

Chapter 8: Patient-reported Health Instruments used for people with heart failure

Heart failure is a common clinical syndrome resulting from cardiac disease. It is recognised by a constellation of symptoms and signs due to a failing heart, including dyspnoea, raspy breathing/wheezing, persistent coughing, blood-tinged sputum, weight gain due to fluid retention, swollen feet, ankles, legs, abdomen, sleeplessness, fatigue, listlessness, poor effort tolerance. The most common cause of heart failure in the developed world is coronary heart disease (CHD), although hypertension often co-exists.

Heart failure results in high levels of ill-health, disability and mortality, and is a heavy burden on health services. Quality of life, physical ability and prognosis for heart failure are poor, and less than half survive one year after first diagnosis. It is an area where rapid investigation, confirmation of diagnosis and prescribing of appropriate treatment is essential. Given the nature of the symptoms, and their potential impact on people's lives, both physically, socially and psychologically, it is an area where patient-based outcome assessments are important. However, the high mortality rate makes longer-term, patient-based outcome assessment difficult.

Search terms and results: identification of articles

At the time of the review, the PHI database contained 12,562 records (up to June 2005). Record abstracts and titles were initially searched using the terms 'heart failure *or* heart disease *or* cardiac disease *or* cardiac failure'; a further search was run using the terms 'cardiac *or* cardiovascular'. Finally, a search was made of the PHI keywords field using the subject classification keyword 'cardiovascular'. These searches generated 821 records, as shown in Table 8.1. All records were reviewed. When assessed against the review inclusion criteria, 173 articles were retrieved and reviewed in full. Of these, 89 articles were included in the review.

Table 8.1 Number of articles identified by the literature review

<i>Source</i>	<i>Results of search</i>	<i>No. of articles considered eligible</i>	<i>Number of articles included in review</i>
PHI database: original search (up to June 2005) Total number = 12,562	799	130	64
Additional PHI database search (July-December 2005) Total number = 4021	22	12	6
Supplementary searching		31	19
TOTAL	821	173	89

Supplementary searches included scanning the reference lists of key articles, checking instrument websites, where found, and drawing on other bibliographic resources. All titles of issues of the following journals published between January and September 2006 were scanned:

- Heart and Lung
- Journal of Cardiopulmonary Rehabilitation
- Journal of Cardiac Failure

- Health and Quality of Life Outcomes
- Medical Care
- Quality of Life Research

Identification of patient-reported health instruments

Five generic and four heart failure-specific instruments were included in the review. Instruments where there was no evidence that an English-language version had been tested were excluded. The developmental and evaluative studies relating to generic instruments are shown in Tables 8.2 to 8.5; those for heart failure-specific instruments are shown in Table 8.6 to 8.11. Table 8.12 provides an overview of other records of heart failure-specific instruments and generic cardiovascular disease (CVD) instruments used with heart failure patients.

RESULTS: GENERIC PATIENT-REPORTED HEALTH INSTRUMENTS

Five generic instruments were identified which were evaluated with patients with heart failure. For full details of the development, domains and scoring methods are detailed in Chapter 3.

The following instruments measurement properties are reported:

- a) SF-36
- b) SF-12
- c) SIP
- d) EQ-5D
- e) Other utility measures

a) SF-36

21 studies assessed the SF-36 and eight examined the SF-12 in relation to with adults with heart failure. Most of these reported construct validity. The studies were based on population surveys and clinical samples of patients.

Reliability

Relatively few of the included studies assessed the reliability of the SF-36 when used with patients with heart failure. Internal consistency has been reported to be good for all the SF-36 sub-scales (Cronbach's $\alpha > 0.80$) except for social functioning and general health perceptions (Wolinsky et al., 1998). Green et al. (2000) also reported social functioning to have poor reproducibility.

Validity

Jenkinson et al. (1997a) reported that the SF-36 was able to discriminate between patients aged 60 years and over with chronic heart failure and people aged 65 years and over, who reported no chronic illness. Hobbs et al. (2002) found that, in their population screening survey, people with heart failure had more severe physical impairment with the SF-36 than those with chronic lung disease or arthritis. Analyses of self-reports of chronic conditions in international surveys showed that arthritis, chronic lung disease and congestive heart failure (CHF) were the conditions with the greatest differences in physical component summary scores (Alonso et al., 2004). These differences were consistent across all SF-36 scales.

In a study of heart failure (HF) clinic patients, Havranek et al. (1999) reported significant correlations between the MOS Rand SF-36 physical component score, the Minnesota Living with Heart Failure Questionnaire (MLHFQ), timed walking, a visual analogue scale rating health status, and time-trade-off techniques. But there was no significant correlation between the MOS Rand SF-36 mental health component and 6-minute timed walking. Lalonde et al. (1999) found that the SF-36 Physical Component scale, but not the General Health Perceptions scale, was able to discriminate between CHD patients with various levels of physical disability). It correlated significantly with the Beck Depression Index, Hospital Anxiety and Depression Scale (HADS) and the Cardiac Depression Scale in a cardiac population (including HF patients) (Birks et al., 2004).

Socio-demographic variables

The SF-36 has been administered mainly to HF clinic patients or population samples, of both sexes, with ages ranging from 28-87 years, where given. Distributions or variations by socio-demographic characteristics were not given.

Heart failure-specific patient-reported health instruments

The general health perception scale of the Rand SF-36 has been reported to correlate significantly but modestly ($r = 0.45$) with the QoL domain of the Kansas City Cardiomyopathy Questionnaire (KCCQ), while the SF-36 social limitation scale correlated more highly with the KCCQ social limitation domain ($r = 0.62$) (Green et al., 2000). Oldridge et al. (2002) reported highly significant Pearson correlation coefficients between the SF-36, the Seattle Angina Questionnaire, the MacNew and the MLHFQ (ranging from 0.63 to 0.78 for the SF-36 and these instruments).

However, the SF-36 was not able to discriminate between patients with heart failure, angina or myocardial infarction (MI). Apart from the physical functioning subscale; the SF-36 was also significantly associated with anxiety and depression (measured with the HADS). Dempster et al. (2004) examined the MacNew and the SF-36 and showed that the range of domain correlations between the instruments ranged from low to high ($r = 0.18$ to 0.85), although the highest were achieved for correlations between similar domains ($r = 0.52$ to 0.85).

Sneed et al. (2001) compared the SF-36 with the MLHFQ with a small sample of HF clinic attendees; the SF-36 was better able to differentiate physical and emotional aspects of QoL. However, Wolinsky et al. (1998) tested the SF-36 and the Chronic Heart Failure Questionnaire (CHQ), slightly adapted for use with coronary artery disease (CAD) and HF patients, among outpatients with CAD or chronic HF. While the SF-36 was more comprehensive in its coverage of health status domains, the CHQ was more psychometrically sound and had fewer problems with floor and ceiling effects, and was more reproducible and internally consistent.

Measures of HF Function

Arterburn et al. (2004) reported the SF-36 was associated with body mass index. While Hobbs et al. (2002) reported the SF-36 to be significantly correlated with New York Heart Association (NYHA) status, Havranek et al. (1999) reported significant correlations between the MOS Rand SF-36 physical component score and timed walking, and no significant correlation between the MOS Rand SF-36 mental health component and 6-minute timed walking.

Generic health status

Lalonde et al. (1999) reported low to moderate correlations (between 0.12 and 0.51) between the SF-36 and rating scale, time trade-off and standard gamble health utility measures (although, technically, these are preference measures rather than comparable general health status instruments); significance levels were not reported.

Responsiveness

Gwadry-Sridhar et al. (2005), in an RCT of an educational intervention with HF inpatients, found no significant effect of time by intervention, or treatment intervention, in either of the SF-36 mental or physical summary scores, in contrast to the more sensitive MLHFQ. Green et al. (2000) reported that the Rand SF-36 was less responsive to important clinical change in HF patients than the MLHFQ. Wyrwich et al. (1999) compared change in the SF-36 and CHQ, and examined standard errors in detail. Both measures compared well at follow-up assessments of change. The physical component summary score has been shown to be predictive of decline in HF patients over four years (Bayliss et al., 2004); and the general health and physical role sub-scales were sensitive to changes in depression in patients with heart failure (Sullivan et al., 2004).

