**BCRL QUESTIONNAIRES: CLIMATE AND INDIGENOUS GROUPS**

Susan Gordon, Lorraine Sheppard, Anita Selby

Valid and reliable subjective questionnaires are essential to enable research regarding the effect of breast cancer-related lymphoedema (BCRL) on quality of life (QoL). This review was undertaken to determine the reliability and validity of four current subjective questionnaires for the evaluation of BCRL, particularly with respect to climate and ethnic or indigenous groups. Searches were performed using Medline and CINAHL databases. No studies specifically targeted indigenous groups and limited evidence is available to support the use of current questionnaires to diagnose or provide an early indication of onset of BCRL.

**Key words**
- Breast-cancer related lymphoedema (BCRL)
- Climate
- Indigenous groups
- Quality of life (QoL)

Breast cancer-related lymphoedema (BCRL) is a chronic, debilitating swelling of the upper limb which occurs secondary to medical intervention for breast cancer. Established risk factors include axillary lymph node dissection (ALND) (Levitt, 2000; Purushotham et al, 2005), adjuvant radiation therapy to the axilla (Senkus-Konefka and Jassem, 2006), increased body mass index (BMI) and older patient age (Kocak and Overgaard, 2000).

Current prevention advice related to patient and lifestyle factors is largely anecdotal, with a poor evidence base (Nielsen et al, 2008). Climate is suggested to be a risk factor for the development of lymphoedema (Nielsen et al, 2008). Exposure to suggested risk factors, including heat, insect bites and sunburn, are inevitable in tropical and dry climate zones and have been identified by patients as contributing to their BCRL experience, including the onset and aggravation of symptoms (Beaulac et al, 2002; Goffman et al, 2004; Graham 2002; Hayes et al, 2005; Radina et al, 2004; Thomas-MacLean et al, 2005).

Women with BCRL living in North Queensland, Australia report alterations in social behaviour and compliance with management practices due to high temperatures and humidity (personal communication). They report participating less in outdoor activities such as family gatherings and daily walks, and decreased use of compression garments, or even stopping wearing them altogether. Heat has been identified in BCRL qualitative research as having detrimental effects in that it causes discomfort, self-consciousness and hygiene issues, all of which have a negative impact on social aspects of quality of life (QoL) (Carter, 1997; Johansson et al, 2003; Fu, 2005; Ridner, 2005). A study undertaken in Germany, which is classified by Peel et al (2007) as having temperate and cold climates, reported compliance with wearing compression garments to be less than 30% (Bani et al, 2007). However, the effect of different climates on compliance with self-management practices for BCRL has not been investigated.

To identify and monitor BCRL it is essential to have valid and reliable assessment questionnaires that have been established for use in different geographic and climatic regions and for use with different cultural groups, including indigenous populations. Reports of prevalence vary according to methodology, sample and location of the study, with lymphoedema present in up to 42% of participants (Nielsen et al, 2008). A definitive prevalence rate and the relative severity of BCRL in different climates, particularly in a tropical climate, have
not been established. Additionally, the lived experience and effects of BCRL on QoL in the tropics has not been thoroughly investigated. The tropics are defined as falling within the latitude points of the Tropic of Cancer and the Tropic of Capricorn of 23ºN and 23ºS, respectively (Peel et al, 2007). As an example of a tropical climate, the mean temperatures in Townsville, Australia are maximum 25–31.4ºC and minimum 13.6–24.2ºC, with mean humidity varying over the year from 60 to 75% (Bureau of Meterology, 2009).

A literature review using a systematic approach was undertaken to identify the reliability and validity of questionnaires currently used to subjectively assess QoL in patients with BCRL. Specific consideration was given to assessing investigations with respect to the geographic location and climate in which the studies were undertaken, and the ethnicity and indigenous background of participants.

**Methods**
An extensive search of the literature was performed through Medline via Ovid, searching journals from 1950 to January 2008. With Ovid as a server, Medline maps similar words to subject headings (e.g. ‘breast neoplasms’ is the medical subject heading [MeSH] for breast tumour and breast cancer; ‘lymphedema’ is the MeSH heading for lymphoedema).

