or disability adjusted life year$ or DALYS$ or COOP or SF-12 or SF-20 or SF-36 or SF-6 or standard gamble or summary score$ or time trade off or health index or health profile or health status or ((patient or self$) adj (rated or reported or based or assessed)) or ((disability or function$ or subjective or utilit$ or well?being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire$ or profile$ or scale$ or score$ or status or survey$))))\)

\textit{or}

\((\text{((bibliograph$ or interview$ or overview or review) adj5 (HRQL or HRQoL or QL or QoL or qualit$ of life or quality adjusted life year$ or QALYS$ or disability adjusted life year$ or DALYS$ or COOP or SF-12 or SF-20 or SF-36 or SF-6 or standard gamble or summary score$ or time trade off or health index or health profile or health status or ((patient or self$) adj (rated or reported or based or assessed)) or ((disability or function$ or subjective or utilit$ or well?being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire$ or profile$ or scale$ or score$ or status or survey$))))\)}

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\(^1\) Note: the bibliography includes approximately 1,650 hand searched additions.
APPENDIX B: Psychometric criteria

Appraisal of PROMs

The methods that will be used for assessing the performance of PROMs were developed and tested against multidisciplinary consensus and peer review. They focus on explicit criteria to assess reliability, validity, responsiveness, precision, acceptability, and feasibility. A pragmatic combination of the criteria developed and used in previous reports to DH by the Oxford and LSHTM groups will be used.

The appraisal framework focuses on psychometric criteria and PROMs must fulfil some or all to be considered as a short-listed instrument. Practical or operational characteristics are also assessed (acceptability and feasibility).

Once evidence has been assessed for eligibility, records considered as inclusions will be assembled for each PROM identified. Measurement performance and operational characteristics will be appraised independently by two reviewers using the following rating scale, and inter-rater reliability calculated.

Psychometric evidence:
- = evidence does not support criteria
0 = not reported or no evidence in favour
+ = some limited evidence in favour
++ = some good evidence in favour, but some aspects do not meet criteria or some aspects not reported
+++ = good evidence in favour

PROMs for which there are strong psychometric properties will be judged in terms of operational characteristics and clinical credibility.
### Appraisal criteria (adapted from Smith et al., 2005 and Fitzpatrick et al., 1998; 2006)

<table>
<thead>
<tr>
<th>Appraisal component</th>
<th>Definition/test</th>
<th>Criteria for acceptability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reliability</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test-retest reliability</td>
<td>The stability of a measuring instrument over time; assessed by administering the instrument to respondents on two different occasions and examining the correlation between test and retest scores</td>
<td>Test-retest reliability correlations for summary scores ≥0.70 for group comparisons</td>
</tr>
<tr>
<td>Internal consistency</td>
<td>The extent to which items comprising a scale measure the same construct (e.g. homogeneity of items in a scale); assessed by Cronbach’s alpha’s and item-total correlations</td>
<td>Cronbach’s alphas for summary scores ≥0.70 for group comparisons. Item-total correlations ≥ 0.20</td>
</tr>
<tr>
<td><strong>Validity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Content validity</td>
<td>The extent to which the content of a scale is representative of the conceptual domain it is intended to cover; assessed qualitatively during the questionnaire development phase through pre-testing with patients. Expert opinion and literature review</td>
<td>Qualitative evidence from pre-testing with patients, expert opinion and literature review that items in the scale represent the construct being measured. Patients involved in the development stage and item generation</td>
</tr>
<tr>
<td>Construct validity</td>
<td>Evidence that the scale is correlated with other measures of the same or similar constructs in the hypothesised direction; assessed on the basis of correlations between the measure and other similar measures</td>
<td>High correlations between the scale and relevant constructs preferably based on a priori hypothesis with predicted strength of correlation. Statistically significant differences between known groups and/or a difference of expected magnitude</td>
</tr>
<tr>
<td></td>
<td>The ability of the scale to differentiate known-groups; assessed by comparing scores for sub-groups who are expected to differ on the construct being measured (e.g. a clinical group and control group)</td>
<td></td>
</tr>
<tr>
<td>Responsiveness</td>
<td>The ability of a scale to detect significant change over time; assessed by comparing scores before and after an intervention of known efficacy (on the basis of various methods including t-tests, effect sizes (ES), standardised response means (SRM) or responsiveness statistics</td>
<td>Statistically significant changes on scores from pre to post-treatment and/or difference of expected magnitude</td>
</tr>
<tr>
<td>Floor/ceiling effects</td>
<td>The ability of an instrument to measure accurately across full spectrum of a construct</td>
<td>Floor/ceiling effects for summary scores &lt;15%</td>
</tr>
<tr>
<td><strong>Practical properties</strong></td>
<td>Acceptability</td>
<td>Acceptability of an instrument reflects respondents’ willingness to complete it and impacts on quality of data</td>
</tr>
<tr>
<td></td>
<td>Feasibility/burden</td>
<td>The time, energy, financial resources, personnel or other resources required of respondents or those administering the instrument</td>
</tr>
</tbody>
</table>
APPENDIX C: Generic PROMs