Interpretation

Expert consensus

Wyrwich et al. (2005) used Delphi and consensus panel techniques with expert panels of physicians to examine clinically important differences for the SF-36 and a modified CHQ. They reported on panel-derived thresholds for change over time.

Precision

Large ceiling effects (> 15%) have been found for the SF-36 role-physical, social functioning and role-emotional subscales, which potentially mask patient improvement or deterioration, and reduce scale sensitivity (Wyrwich et al., 1999). Ceiling effects were confirmed by Wolinsky et al. (1998).

Acceptability

In a study by Gwadry-Sridhar et al. (2005), 12 out of 134 patients were reported to find the questionnaire battery (which included the MLHFQ and SF-36) cumbersome and did not respond. High non-response to follow-up was reported in a study by Lalonde et al. (1999) with 75 (36%) participants refusing to come back for the second interview and 41% (20%) missing the second interview for various reasons. A study by Wolinsky et al. (1998) reported a 79% completion rate.

Feasibility

The SF-36 took 10-15 minutes to complete depending on whether self-completed or interviewer-read in a study by Sneed et al. (2001).

b) SF-12

Reliability

The internal consistency of the SF-12 is reportedly good, with all coefficients exceeding 0.70 in HF patients (Bennett et al., 2002), and in general CVD populations (Lim and Fisher, 1999), although Bennett et al. (2003) reported that the SF-12 was less reliable than the CHQ or the MLHFQ.

Validity

The construct validity was supported by associations with reported hospital admissions among mixed CVD populations (Lim and Fisher, 1999). Analyses have generally supported the convergent and discriminant validity of the SF-12 with HF patients (Bennett et al., 2002). Jenkinson and Layte (1997) have reported on the construction of the physical and mental component scales.

Socio-demographic variables

Lim and Fisher (1999) reported that the instrument discriminated between men and women, and being older in their study of mixed heart and stroke patients.

Heart failure-specific patient-reported health instruments

Correlations between the SF-12 and the CHQ and MLHFQ are moderate to high, being lower among the physical component summary score of the SF-12 and the CHQ and MLHFQ, than the mental component summary score of the SF-12 and the CHQ and MLHFQ (Bennett et al., 2002).

Measures of HF Function

The SF-12 physical component scale, but not the mental component scale, has correlated significantly with NYHA status in HF patients (Bennett et al., 2002).

Responsiveness

Bennett et al. (2003) reported that the SF-12 was less responsive to change in patients' condition than the CHQ or the MLHFQ. Ni et al. (2000) found the SF-12 to be more responsive to change in mental health, but less responsive to change in physical health at follow-up, than the MLHFQ. Ni et al. (2000) also found that the MLHFQ performed better than the SF-12 in ability to distinguish differences in perceived global health transition, and concluded that the SF-12 alone should not be used to measure changes in QoL of patients with HF. Spertus et al. (2005) found that the SF-12 and the EQ-5D did not exhibit much sensitivity to the magnitude of observed clinical change, unlike the KCCQ which demonstrated the highest discriminative abilities. Jenkinson et al. (1997b) reported that the SF-36 and SF-12 physical and mental component summary scores indicated the same magnitude of change over time.

Precision

Floor and ceiling effects with HF patients have been reported to be non-existent (Bennett et al., 2002; Ni et al., 2000).

Acceptability

SF-12 physical component and mental component sub-scales were missing for 13% of patients in the Bennett et al. study (2002) of clinic patients. Lim and Fisher (1999) reported a 22% non-completion rate in a mixed CVD population sample.

Feasibility

No specific evidence was found.

Table 8.2: Evaluative studies relating to the SF-36 when completed by patients with heart failure

Study/ Country	Population (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-36							
Alonso et al. (2004) 8-country survey of general adult population (IQOLA)	Different country population samples examining prevalence of chronic conditions and SF-36 scores (including HF) Age: mean 44.4 Postal <i>Descriptive data only presented</i>						
Arterburn et al. (2004) USA	Study of male veterans enrolled in general internal medical clinics (30,921) Age: mean by body mass index ranged from 57 to 66 Postal		Construct ✓				
Bayliss et al. (2004) USA	Medical Outcomes Study - longitudinal (1574 patients, including HF; n with HF unspecified) Age: mean 57.6 Self-administration			✓			
Birks et al. (2004) UK	Cardiac support group patients, including HF patients (396) Age: range 37-90, mean 67 Postal		Construct ✓				
Cunningham et al. (2003) USA	Patients (including HF) receiving care across 48 physician groups (5701) Age: 45% aged 50+ Postal		Construct ✓				

Study/ Country	Population (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-36							
Dempster et al. (2004) UK	IHD patients (mixed group, including 'other' unspecified) (117) Age: mean 60.61 Inpatients Interview		Construct ✓ Concurrent ✓				
Green et al. (2000) USA	Two patient cohorts with stable or decompensated CHF with LVEF < 40% (129) Age: mean 64.3 Outpatients Postal	Internal consistency ✓ Test-retest ✓	Construct ✓ Concurrent ✓	✓			
Gwadry-Sridhar et al. (2005) Canada	Clinically diagnosed HF patients and LVEF < 40%, RCT educational intervention (134) Age: mean 67 intervention group, 65 control group Interview and telephone interview follow-up Inpatients		Construct ✓	✓		✓	
Havranek et al. (1999) USA	HF clinic patients (50) Age: mean 52.5 Outpatients Interview		Construct ✓				
Hobbs et al. (2002) UK	Patients in screening study of prevalence of HF and LV systolic dysfunction (5961) Age: 45+ Population sample Self-administration		Construct ✓				

Study/ Country	Population (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-36							
Jenkinson et al. (1997a) UK	HF patients (61) Age: range 60-92, mean 81 Outpatients Self-administration		Construct ✓	✓			
Jenkinson et al. (1997b) UK	Patients treated for HF (61), sleep apnoea, inguinal hernia Age: HF patients range 60-92, mean 82 Outpatients Self-completion			✓			
Lalonde et al. (1999) Canada	Outpatients with CHD (including HF), their ('healthy') friends and family, and hospital staff (878) Age: mean 55 Interviews	Test re-test ✓ Internal consistency ✓	Construct ✓ Concurrent ✓				
O'Leary and Jones (2000) UK	Patients with chronic LV dysfunction, including LVEF =/ $<$ 50% (60) Age: mean 60 Outpatients Self-administration		Construct validity ✓ Concurrent ✓				
Oldridge et al. (2002) USA	HF patients sampled from electronic medical records as having MI (161), angina or heart failure Age: MI patients mean 69 Postal		Construct ✓ Concurrent ✓				
Sidorov et al. (2003) USA	HF patients in disease management programme (268) Age: means 75.2 Outpatients, inpatients, community patients referred for discharge planning Self-administration		Construct ✓	✓			

Study/ Country	Population (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Sneed et al. (2001) USA	Patients attending HF clinic (30) Age: mean 57, range 35-88 Self-completed or interview if patient unable to read Outpatients		Construct ✓				✓
Sullivan et al. (2004) USA	Elderly outpatients with heart failure diagnosed in primary care and confirmed with 'chart review' (139, plus 80 spouses) Age: mean 75, 83% female Outpatients Self-administration		Construct ✓	✓			
Wolinsky et al. (1998) USA	Outpatients with CAD or chronic HF (560) Age: not given Telephone interview	Internal consistency ✓	Construct ✓		✓	✓	
Wyrwich et al. (1999) USA	Patients with a history of cardiac problems - CAD/CHF/both, participating in RCT of computerised medication reminders to physicians (605) Age not given Outpatients Interview			✓	✓		
Wyrwich et al. (2005) USA	Expert consensus panels of physicians (3); further details of numbers not given			✓			