The following search terms were used: ‘breast neoplasms’ or ‘breast’ and ‘carcinoma’ or ‘neoplasms’; ‘lymphedema’; ‘quality of life’ or ‘questionnaires’ or ‘outcome assessment (health care)’ or ‘patient satisfaction’ or ‘treatment outcome’; ‘reproducibility of results’ or ‘sensitivity or specificity’ or ‘psychometrics’ or ‘evaluation studies as topic’ or ‘validation studies as topic’. Limits of English language and female gender were applied to the searches. The combinations of these terms with ‘and’ yielded nine results. The search was repeated using the CINAHL database via OVID, revealing three more results. Examination of the reference lists of articles identified a further ten papers for review. When these search terms were repeated in each database with the added term ‘climate’, zero results were identified, likewise when the terms ‘ethnicity’ or ‘indigenous’ were added.

Inclusion criteria were that all study participants had to be treated for breast cancer and all studies had to compare outcomes for those with lymphoedema to those without lymphoedema. Studies using generic QoL questionnaires were excluded, as the purpose of the review was to include questions and statements that were exclusive to arm morbidity associated with BCRL.

Reports were critically appraised using a checklist questionnaire developed by the author as an amalgamation of existing critical appraisal questionnaires for diagnostic accuracy. The questionnaire was developed for the author’s ease to address themes of study design, sample, reference and index standards, methodologies, results and analysis, and applicability of findings. It has not been validated, peer-reviewed, or piloted, but draws upon a range of known critical appraisal questionnaires for examining diagnostic studies.

**Results**
**Identification of studies**
The search identified 22 research papers. Of these, three were excluded as they were not relevant to the review (truncal oedema, surgical intervention, objective measures). Eight papers examined generic QoL questionnaires (Short-form Questionnaire – 36-Item Survey [SF-36], European Organisation of Research and Treatment of Cancer Quality of Life Questionnaire [EORTC QLQ C30], and the Functional Living Index – Cancer (FLIC)) and were also excluded as they were not specific to BCRL. However, these are the three most frequently utilised generic questionnaires in the literature. Both the SF-36 and the FLIC have been shown to distinguish physical functioning deficits between lymphoedema and non-lymphoedema groups (Wilson et al, 2005). However, the lack of questions which are specific to the patient population with BCRL consider these generic questionnaires inappropriate, and more specific measures may be required to assess other domains of QoL, such as emotional aspects (Wilson et al, 2005; Launois and Alliot, 2000).

Three papers examining the Functional Assessment of Cancer Therapy – Breast (FACT-B) were excluded as the FACT-B+4 is a more specific arm morbidity scale. Seven of the remaining papers were not validation or reliability studies, but merely identified trends and treatment effects using QoL questionnaires and thus were excluded. Four validation papers using BCRL-specific QoL questionnaires met the inclusion criteria and were critically appraised. Table 1 identifies the BCRL-specific

<table>
<thead>
<tr>
<th>Validation and reliability studies regarding BCRL-specific QoL tools</th>
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<tr>
<td><strong>QoL tool</strong></td>
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<tr>
<td>Functional Assessment of Cancer Therapy – Breast, plus arm morbidity scale (Coster et al, 2001)</td>
</tr>
<tr>
<td>Upper Limb Lymphedema Scale – 27 Item (Launois and Alliot, 2000)</td>
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<tr>
<td>Lymphedema and Breast Cancer Questionnaire (Armer et al, 2003)</td>
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<tr>
<td>Telephone questionnaire (Norman et al, 2001)</td>
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Table 2