1. **SF-36: Medical Outcomes Study 36-item Short Form Health Survey (Ware and Sherbourne, 1992; Ware et al., 1994; Ware, 1997)**
   The Medical Outcomes Study (MOS) Short Form 36-item Health Survey (SF-36) is derived from the work of the Rand Corporation during the 1970s (Ware and Sherbourne, 1992; Ware et al., 1994; Ware, 1997). It was published in 1990 after criticism that the SF-20 was too brief and insensitive. The SF-36 is intended for application in a wide range of conditions and with the general population; the instrument captures both mental and physical aspects of health. International interest in this instrument is considerable, and it is by far the most widely evaluated measure of health status (Garratt et al., 2002).

   Items were derived from several sources, including extensive literature reviews and existing instruments (Ware and Sherbourne, 1992; Ware and Gandek, 1998; Jenkinson and McGee, 1998). The original Rand MOS Questionnaire (245 items) was the primary source, and several items were retained from the SF-20. The 36 items assess health across eight domains (Ware, 1997), namely Physical Functioning (PF: ten items), Role limitation due to Physical health problems (RP: four items), Bodily Pain (BP: two items), General Health perception (GH: five items), Vitality (VT: four items), Social Functioning (SF: two items), Role limitation due to Emotional health problems (RE: three items), and Mental Health (MH: five items). An additional health transition item, not included in the final score, assesses change in health compared with one year ago.

   There are between three and six categorical response options for each item. Scoring uses a weighted scoring algorithm and a computer-based programme is recommended. Eight domain scores give a health profile; scores are transformed into a scale from 0 to 100, where 100 denotes the best health. Scores can be calculated when up to half of the items are omitted. Two component summary scores for physical and mental health (PCS and MCS, respectively) can also be calculated. The SF-36 can be self-, interview-, or telephone-administered.

2. **Medical Outcome Short Form 8-Item Health Survey (SF-8)**
   The SF-8 was devised to provide a shorter alternative to the SF-36 for use in large surveys of general and specific populations; it was constructed on the basis of empirical studies linking each item to a comprehensive pool of widely used questionnaire items proven to measure the same concept (Ware et al., 2001). The measure comprises eight subscales, each with a single item, namely Physical Functioning, Role limitation-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role limitation-Emotional, and Mental Health. The SF-8 is scored using a normative algorithm, based on a general US population. There are five or six possible responses to each item, covering the previous four weeks, and responses are weighted based on the algorithm. Two component summary scores for physical and mental health (PCS and MCS, respectively) can also be calculated.