Study/ Country	Population (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-12							
Bennett et al. (2002) USA	HF clinic patients sampled from electronic medical records for diagnostic data (211) Age: 72% < 65 Outpatients Telephone interviews	Internal consistency ✓	Construct ✓ Concurrent ✓		✓	✓	
Bennett et al. (2003) USA	Convenience sample of HF patients (211) Age: mean 57 Outpatients Telephone interviews	Internal consistency ✓	Construct ✓	✓			✓
Conard et al. (2006) USA	HF patients, 13 centres, LVEF < 40% (539) Age: 59.5 burdened economically, 62.1 not burdened Outpatients Self-administration		Construct ✓				
Jenkinson et al. (1997b) UK	Three longitudinal datasets of patients treated for HF, sleep apnoea, and inguinal hernia (61 HF patients) Age: HF patients range 60-92, mean 82 Outpatients Self-completion			✓			
Jenkinson and Layte (1997) UK	Population survey, comparison of patient groups including HF (9332); construction of SF-12 summary scores Age: HF group mean 81, range 60-92 Postal		Construct ✓				

Study/ Country	Population (N) Age (years) Method of administration Setting	Measurement and Practical properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
SF-12							
Lim and Fisher (1999) Australia	Population survey: AMI, IHD, 'other heart conditions' - not specified (1831) Age: 61% aged 65+ Postal	Internal consistency ✓	Construct ✓			✓	
Ni et al. (2000) USA	Clinic attendees with chronic and symptomatic HF (87) Age: 24% aged 60+ Outpatients Mode of administration: not given		Construct ✓	✓	✓		
Spertus et al. (2005) USA	Clinic attendees in 14 centres (476) Age: mean 61 Self-administration Outpatients		Construct ✓	✓			

c) Sickness Impact Profile (SIP)

Grady et al. (2003a), in a study of post-left ventricular assist device (LVAD) implantation and heart transplantation patients, reported that the SIP showed improvement for work and home management disability after heart transplantation. Mobility, self-care ability, physical ability and overall functional ability improved after LVAD implant and after heart transplant. Grady et al. (2003b), also reporting on LVAD implantation patients, found that functional disability measured with the SIP decreased post-discharge. Janz et al. (2004) used the emotional behaviour domain of the SIP, alongside generic domain specific measures, in an intervention trial of a disease management programme in 457 older women with heart disease (including HF). Women in the intervention arm were more likely to have improvements on the SIP, compared to controls. Avis et al. (1996) provided evidence supporting the construct validity and reliability of the SIP subscales for cognitive functioning, social functioning and productivity.

Table 8.3: Developmental and evaluation studies relating to the Sickness Impact Profile

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Sickness Impact Profile (SIP)							
Avis et al. (1996) USA	Clinic patients and healthy patients (129 CVD patients) Age: mean 63 Interview <i>Selected SIP subscales only</i>	Internal consistency ✓ Test-retest ✓	Construct ✓			✓	
Grady et al. (2003a) USA and Australia	Post LVAD and heart transplant patients from medical centres in two countries (40) Age: mean 51.1 Inpatients Self-administration		Construct ✓	✓			
Grady et al. (2003b) USA and Australia	Post LVAD (62) Age: not discharged mean 52.8, discharged mean 50.2 Inpatients Self-administration		Construct ✓	✓			
Janz et al. (2004) USA	CHD patients, including heart failure, participating in psychological stress intervention trial Age: mean 73 (intervention), 72.1 (control); 100% female Outpatients and 'physician's offices' Telephone interviews (457) <i>Physical subscale only; Emotional behaviour subscale only used as outcome variable</i>		Construct ✓	✓			

d) EuroQoL/EQ-5D

There were five reports of the use of the EQ-5D in heart failure.

Reliability

No specific evidence was found.

Validity

The EQ-5D was found to correlate significantly with the MLHFQ, the NYHA functional status, and age-group, and has been reported to have higher response rates, reflecting its brevity (Calvert et al., 2005).

Responsiveness

Sullivan et al. (2004), in a study of older people with heart failure, reported that the EQ-5D thermometer scale was sensitive to independent measures of depression over time. The VAS scale of the EQ-5D, along with the KCCQ, was reportedly sensitive to variability in the health status of advanced HF (Hauptman et al., 2004). Spertus et al. (2005) found the EQ-5D and the SF-12 did not show much sensitivity to the magnitude of observed clinical change, unlike the KCCQ which demonstrated the highest sensitivity. Feldman et al. (2005) reported that EQ-5D scores improved for patients in a basic home health-care intervention arm, but not in the augmented intervention group, compared with controls. In contrast, the KCCQ mean summary scores improved for both intervention arms, compared with controls.

Precision

No specific evidence was found.

Acceptability

No specific evidence was found.

Feasibility

No specific evidence was found.

Table 8.4: Developmental and evaluation studies relating to the EQ-5D

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
EQ-5D							
Calvert et al. (2005) UK and 11 other countries	HF patients enrolled in study of cardiac re-synchronisation in HF (813) Age: mean 65 Self-administered		Construct ✓ Concurrent ✓			✓	
Feldman et al. (2005) USA	Patients with diagnosed HF in home health-care intervention trial (628) Age: 71.2 usual care, 72.4 basic care, 71.8 augmented care Home care patients Mode of administration not given		Construct ✓	✓			
Hauptman et al. (2004) USA	HF patients in multi-centre cohort study with LVEF < 40 (547) Age: mean 61 (advanced HF), 61 (non-advanced HF) Outpatients Mode of administration: not given		Construct ✓	✓			
Spertus et al. (2005) USA	Clinic attendees in 14 centres (476) Age: mean 61 Self-administration Outpatients		Construct ✓	✓			
Sullivan et al. (2004) USA	Elderly outpatients with heart failure diagnosed in primary care and confirmed with 'chart review' (139, plus 80 spouses) Age: mean 75, 83% female Outpatients Self-administration		Construct ✓	✓			

e) Other utility measures

Havranek et al. (1999) reported significant correlations between time-trade-off techniques and the MOS Rand SF-36 physical component score, the MLHFQ, a 6-minute walking test and a visual analogue scale rating health status. Utilities did not vary by age, sex or ethnicity of the patient. In a study of HF clinic patients, Havranek et al. (1999) reported significant correlations between the MOS Rand SF-36 physical component score, the MLHFQ, timed walking, a visual analogue scale rating health status, and time-trade-off techniques. Havranek et al. (2004) reported that the DASI correlated significantly with utility scores (time trade-off).

Kirsch and McGuire (2000) examined the feasibility of developing a QALY from the NYHA classification of heart failure, and concluded that constant proportionality did not hold across more severe health states, questioning the use of QALYs as representing cardinal preference structures. Lalonde et al. (1999) compared preference-based (rating scale, time trade-off, and standard gamble) and non-preference-based (SF-36) measures of HRQoL in CHD patients (including HF) and healthy people. While all measures were stable over 3-6 weeks, in contrast to SF-36 subscales, the utility measures were less able to discriminate between patients with various levels of disability. A large proportion of respondents also refused to return for the second interview, suggesting this battery of instruments (i.e. administered together) was not acceptable.

Table 8.5: Developmental and evaluation studies relating to Time Trade-off

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Havranek et al. (1999) USA	HF clinic patients (50) Age: mean 52.5 Outpatients Interview	Test-retest ✓	Construct ✓				
Havranek et al. (2004) USA and Canada	Patients in multi-site drug trial (153) Age: mean 68.3 In- or outpatients not specified Postal and telephone interview		Construct ✓				
Lalonde et al. (1999) Canada	Outpatients with CHD (including HF), their ('healthy') friends and family, and hospital staff (878) Age: mean 55 Interviews	Internal consistency ✓ Test-retest ✓	Construct ✓ Concurrent ✓			✓	

RESULTS: HEART FAILURE-SPECIFIC PATIENT-REPORTED HEALTH INSTRUMENTS

Four heart failure-specific instruments were identified which were evaluated with patients with various cardiovascular conditions resulting in heart failure. Full details of the development, domains and scoring methods are detailed in Tables 8.6 and 8.7.

