EVIDENCE SYNTHESIS

Reliability, validity and feasibility of quality of life instruments for adult patients with cancer undergoing chemotherapy: result from a systematic review

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Abstract

Aim The aim of this review was to analyse the literature critically and present the best available evidence related to quality of life (QoL) instruments that consists of all four subscales of physical, psychological, social and spiritual, which can be used in the clinical setting to assess adult patients with cancer on chemotherapy.

Inclusion criteria This review included randomised control trials and observational studies without control group related to QoL instruments used for cancer chemotherapy. The types of participants for this review included all adults with cancer over the age of 18 years who have undergone chemotherapy. The QoL instruments for this review included instruments that consist of all subscales of physical, psychological, social and spiritual. In order to retrieve QoL instruments that were current and not outdated, this review included studies reported in the recent 10 years.

Search strategy A three-step search strategy was utilised to search for primary research articles published in the English language from January 1998 to December 2009. An initial search of MEDLINE and CINAHL was undertaken followed by analysis of the text words contained in the title and abstract, and the text terms used to describe the article. A second search strategy using all the identified keywords and the index terms was used for the 20 databases. The third search strategy was to search for additional studies from the relevant list of all identified articles.

Methodological quality The two independent reviewers appraised the included articles for methodological quality using the modified Elliot tool for reliability and validity.

Results A total of 3149 references was retrieved during the initial search. Only 13 articles with validation of the QoL instruments that contained all the four subscales of physical, psychological, social and spiritual were included in this review. Four QoL instruments were identified. These include the City of Hope QOL – Ovarian Cancer Tool (QOL-OVCA), QOL-Breast cancer version (QOL-BC), New India QoL tool and QoL Index-Cancer version (QLI-CV). Among the four identified QoL instruments, the frequency of assessment was more than once for QLI-CV, with intervals of 2 weeks to 6 months. Regarding the number of items, the QOL-BC instrument has the most number of items. All identified QoL instruments have content validity done. For reliability examination, all the identified QoL instruments have Cronbach’s alpha of 0.7 and above for subscales. The correlation between subscales scores and overall QoL score was 0.53–0.93, 0.39–0.95 and 0.65–0.83 for QOL-OVCA, QOL-BC and QLI-CV, respectively.

Conclusion In this review, there was one article on development of new QoL instrument, the New India QoL tool, which has comprehensive validity examinations – the least number of items that may be useful in the clinical setting but need further psychometric testing in different settings or languages. The QLI-CV instrument has had comprehensive intra- and inter-method validation on different languages, different cultural settings and various types of cancer. However, the instrument may not be feasible because the method to calculate the QoL score is not straightforward.

Key words: cancer, chemotherapy, quality of life, reliability, validity.

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Background

Chemotherapy is one of the treatments that destroy cancer cells, sometimes referred to as ‘anti-cancer’ drugs or ‘antineoplastics’. Chemotherapy act as biologic response modifiers, hormone therapy or monoclonal antibodies to treat cancer. Chemotherapy can be prescribed as neoadjuvant or adjuvant. Neoadjuvant chemotherapy is prescribed prior to surgery to diminish tumour mass. Adjuvant chemotherapy is prescribed post surgery to eliminate occult micrometastatic disease, hoping to increase disease-free survival.

The use of chemotherapeutic agents for treatment of cancer has expanded widely with multiple potent agents being administered at higher but more tolerable doses. The majority of these patients receive several cycles of chemotherapy over a period of months, resulting in a toxic physiologic environment that causes adverse effects including fatigue, alopecia and potentially life-threatening neutropenia. The incidence of adverse effects will continue to increase as more aggressive chemotherapy continues to be used more frequently. These adverse effects of chemotherapy can be severe, such as anaemia, neurological injury, or cognitive decline and may lead to a significant impact on the patients’ quality of life (QoL).

The World Health Organization defines QoL as an individual’s perception of their position in life, in the context of the culture and values systems in their life, and in relation to their goals, expectations, standards and concerns. It is a broad concept, incorporating a person’s physical health, psychological state, level of independence, social relationships, personal beliefs and relationship to salient features of the environment. Quality of life is intrinsic and subjective, which is influenced by the individual’s personal values and life experiences. Hence, measurement of QoL is to evaluate the patient’s aspects of life including emotional, physical, functional, social, financial and spiritual status. These factors are important to the individual as well as a society and are integral in describing overall QoL. QoL instruments for patients with cancer that were developed before the 1980s, majority were focused on patients’ functional status and emotional aspects. For a decade, most experts in the QoL for oncology patients suggested that the subscales of physical, psychological, social and spiritual for patients with cancer, in which used QoL instruments that consist of physical, psychological, social and spiritual psychometric properties, was identified. This systematic review aims to fill that gap.

The QoL instruments that encompass all four subscales of physical, psychological, social and spiritual for cancer patients were developed and published in the 1970s–1990s (the late twentieth century). This systematic review intended to focus on studies reported in the recent 10 years, which used QoL instruments that consist of physical, psychological, social and spiritual for patients with cancer, in order to retrieve instruments that were current and not outdated.

This systematic review was undertaken to determine the reliability, validity and feasibility of QoL instruments for cancer patients. In this effort, the authors of this review hope to gather information to help clinicians when selecting a valid and reliable instrument for use in clinical practice. In addition, the instruments selected must be easy to use and interpret whilst not being a burden to clinicians or patients.

Validity and reliability are necessary when assessing an instrument. Validity is the accuracy of the instrument to measure what it claims to measure. Validity of an instrument is assessed by establishing evidence about the structure and content of the instrument, factor analysis or statistical evidence of relationships between variables. Content validity process is the evidence of content of the instrument being examined by experts in QoL or oncology, and cancer patients. Content of instrument that is examined by experts alone is considered incomplete validity. Content validity also can be established by statistical analysis of relationships between variables, or factor analysis, or comparing the findings by using more than one QoL instrument to the

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same groups of participants. A weak relationship is when the correlation coefficients are 0.10–0.30, whilst correlation coefficients of more than 0.50 indicate a strong inter-instrument relationship. When comparing with other instruments, validity is supported if there are similar changes in each participant’s scores for both instruments. Factor analysis examines correlations of variables within a set of items in the instrument. The items are considered acceptable and to be retained if the Eigenvalues of the factor analysis are greater than 1.0, which represent the amount of the total variance explained by these items. Kaiser–Meyer–Olkin (KMO) and Bartlett’s test of sphericity are tests to examine the adequacy of sampling. Kaiser–Meyer–Olkin Values of 0.6 or above in the factor analysis are acceptable, and values that are closer to 1 are considered better. Bartlett’s test of sphericity is considered appropriate if $P < .05$.

Reliability refers to the consistency and stability of the instrument to produce the same result on repeated measures. Reliability of instrument is usually assessed by Cronbach’s alpha or Guttman split-half to test for homogeneity; test–retest to test for stability; and inter-rater to test for equivalence. Cronbach’s alpha is the most common statistical test of an instrument with Likert-type response levels. Values of Cronbach’s alpha between 0.7 and 0.9 indicate good reliability, and are excellent if above 0.9. Guttman split-half reliability is to divide the instrument into half, and tests the consistency of the two divided sets of instrument items. The instrument is considered reliable if the correlation coefficients of the two sets of items are similarly equal. Test–retest reliability is to test the consistency of the instrument on two or more separate occasions to the same participants. These separate occasions’ scores are compared and expressed as ‘Pearson’. Value of Pearson correlation that is above 0.70 is considered a reliable instrument. A reliability correlation of 0.89 or above indicates little measurement error of the instrument, 0.49 reflects a high measurement error and a correlation that is closer to zero reflects no significant relationship between two scores. Feasibility was examined by the time taken to complete answering the instrument, number of items in the instrument, ease of use, method on calculation of scoring, language used, whether it needs translation. This is important in the clinical setting to consider cost of training, language translation or manpower, and time.