3. **Sickness Impact Profile (Bergner et al., 1976; revised: Bergner et al., 1981)**
   The Sickness Impact Profile (SIP) was developed in the USA to provide a broad measure of self-assessed health-related behaviour (Bergner et al., 1976; Bergner et al., 1981). It was intended for a variety of applications, including programme planning and assessment of patients, and to inform policy decision-making (Bergner et al., 1976; Bergner et al., 1981; McDowell and Newell, 1996).
Instrument content was informed by the concept of ‘sickness’, which was defined as reflecting the change in an individual’s activities of daily life, emotional status, and attitude as a result of ill-health (McDowell and Newell, 1996). Item derivation was based on literature reviews and statements from health professionals, carers, patient groups, and healthy subjects describing change in behaviour as a result of illness. The SIP has 136 items across 12 domains: Alertness Behaviour (AB: ten items), Ambulation (A: 12 items), Body Care and Movement (BCM: 23 items), Communication (C: nine items), Eating (E: nine items), Emotional Behaviour (EB: nine items), Home Management (HM: ten items), Mobility (M: ten items), Recreation and Pastimes (RP: eight items), Sleep and Rest (SR: seven items), Social Interaction (SI: 20 items), and Work (W: nine items).

Each item is a statement. Statements that best describe a respondent’s perceived health state on the day the instrument is completed are ticked. Items are weighted, with higher weights representing increased impairment. The SIP percentage score can be calculated for the total SIP (index) or for each domain, where 0 is better health and 100 is worse health. Two summary scores are calculated: Physical Function (SIP-PhysF), a summation of A, BCM, and M, and Psychosocial Function (SIP-PsychF), a summation of AB, C, EB, and SI. The five remaining categories are scored independently. The instrument may be self- or interview-administered.

Preference-based generic measure

1. European Quality of Life instrument, EQ-5D (The EuroQol Group, 1990; Brazier et al., 1993)

The European Quality of Life instrument (EuroQol), now generally known as the EQ-5D, was developed by researchers in five European countries to provide an instrument with a core set of generic health status items (The EuroQol Group, 1990; Brazier et al., 1993). Although providing a limited and standardized reflection of HRQoL, it was intended that use of the EuroQol would be supplemented by disease-specific instruments. The developers recommend the EuroQol for use in evaluative studies and policy research; given that health states incorporate preferences, it can also be used for economic evaluation. The EuroQol can be self or interview-administered.

Existing instruments, including the Nottingham Health Profile, Quality of Well-Being Scale, Rosser Index, and Sickness Impact Profile were reviewed to inform item content (The EuroQol Group, 1990). There are two sections to the EuroQol: the EQ-5D and the EQ thermometer. The EQ-5D assesses health across five domains: Anxiety/Depression (AD), mobility (M), Pain/Discomfort (PD), Self-Care (SC), and Usual Activities (UA). Each domain has one item and a three-point categorical response scale; health ‘today’ is assessed. Weights based upon societal valuations of health states are used to calculate an index score of –0.59 to 1.00, where –0.59 is a state worse than death and 1.00 is maximum well-being. A score profile can be reported. The EQ thermometer is a single 20cm vertical visual analogue scale with a range of 0 to 100, where 0 is the worst and 100 the best imaginable health.
## GENERIC INSTRUMENTS DOMAINS AND SCORING