Climatic zones, sample, and methods of validity and reliability studies

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<tr>
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<tbody>
<tr>
<td>Type of study</td>
<td>Longitudinal</td>
<td>Longitudinal</td>
<td>Cross-sectional</td>
<td>Cross-sectional</td>
</tr>
<tr>
<td>Location of study</td>
<td>France</td>
<td>United Kingdom</td>
<td>Missouri, USA</td>
<td>Pennsylvania, USA</td>
</tr>
<tr>
<td>Climatic zones (23)</td>
<td>Temperate and cold</td>
<td>Temperate</td>
<td>Cold and temperate</td>
<td>Polar and cold</td>
</tr>
<tr>
<td>Domains of questionnaire</td>
<td>Physical, psychological, social</td>
<td>Physical, social, emotional, functional, breast concerns, arm morbidity</td>
<td>Physical symptoms</td>
<td>Physical symptoms</td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td>Inclusion criteria: patients suffering from BCRL secondary to breast cancer, age &gt; 18 years Exclusion criteria: advanced cancer, ongoing radiotherapy or chemotherapy, signs of plexitis, past medical history of lymphangitis &lt;2 months</td>
<td>Not explicitly stated. Group of breast cancer patients and group of lymphoedema patients</td>
<td>Not explicitly stated. All had known breast cancer</td>
<td>Not explicitly stated. All had known breast cancer</td>
</tr>
<tr>
<td>Sample size</td>
<td>n=301 with BCRL</td>
<td>n=308, 279 with breast cancer</td>
<td>Study A – 80 (identified symptoms predictive of BCRL) Study B – 103 (identified the degree of absolute prediction of maximal difference)</td>
<td>n=43</td>
</tr>
<tr>
<td>Definition of lymphoedema</td>
<td>Methods not identified. Low volume: 300mL&lt;x&lt;500mL Medium volume: 500mL&lt;x&lt;800mL Large volume: &gt;800mL</td>
<td>No. Clinical diagnosis of lymphoedema from health professional, but threshold not provided</td>
<td>&gt;2cm at one or more points using circumferential measurements from five anatomical points</td>
<td>Circumferential measurements at six points along the arm; mild BCRL =&lt;2cm Moderate BCRL=2cm &lt;x&lt;5cm Severe BCRL=&gt;5cm</td>
</tr>
<tr>
<td>Repeatability of methods</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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QoL questionnaires identified in the literature.

Table 2 describes each study. Table 3 presents the validity findings for each study, and Table 4 outlines the reliability findings.

The following is a narrative summary of the subsections and scoring of the questionnaires identified.

**Functional Assessment of Cancer Therapy — Breast (FACT-B+4)**

The FACT-B+4 questionnaire with arm subscale was developed from the FACT-B, a questionnaire specific for breast cancer. The FACT-B measures current (in the last week) QoL, using 36 items in five different domains:

- **Physical well-being**
- **Social/family well-being**
- **Emotional well-being**
- **Functional well-being**
- **Breast cancer concerns**

Items are scored along a five-point Likert scale, completed in writing by the patient. With a total score of up to 144, a higher score indicating better QoL (Beaulac et al, 2002). The addition of the arm subscale with four upper limb items to the existing questionnaire regarding arm swelling and tenderness increases the
Upper limb lymphoedema (ULL-27)

The ULL-27 contains three dimensions for which scores are calculated, for current (within the past month) physical (14 questions), psychological (seven questions), and social aspects (six questions) (Launois and Alliot, 2000). The questionnaire is self-administered, specific to upper limb lymphoedema and has responses in a five-point Likert scale.

### Table 3

**Comparisons of validity of BCRL-specific QoL measurement tools**

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<tr>
<td><strong>Content (face validity)</strong></td>
<td>Preliminary study: semi-</td>
<td>Developed following consultation with two breast surgeons, two nurses, a psycho-oncologist and breast cancer patients and focus group</td>
<td>Reviewed and revised by expert oncological advanced practice nurses and expert patient educators for clarity, format, education level, and coverage of the symptom domain</td>
<td>Development through literature review, consultation with experts, and focus groups of women with breast cancer and women with BCRL</td>
</tr>
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<td><strong>Discriminant validity; correlations to objective measures; sensitivity and specificity</strong></td>
<td>Discriminant validity — good correlations between physical scores and severity, but severity not defined</td>
<td>Discriminant validity — between BCRL and non-BCRL significant for social, arm subscale, breast cancer concerns subscales, and total FACT-B+4</td>
<td>BCRL predicted by presence of heaviness in past year and swelling now, (p=0.0007)</td>
<td>Sensitivities of 0.93–0.96 and specificities of 0.69–0.75 for the presence of any lymphoedema; specificity of &gt;0.90 for moderate lymphoedema</td>
</tr>
<tr>
<td><strong>Responsive to change over time</strong></td>
<td>Demonstrated</td>
<td>Demonstrated</td>
<td>Not demonstrated</td>
<td>Not demonstrated</td>
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### Table 4