In this review, reliability analysis was categorised into intra- and inter-method reliability. Reliability analysis that examines the ability to produce similar results when applying two different QoL instruments, or same instrument but in different languages on the same population, was categorised as inter-method reliability in this review, which is more accurate. Reliability analysis that examines the reproducibility of a QoL instrument, which is by applying single instrument to the same population at different time intervals in this review, was categorised as intra-method reliability.

**Objectives**

The objective of this review was to analyse the literature critically and present the best available evidence related to QoL instruments that consist of all four subscales of physical, psychological, social and spiritual, which can be used in the clinical setting to assess adult patients with cancer on chemotherapy.

Questions to be answered were:

1. What is the available QoL instruments that can be used to assess adult cancer patients undergoing chemotherapy?
2. What are the reliability and validity of identified QoL instruments for adult cancer patients undergoing chemotherapy?
3. What is the optimal frequency of assessment using identified QoL instruments?
4. What is the feasibility of the use of identified QoL instruments by clinicians?

**Criteria for considering studies for this review**

Studies that met the following inclusion criteria were included in the systematic review:

- **Type of studies**
  
  This review included randomised control trials (RCTs) and observational studies without control group related to QoL instruments that contained all four subscales of physical, psychological, social and spiritual used for cancer chemotherapy.

- **Type of participants**
  
  This systematic review included all adults with cancer over the age of 18 years who have undergone chemotherapy.

- **Type of interventions**
  
  This review considered studies of QoL instruments that contained all four subscales of physical, psychological, social and spiritual used in conjunction with cancer chemotherapy.

- **Type of outcome measures**
  
  The primary outcomes included were:
  - Number of QoL instruments used in conjunction with cancer chemotherapy
  - Validity and reliability of the QoL instruments that consist of all subscales of physical, psychological, social and spiritual
  - The types of measures or scale used, which consist of all subscales of physical, psychological, social and spiritual

  The secondary outcomes included were frequency of assessment, and the suitability of the QoL instrument for use in the clinical setting. The suitability of the instruments to be included were to fulfil the following characteristics:
  - Short
  - Easy to use
  - Multidimensional
  - Prospective design
  - Not burdensome
  - Easy to score and interpret
  - Clearly defined end points
  - Sensitive to changes in patient’s health status

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• Capable of international and cross-cultural standardisation
• Contain global questions regarding the cancer experience
• Captures cancer-specific morbidity
• Captures cancer treatment-specific morbidity
• Self-administered
• Standardised, reliable and valid
• Measures distress in addition to frequency and degree
• Captures baseline status and can be administered longitudinally

Search strategy

The search strategy aimed to find both published and unpublished studies in the English language only. A search strategy was developed to guide the systematic review. A three-step search strategy was utilised in each component of this review. An initial search of MEDLINE and CINAHL was undertaken followed by analysis of the text words contained in the title and abstract, and the text terms used to describe the article. A second search strategy using all the identified keywords and the index terms were undertaken across all included databases (Appendix I). The third search strategy was to search for additional studies, which were listed in the reference lists of all included articles.

To focus on the QoL instruments, which were developed in the recent 10 years that contained all four subscales of physical, psychological, social and spiritual, the following databases were searched 10 years preceding from 1998 to 2009:

- CINAHL
- Biomedical Collection
- MEDLINE
- Embase
- Expanded Academic Index
- Ovid nursing
- PsycINFO
- PsycARTICLES
- APAIS Health and Austhealth On Informit
- Current Contents
- Social Science Citation Index
- Sociological Abstracts
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Evidence-Based Medicine (EBM) Reviews – Health Technology Assessment
- EBM Reviews ACP Journal Club
- EBM Reviews Cochrane Central Register of Controlled Trials (CENTRAL)

The grey literature search included:

- Digital Dissertations
- Mednar
- PsycEXTRA
- Australian Centre for Evidence Based Clinical Practice
- Clinical Medicine Netprints Collection (http://clinmed.netprints.org/collections/)

Every electronic database has its own indexing terms; search strategies were developed for each database although many of the terms used were the same. During the process of conducting the search, consideration was given to the diverse terminology used and the spelling of keywords as it might influence the identification of relevant studies. Experts in oncology QoL such as Dr Cheung Yin Bun were contacted regarding QoL research done in Singapore oncology population. Extensive hand-searching was conducted on journals such as Annals Academy of Medicine Singapore, Acta Oncologica, American Cancer Society, British Journal of Cancer, Clinical Therapeutics, Health and Quality of Life Outcomes, Journal of Clinical Epidemiology, Journal of Evaluation in Clinical Practice, Pharmacoeconomics, Quality of Life Research for published articles by Dr Cheung.

Methods of the review

Two reviewers independently reviewed the titles and abstracts based on the inclusion criteria identified after articles search. If the title and abstracts were inconclusive, full reports were retrieved, and thorough evaluation against the inclusion criteria was undertaken. The reference lists of all retrieved articles were further searched for additional references. The decision to include or exclude the study was undertaken by two independent reviewers. For data that was not clear from the trial report, attempts were made to obtain the data by contacting the authors. For example, the demographics of participants in articles reported by Vidhubala et al.35 and Rustoen et al.36 were sought by electronic mail to the authors to obtain the data.

Papers that have been published in duplicate were included only once. The decision for study eligibility was made by two reviewers and was checked by the third reviewer, who is an expert in the fields of oncology and systematic review.

Assessment of methodological quality

The standardised Joanna Briggs Institute (JBI) Meta Analysis of Statistics Assessment and Review Instrument critical appraisal tools for quantitative effectiveness studies were considered inappropriate for assessing studies reporting validity, reliability and feasibility of QoL instruments. Hence, the reviewers of this systematic review seek assistance from JBI Collaboration Support Unit (CSU). With the assistance of JBI CSU, a critical appraisal tool (Appendix II) was adapted from Elliot.28 The appraisal tool used in this systematic review for assessing the quality of included studies was a modified version of the Elliot appraisal tool. Criteria numbers five and seven of the original version of Elliot28 were removed by two reviewers, as the majority of included articles were not reporting on the process of development of the instrument.

The papers selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review using the modified Elliot28 tool for reliability and validity (Appendix II). If there were disagreements between the reviewers, they were resolved through discussion, or with a third reviewer.

Data extraction

For this systematic review, a data extraction tool was developed (Appendix III) after reviewing and modifying from
other systematic review articles37–39 that were published in the JBI Library. The data extracted included details about the authors, study design, population, QoL instrument, validity and reliability of the instrument, measure or scale of the instrument, and frequency of assessment, which related to the review questions.

Data on the type and language of instrument used, country of the study conducted, population and sample size were retrieved from the article. Data on validity analysis, such as content validity, were retrieved when available. Data of reliability analysis on total or subscales’ Cronbach’s alpha were retrieved from the article if available. Data of feasibility on the number of items content in instrument, time spent to answer the questionnaire and response rate were retrieved when available.

Data synthesis
The studies included in this review were quantitative papers. The results were present as a narrative summary of the results. Validity, reliability and feasibility data of the QoL instruments were presented in table form (Table 1). Each paper was analysed separately.