### Table 5: Domains and Scoring

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Domains (No. Items)</th>
<th>Response options</th>
<th>Score</th>
<th>Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SF-36</strong></td>
<td>Physical functioning (PF) (10), Role limitation-Physical (RP) (4), Bodily Pain (BP) (2), General Health (GH) (5), Vitality (VT) (4), Social Functioning (SF) (2), Role limitation-Emotional (RE) (3), Mental Health (MH) (5); health transition (1)</td>
<td>Categorical: 3-6 options Recall: standard 4 weeks, acute 1 week</td>
<td>Algorithm Domain profile (0-100, 100 best health) Summary scores: Physical Component (PCS) and Mental Component (MCS) (mean 50, sd 10).</td>
<td>Interview or self. 5-10 mins.</td>
</tr>
<tr>
<td><strong>SF-8</strong></td>
<td>One item for each of 8 subscales: PF, RP, BP, GH, VT, SF, RE, MH (see SF-36 above).</td>
<td>Categorical: 5-6 options Recall: 4 weeks</td>
<td>Algorithm Summary scores: PCS and MCS (see SF-36 above)</td>
<td>Interview or self. 1-2 mins.</td>
</tr>
<tr>
<td><strong>SIP</strong></td>
<td>Alertness behaviour (AB) (10), Ambulation (A) (12), Body care and movement (BCM) (23), Communication (C) (9), Eating (E) (9), Emotional behaviour (EB) (9), Home management (HM) (10), Mobility (M) (10), Recreation and pastimes (RP) (8), Sleep and rest (SR) (7), Social interaction (SI) (20), Work (W) (9)</td>
<td>Applicable statements checked. Items weighted: higher weights indicate increased impairment Recall: current health</td>
<td>Algorithm Domain profile (0-100%, 100 worst health); Index (0-100%) Summary: Physical (A, BCM, M), Psychosocial function (AB, C, EB, SI)</td>
<td>Interview (range: 21-33) Telephone: PF only (11.5) Self (19.7)</td>
</tr>
<tr>
<td><strong>EQ-5D</strong></td>
<td>EQ-5D: Anxiety/Depression (1), Mobility (1), Pain/Discomfort (1), Self-Care (1), Usual Activities (1). EQ-thermometer: Global health (1)</td>
<td>EQ-5D: Categorical: 3 options - 1 (no problems), 2 (some problems), and 3 (severe problems) EQ-thermometer: VAS current health.</td>
<td>EQ-5D: Summation: responses scored for each individual health state, then multiplied by the duration of time in that health state to obtain utility index (-0.59-100, where -0.59 is a state worse than death and 1.00 is maximum well-being). EQ-thermometer: VAS (0-100, 100 representing best imaginable health).</td>
<td>Interview or self.</td>
</tr>
</tbody>
</table>
Table 6: Summary of generic instruments: health status domains (after Fitzpatrick et al., 1998)

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Physical function</th>
<th>Symptoms</th>
<th>Global judgement of health</th>
<th>Psychological well-being</th>
<th>Social well-being</th>
<th>Cognitive functioning</th>
<th>Role activities</th>
<th>Personal constructs</th>
<th>Satisfaction with care</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-36</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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</tr>
<tr>
<td>SF-8</td>
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<td>x</td>
<td>x</td>
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<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
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<td>x</td>
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<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
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<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>
APPENDIX D: Cancer-specific PROMs

1. Cancer Rehabilitation Evaluation System – Short-Form (CARES-SF)
The CARES-SF was derived directly from the 139-item version of the CARES (originally the Cancer Inventory of Problem Situations, CIPSI), which has well-documented and sound psychometric properties (Ganz et al., 1990; Schag et al., 1990). Empirical data and clinical considerations were used to develop an instrument that was clinically useful and valid in documenting rehabilitation problems and quality of life. An effort was made to retain representation in all content domains of the original CARES whilst reducing respondent burden; this process was assisted by data from previous research and analyses on the psychometric properties of the long form. Four cancer professionals reviewed the data independently to confirm the content validity of the short form (Schag et al., 1991). The scale consists of 59 items, which together generate a single global score as well as five sub-scores representing the following domains: physical, psychosocial, marital, and sexual functioning, and medical interaction. The CARES-SF rates the degree to which a given problem applied during the four weeks prior to the measure being administered. Scoring is based on a 5-point Likert scale from 0 (not at all) to 4 (very much), with higher scores indicating greater difficulty or impairment.