Measurement properties are reported for the following instruments:

- a) Chronic Heart Failure Questionnaire
- b) Kansas City Cardiomyopathy Questionnaire
- c) MacNew (ex-QLMI: Quality of Life after Myocardial Infarction Questionnaire)
- d) Minnesota Living with Heart Failure Questionnaire

a) Chronic Heart Failure Questionnaire (CHQ) (Guyatt et al., 1989)

This 16-item instrument aims to measure subjective health status in heart failure patients, and is complex to administer as open-ended questions are used to yield score weights. It covers dyspnoea, fatigue, and emotional functions; it has a time recall period of two weeks. It was developed by presenting 123 items to a sample of 88 patients, who rated their importance. Item selection was based on frequency and importance ratings. A section of the CHQ is individualised, and patients are asked to nominate those activities associated with shortness of breath and that affect them most often/importantly. It requires a trained interviewer. Administration takes 10-20 minutes.

b) Kansas City Cardiomyopathy Questionnaire (KCCQ) Green et al., 2000)

This instrument aims to describe HRQoL over the previous two weeks in patients with congestive heart failure (CHF). It contains 23 items, covering physical function, clinical symptoms, social function, self-efficacy and knowledge and QoL ('enjoyment'), each with different Likert scaling wording, including limitations, frequency, bother, change in condition, understanding, levels of enjoyment and satisfaction. It is self-administered. A change of 5 points on the scale scores, either as a group mean or an intra-individual change is regarded as clinically important (Rumsfeld et al., 2003).

c) MacNew (ex-QLMI: Quality of Life after Myocardial Infarction Questionnaire) (Lim et al., 1993; Valenti et al., 1996)

While not solely heart failure-specific, MacNew measures HRQOL in heart disease (myocardial infarction, coronary disease and heart failure) in the previous two weeks. This instrument is a modification of the earlier Quality of Life after Myocardial Infarction (QLMI) Questionnaire, which had questionable validity (see review by Hofer et al., 2004). MacNew contains 27 items in three domains (Emotional, Physical, and Social). It takes up to 10 minutes to complete, and respondent burden is low.

**d) Minnesota Living with Heart Failure Questionnaire
(MLHF/MLHFQ/LHFQ/LiHFe) (Rector et al., 1987)**

This contains 21 items that ask about patients' perceptions of the effects of heart failure and its treatment on physical, socioeconomic and psychological aspects of their life, rated on a 6-point Likert scale. Subscale scores for emotional and physical domains can be obtained. It is easy to administer by self-administration or interview. The items were drawn from the SIP. Patients with congestive heart failure were asked to select 21 items from the SIP, and these formed the MLHFQ. Some concern has been expressed about its content validity and whether all relevant items have been included (Dunderdale et al., 2005; O'Leary and Jones, 2000).

HEART FAILURE-SPECIFIC INSTRUMENTS:

Table 8.6: Details of Heart failure-specific patient-reported health instruments

<i>Instrument</i>	<i>Domains (no. items)</i>	<i>Response options</i>	<i>Score</i>	<i>Administration Completion time</i>
Chronic Heart Failure Questionnaire (CHQ) (Guyatt et al., 1989)	<i>16 items in 3 domains:</i> Dyspnoea (5) Fatigue (4) Emotional function (7) <i>Plus open-ended probes (3) for most important activities causing symptoms</i>	1-7 response scales of frequency or severity	Summed to yield subscale scores Weighting based on open-ended responses Minimum (worse function) to maximum (best function) scores in the 3 domains are: dyspnoea 5-35; fatigue 4-28; emotional 7-49	Interview 10-20 mins
Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green et al., 2000)	<i>23 items in 5 domains</i> 1. Physical limitation (6) 2. Symptoms (8) 3. Self-efficacy and knowledge (2) 4. QoL/mood (3) 5. Social limitation (4)	6-point Likert scales, including severity and frequency	Summation of physical limitation, symptoms, social limitation and QoL domains. 0-100, higher scores represent fewer symptoms/better function/better QoL	Self-administered 4-6 mins
MacNew (ex-QLMI – Quality of Life after Myocardial Infarction) (Lim et al., 1993)	<i>23- 27 items in 3 overlapping domains:</i> Emotional Physical Social <i>In previous 2 weeks</i>	Item scores 1 = poor to 7 = high	Summation; domain scores calculated by taking the average of responses to items in each domain; averaging all items gives a global score.	Self-administered (modification of original interviewer-administered QLMI instrument) 5-10 minutes to complete
Minnesota Living with Heart Failure Questionnaire (MLHFQ) (Rector et al., 1987)	<i>21 items on impact of heart failure on:</i> Physical aspects of daily life (9) Emotional/psychological (5) Social/economic (7) <i>In previous 4 weeks.</i>	6-point Likert scales (0 = not at all, to 5 = very much)	Summation; range 0 (best) to 105 (worst QoL). Physical and emotional domains can also be summed.	Self-administered or interview

Table 8.7: Summary of heart failure-specific instruments: health status domains (*after Fitzpatrick et al., 1998*)

<i>Instrument</i>	<i>Instrument domains</i>								
	Physical function	Symptoms	Global judgement of health	Psychol. well-being	Social well-being	Cognitive functioning	Role activities	Personal construct	Treatment satisfaction
Chronic Heart Failure Questionnaire (CHQ)		X		X					
Kansas City Cardiomyopathy Questionnaire (KCCQ)	X	X		X	X		X	X	
MacNew (ex QLMI – Quality of Life after Myocardial Infarction)	X	X		X	X		X	X	
Minnesota Living with Heart Failure Questionnaire (MLHFQ)	X	X		X	X		X		

RESULTS: HEART FAILURE-SPECIFIC PATIENT-REPORTED HEALTH INSTRUMENTS

a) Chronic Heart Failure Questionnaire (CHQ)

The CHQ has been used with a wide range of HF patients, and age groups, including both sexes. Ten studies examined this instrument.

Reliability

Bennett et al. (2003) reported that the CHQ was more reliable, and more responsive to change in patients' condition, than the SF-12. It had comparable Cronbach's alphas as the MLHFQ (totals: 0.93 and 0.95, respectively; range for subscales 0.86-0.92 and 0.89-0.94, respectively). Bennett et al. (2002) supported the high internal consistency of the instrument in HF patients (all coefficients exceeding 0.70). The measure also had satisfactory reproducibility (Guyatt et al., 1989; O'Keefe et al., 1998).

Validity

Analyses have supported the convergent and discriminant validity of the instrument with HF patients, and the factor structure has been supported (Bennett et al., 2002). The measure can distinguish between patients receiving medication (digoxin) or placebo Jaeschke et al. (1990).

Socio-demographic variables

Age, sex, ethnic status, and income have been reported to be associated with higher scores on some of the subscales, in expected directions (Clark et al., 2003).

Heart Failure-specific patient-reported health instruments

The CHQ and LHFQ have been shown to be significantly and highly correlated (Bennett et al. 2002), and the CHQ and KCCQ have significant, but low to high, correlations (Clark et al., 2003).

Measures of Heart Function

Guyatt (1993) reviewed the psychometric properties of the measure during its development, including its significant correlations with change in walking test scores; the instrument's dyspnoea score also correlated significantly with heart failure scores. The instrument also correlates significantly with NHYA status in HF patients (Bennett et al., 2002). However, the measure was not found to be associated with left ventricular ejection fraction (LVEF) and co-morbidity in one cross-sectional study of HF patients (Clark et al., 2003).

Generic health status

Wolinsky et al. (1998) tested the SF-36 and the CHQ (slightly adapted for use with CAD and HF patients) among outpatients with CAD or chronic HF. While the SF-36 was more comprehensive in its coverage of health status domains, the CHQ was more psychometrically sound, having fewer problems with floor and ceiling effects, and was more reproducible and internally consistent. The CHQ correlates moderately to highly, although significantly, with the SF-12 subscales (Bennett et al., 2002).