Review results
Description of studies
The search yielded 3149 references from 20 databases. The search from citations in the included articles yielded 45 additional references. The two reviewers, after eliminating 518 duplicate articles, independently assessed the remaining 2676 articles’ titles and abstracts against the inclusion criteria of this review (Appendix I). Two thousand five hundred and fifty-nine articles were excluded because these articles were non-research articles, or the study populations of these articles were non-cancer adult patients. The remaining 117 articles that met the inclusion criteria were included for full text examination. Ninety-two articles were excluded because the QoL instruments used in the studies did not contain all four subscales of physical, psychological, social and spiritual. The remaining 25 articles, which used QoL instruments that contained all the four subscales on participants with cancer chemotherapy, were assessed on whether validity or reliability examinations of the QoL instruments were performed by the authors. As a result, another 12 articles were eliminated (Fig. 1). A total of 13 articles were included in this review, and the methodology used to validate the QoL instruments were appraised using the modified version of the Elliot appraisal tool (Appendix II).28

The list of excluded articles is provided in Appendix IV. The reasons for exclusion are either the instruments did not contain the four subscales or the instruments were used to measure treatment effect of cancer treatment/disease process without performing validation examination of the instrument. The sample sizes of these included articles ranged from 27 to 1383. Four articles reported having a small sample size of below 60,42,43,45,50 eight articles reported having medium sample size of 101–400 participants,35,36,41,44,46–49 and one article reported large sample size of 1383.40 The majority of the articles did not reveal the sample power strength except for articles by Freihat and Ebert.42,48 Five of the articles included in this systematic review were focused on breast cancer population.41,42,46–48 One study was focused on prostate cancer population,44 another on ovarian cancer40 and the rest were a mixture of cancer types.13,35,36,41,44,49,50 Three articles did not mention types of cancer treatment received by the studies’ sample.13,36,50

Methodological quality
Among the 13 included articles, 3 were RCTs,41,43,50 2 were longitudinal studies without control group6,45 and 8 studies were cross-sectional studies.35,40,42,44,46–49 Though 3 articles were RCT, 2 were conducted on a small sample size of less than 55 participants, which might affect the study’s outcomes51,52.

In this review, there was one article on development of new QoL instrument,33 the other 12 included articles performed validation examinations on the original or translated versions of three developed QoL instruments. Majority of these included articles only performed intra-method reliability assessment of the QoL instruments. There were three articles that performed both intra-method and inter-method reliability assessment of the QoL instruments, which were more comprehensive.56,40,49 These articles were comparing the instrument with the original language versions of QoL instruments or comparing with QoL instrument in different languages.59

Among the 13 included articles, only 4 articles reported validity examinations of content validity, or factor analysis of the QoL instruments.35,40,42 Of these 4 articles that reported validity examinations of QoL instruments, only Vidhubala35 conducted comprehensive validity examinations of factor analysis and content validity by both experts and patients.

Results
Available QoL instruments identified
There were a total of four QoL instruments identified from these included articles (Table 2). All of the instruments were self-administered questionnaires. The identified instruments include City of Hope QOL – Ovarian Cancer Tool (QOL-OVCA), QOL-Breast cancer version (QOL-BC), New India QoL tool and QoL Index-Cancer version (QLI-CV). Instruments vary considerably in subscales, cancer specific and length. Although all the QoL instruments included in this review consist of all of the four subscales of physical, psychological, social and spiritual, the psychological and spiritual subscales were grouped as one subscale in the QLI-CV. The numbers of items (questions) in these QoL instruments range from 36 to 70 items.

Reliability and validity of identified QoL instruments
QOL-OVCA
The QOL-OVCA was adapted from the City of Hope four-dimensional QoL instrument by Ferrell and associates,53–57
Table 1 Systematic review data extraction of the 13 included articles

<table>
<thead>
<tr>
<th>Author (years)</th>
<th>Type and version of QoL instruments used</th>
<th>Study design</th>
<th>Population</th>
<th>Sample size</th>
<th>Validity</th>
<th>Reliability</th>
<th>Feasibility</th>
<th>Frequency of assessment</th>
<th>Author's conclusion</th>
<th>Reviewer's conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrell et al. (2005)</td>
<td>City of Hope QOL Ovarian Cancer Tool, English version</td>
<td>Cross-sectional</td>
<td>Ovarian cancer patients</td>
<td>1383</td>
<td>Factor analysis</td>
<td>40 items with score range from 0 to 10: 0 (worst outcome) to 10 (best outcome)</td>
<td>Once</td>
<td>Has high coefficient alphas that compared favourably with the generic QoL instrument.</td>
<td>■ Coefficient alphas: physical well-being = 0.8; psychological well-being = 0.91; social well-being = 0.76; spiritual well-being = 0.70; overall QoL = 0.92. ■ Correlation coefficient (r) among subscales’ scores: 0.16–0.71 between subscales scores and overall QoL score: 0.53–0.93.</td>
<td>■ Cronbach’s alpha of each subscale was similar to the generic version of the instrument.</td>
</tr>
<tr>
<td>Ferrell et al. (1998)</td>
<td>QOL-Breast cancer version (QOL-BC), English version</td>
<td>RCT</td>
<td>Breast cancer patients</td>
<td>298</td>
<td>Content validity by oncology experts of researchers and nurses</td>
<td>Pearson's correlation between total QoL and subscales of: psychological = 0.95; social subscale = 0.86; physical subscale = 0.74; spiritual subscale = 0.39</td>
<td>Nil</td>
<td>Strong correlation between total QoL and variables of physical symptoms (e.g., fatigue and pain); spiritual well-being (e.g., uncertainty and the importance of spiritual support). Seventeen variables were statistically significant in predicting overall QoL, which account for 91% of the variance in overall QoL. Findings on variance in relation to the three age strata (younger than 40 years, 40–60 years and older than 60 years) were consistent with previous research reports. Symptoms specific to breast cancer treatment (e.g., menstrual changes, vaginal dryness and fertility concerns) may influence the quality of survivorship.</td>
<td>■ Cronbach’s alpha was similar to other previously reported internal consistency.</td>
<td>■ Strong positive association between the total QoL and subscales except the spiritual subscale. ■ The findings on the in-depth interview with breast cancer survivors were not reported in this study report.</td>
</tr>
<tr>
<td>Ebert (2006)</td>
<td>QOL-BC, English version</td>
<td>Cross-sectional</td>
<td>Breast cancer patients</td>
<td>60</td>
<td>Content validity by nursing oncology experts</td>
<td>Test-retest reliability after 2 weeks: overall = 0.89; physical subscales = 0.88; psychological subscales = 0.88; social subscales = 0.81; spiritual subscales = 0.90; Cronbach’s alpha: overall = 0.94; physical subscales = 0.81; psychological subscales = 0.92; social subscales = 0.75; spiritual subscales = 0.64</td>
<td>Nil</td>
<td>Small sample size.</td>
<td>■ Cronbach’s alpha was similar to other previously reported internal consistency.</td>
<td>■ Test-retest reliability 20–30 min to complete three instruments: 46 items on 0–10 Likert scale: 0 (worst outcome) to 10 (best outcome). 31 of the 46 items are reverse scored.</td>
</tr>
</tbody>
</table>
New India QoL, English version

Cross-sectional Cancer patients

400

Content validity by 18 experts in medical and psychological fields:
- Relevance: 81–100%
- Clarity: 63–100%
- Comprehensiveness to the globally applied QoL concept: 100%

Pilot study on 30 patients

Factor analysis:
- Kaiser-Meyer-Olkin = 0.83
- Bartlett’s test of Sphericity: adequate, \( P = 0.00 \)

Eigenvalues of all the factors: 8.55–1.10, accounted for 62.6% of variance

Cronbach’s alpha overall = 0.90

Guttman split-half reliability = 0.74

No mention of response rate

12–15 min to complete the questionnaire

16 items of direct scoring, 22 items of reverse scoring

Once

Content and factorial validity of the instrument were established.

The instrument was less time consuming and is feasible to use in a busy setting.

Study only in one centre and culture.