**Comparisons of reliability calculations in BCRL validation papers**

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<tr>
<td><strong>Internal consistency</strong></td>
<td>Cronbach’s alpha Physical: 0.93</td>
<td>Cronbach’s alpha Physical: 0.71</td>
<td>Cronbach’s alpha Overall (physical) = 0.785 for all 19 items</td>
<td>Weighted kappa statistic 0.70–0.84</td>
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<td>Psychological: 0.86</td>
<td>Emotional: 0.77</td>
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<td>Social: 0.82</td>
<td>Social: 0.76</td>
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<tr>
<td></td>
<td>Functional: 0.81</td>
<td>Breast cancer subscale: 0.62</td>
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<td></td>
<td>Arm subscale: 0.83</td>
<td>Arm subscale — 0.93</td>
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<tr>
<td></td>
<td>Overall FACT-B+4: 0.88</td>
<td>Timeframe: five days</td>
<td>Sample of healthy women without breast pathology; r=0.98</td>
<td>Not demonstrated</td>
</tr>
<tr>
<td><strong>Test-retest reliability</strong></td>
<td>Physical — 0.86</td>
<td>FACT-B+4 — 0.97</td>
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<tr>
<td></td>
<td>Psychological — 0.80</td>
<td>Arm subscale — 0.93</td>
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<tr>
<td></td>
<td>Social — 0.70</td>
<td>Timeframe: two hours</td>
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<tr>
<td></td>
<td>Timeframe unknown</td>
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of physical lymphoedema presence, frequency of symptoms and symptom management strategies, both now and in the past year (Armer et al, 2003). It asks about the presence of 19 physical symptoms giving a maximal score of 38 (Armer et al, 2003).

Telephone questionnaire
A telephone questionnaire was developed with the rationale of finding a method to detect lymphoedema, which would have excellent agreement with objective measures, without the time and financial expense of previous methods used to measure the limbs (Norman et al, 2001). The questionnaire asked for a yes/no response to questions regarding the size of the patient’s hands/upper arms and upper arms. They were then asked to grade the differences in arm size by choosing from three categories: 1. Very slight, they are the only person that would notice 2. Noticeable to people who know you well but not to strangers 3. Very noticeable.

Further detail was gathered using functional questions regarding the effect of swelling and reports pertaining to the previous three months with respect to frequency, severity and the associated distress experienced by the participant.

Critical appraisal
From reviewing the literature, it can be seen that a significant number of QoL questionnaires are utilised for measuring the effects of BCRL. However, few studies utilise BCRL-specific questionnaires. Four papers which assessed validity and reliability of specific questionnaires for a BCRL patient population were critically appraised.

Sample and methods
Although study samples appeared to be representative of those who would complete the questionnaire in clinical practice, the studies either utilised a sample of convenience or recruited randomly, but no response rates were reported. Because of the recruitment strategies, there is the potential for selection bias (Akechi et al, 2001). The papers also do not report the use of power and sample size calculations. Inclusion and exclusion criteria were only explicitly stated by one paper (Launois and Alliot, 2000).

Three of the papers provided enough information to allow other researchers to repeat the method (Coster et al, 2001; Armer et al, 2003; Norman et al, 2001). The fourth paper (Launois and Alliot, 2000) was associated with another paper written in French that may include the method in more detail; however, the paper was not obtainable for this review (Alliot and Launois, 2002).

Validity and reliability
Face validity
All papers described rigorous development for the questionnaires and established face validity. The ULL-27 displayed the highest internal consistency score for each domain of QoL, as compared to the corresponding domains for the FACT-B+4 (Launois and Alliot, 2000; Coster et al, 2001).

Discriminant validity
The telephone questionnaire and symptoms from the LBCQ were established as being predictive of BCRL. Various discriminant features were assessed in each study that were relevant to each assessment questionnaire. The ULL-27 was able to discern the severity of BCRL, and the FACT-B4, LBCQ and the telephone survey were able to identify women with and without BCRL.

Test-retest reliability
This was highest for the LBCQ, however, the test was performed on a healthy population with no breast pathology (Armer et al, 2003). Therefore, the test-re-test reliability of the LBCQ on a BCRL patient group has not been established. The highest test-retest reliability for a BCRL patient group was for the FACT-B+4 (r=0.97; timeframe five days).