2. European Organization for Research and Treatment of Cancer core Quality of Life Questionnaire (EORTC QLQ-C30)
The EORTC QLQ-C30 (Aaronson et al., 1993) is a 30-item questionnaire composed of five multi-item functional subscales: physical, role, cognitive, emotional and social functioning; three multi-item symptom scales: fatigue, nausea/vomiting and pain; a global health/QoL subscale; and six single items assessing other cancer-related symptoms - dyspnoea, sleep disturbance, appetite, diarrhoea and constipation - and the financial impact of cancer. The questionnaire employs 28 four-point Likert scales with responses from ‘not at all’ to ‘very much’, and two seven-point Likert scales for the global health and QoL domain; total scores range from 0 to 100. For functional and global QoL scales, higher scores represent a better level of functioning. For symptom-oriented scales, a higher score represents more severe symptoms. Extensive patient input during an international field study contributed to the development of the QLQ-C30, initially with lung cancer patients (Aaronson et al., 1993) and subsequently with patients with heterogeneous diagnoses (Osoba et al., 1994). Content validity of the QLQ-C30 has been maintained via modifications to improve the content, specifically in terms of the Role Functioning scale and a conceptual difficulty (undue emphasis on physical functioning) in the global QoL scale (Osoba et al., 1997).

3. EORTC Breast Cancer module (EORTC QLQ-BR23)
The EORTC breast cancer module comprises 23 items on areas relevant to patients with breast cancer that are not, or not sufficiently, covered by the core questionnaire; it should be noted that the module is designed to be used in conjunction with the EORTC QLQ-C30 and not as a free-standing instrument (Sprangers et al., 1996). Items were derived from literature searches, reviews of existing questionnaires, and interviews with patients and medical specialists; a provisional 35-item module was pre-tested with Dutch and Danish patient samples. The revised, 23-item version was tested for reliability and validity with Dutch, Spanish, and American breast cancer patients at different stages of treatment. The EORTC QLQ-BR 23 consists of two functional scales (body image and sexuality), three symptom subscales (arm/hand, breast, and systemic side-effects), and single items covering sexual enjoyment, distress at hair loss, and future perspective.
4. Functional Assessment of Cancer Therapy – General (FACT-G)
The 27-item FACT-G (Cella et al., 1993) measures global health-related QoL and four different dimensions of QoL (i.e. physical, social, emotional, and functional well-being). The instrument is considered appropriate for use with any form of cancer and there are a number of scales that can be added to the FACT-G in order to measure disease- and treatment-specific components of the cancer experience. Answers are provided on a scale of ‘Not at all; A little; Somewhat; Quite a bit; Very Much’, in the context of the previous seven days. Items are scored from 0-4, with negatively-phrased items requiring reverse response scores. Higher scores represent better well-being on each of the dimensions or better global QoL when combined. Items were generated using semi-structured interview input from cancer patients and oncology specialists. Patients first completed other QoL questionnaires in order to provide them with insight into potential QoL issues of relevance to them, whilst the specialists reviewed these instruments and endorsed any items they felt were important, as well as highlighting any QoL issues they felt were not covered in these instruments. Pilot testing and data reduction were conducted (Cella et al., 1993).

5. Functional Assessment of Cancer Therapy – Breast (FACT-B)
The FACT-B is a 10-item breast cancer specific module that supplements the Functional Assessment of Cancer Therapy – General (FACT-G) (Brady et al., 1997). The 10 items are added to the 27 core items of the FACT-G, yielding a 37-item questionnaire. The FACT-B consists of five subscales: physical wellbeing (PW, 7 items), social and family wellbeing (SW, 7 items), emotional wellbeing (EW, 6 items), functional wellbeing (FW, 7 items) and the Breast Cancer subscale (BCS, 10 items). Scores can be produced through three different calculations, namely, a combined total of all domains (FACT-B total), the Breast Cancer Score (BCS), and a Treatment Outcome Index (TOI) calculated by summing the FACT-G physical and functional domains and the BCS. Answers are provided on a scale of ‘Not at all; A little; Somewhat; Quite a bit; Very Much’, in the context of the previous seven days. Items are scored from 0-4, with negatively-phrased items requiring reverse response scores. Higher scores represent better well-being or QoL. A 4-item arm morbidity subscale has been developed for use in conjunction with the FACT-B: the FACT-B+4; the four arm morbidity items were selected following consultation with breast cancer health professionals and breast cancer patients (Coster et al., 2001).