26 (6.5%) of the samples were removed due to outlier or extreme values.

Comprehensive validity and reliability of instrument with strong validity and reliability.

Newly developed instrument specifically for Indian scenario

Study only in one centre and culture. The instrument has the fewest items.

Items related to the social subscale were split into other factors (e.g., self-sufficiency and independence, interpersonal relationship, external support, and mobility).

No mention of:
- The response rate
- The proportion of sample’s gender
- The instrument has the fewest items.
- Items related to the social subscale were split into other factors labels (e.g., self-sufficiency and independence, interpersonal relationship, and mobility).
- No mention of:
- The response rate
- The proportion of sample’s gender

Quality of Life Index-Cancer version (QLI-CV), English version

RCT Lung/breast/ head and neck cancer patients

52 Nil

Cronbach’s alpha (24 h after first cycle of chemotherapy):
- Overall: 0.94
- Health and functioning subscale: 0.91
- Socioeconomic subscale: 0.73
- Psychological/spiritual subscale: 0.66
- Family subscale: 0.68

No mention of:
- The response rate
- The proportion of sample’s gender

10 min to complete the questionnaire

34 matched items for satisfaction and importance (total of 68 items)

Guttman split-half reliability = 0.74

6-point Likert scale, higher score indicate higher QoL.

Eight time points at:
- Before chemo,
- 24 h post chemotherapy,
- Daily from day 3 to day 8,
- By interview and self-administered questionnaire

RCT

Small sample size

80.8% was breast cancer patients

Both groups had similar baseline characteristics

Moderate to high internal consistency.

No validity test done

The psychological and spiritual subscales were combined unlike other instruments where it is presented/captured as an explicit QoL subscale.
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Type and version of QoL instruments used</th>
<th>Study design</th>
<th>Population</th>
<th>Sample size</th>
<th>Validity</th>
<th>Reliability</th>
<th>Feasibility</th>
<th>Frequency of assessment</th>
<th>Author’s conclusion</th>
<th>Reviewer’s conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harrington et al. (2009)⁴⁴</td>
<td>QLI-CV, English version</td>
<td>Cross-sectional</td>
<td>Prostate cancer patients</td>
<td>132</td>
<td>Nil</td>
<td>Reliability coefficients (without items 21 and 22 which were employment related): overall scale = 0.95, health and function subscale = 0.91, social and economic subscale = 0.77, psychological/spiritual subscale = 0.93, family subscales = 0.77</td>
<td>Nil</td>
<td>No mention of time spent to answer the questionnaire, 33 matched items for satisfaction and importance (total of 66 items) on a 6-point Likert scale, scores from 0 to 30 with higher scores indicating more satisfactory QoL, large amount of missing data and inconsistent pattern of response for two items related to employment</td>
<td>Once</td>
<td>To include body image assessment in QoL instrument</td>
</tr>
<tr>
<td>Hanchett (2001)⁴⁵</td>
<td>QLI-CV, English version</td>
<td>Longitudinal</td>
<td>Cancer patients</td>
<td>27</td>
<td>Nil</td>
<td>Variance testing scores of: social and economic: $F = 32.2, P = 0.002$, health and function: $F = 0.657, P = 0.771$, psychological/spiritual: $F = 2.365, P = 0.21$, family: $F = 1.03, P = 0.479$, overall scores: $F = 3.794, P = 0.149$</td>
<td>Nil</td>
<td>No mention of time spent to answer the questionnaire, 33 matched items for satisfaction and importance (total of 66 items) with Likert scale of 1-5, total score of 0-30</td>
<td>Twice: first week of admission and 4 weeks later</td>
<td>Stability of overall QLI scores is consistent with the findings of other QoL researchers who have repeated surveys during a 4- to 8-week time period, significant difference in the subscale scores of social and economic, no significant difference of variance testing in the subscales scores of health and function, psychological/spiritual, family and overall scores, QLI-CV is not specific or sensitive to treatment or type of service, most of the correlations reported were low to moderate, although they were statistically significant, items in the Social Support Questionnaire (SSQ) referring to family relationships could have influenced responses in the QLI-CV family subscale, especially if the participants answered the SSQ first, no predictable correlation between physical health, activities of daily living and overall QoL,ings</td>
</tr>
<tr>
<td>Sammarco (2001)⁴⁶</td>
<td>QLI-CV, English version</td>
<td>Cross-sectional</td>
<td>Breast cancer patients</td>
<td>101</td>
<td>Nil</td>
<td>Alpha coefficient: Overall scale = 0.95, health and functioning subscale = 0.86, socioeconomic subscale = 0.81, psychological/spiritual subscale = 0.96, family subscale = 0.82</td>
<td>Nil</td>
<td>No mention of time spent to answer the questionnaire, 35 matched items for satisfaction and importance (total of 70 items) on a 6-point Likert-type scale, scores range from 0 to 30, higher scores denote greater perceived QoL</td>
<td>Once</td>
<td>No mention of time spent to answer the questionnaire, high internal consistency</td>
</tr>
<tr>
<td>Author(s)</td>
<td>QLI-CV, Language Version</td>
<td>Study Design</td>
<td>Patient Group</td>
<td>N</td>
<td>Cronbach's Alpha (Entire Instrument)</td>
<td>Cronbach's Alpha (Subscales)</td>
<td>Notes</td>
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<tr>
<td>Sammarco (2003)</td>
<td>QLI-CV, English version</td>
<td>Cross-sectional</td>
<td>Breast cancer patients</td>
<td>103</td>
<td>Nil</td>
<td>0.97 health and functioning subcale = 0.88, socioeconomic subcale = 0.78, psychological/spiritual subcale = 0.90, family subcale = 0.79</td>
<td>No mention of time spent to answer the questionnaire</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freihat (2005)</td>
<td>QLI-CV, Arabic version</td>
<td>Cross-sectional</td>
<td>Breast cancer patients</td>
<td>102</td>
<td>Nil</td>
<td>0.98</td>
<td>Once</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rustøen et al. (1999a)</td>
<td>QLI-CV, Norwegian version</td>
<td>Longitudinal</td>
<td>Cancer patients</td>
<td>131</td>
<td>High internal consistency in Arabic version</td>
<td>Test-retest (6): entire instrument = 0.78, subscales = 0.65-0.83, Cronbach’s alpha: entire instrument = 0.93, subscales = 0.79-0.88</td>
<td>High dropout rate 76% of participants were female, 55% of participants were with breast or gynaecological cancer, Intra- and inter-method of reliability were performed, Comprehensive validity test, Unstable psychological/spiritual and family subscales</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No mention of time spent to answer the questionnaire, Some patients dropped out 4.5% of participants who did not complete the survey stated that it would be emotionally difficult to complete the study ... years). The mean score of the QoL was lower than previous studies; it may be due to cultural and people's values differences.

Comprehensive validity test, Unstable psychological/spiritual and family subscales

Test-retest reliability and face validity

The instrument has high internal reliability with real world application. The instrument retained high internal consistency when translated into Arabic. 4.5% of participants who did not complete the survey stated that it would be emotionally difficult to complete the study questions (age: 35–42 years). The mean score of the QoL was lower than previous studies; it may be due to cultural and people's values differences.