Responsiveness

Bennett et al. (2003) reported that the CHQ was more reliable, and more responsive to change in patients' condition than the SF-12. It correlates moderately highly, and significantly, with change in dyspnoea (0.65), change in walking test score (0.60) and change in heart failure scores (0.42) (Guyatt et al., 1989). Reviews by Guyatt (1993, 1994) of the measure's development also reported that the CHQ dyspnoea score was sensitive to improvements in patients' condition over time. O'Keeffe et al. (1998) found it was responsive to change at clinical re-assessment 3-8 weeks post-baseline assessment, and effect sizes for detecting deterioration were greater than those for detecting improvement.

Wyrwich et al. (1999) compared change in the SF-36 and CHQ, and examined standard errors in detail. They reported that both measures compared well at follow-up assessments of change. Jaesche et al. (1989) reported minimal clinically important differences. Wyrwich et al. (2005) used Delphi and consensus panel techniques with expert panels of physicians to examine clinically important differences for the SF-36 and a modified CHQ and reported on panel-derived thresholds for change over time.

Precision

The CHQ has fewer respondents at the floor and ceiling end of the scale than the MLHFQ (Bennett et al., 2002).

Acceptability

81% answered all CHQ questions in a study by Wolinsky et al. (1998).

Feasibility

No specific evidence was found.

Table 8.8: Developmental and evaluation studies relating to the Chronic Heart Failure Questionnaire (Guyatt et al., 1989)

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Bennett et al. (2003) USA	Convenience sample of HF patients (211) Age: mean 57 Outpatients Telephone interviews	Internal consistency ✓	Construct ✓	✓			✓
Bennett et al. (2002) USA	HF clinic patients sampled from electronic medical records for diagnostic data (211) Age: 72% < 65 Outpatients Telephone interviews	Internal consistency ✓	Construct ✓ Concurrent ✓		✓	✓	
Clark et al., (2003) USA	HF patients in medication adherence study (212) Age: mean 63 Interview		Construct ✓ Concurrent ✓				
Guyatt et al. (1989) Canada	HF patients participating in drug trial (20) Age: 69.1 Interview In- or outpatients not specified	Test-retest ✓	Construct ✓	✓			
Jaeschke et al. (1989) Canada	HF patients from 3 studies (75) Age: not given In- or outpatients not specified Mode of administration: not given			✓			
Jaeschke et al. (1990) Canada	HF patients in drug trial (20) Age: not given Interview In- or outpatients not specified		Construct ✓				
O’Keeffe et al. (1988) UK	HF clinic patients (60) Age: mean 82 Outpatients Interview	Internal consistency ✓		✓			

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Chronic Heart Failure Questionnaire (Guyatt et al., 1989)							
Wolinsky et al. (1998) USA	Outpatients with CAD or chronic HF (560) Age: not given Telephone interview	Internal consistency ✓	Construct ✓		✓		
Wyrwich et al. (1999) USA	Patients with a history of cardiac problems – CAD/CHF/both, participating in RCT of computerised medication reminders to physicians (605) Age not given Outpatients Interview			✓	✓		
Wyrwich et al. (2005) USA	Expert consensus panels of physicians (3); further details of numbers not given			✓			

b). Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green et al., 2000)

The KCCQ has been used with a wide range of heart failure patients. 13 studies examined this instrument.

Reliability

The development research for the instrument reported Cronbach's alphas for the subscales to range between 0.62 (self-efficacy) and 0.93 (functional status); the scale was shown to be reproducible at 3.3 months (mean duration of follow-up) (Green et al., 2000).

Validity

The development research for the KCCQ also indicated that the instrument had good validity overall (Green et al., 2000). Morgan et al. (2006) found that patients with difficulty taking medication had significantly worse HF symptoms, more social limitations, less self-efficacy and poorer QoL with the KCCQ, than patients with no difficulty taking their medications.

Socio-demographic variables

Age, sex, ethnic status, and income have been found to be associated with higher scores on some of the subscales, in expected directions (Clark et al., 2003).

Heart failure-specific patient-reported health instruments

Clark et al. (2003) reported correlations between the GHFQ and the KCCQ questionnaire of 0.16 to 0.37.

Measures of HF- Function

The QoL domain, the social limitation domain, functional status score and clinical summary score of the KCCQ all correlated significantly with NYHA class during the developmental testing of the measure (Green et al., 2000). However, Subramanian et al. (2005), in their longitudinal survey of older adults, reported only slight agreement between the instrument and clinician-reported NYHA functional classifications. The measure was not found to be associated with left ventricular ejection fraction or comorbidity in a cross-sectional study of heart failure patients (Clark et al., 2003). It has also been reported that, while the KCCQ correlated significantly with the NHYA, it was not associated with B-type natriuretic peptide (BNP) levels, regardless of the threshold used to define a clinically meaningful BNP change (Luther et al., 2005). Myers et al. (2006) found that only the QoL component of the KCCQ was significantly associated with peak VO_2 ; however, the physical limitation component and clinical summary score were significantly associated with 6 minute walk test.

Generic health status

The QoL domain of the instrument correlated significantly but modestly ($r = 0.45$) with the general health perception scale of the Rand SF-36; it correlated more highly, and significantly, with the emotional domain of the MLHFQ ($r = 0.62$); the KCCQ social limitation domain was significantly correlated with the SF-36 social limitation scale ($r = 0.62$) (Green et al., 2000).

Responsiveness

Spertus et al. (2005) found that the KCCQ demonstrated the highest sensitivity to the magnitude of observed clinical change (cardiologists' assessments), compared with the SF-12, and the EQ-5D. Green et al. (2000) also reported it was more responsive to important clinical change in HF patients than the Rand SF-36 and the MLHFQ. The KCCQ, along with the VAS scale of the EQ-5D, was sensitive to variability in the health status of advanced heart failure (Hauptman et al., 2004). Rumsfeld et al. (2003) showed it was sensitive to changes in symptoms of depression in these patients. In a home health-care trial, mean KCCQ summary scores improved for both basic and augmented care intervention arms, compared with controls, while EuroQoL scores improved for patients in only the basic home health-care intervention arm (Feldman et al., 2005). In a study of older people with heart failure, Sullivan et al. (2004) reported that it was sensitive to independent measures of depression over time.

Precision

No specific evidence was found.

Acceptability

No specific evidence was found.

Feasibility

No specific evidence was found.

Table 8.9: Developmental and evaluation studies relating to the Kansas City Cardiomyopathy Questionnaire (Green et al., 2000)

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Kansas City Cardiomyopathy Questionnaire (KCCQ)							
Clark et al. (2003) USA	HF patients in medication adherence study (212) Age: mean 63 Interview		Construct ✓ Concurrent ✓				
Conard et al. (2006) USA	HF patients, 13 centres, LVEF < 40% (539) Age:59.5 (burdened economically), 62.1 (not burdened) Outpatients Self-administration		Construct ✓				
Feldman et al. (2005) USA	Patients with diagnosed HF in home health care intervention trial (628) Age: 71.2 usual care, 72.4 basic care, 71.8 augmented care Home care patients Mode of administration: not given		Construct ✓	✓			
Green et al. (2000) USA	Two patients cohorts with stable or decompensated CHF with LVEF < 40% (129) Age: mean 64.3 Outpatients Postal	Internal consistency ✓ Test-retest ✓	Construct ✓ Concurrent ✓	✓			
Hauptman et al. (2004) USA	HF patients in multi-centre cohort study with LVEF < 40% (547) Age: mean 61 advanced HF, 61 non-advanced HF Outpatients Mode of administration: not given			✓			