Sensitivity and specificity
The paper by Norman et al (2001) regarding the telephone questionnaire was the only research to perform sensitivity and specificity calculations for the detection of BCRL. It revealed very high sensitivities but lower specificities for detecting BCRL. Sensitivity and specificity measures were lower for mild compared to no lymphoedema, as compared to detecting moderate lymphoedema.

Structure of tool and domains assessed
The four questionnaires identified in this review can be classified into two categories: a QoL questionnaire which assessed multiple domains of health (ULL-27 and FACT-B+4), or one that specifically addressed physical symptom identification (LBCQ and telephone questionnaire). The difference between the two categories was that the QoL questionnaires assessing multiple domains did not have a threshold which defined lymphoedema. Instead, they measured change in QoL over time, for example, pre-surgery and follow-up measures. The subjective and individual experience of BCRL in all its domains would make it hard to identify global cut-off scores which identified a poorer experience of QoL. Further, a questionnaire measuring multiple domains measures the impact of BCRL on QoL, but cannot be used in isolation as a diagnostic questionnaire.

Conversely, the two questionnaires which only addressed physical symptoms had greater ability to identify a cut-off lymphoedema threshold score. These measures were shown to have high correlations with objective measures and high discriminant validity between BCRL and non-BCRL groups. Further, sensitivity studies would be interesting, as questionnaires such as these are suggested to be as effective as self-monitoring questionnaires for early detection of BCRL for those in the ‘at risk’ population (Norman et al, 2001). However, during monitoring for BCRL following breast cancer treatment, an holistic view is imperative and subjective monitoring using a QoL questionnaire with multiple domains should be administered.
Climates
All studies were undertaken in cold or temperate climate zones, however, the season was not indicated (Table 2). Hence, validity and reliability have only been established for questionnaire use in these climatic regions. Therefore, the confidence of the established psychometric properties cannot be guaranteed when they are utilised in tropical, dry or polar climatic regions (Peel et al, 2007).

Discussion
Several studies have documented the adverse psychological and emotional effects that BCRL has on QoL, including self-image, coping, fulfilling roles, and participation in activities (Beaulac et al, 2002; Radina et al, 2004; Carter, 1997; Johansson et al, 2003; Wilson et al, 2005; Akechi et al, 2000; Engel et al, 2003; Gordon et al, 2005; Kwan et al, 2002; Radina and Armer, 2004; Erickson et al, 2001). However, the QoL questionnaires appear to be less sensitive in detecting significant differences between the psychological and emotional domains, than they are in detecting differences in the physical domains, between those with and without a diagnosis of BCRL. The ULL-27 revealed discriminant validity for the physical and social subsections of the scale, but not for the emotional subsection (Launois and Alliot, 2000). However, for the purpose of observing the effects of living with lymphoedema in the tropics and hot, dry climates, it is believed that a question such as this would be interesting to explore. Ridner (2005) found ‘a change in wardrobe’ (a change in clothing choice) was one of 10 themes that arose from qualitative findings in a mixed methods study of 128 patients.

In North Queensland where the monthly mean maximum temperature varies from 25°C to 33°C, women with BCRL report increased discomfort and swelling during the summer months. Most report that this is even worse when high temperatures are coupled with high humidity in the wet season.

Symptoms following surgery for breast cancer, particularly with ALND, are not exclusively experienced by those who develop BCRL. Many women who are not diagnosed with BCRL do report symptoms which could be attributable to BCRL after treatment, and this may alter the specificity of QoL questionnaires. These symptoms include the presence of post-operative swelling and paresthesia near the surgical site. Patients are reported to have reduced QoL in the period directly after surgery and up to four weeks post surgery, which then improves by twelve weeks post surgery (Coster et al, 2001). However, patient complaints of symptoms are a good indicator of future problems and continual monitoring is necessary for an early diagnosis of BCRL (Engel et al, 2003). Early diagnosis and early referral may enhance response to treatment and improve QoL (Functional Assessment of Chronic Illness Therapy (FACIT), 2008).

While most studies utilising QoL questionnaires include an objective measure to establish BCRL, rarely are QoL questionnaires compared within a study to make recommendations about the most valid, reliable, sensitive or specific assessment questionnaire. Certainly this is true with respect to ethnic groups and climatic variation.