The four-factor solution explained only 45.4% of the variance versus 91% reported by Ferrans and Powers. All subscales were correlated with each other and with the entire instrument, except family subscale. The family subscale was the least stable subscale from test to retest. The QLI represents a universal formula that applies across different disease categories but not sensitive enough to differentiate between different groups.
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Type and version of QoL instruments used</th>
<th>Study design</th>
<th>Population</th>
<th>Sample size</th>
<th>Validity</th>
<th>Reliability</th>
<th>Frequency of assessment</th>
<th>Author’s conclusion</th>
<th>Reviewer’s conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rustøen et al. (1999b)</td>
<td>QLI-CV, Norwegian version</td>
<td>Cross-sectional</td>
<td>Cancer patients</td>
<td>131</td>
<td>Nil</td>
<td>Cronbach’s alpha: test = 0.93, retest = 0.95</td>
<td>10–15 min to complete the questionnaire</td>
<td>Mean score of 21.46 similar to other versions of QLI, mean of 20.7–22.3</td>
<td>Once</td>
</tr>
<tr>
<td>Rustøen et al. (2000)</td>
<td>QLI-CV, Norwegian version</td>
<td>RCT</td>
<td>Cancer patients</td>
<td>41</td>
<td>Nil</td>
<td>Test-retest correlation coefficient: — unstable items of QoL: family subscale: family’s health ( r = 0.35 ), family’s happiness ( r = 0.22 ), family’s finances ( r = 0.03 ); relationship with spouse ( r = 0.61 ), 0.5, 0.01 health and functioning subscale: your health ( r = 0.53 ), 0.70, 0.30 psychological/spiritual subscale: peace of mind ( r = 0.71 ), 0.39, 0.27 socioeconomic subscale: emotional support from others ( r = 0.71 ), 0.51, 0.31</td>
<td>Four times during a 9-month period: 3–4-week interval between test 1 and test 2, 8 weeks between tests 2 and test 3, and 6 months between test 3 and 4.</td>
<td>Response rate of 28.2%. No mention of time spent to answer the questionnaire. 34 matched items for satisfaction and importance (total of 68 items) on 6-point Likert scales, total score range from 0 to 30, high score indicates better QoL.</td>
<td>The correlations between the importance of individual items were only moderate. Items of family subscale were quite unstable. Items of family subscale were unstable especially at 9 months, ( r ) ranged from 0.01 to 0.70. Most unstable items tended to become less important over time.</td>
</tr>
</tbody>
</table>

QoL, quality of life; RCT, randomised control trial.
using qualitative data from more than 20,000 pieces of correspondence written by women with ovarian cancer. The instrument is ovarian cancer specific. Thirty-one of the 46 items are reverse scored. There was one study included in this review which validates the QOL-OVCA instrument (Table 2).40

Validity. Factor analysis was performed for construct validity, with a four-factor solution identified, which confirmed the instrument is multidimensional.

Reliability – intra-method validity. Reliability examination was conducted on 1383 ovarian cancer patients. The Cronbach’s alpha of each subscale was 0.70 and above. The correlation coefficient among the four subscales scores ranged from 0.16–0.71. Correlation between each subscale score and overall QoL score ranged from 0.53–0.93. Items of ‘childbearing segment of the lifecycle’ and ‘survivorship guilt’ have item-total correlation of less than 0.20.

Reliability – inter-method. The Cronbach’s alpha of each subscale was 0.70 and above, which was similar when compared with the generic version of the instrument (Table 2).

QOL-BC
The City of Hope QOL instrument was developed by Hassey-Dow and Ferrell.58 The QOL-BC was adapted from the QOL-Cancer Survivors Scale and designed by the research of Hope Center of California, for assessing the QoL in women with breast cancer.58–61 This questionnaire originally included 46 items on a scale of 0–10; the lower the total score, the better the QoL. There were two studies included in this review,61–62 which performed validation of the QOL-BC on patients with breast cancer (Table 2). Ebert’s study62 was a cross-sectional study on a convenience sample, whereas Ferrell’s41 was an RCT.

Validity. Both authors reported examination of content validity of the QOL-BC by experts in nursing oncology. In addition, content validity by a panel of QoL researchers was reported by Ferrell.41

Reliability – intra-method. Ferrell41 performed correlation analysis between total QoL and subscales. Ferrell41 found that there was a high correlation between total QoL (Pearson’s r = 0.89) and subscales of psychological, social and physical (Pearson’s r = 0.95–0.74) except for spiritual subscale (r = 0.39). Ferrell41 reported that multiple regression was performed, and 17 variables of the instrument, such as control, pain, uncertainty, satisfaction, future, appearance and fatigue were found to be statistically significant, which account for 91% of the variance in overall QoL. The findings of greater distress and life disruption on younger women with breast cancer by Ferrell41 were consistent with previous research report as cited by the author. Ebert42 performed Cronbach’s alpha and test–retest reliability assessment on the same instrument. The Cronbach’s alpha reported by Ebert42 was 0.94 for the overall instrument, 0.81, 0.92, 0.75 and 0.64 for subscales of physical, psychological, social and spiritual, respectively. Ebert42 also reported high test–retest reliability for the overall QoL and the subscales, which ranged from 0.90–0.81.

New India QoL Tool
In this review, there was only one study reported on the development of the new QoL instrument (Table 2).35 The New India QoL tool was developed by Vidhubala and tailored to Indian patients with cancer.35 The items included in this instrument were drawn from literature, the WHO-QOL-100, EORTC, the Indian QOL general instrument and other QoL instruments. The New India QoL tool comprises 10 factors consisting of 38 items. There is only one item on belief (spirituality), which is listed under the subscale labelled optimism and belief.

Validity. The New India QoL tool was validated using a convenience sample that involved all types of cancer. Content validity assessment and principal component method assessment were performed to examine the validity of the instrument. The content was examined by a pilot study on 30 patients, and 18 medical and psychological
### Table 2 Summary of review results

<table>
<thead>
<tr>
<th>QoL instruments</th>
<th>Number of studies</th>
<th>Validity and reliability</th>
<th>Feasibility</th>
<th>Frequency of assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Number of items</td>
<td>Time spent to answer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intra-method</td>
<td>Inter-method</td>
<td></td>
</tr>
<tr>
<td>City of Hope QoL Ovarian Cancer Tool</td>
<td>1</td>
<td>Factor analysis: a four-factor solution was identified</td>
<td>Cronbach’s alphas: &gt;0.7</td>
<td>45</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Correlation coefficient:</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>– Among subscales: 0.16–0.71</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>– Between subscales and overall QoL: 0.53–0.93</td>
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<tr>
<td></td>
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<td>Item–total correlation &lt; 0.2 for 2 items of:</td>
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<tr>
<td></td>
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<td>1. Childbearing segment of the lifecycle</td>
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<td>2. survivorship guilt</td>
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<td></td>
<td></td>
<td></td>
<td>Cronbach's alphas of each subscale were similar to generic version</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Nil</td>
<td>46</td>
</tr>
<tr>
<td>QOL-Breast cancer version</td>
<td>2</td>
<td>Content validity by oncology experts of researchers and nurses</td>
<td>Pearson’s correlation between total QoL and subscales: 0.39–0.95</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Multiple regression: 17 variables account for 91% of the variance in overall QoL</td>
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<tr>
<td></td>
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<td>Test–retest reliability:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>– Overall QoL and subscales: 0.81–0.90</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Cronbach’s alpha:</td>
<td>38</td>
</tr>
<tr>
<td>New India QoL tool</td>
<td>1</td>
<td>Content validity by 18 experts in medical and psychological fields</td>
<td>Cronbach’s alpha overall: 0.90</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pilot study on 30 patients</td>
<td>Guttman split-half reliability: 0.74</td>
<td></td>
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<td></td>
<td></td>
<td>Factor analysis:</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>– Kaiser–Meyer–Olkin: 0.83</td>
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<tr>
<td></td>
<td></td>
<td>– Bartlett’s test of Sphericity: $P = 0.00$</td>
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<tr>
<td></td>
<td></td>
<td>– All factors’ Eigenvalues: 8.55–1.10, accounted for 62.6% of variance</td>
<td></td>
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</tr>
<tr>
<td>QoL Index-Cancer version</td>
<td>9</td>
<td>Content validity by a QoL research knowledgeable person</td>
<td>Cronbach’s alpha:</td>
<td>66</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pilot study with 14 patients with cancer</td>
<td>– Overall: 0.93–0.98</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Eigenvalues of eight factors: &gt;1</td>
<td>– Subscales: 0.68–0.96</td>
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<td></td>
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<td>– Re-test: 0.95</td>
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<td></td>
<td></td>
<td></td>
<td>– Subscales: 0.82–0.91</td>
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<td></td>
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<td></td>
<td>Pearson’s correlation between:</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>– Total scales and subscales: 0.61–0.76</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>– Subscales: 0.53–0.73</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Pearson’s correlation test–re-test:</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td>– Entire QoL: 0.78</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>– Subscales: 0.65–0.83</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Variance testing: $P = 0.002$</td>
<td></td>
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<td>Items stability: Weak correlation coefficient on items of:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>– Your health</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>– Emotional support from others</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>– Peace of mind</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparing with English version:</td>
<td>68</td>
<td>10–15 min</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Similar mean score</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Higher Cronbach’s alpha of family subscale</td>
<td>70</td>
<td>40 min for four sets of survey instruments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lower test–retest reliability</td>
<td>43</td>
<td>1 time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lower construct validity</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Comparing with other languages version:</td>
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<tr>
<td></td>
<td></td>
<td>Similar mean score</td>
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</tbody>
</table>