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green et al., 2000)							
Luther et al. (2005) USA	Patients with systolic HF in 14 centres (342) Age: mean 60.4 Outpatients Mode of administration not given		Construct ✓				
Morgan et al. (2006) USA	HF patients with LVEF < 40% (522) Age: mean 58.1 (difficulty taking medications), 61.4 (no difficulty taking medications) Outpatients Self-administration		Construct ✓				
Rumsfeld et al. (2003) USA	HF patients with LVEF < 40% (460), in depressed and non-depressed groupings, multi-centre study Age: 57.3 and 62.6, respectively Outpatients Self-completion		Construct ✓	✓			
Myers et al. (2006) USA	HF patients (41) Age: mean 68 Outpatients Self-administration		Construct ✓				
Prasun et al. (2005) USA	Heart failure patients with LVEF \leq 40%, participating in RCT of patient-directed flexible diuretic protocol (66) Age: mean 65 intervention, 70 control group Outpatients Mode of administration: self-completion		Construct ✓	✓			

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green et al., 2000)							
Spertus et al. (2005) USA	Clinic attenders in 14 centres (476) Age: mean 61 Self-administration Outpatients		Construct ✓	✓			
Subramanian et al. (2005) USA	Longitudinal study of older adults (156 with complete 6-month follow-up data) Age: mean 63 Face-to-face or telephone interview		Construct ✓				
Sullivan et al. (2004) USA	Elderly outpatients with heart failure diagnosed in primary care and confirmed with 'chart review' (139, plus 80 spouses) Age: mean 75, 83% female Outpatients Self-administration		Construct ✓	✓			

c) MacNew (ex-QLMI - Quality of Life after Myocardial Infarction)

This instrument is a modification of the earlier Quality of Life after Myocardial Infarction (QLMI) Questionnaire. Just three studies were identified which used the MacNew.

Reliability

None of the included papers reported on reliability, although the instrument has been reviewed with favourable conclusions for its internal consistency by Höfer et al. (2004).

Validity

The review by Höfer et al. (2004) also reported favourable results for construct validity confirmation of the instrument's factor structure. However, Dempster et al. (2004) reported that a five-factor solution was more appropriate than the three factors reported for it.

HF-specific patient-reported health instruments

Oldridge et al. (2002) reported highly significant Pearson correlation coefficients between the MacNew, the Seattle Angina Questionnaire and the MLHFQ (ranging from 0.624 to 0.904).

Generic health status

Oldridge et al. (2002) reported a highly significant Pearson correlation coefficient between the MacNew physical limitations domain and the SF-36 physical component summary at 0.63 for HF patients. The correlation between the SF-36 mental component summary and the MacNew was 0.70 for HF patients. Dempster et al. (2004) showed that the range of domain correlations between the MacNew and the SF-36 ranged from low to high ($r = 0.18$ to 0.85), although the highest were achieved for correlations between similar domains ($r = 0.52$ to 0.85).

Responsiveness

Dixon et al. (2002) reported the MacNew scores of HF patients to be significantly lower than those of other heart patients at four-month follow-up. Their change data suggested that a value of 0.5 may be a useful indicator of the minimal clinically important difference. The review by Höfer et al. (2004) also reported good results for responsiveness and sensitivity to changes post-intervention.

Precision

No specific evidence was found.

Acceptability

The review by Höfer et al. (2004) review reported favourable results for acceptability (high response rates).

Feasibility

No specific evidence was found.

Table 8.10: Developmental and evaluation studies relating to the MacNew (ex-QLMI - Quality of Life after Myocardial Infarction) instrument (Lim et al., 1993)

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
MacNew (ex-QLMI – Quality of Life after Myocardial Infarction)							
Dempster et al. (2004) UK	IHD patients (mixed group, including 'other' unspecified) (117) Age: mean 60.61 Inpatients Interview		Construct ✓ Internal ✓				
Dixon et al. (2002) Australia	Discharged hospital patients with acute MI, HF, and angina taking part in longitudinal QoL study (1506) Age: mean 66.2 at baseline, 67.1 at follow-up Postal			✓			
Oldridge et al. (2002) USA	Study of HF patients sampled from electronic medical records as having MI (161) angina or heart failure Age: MI patients - mean 69 Postal		Construct ✓				

d) Minnesota Living with Heart Failure Questionnaire (MLHFQ/MLHFQ/LHFQ/LiHFe) (Rector et al., 1987)

This is the most popular heart failure-specific-instrument, and has been used with in- and outpatients of both sexes, with ages (where reported) ranging from 25-87 years. Items for the MLHFQ were drawn from the SIP. 28 studies which examined the MLHFQ were identified.

Reliability

Initial studies indicated good results for the reliability of the instrument (Rector et al., 1993a, 1993b). Cronbach's alphas are high, with studies reporting them to be between 0.80 and 0.94 (Gorkin et al., 1993; Heo, 2005). Bennett et al. (2003) reported that the MLHFQ was more reliable than the SF-12, and was comparable with the CHQ (Cronbach's alpha totals: 0.95 and 0.93, respectively; range for subscales 0.89-0.94 and 0.69-0.92, respectively, for the MLHFQ and the CHQ). Bennett et al. (2002) and O'Leary and Jones (2000) supported the high internal consistency of the instrument. Test-retest reliability is good, with correlation coefficients between $r = 0.87$ and 0.93 (Rector and Cohn, 1992; Rector et al., 1993b).

Validity

Early studies by Rector et al. (1987) found that the instrument correlated highly with patients' global assessments of restrictions on their lives ($r = 0.80$). A review of medication trials of beta blockers with heart failure patients by Reddy and Dunn

(2000) [not shown in Table, as review data], reported inconsistent results for the effect of beta-blockers on MLHFQ scores. Item and factor analyses indicate that some items need to be removed and others reworded (Heo, 2005).

Socio-demographic variables

This instrument has been used with a wide range of patient groups, with documented ages ranging from 28-87 years. The MLHFQ is apparently sensitive to age, independently of symptoms (Rector et al., 2006), although O'Leary and Jones (2000) reported no significant associations between the MLHFQ and age or sex.

Heart failure-specific patient-reported health instruments

Oldridge et al. (2002) reported highly significant Pearson correlation coefficients between the MLHFQ, the MacNew and the Seattle Angina Questionnaire (ranging from 0.624 to 0.904). The CHQ and MLHFQ are also highly correlated (Bennett et al., 2002).

Measures of HF Function

Havranek et al. (1999) reported significant correlations between the MLHFQ and a 6-minute walking test. O'Leary and Jones (2000) found moderate, significant correlations between MLHFQ scores and exercise capacity (VO₂ max) and duration (0.49 and 0.38, respectively). No significant association was found with echocardiographic measurements; significant associations were found with NYHA classes, though not between classes II and IV.

Zambroski et al. (2005) reported that the MLHFQ was sensitive to symptom prevalence and burden, and NYHA functional classification. The latter finding was supported by Rector et al. (1987, 2006; Gorkin et al., 1993; Calvert et al., 2005). Bennett et al. (2002) found that only the MLHFQ physical subscale differentiated between patients with NYHA class III and IV, although it discriminated between the other classes. A secondary analysis of a 'convenience sample' of nine experimental or quasi-experimental studies in the USA [not shown in Table, as secondary review analysis] showed mixed results for associations between the MLHFQ and NYHA classes, and it was unable to discriminate between LVEF values (Riegel et al., 2002). The MLHFQ was also reported to be insensitive to clinical indicators of cardiac function and symptoms in a study of outpatients by Carels (2004).

Generic health status

In a study of heart failure clinic patients, Havranek et al. (1999) reported significant correlations between the MLHFQ and the MOS Rand SF-36 physical component score and time-trade-off techniques. Oldridge et al. (2002) also found highly significant Pearson correlation coefficient between the MLHFQ physical limitations domain and the SF-36 physical component summary at 0.63; the correlation between the SF-36 mental component summary and the MLHFQ was 0.72. O'Leary and Jones (2000) reported moderate to high significant correlations between the MLHFQ and all eight Rand MOS SF-36 domains ($r = -0.46$ to -0.75). The MLHFQ also correlates significantly with the EQ-5D (Calvert et al., 2005).