6. Functional Living Index – Cancer (FLIC)
Also known as the Manitoba Functional Living Questionnaire, the FLIC (Schipper et al., 1984) is a functionally oriented QoL instrument comprising 22 items in five subscales, namely, physical well-being and ability, emotional state, sociability, family situation, and nausea. Questions are answered using a 7-point Likert-type linear analogue scale with the respondent marking the answer with a vertical line on the continuum. Each interval is divided in half and the responses scored to the nearest whole number; higher scores indicate higher QoL. An overall score is derived by summing all items, the minimum being 0 and the maximum 154. The FLIC was developed initially by a team of patients and their spouses, and health-care and oncology specialists (Clinch, 1996) before being validated longitudinally on 837 cancer patients (Schipper et al., 1984). This was followed by a pilot study with lung cancer patients aimed at testing the feasibility and sensitivity of the instrument; sensitivity of the instrument to change was confirmed but problems with compliance were identified (Finkelstein et al., 1988).
## CANCER-SPECIFIC INSTRUMENTS DOMAINS AND SCORING

### Table 7: Domains and Scoring

<table>
<thead>
<tr>
<th>Instrument name (total no. items)</th>
<th>Domains (no. items)</th>
<th>Response options</th>
<th>Scoring</th>
<th>Mode of administration Completion time</th>
<th>Licensing information</th>
</tr>
</thead>
</table>
| CARES-SF (59)                    | Set of problem statements in five domains:  
- Physical – incl. role activities, pain (10)  
- Psychosocial, incl. cognitive problems, body image (17)  
- Medical interaction (4)  
- Marital (6)  
- Sexual (3)  
Plus, 19 miscellaneous items:  
- treatment-related (7)  
- dating (2)  
- compliance (1)  
- economic barriers (3)  
- evacuation (3)  
- prosthesis (1)  
- weight gain (1)  
- transportation (1) | 5-point Likert scale from 0=not at all (no problem) to 4=very much (severe problem) | Global score, and subscale scores          | Self-administration 11 mins             | -                     |
| **European Organization for Research and Treatment of Cancer Quality of Life core Questionnaire, EORTC QLQ-C30 (30)** | Global health status/QoL (2)  
*Functional scales:*  
- Physical functioning (5)  
- Role functioning (2)  
- Cognitive functioning (2)  
- Emotional functioning (4)  
- Social functioning (2)  
*Symptom scales:*  
- Fatigue (3)  
- Nausea & vomiting (2)  
- Pain (2)  
- Dyspnoea (1)  
- Insomnia (1)  
- Appetite loss (1)  
- Constipation (1)  
- Diarrhoea (1)  
- Financial difficulties (1)  
  4-point Likert scales where 1=not at all (best), 4=very much (worst).  
  7-point Likert scales for global health and overall QoL questions, where 1=very poor, 7=excellent  
  Except for PF, responses are based on the past week  
  Subscale scores transformed into 0-100 scores using an algorithm. Higher scores on functional scales and global items indicate better functioning; higher scales on symptom scales indicate worse symptomatology. Aggregation of subscale scores not recommended by developers.  
  11 mins  
  No charge for use in academic settings, but written consent required for each study. Royalty fee, based on no. of patients, payable for commercial studies. |  
| **EORTC BR23 (30+23)** | EORTC core questionnaire (see above) plus 23 breast cancer items:  
- body image (4)  
- sexual functioning (3)  
- sexual enjoyment (1)  
- future perspective (1)  
4 symptom subscales:  
- breast (4)  
- arm (3)  
- systemic side-effects (7)  
- upset by hair loss (1)  
  4-point Likert scales where 1=not at all (best), 4=very much (worst)  
  Responses based on the past week  
  As QLQ-C30 above  
  15 mins  
  As QLQ-C30 above  
  As QLQ-C30 above |
| **Functional Assessment of Cancer Therapy – General version, FACT-G (27)** | Four domains:  
- Physical Well-being / symptoms, PW (7)  
- Social / family Well-being, SW (7)  
- Emotional Well-being, EW (6)  
- Functional Well-being / personal constructs, FW (7) | 5-point Likert scales, where 0=not at all, 4=very much  
Responses based on the past seven days | Higher scores represent better well-being / global QoL. Negatively-phrased items require reverse response scores.  
Three scoring options:  
- subscale  
- overall total  
- Trial Outcome Index (TOI): PW + FW | Interview, telephone, or self-administration.  
Computerised modes of administration under development | Use of English versions of FACT/FACIT measures is free of charge, on condition of sharing data. Users must complete an agreement and submit project information for each study. |
| **FACT-B (27+10)** | Four subscales of the FACT-G (see above) plus Breast Cancer Subscale, BCS (10) | As FACT-G above | Higher scores represent better well-being / global QoL. Negatively-phrased items require reverse response scores.  
Three possible scoring options:  
- combined total all domains (FACT-B total)  
- BCS only  
- Treatment Outcome Index (TOI) = sum of FACT-G PW + FW + BCS | As FACT-G above 10-15 mins | As FACT-G above |
| **FLIC** | 22 items covering:  
- Physical well-being / ability  
- Emotional state  
- Sociability  
- Family situation  
- Nausea | 7-point Likert-type linear analogue scale  
1=worst, 7=best rating | Overall score produced by summing all items; minimum=0, maximum=154 | Self-administration  
<10 mins | - |
Table 8: Summary of cancer-specific instruments: health status domains (after Fitzpatrick et al., 1998)