Detailed results in Table 1 of Systematic review data extraction of the 13 included articles. QoL, quality of life.
experts. Factorial validity of the instrument reported KMO of 0.83, Bartlett’s test of Sphericity was adequate with \( P = 0.00 \), Eigenvalues of all the factors ranged from 8.55 to 1.10, which accounted for 62.6% of variance.

Reliability – intra-method. The overall Cronbach’s alpha of the New India QoL tool was 0.90 and split-half reliability was 0.74 (Table 2). The Guttman split-half reliability was 0.74. No information on the individual subscale reliability was provided.

QLI-CV

The Ferrans and Powers QLI was originally developed to measure the QoL of healthy persons, as well as those undergoing hemodialysis. This instrument is slightly different from other QoL instruments. Where most instruments assess the continuum of the presence or absence of QoL well-being, the QLI-CV combines patient’s perception of satisfaction with and importance of matters pertaining to QoL. It might be beneficial to ask the participants not only to quantify the satisfaction, the various functions and symptoms but also to express their view on their importance. This approach would provide a better basis for the assessment of the clinical relevance of QoL data.

There were nine studies included in this review, which validated the QLI-CV instrument (Table 2). All these studies were cross-sectional or longitudinal study with convenience sample except two were RCT. The QLI-CV instrument used by these authors was either the original version or Arabic version or Norwegian version.

Validity. Among these nine articles, only Rustøen conducted content and construct validity assessment. The content validity assessment performed by Rustøen was by a QoL research knowledgeable person, and the Eigenvalues of eight factors of the construct validity were above 1. In addition, Rustøen also conducted a pilot study on 14 oncology patients.

Reliability – intra-method. Seven articles performed Cronbach’s alpha to assess the reliability of QLI-CV instrument. The overall Cronbach’s alpha for QLI-CV instrument was 0.98–0.93; the subscales were 0.96–0.77, except for family subscale that was reported by Wickham, which was 0.68. Rustøen also retested the Cronbach’s alpha on the same sample. The test results reported by Rustøen for the overall instrument was 0.93 and subscales were 0.79–0.88, and the retest results for the overall instrument was 0.95 and subscales were 0.82–0.91.

Besides performing Cronbach’s alpha to assess the reliability of QLI-CV, Rustøen also performed test–retest correlation, correlation of total scale with subscales, and correlation between subscales. The test–retest Pearson’s correlation at 3 to 4 weeks interval was 0.65–0.83 for subscale and 0.78 for the entire instrument. The correlations between total scale and subscales of family, health and functioning, psychological/spiritual and socioeconomic were 0.61, 0.74, 0.75 and 0.76, respectively. The correlations between subscales were 0.53 between family subscale and psychological/spiritual subscale, and 0.73 between psychological/spiritual subscale and health and functioning subscale.

Amongst the two articles that did not perform Cronbach’s alpha analysis, one article performed variance testing and the other article performed a comparison of items stability on the QLI-CV instrument. The article by Hanchett only performed variance testing of the QLI-CV instrument. The findings of the variance testing were social and economic subscale (\( F = 32.2 \ P = 0.002 \)), health and function subscale (\( F = 0.657 \ P = 0.771 \)), family subscales (\( F = 1.03 \ P = 0.479 \)), psychological/spiritual subscale (\( F = 2.365 \ P = 0.21 \)) and overall scores (\( F = 3.794 \ P = 0.149 \)). The comparison of items stability was performed on the QLI-CV instrument at three interval periods of 1 month, 3 months and 9 months. Items with weak correlation coefficient, which correlation coefficient result of or less than 0.30 were ‘your health’ in health and functioning subscale, ‘emotional support from others’ from socioeconomic subscale, ‘peace of mind’ from psychological/spiritual subscale, and all the three items in family subscale. Harrington reported removal of two items related to employment from the social/economic subscale due to a great number of missing data and inconsistent pattern of response.

Reliability – inter-method. Besides intra-method validation, Rustøen also performed inter-method validation of the Norwegian version of QLI-CV instrument with the original English version of QLI-CV and different languages of QLI-CV including the English version. When comparing the Norwegian version of QLI with original or Swedish version of QLI used by seven previous studies, the author reported that there were similar mean scores on QoL across different types of disease. When comparing the Norwegian version of QLI with studies done by Ferrans, Rustøen reported that the Cronbach’s alpha of the family subscale was much higher than Ferrans’ study, and 3 to 4 weeks test–retest reliability was lower than Ferrans’ study. In addition, the four factors of the construct validity explained only 45% of the variance in the Norwegian sample, whereas in Ferrans’ study, it was reported as 91%.

Optimal frequency of assessment using identified QoL instruments

The majority of the included articles involved a one-time cross-sectional study, which required the participants to answer the questionnaire once only (Table 2). QLI-CV was the only instrument, which required participants to answer the questionnaire more than once in four longitudinal studies. The frequency of QoL assessment varies in these four longitudinal studies. Two studies performed assessment twice with 1-month interval. One study had four assessments during the 9-month study period with 3–4-week interval between test 1 and test 2, 8 weeks
between test 2 and test 3, and 6 months between test 3 and 4. Another study performed eight assessments at different intervals throughout the study period, before chemotherapy, and daily from day 2 to day 8 post chemotherapy.

Feasibility of the use of identified QoL instruments
All of the QoL questionnaires were self-administered. Only one study was different in the early stage that data collection was conducted via telephone interview. Majority of the studies did not mention the time taken to answer the QoL instruments (Table 2).

City of Hope QOL-OVCA
The QOL-OVCA instrument reported by Ferrell did not mention the time taken to complete the 11-point Likert scale 45-item questionnaire.

City of Hope QOL-BC
The QOL-BC instrument by Ferrell has 47 items, and the one by Ebert has 46 items. Ebert mentioned that the participants took 20–30 min to complete three instruments, but there was no mention of the time taken to complete the questionnaire by Ferrell. The Likert scale of the instrument was an 11-point scale from 0 to 10, with 10 being the best outcomes. The scoring was reversed in 31 items of the QOL-BC instrument used by Ebert, but no mention in Ferrell’s research.

New India QoL-Cancer Tool
The New India QoL tool was a 38-item instrument on a 4-point Likert scale with a score of 1 being very much and 4 being not at all. Out of the 38 items, 22 items were reverse scored. The time taken to complete the instrument was reported as 12–15 min, but the response rate was not reported.