Responsiveness

While the MLHFQ has been reported to be sensitive to change in patients' condition over time (Aranda et al., 2004; Gary et al., 2004b; Prasun et al., 2005; Park et al.,

2005; Rector and Cohn, 1992; Rector et al., 1993a, 1993b), others have reported that the MLHFQ is not sensitive to trial interventions (Feldman et al., 2004). Not all investigators used independent measures of change in patients' condition, and it is possible that, in some cases, lack of change could be due to the insensitivity of the MLHFQ. Doughty et al. (2002) found that only the physical dimension was sensitive to heart failure management interventions, compared with controls.

The instrument is reportedly responsive to changes due to exercise therapy (Chang et al., 2005; Gary et al., 2004a). Gwadry-Sridhar et al. (2005), in an RCT of an educational intervention with HF inpatients, reported a significant effect of both time and treatment intervention with the MLHFQ, but not with the SF-36. Bennett et al. (2003) also found that the MLHFQ performed better than the SF-12 with regard to responsiveness to change. Ni et al. (2000) found the SF-12 to be more responsive to changes in mental health, but less responsive to change in physical health at follow-up, than the MLHFQ; the MLHFQ also performed better than the SF-12 in ability to distinguish differences in perceived global health transition. Green et al. (2000) reported that the MLHFQ was less responsive to important clinical change in HF patients than the KCCQ.

Sethares and Elliott (2004), in their RCT of tailored message intervention, assessed heart failure patients in hospital and post-discharge. For both treatment and control groups, there were significant differences in their MLHFQ scores between baseline and follow-up assessments, indicating improved QoL. Although no clinical evidence of improvement was provided, this could suggest some support for the instrument's responsiveness to expected clinical improvement post-discharge. However, there were no differences detected between groups, which indicated either that the intervention had no effect or that the measure was insensitive. Rector and Cohn (1992) reported that changes in total and physical MLHFQ scores were significantly, but weakly, associated with changes treadmill exercise tests at follow-up, but more strongly associated with patients' own assessments of changes in dyspnoea and fatigue.

Precision

Results for floor and ceiling effects are mixed. While Bennett et al. (2002) found that the MLHFQ had more respondents at the floor and ceiling end of the scale than the CHQ, Ni et al. (2000) reported that no respondents had the highest or lowest possible scores, excluding an obvious floor or ceiling effect. O'Leary and Jones (2000) reported that the instrument had no floor effects, and a very small ceiling effect (4% of respondents scored at the ceiling).

Acceptability

Two MLHFQ items were reported to be missing for large numbers of respondents in one study: difficulty working to earn a living (27%) and difficulty with sexual activities (22%) (Bennett et al., 2002). In a study by Gwadry-Sridhar et al. (2005), 12 out of 134 patients reported finding the questionnaire battery (which included the MLHFQ and SF-36) cumbersome and did not respond.

Feasibility

No specific evidence was found.

Table 8.11: Developmental and evaluation studies relating to the Minnesota Living with Heart Failure Questionnaire (Rector et al., 1987)

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Minnesota Living with Heart Failure Questionnaire (MLHFQ)							
Aranda et al. (2004) USA	HF patients participating in trial (313) Age: means 63.5, 66.3, 66.8 in different treatment groups In- or outpatients not specified Mode of administration not given		Construct ✓	✓			
Arena et al. (2002a) USA	Patients with compensated HF (31) Age: mean 52.8 In- or outpatients not specified Mode of administration not given		Construct ✓				
Bennett et al. (2002) USA	HF clinic patients sampled from electronic medical records for diagnostic data (211) Age: 72% < 65 Outpatients Telephone interviews	Internal consistency ✓	Construct ✓ Concurrent ✓		✓	✓	
Bennett et al. (2003) USA	Convenience sample of HF patients (211) Age: mean 57 Outpatients Telephone interviews	Internal consistency ✓	Construct ✓	✓			✓
Calvert et al. (2005) UK + 11 other countries	HF patients enrolled in cardiac resynchronisation in HF study (813) Age: mean 65 Self-administered		Construct ✓ Concurrent ✓				
Carels (2004) USA	HF clinic patients (58) Age: mean 67.7 Outpatients Self-administered		Construct ✓				

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Minnesota Living with Heart Failure Questionnaire (MLHFQ)							
Doughty et al. (2002) New Zealand	HF patients participating in RCT of HF management (197) Age: 72.5 (intervention), 73.5 (control) Post-discharge patients Mode of administration not given			✓			
Chang et al. (2005) USA	HF patients trial of relaxation therapy, LVEF \leq 40% (95) Age: means 69.7, 68.7 and 69.2 in different study arms Outpatients/primary care patients Self-administered and postal		Construct ✓	✓			
Feldman et al. (2004) USA	Women with LVEF < 45% plus symptoms (32) in exercise RCT Age: mean 67 (intervention group), 69 (control group) Mode of administration at baseline not specified; telephone interview follow-up		Construct ✓	✓			
Gary et al. (2004b) USA	Exercise trial, females with heart failure, LVEF > 45%, symptoms, NYHA class II & III (32) Age: 67 (intervention group), 69 (control group) Heart clinic and local practice patients Mode of administration at baseline not given; telephone follow-up		Construct ✓	✓			
Gorkin et al. (1993) USA	Patients enrolled in quality of life study (158). White males only with LVEF \leq 35%, and no MI within previous 30 days. Age: mean 59.6 (NYHA Class I), 61.9 (NYHA Class II or III) Mode of administration not given, battery administered during assessment visit.	Internal consistency ✓	Construct ✓				

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Minnesota Living with Heart Failure Questionnaire (MLHFQ)							
Green et al. (2000) USA	Two patient cohorts with stable or decompensated CHF with LVEF < 40 (129) Age: mean 64.3 Outpatients Postal	Internal consistency ✓ Test-retest ✓	Construct ✓	✓			
Gwadry-Sridhar et al. (2005) Canada	Clinically diagnosed HF patients and LVEF < 40%, RCT educational intervention (134) Age: mean 67 (intervention group), 65 (control group) Inpatients Interview with telephone interview follow-up		Construct ✓	✓			
Havranek et al. (1999) USA	HF clinic patients (50) Age: mean 52.5 Outpatients Interviews		Construct ✓ Concurrent ✓				
Heo (2005) USA	HF patients (638) enrolled in 4 separate studies Age: not given Inpatients Mode of administration: not given	Internal consistency ✓	Construct ✓				
Ni et al. (2000) USA	Clinic attendees with chronic and symptomatic HF (87) Age: 24% aged 60+ Outpatients Mode of administration: not given		Construct ✓	✓	✓		
O'Leary and Jones (2006) UK	Cardiac clinic patients with chronic LV dysfunction, including LVEF =/< 50% (60) Age: mean 60 Outpatients Self-administration	Internal consistency ✓ Test re-test ✓	Construct ✓ Concurrent ✓	✓			

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Minnesota Living with Heart Failure Questionnaire (MLHFQ)							
Oldridge et al. (2002) USA	Study of HF patients sampled from electronic medical records as having MI (161), angina or heart failure Age: mean 69 (MI patients) Postal		Construct ✓ Concurrent ✓				
Park et al. (2005) USA	RCT of LVADs with end stage HF patients NYHA class IV, symptoms 90 days plus (129) Age: mean 68 (medical management group), 66 (LVAD group) In- or outpatients not specified Mode of administration not specified		Construct ✓	✓			
Rector et al. (1987) USA	Patients with LV dysfunction participating in several studies (83; 84% males) Age: mean 61 In- or outpatients not specified Self-administration	Internal consistency ✓	Construct ✓				
Rector and Cohn (1992) USA	HF patients enrolled in multi-site drug trial (198; 78% males) Age: mean 58 In- or outpatients not specified Self-administration	Test re-test ✓	Construct ✓	✓			
Rector et al. (1993a) USA	Patients in preventative drug trial without symptoms of HF (172) and patients with HF (77; 86% males) Age: mean 63 In- or outpatients not specified Mode of administration not given	Test re-test ✓	Construct ✓	✓			
Rector et al. (1993b) USA	Patients enrolled in multi-site veterans centre drug trial (804) Age: mean 61 Ambulatory patients Self-administration	Test re-test ✓	Construct ✓	✓			