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Instrument domains</th>
<th>Physical function</th>
<th>Symptoms</th>
<th>Global judgement of health</th>
<th>Psychological well-being</th>
<th>Social well-being</th>
<th>Cognitive functioning</th>
<th>Role activities</th>
<th>Personal constructs</th>
<th>Satisfaction with care</th>
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</thead>
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<tr>
<td>CARES-SF</td>
<td></td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
<td></td>
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<td>EORTC QLQ-C30</td>
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<td>x</td>
<td>x</td>
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<td>x</td>
<td>x</td>
<td></td>
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<tr>
<td>EORTC QLQ-BR23*</td>
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<td>(x)</td>
<td>x</td>
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<td>x</td>
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<td>x</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

* crosses in bold indicate content of the breast cancer-specific module; crosses in brackets are covered by the core questionnaire
APPENDIX E: PROM licensing and contact details

European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
EORTC Headquarters
Quality of Life Department
Ave. E. Mounier 83, B.11
1200 Brussels Belgium
Fax: +32 (0)2 779 45 68
Tel: +32 (0)2 774 1678
E mail: ken.cornelissen@eortc.be
http://groups.eortc.be/qol/questionnaires qlqc30.htm
http://groups.eortc.be/qol/questionnaires_modules.htm

Functional Assessment of Cancer Therapy – General Version (FACT-G)
FACIT.org
381 South Cottage Hill Ave
Elmhurst, IL 60126 USA
Tel: (+1) 877 828 3228
Fax: (+1) 630 279 9465
E mail: information@facit.org
http://www.facit.org/qview/qlist.aspx
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Lemieux J, Beaton DE, Hogg-Johnson S, Bordeleau LJ, Goodwin PJ. Three methods for minimally important difference: no relationship was found with the net proportion of patients improving. *Journal of Clinical Epidemiology* 2007; 60(5):448-455.


Osoba D, Aaronson NK, Zee B, Sprangers MAG, Te Velde A. Modification of the EORTC QLQ-C30 (version 2.0) based on content validity and reliability testing in large samples of patients with cancer. *Quality of Life Research* 1997; 6(2):103-108.