QLI-CV
The QLI-CV instrument used by the nine authors consists of 33 to 35 matched items for satisfaction and importance on a 6-point Likert scale, except Hanchett, who used a 5-point Likert scale on the same instrument. The scores for satisfaction and importance were combined to generate the QoL score; the higher the score, the better the QoL. Wickham was the only author who collected data via interview during the first assessment, and the mode of subsequent assessment by mail was similar to other authors. The total time taken to complete the questionnaire varied from 10 min, 10–15 min, and 40 min for four sets of survey instruments.

Discussion
QoL instruments were developed as early as the 1970s for the healthy or non-cancer population. However, a precise definition remains elusive as no consensus was drawn on the definition of QoL and measures used to assess it till the last decade. QoL instruments for patients with cancer that were developed in the early stage were focused on patients’ functional status and emotional aspects. Hence, the QoL instruments used and validated in the clinical trial studies during this period were either targeted on healthy or non-cancer population, or with QoL instruments that contained limited subscales.

As there is no ‘gold standard’ criterion or instrument to measure QoL, the theoretical framework that support the development of the instrument and the context of the instrument being tested on should be considered in order to select an appropriate and relevant QoL instrument. Within the health-oriented framework, QoL instruments used by clinicians should be health oriented, focused on issues that are objectives of the health care system and feasible to patients. In the last decade, consensus from oncology QoL experts suggested adopting a more realistic approach on QoL instrument, which is with minimum subscales, and is health related and health sensitive, able to provide as much relevant information as possible in relation to patients’ condition and cancer treatment. The experts also suggested that spiritual should be included to measure QoL of patients with cancer other than physical, psychological and social functioning. The experts in the QoL field agreed that it was more appropriate to make modifications where needed on existing instruments, rather than developing new instrument. This could be the reason why no published article on development of QoL instrument for oncology patient with chemotherapy that contained all the four subscales was found within the limited years of publication set by this review, except for the New India QoL tool.

Reliability and validity of identified QoL instruments
Both the QoL instruments of QOL-BC and the New India QoL tool only underwent intra-method examination on the original version for validity and reliability assessment. Only one study was a developmental study of a new instrument, the New India QoL tool.

The QOL-OVCA underwent both validity and reliability examinations by the author of the article included in this review. The instrument demonstrated high internal consistency, and correlation of moderate to high between subscales and total QoL. The instrument yielded similar high Cronbach’s alpha result when it underwent inter-method comparison with the generic QoL instrument by the author. However, the content validity was only on factor analysis, which may be insufficient. The author suggested removing items on ‘childbearing segment of the lifecycle’ and ‘survivorship guilt’ from the instrument because of item–total correlation of less than 0.20. However, there was no reliability examination done on the instrument after removing these items.

The City of Hope QoL tool – QOL-BC underwent validity and reliability examinations in the two included article. The instrument demonstrated a statistically significant result in reliability of internal consistency and test–retest. Content validity was considered incomplete as the authors only performed it by the panel of experts but not on cancer
patients. There was no comparison of the instrument with other instruments by the authors. However, the content validity and reliability of this instrument have been already established in several studies.

The New India QoL tool underwent comprehensive validity examinations in this included article during the process of instrument development. However, there was no content validity of repeat pilot study on cancer patient on the final version of the instrument, which may make the validity examination incomplete. The instrument demonstrated high reliability and validity on Indian population after 6.5% of the outlier or extreme values were removed. The reliability examinations of overall Cronbach’s alpha and Guttman split-half may not be sufficient for the development of a new instrument. There was no comparison of the instrument with other instruments by the author. No validation of the instrument by other region or cultural group was reported at the time of literature search.

The reliability and validity of the QLI-CV has been reasonably well documented in the clinical rather than research setting. The instrument has high internal consistency, and the total index correlated highly with a measure of life satisfaction.

In this review, the QLI-CV underwent intra- and inter-method reliability and comprehensive statistical analyses on the English version and translated versions by different authors, on different cultural populations. Of the nine articles included in this review, only Rustoen performed content and construct validity assessment on the instrument. The instrument seems to be reliable after being translated into different languages, though the Arabic version of the instrument by Freihat only have one Cronbach’s alpha value reported. The various versions of the instrument demonstrated good to excellent internal consistency, except for Wickham who reported a moderate Cronbach’s alpha value on family subscale. However, the mean score, test–retest reliability and the four-factor solution of the Norwegian version were not as high as the original English version used in the American sample. This could be attributed to differences in cultural values of the importance of all subscales and the way illness is experienced, which can cause validity and reliability problems. This is because instruments are likely to be biased in the setting in which they were originally developed and tested. In addition, the process of translation, back-translation and review of the QoL instruments to another language may affect the cross-cultural sensitivity of the instruments. Two authors, Hanchett and Rustoen, cited that the instrument is not specific or sensitive to differentiate between different groups, treatment or type of service when they compared their findings with other studies. One author, Rostoen, found that there were unstable items of the Norwegian version instrument, and these items were less important over time during the longitudinal study.

**Feasibility of the use of identified QoL instruments**

QoL is a subjective issue, and there was consensus that it should be rated by patients themselves with the use of self-administered scale. Different QoL instruments have different numbers of items although all contain the four subscales of physical, psychological, spiritual and social. There were also differences in the number of items of the same QoL instruments used by different authors in this review. For example, 46 items of City of Hope QOL-BC were used by Ebert, and 47 items of City of Hope QOL-BC were used by Ferrell. Another example was the QLI instrument, which 33-item instrument was used by Harrington, Freihat and Hanchett; 34-item instrument was used by Wickham and Rustoen; and 35-item instrument was used by Sammarco. The differences were often merely some additional items adapted to different patient groups, for example, split or combine items of job and unemployment for subscale of socioeconomic.

The QoL instruments included in this review were self-administered. The time taken to complete the 46-item City of Hope QOL-BC instrument was about 20–30 min. The New India QoL tool has fewer items (38 items), which took about 12–15 min to complete and is considered feasible to use in a busy setting. The QLI-CV has the most number of items, which is 33–35 matched items for satisfaction and importance (total of 66–70 items), but took the shortest time (about 10–15 min) to complete. The advantages of using short instruments include fewer burdens or time constraint on patients, higher response rate and less missing values and/or incomplete questionnaires. Unfortunately, there was no information reported on the response rate for the New India QoL tool, which consists of the least items among the identified instruments in this review. One out of two articles using QOL-BC instrument reported response rate of 84.5%. For this review, the QLI-CV instrument, which participants took the shortest time to complete the most items, has the poorest response rate. There were six out of nine articles using QoL instrument of QLI-CV reported response rate of less than 32%.

Regarding the method of calculation, there was no mention of the QOL-OVCA, QOL-BC and the New India QoL tool.
Calculation of the QLI-CV score may not be so straightforward, as high scores are produced by combinations of high satisfaction/high importance responses.\textsuperscript{62}

In this review, only Vidhubala\textsuperscript{35} and Rustøen\textsuperscript{36} reported comprehensive validity and reliability being conducted on the New India QoL tool and the QLI-CV, respectively. Unfortunately, there was no content validity examination on the final version of the New India QoL tool being reported and no comparison with any existing QoL instrument.\textsuperscript{35} The other 11 included articles used various types of examination yet 7 reported only basic information for reliability test of Cronbach’s alpha,\textsuperscript{40,42–44,46–48} or correlation,\textsuperscript{41,50} or variance test.\textsuperscript{45} No validity assessment was reported for QLI-CV by 8 articles,\textsuperscript{41–50} and QOL-OVCA.\textsuperscript{40} Majority of the articles did not compare the findings with other QoL instruments or original version of the QoL instrument except for Ferrell and Rustøen.\textsuperscript{36,40,49} All the included QoL instruments were feasible to patients, but there was insufficient evidence to conclude the optimal frequency of QoL assessment in this review.