Clothing choices and the tropics
During the development of the ULL-27, an item regarding dress style (‘do you have difficulties in the choice of your dressing due to your arm?’) was deleted from the original draft. The authors’ rationale was that they anticipated that it would not be stable across studies and populations (Launois and Alliot, 2000). However, for the purpose of observing the effects of living with lymphoedema in the tropics and hot, dry climates, it is believed that a question such as this would be interesting to explore. Ridner (2005) found ‘a change in wardrobe’ (a change in clothing choice) was one of 10 themes that arose from qualitative findings in a mixed methods study of 128 patients.

Implications for practice: climate
In North Queensland where the monthly mean maximum temperature varies from 25°C to 33°C, women with BCRL report increased discomfort and swelling during the summer months. Most report that this is even worse when high temperatures are coupled with high humidity in the wet season (personal communication). It is possible, however, that women from any climate where large variations in seasonal conditions occur will report similar changes. Hence, studies investigating BCRL should report the season and climatic conditions during which the study was undertaken.

No investigations have validated any subjective questionnaires regarding BCRL for use in the tropical, dry or polar regions as defined by Koppen (Peel et al, 2007). Nor have the relationships between self-reported symptoms, QoL, and presence and severity of BCRL been examined in any of these conditions.

regions. The authors hypothesised that compliance with compression garment use in the management of BCRL may be less in tropical and extremely hot, dry climates, and that both compliance and non-compliance can potentially have a detrimental effect on QoL, i.e. wearing tight garments in hot climates causes considerable discomfort, while not wearing them increases the swelling associated with lymphoedema. Summer and clothing changes have already been identified as major themes arising from qualitative studies (Beaulac et al, 2002; Goffman et al, 2004; Graham, 2002; Hayes et al, 2005; Radina et al, 2004; Thomas-Maclean et al, 2005; Ridner, 2005). It is unknown if incidence of BCRL, or compliance with self-management strategies for BCRL differs according to climate.

Implications for practice: ethnicity
The validation studies were undertaken with samples of predominately Caucasian women of European and North American descent (Launois and Alliot, 2000; Coster et al, 2001; Armer et al, 2003), with only one study including 16% Black American women (Norman et al, 2001). The base FACT-B questionnaire is currently available in 45 different languages (Wan et al, 2007); The FACT-B+4, however, is available in only two different languages; a simplified Chinese version of the FACT-B+4 has been validated with similarly high outcomes (Erickson et al, 2007). From current research, no BCRL-specific questionnaires were identified to have been validated in tropical, dry or polar climates or with indigenous populations. Based on the psychometric properties identified in this review, which only had access to articles written in English, it is recommended that the FACT-B+4 be utilised to assess multiple domains of QoL.

No research has established valid or reliable questionnaires for the assessment of QoL in relation to breast cancer or BCRL in indigenous Australians. Scales need to be developed that incorporate cultural sensitivity, cultural appropriateness, literacy levels and languages other than English, not only for indigenous Australians but for all ethnic groups.

This critical review of the literature confirms the inconclusive nature of the evidence base as it relates to BCRL and identifies the subjective questionnaires currently used to quantitatively measure and monitor the impact of lymphoedema. The potential for self-reported questionnaires which identify physical symptoms to be used as screening and diagnosis questionnaires would be beneficial for early diagnosis for those in the ‘at-risk’ population.

As survival continues to improve for patient populations with breast cancer over time, QoL issues take on increasing importance (Erickson et al, 2001). From current research it is unclear if the questionnaires identified in the literature are sensitive enough to diagnose or provide an early indication of onset of BCRL. Furthermore, research is required to develop reliable and valid subjective assessment questionnaires that have high sensitivity and specificity for use in varying climates and with indigenous populations.

Conclusions
Four validation studies which used BCRL-specific questionnaires were identified for critical appraisal. The studies used various criteria to describe lymphoedema and different structure and scoring methods. Although the questionnaires revealed good to high psychometric properties, no questionnaires were identified to have been validated in tropical, dry or polar climates or with indigenous populations. The potential for self-reported questionnaires which identify physical symptoms to be used as screening and diagnosis questionnaires would be beneficial for early diagnosis for those in the ‘at-risk’ population.

References