Limitations of the review
The search time frame for this systematic review included the last 10 years of published research articles. There were no published articles reporting on the development of QoL instrument found within the listed databases, except for the New India QoL tool, and limited articles reporting on the validation of QoL instruments that contain all four subscales of physical, psychological, social and spiritual for the last 10 years. This was because of search limitation being set on years of the publication, which only includes the last 10 years published research articles. Hence, some articles traced from the reference list of the included articles, which were published before 1998, were excluded for this review.

This systematic review was limited to English language publications. Non-English articles may have been missed, as these articles published may not be included in the databases we searched. Hence, articles that were reported in other languages other than English were not assessed.

Conclusions
In this review, there are 4 QoL instruments being identified, which validity and reliability were reported by 13 articles. However, not all instruments have had comprehensive intra- and inter-method validation on various types of cancer by the authors of these included articles, except the QLI-CV instrument. Nevertheless, we cannot conclude that the QLI-CV is superior to other instruments. The QOL-OVCA and QOL-BC may have comprehensive validation by studies that are not included in this review.

Implications for practice
When selecting the appropriate QoL instrument to be used in the clinical setting, the clinician has to consider
1. The objective of the QoL assessment.
2. The types or gender of patients with cancer. The City of Hope QOL-BC and City of Hope QOL-OVCA are specified for breast or ovarian cancer. Although the QLI-CV and the New India QoL tool were used for all types of cancer patient, gender was absent or underrepresented for QLI-CV, as several of the included articles included a high proportion of women with breast cancer.\textsuperscript{36,43,45,49,50}

3. The feasibility of the instrument by using short instruments may have fewer burdens or time constraints on patients, higher response rate and less missing values and/or incomplete questionnaires.\textsuperscript{77} In view of it, the City of Hope QOL-BC, City of Hope QOL-OVCA, and QLI-CV may be useful in the research setting but may not be feasible in the clinical setting due to the length in numbers of items. All the identified instruments seem to be easy to use by participants, who answered the questionnaires within 20 min. However, the method for calculating the score was not clear, except for QLI-CV, which was not straightforward.

4. The frequency of QoL assessment throughout the treatment period.

Implications for research
The response rates of these identified instruments were low although the time taken to complete the questionnaires were within 20 min. Research in examining shortened version of these instruments should be considered. Otherwise, the New India QoL tool, which has the least items, may be useful in the clinical setting but need further psychometric tests.

Acknowledgements
This research article is derived from a systematic review published in the JBI Library. The citation for the full review is: Mordiff S, Kin Y, Ang NK E. Quality of life tools for adult patients with cancer undergoing chemotherapy: a systematic review 2011; 9(57): 2482–2532. We would like to thank Ms Goh Mien Li for performing the initial literature search to enable the review protocol to be written. We would also like to thank the JBI CSU, Adelaide for their assistance and advice in the conduct of the systematic review, and feedback on the protocol and manuscript.

References


24. King CR. Advances in how clinical nurses can evaluate and improve quality of life for individuals with cancer. *Oncol Nurs Forum* 2006; **33**: 5–12.


43. Wickham RS, Ondanesront Versus Granisetron: Control of Nausea and Emesis, Satisfaction, and Quality of Life. Chicago, IL: University of Illinois at Chicago, Health Sciences Center, 1998.


Appendix I

Electronic databases search strategies

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Appendix I  Continued

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#7 #3 AND #4 AND #5 AND #6                                                                        64
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Current contents
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#2 Topic=(quality of life instrument) AND Topic=(cancer) AND Topic=(chemotherapy) 207
#3 Databases=ABES, SBS, CM, LS, AH Timespan=1998–2009 294
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Refined by: Languages=( ENGLISH )
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Digital Dissertations
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Appendix I  Continued

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**Embase**

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#8 | 'life qualities':ab,ti AND [embase]/lim AND [1998–2009]/py | 18 |
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 PsycINFO

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 Social Science Citation Index

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 Sociological Abstracts

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Appendix II

Quality assessment tool (adapted from Elliot 200728)

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<td></td>
<td></td>
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<td></td>
<td>Mention of these in the three Domains:</td>
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<tr>
<td></td>
<td>Stability: Test–retest reliability, parallel of alternate form.</td>
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<td></td>
<td>Homogeneity: item–total correlation, split-half, KR-20, Cronbach’s’s alpha (&lt;=0.7 will signify good reliability)</td>
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<tr>
<td></td>
<td>Equivalence: inter-rater, parallel or alternate form.</td>
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</tbody>
</table>

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Appendix II

Critical appraisal tool for Reliability and Validity studies

<table>
<thead>
<tr>
<th>Items</th>
<th>Description</th>
<th>Inter method studies</th>
<th>Intra method studies</th>
<th>Yes</th>
<th>No</th>
<th>Not clear</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(A: validation of QoL tool with another tool / B: same tool of different language)</td>
<td>(C: development of QoL tools)</td>
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<tr>
<td>3</td>
<td>Was an appropriate method(s) used to test the validity of the QoL instrument?</td>
<td>Is instrument assessed independently?</td>
<td>Whether there are:</td>
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<td></td>
<td></td>
<td></td>
<td>1. Factor analysis/expert opinion</td>
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<td></td>
<td></td>
<td></td>
<td>2. Construct validity</td>
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<td>3. Regression analysis</td>
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<td>4. Contrasted groups</td>
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<td></td>
<td>5. Hypothesis testing</td>
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<td></td>
<td>6. Convergent divergent</td>
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<tr>
<td>4</td>
<td>Is the validity of the QoL instrument adequate?</td>
<td>Was gold standard being used in study well validated?</td>
<td>What are the result of:</td>
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<td></td>
<td>1. Factor analysis/expert opinion</td>
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<td></td>
<td></td>
<td></td>
<td>2. Construct validity</td>
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<td></td>
<td>3. Regression analysis</td>
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<td>4. Contrasted groups</td>
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<td>5. Hypothesis testing</td>
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<td></td>
<td></td>
<td></td>
<td>6. Convergent divergent</td>
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<tr>
<td>5</td>
<td>Are strengths and weaknesses of the reliability and validity appropriately addressed in the ‘Discussion’, ‘Limitations’, or ‘Recommendations’ sections of the report?</td>
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</tbody>
</table>

Appendix III

Systematic review Data Extraction Form (modified from systematic review articles published in JBI Library37–39)

<table>
<thead>
<tr>
<th>Author (yr)</th>
<th>Type &amp; version of QoL instruments used</th>
<th>Study Design</th>
<th>Population</th>
<th>Sample size</th>
<th>Validity</th>
<th>Reliability</th>
<th>Feasibility</th>
<th>Frequency of assessment</th>
<th>Author’s Conclusion</th>
<th>Reviewer’s Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intra-method</td>
<td>Inter-method</td>
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</tbody>
</table>

Appendix IV

Excluded studies

Retrieved articles excluded after critical appraisal by two reviewers

Reason for exclusion: QoL instruments used did not contain four subscales for all of these following articles


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Rademacher J. Impact of spiritual well-being on quality of life in women undergoing chemotherapy for early stage breast cancer [PhD]. University of Cincinnati, Ohio, USA, 2006.


Kemp JR. *Evaluating the effects of chemotherapy on cognitive function and quality of life in pre-menopausal women with breast cancer [PhD].* University of Kansas, Kansas, USA, 2007.

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**Reason for exclusion:** No reported validity/reliability assessment of QoL instrument for all of these following articles