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
		Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility
Minnesota Living with Heart Failure Questionnaire (MLHFQ)							
Rector et al. (1995) USA	Clinic patients with HF (101) Age: range 50-75, mean 56 Interview		Construct ✓				
Rector et al. (2006) USA	White, male patients enrolled in heart failure drug trial (1651; 77% males) Age: median 62 Outpatients Mode of administration: not specified		Construct ✓				
Sethares and Elliott (2004) USA	Primary diagnosis of chronic HF (70) RCT of tailored message intervention Inpatients and post-discharge follow-up Age: mean 75.70 (treatment group), 76.84 (control group) Interview		Construct ✓	✓			
Sneed et al. (2001) USA	Patients attending HF clinic (30) Age: mean 57 Outpatients Self-administered or interview if patient unable to read		Construct ✓				
Zambroski et al. (2005) USA	Convenience sample HF clinic patients (53) Age: mean 55.5 Self-administered		Construct ✓				

Other heart failure-specific instruments identified from the review

Table 8.12: Overview of other records of heart failure-specific instruments and generic CVD instruments used with heart failure patients.

Instrument Reference	Population (N) Age Method of administration Setting	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments
<i>Heart failure-specific instruments</i>								
Heart Failure Symptom Checklist Grady et al. (2003a) USA and Australia	Post LVAD implantation and heart transplantation patients from medical centres in 2 countries (40) Age: mean 51.1 Inpatients Self-administration		Construct ✓	✓				90 post-LVAD (89 post-transplant) items covering: somatic sensation, psychological state. 0 = not bothered to 3 = very bothered. 6 subscales: cardiopulmonary, gastrointestinal, genitourinary, neurological, dermatological, and psychological. Sensitive to change post LVAD
Grady et al. (2003b) USA and Australia	Post LVAD implantation patients from medical centres in 2 countries (62) Age: mean 52.8 (not discharged), 50.2 (discharged) Inpatients Self-administration		Construct ✓	✓				HFSC not sensitive to change post-discharge LVAD patients, in contrast to changes detected by functional disability (SIP) stress (LVAD stressor scale), coping (Jalowiec Coping Scale), global ratings, and the Quality of Life Index.
Heart Failure Symptom Scale (HFSS) Baker et al. (2005) USA	HF patients from 7 sites: hospital clinics, health plan and physician groups (781) Age: 62% aged 65+ Telephone interview	Internal consistency ✓	Construct ✓ Concurrent ✓					7 items on symptom severity and frequency (5-point response scales) HFSS correlated with SF-12 PCS (0.63), and MCS (0.54). Single factor reported, Cronbach's alpha 0.88

Instrument Reference Country	Population (N) Age Method of administration Setting	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
Left ventricular dysfunction questionnaire (LVD-36) O'Leary and Jones (2000) UK	Cardiac clinic patients with chronic LVD, including LVEF \neq < 50% (60) Age: mean 60 Outpatients Self-administration	Internal consistency ✓ Test-retest ✓	Construct ✓ Concurrent ✓	✓				Newly developed measure; takes 5 minutes to complete 36-item questionnaire, responses are dichotomous and summed, and expressed as a percentage so 100 = worst possible score and 0 = best possible score Tested against the Rand SF-36 and MLHFQ. High repeatability and internal consistency; no floor effects and very small ceiling effects; correlations with the SF-36 ranged from 0.46-0.75, and with the MLHFQ from 0.41 to 0.74; correlations with clinical tests were weak or non-significant, and moderate at best with exercise test; there was evidence of responsiveness to change in health status at follow-up
Memorial Symptom Assessment Scale-Heart Failure Zambroski et al. (2005) USA	Convenience sample HF clinic patients (53) Age: mean 55.5 Self-administered		Construct ✓					32 items on 3 symptom subscales: physical, emotional, HF. Summed to give Prevalence; Burden calculated as mean of frequency, severity and distress of each on 4- and 5-point scales Correlated with NYHA functional class, predicted worse Qol (MLHFQ)

<i>Generic cardiovascular measures used with HF patients</i>								
Instrument	Population (N)	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments
Reference	Age							No other records identified unless stated
Country	Method of administration							
Setting								
Cardiac Depression Scale (CDS)	Cardiac support group patients (396)	Internal consistency ✓	Construct ✓					26 item, self-administration, disease-specific depression scale, originally developed in Australia.
Hare and Davis (1996)	Age: range 37-90, mean 67	Test-retest ✓	Concurrent ✓					In the UK population Cronbach's alphas 0.91 and 0.86. Two domains highly correlated (0.649). Test-retest 0.79.
Birks et al. (2004)	Postal							CDS correlated significantly with SF-36, Beck Depression Inventory & Hospital Anxiety and Depression Scale.
UK								
Cardiac Quality of Life Index	Cardiac patients (222)	Test-retest ✓	Construct ✓	✓				A generic cardiovascular instrument; 30 items. Domains: psychological state, physical and occupational function, social interaction: 0 = very dissatisfied to 100 = very satisfied
<i>scale developers and modifiers:</i>	Age: range 32-65+							High levels of test re-test reliability. Discriminated healthy and cardiac patients. Strong correlation with Spitzer QLI
Padilla and Grant (1983, 1985); Rukholm and McGirr (1994); Rukholm et al. (1998)	Interview-administered							
USA								

Instrument Reference Country	Population (N) Age Method of administration Setting	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments
Duke Activity Status Index (DASI) Hlatky et al. (1989) Arena et al. (2002b) USA	Patients with 'past medical history significant for HF' (33) Age: mean 52.8 Self-administration In- or outpatients not specified	Test-rest ✓	Construct ✓					A generic cardiovascular tool, aiming to measure functional capacity and QoL. It contains 12 items on functional capability: personal care, ambulation, household tasks, sexual function and recreational activities. Yes/no response formats for ability. Each item has a weighted value of 1.75-8.0; the DASI is the sum of these: 0 = worst, 58.2 = best
Gary et al. (2004a) USA	Patients with diagnosed diastolic HF or diastolic dysfunction participating in exercise trial Age: mean 67 (intervention), 69 (controls); range 51 – 86 In- or outpatients not specified Mode of administration not given		Construct ✓	✓				

Instrument Reference Country	Population (N) Age Method of administration Setting	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
<i>(DASI continued)</i> Gary et al. (2004b) USA	Exercise trial, females with heart failure, LVEF 45% or over, symptoms, NYHA class II & III (32) Age: 67 (intervention group), 69 (control group) Heart clinic and local practice patients Mode of administration at baseline not given; telephone follow-up							Results for DASI not clearly presented
Havranek et al. (2004) USA and Canada	Patients in multi-site drug trial (153) Age: mean 68.3 In- or outpatients not specified Postal and telephone interview		Construct ✓					
Myers et al. (2006) USA	HF patients (41) Age: mean 68 Outpatients Self-administration		Construct ✓ Concurrent ✓					

Instrument Reference	Population (N) Age Method of administration Setting	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments
Multidimensional Index of Life Quality (MILQ) Avis et al. (1996) USA	Clinic patients and healthy patients (129 CVD patients) Age: mean 63 Interview	Internal consistency ✓ Test-retest ✓	Construct ✓ Concurrent ✓		✓			Qualitative interviews with CVD patients and healthy people identified 9 domains: mental health, physical health, physical functioning, cognitive functioning, social functioning, intimacy, productivity, financial status, relationship with health professionals. Initial tests on hospital and clinic patients. 7-point satisfaction and 4-point importance response scales. High Cronbach's alphas, exceeding 0.70. Good test-retest (0.73 or higher). Correlated significantly with scales of depression, anxiety, MOS indicators of mental health, physical functioning, health perceptions and SIP domains of mobility, social interaction, work.
NYHA Functional Classification <i>(The Criteria Committee of NYHA, 1994)</i> Subramanian et al. (2005) USA	Longitudinal study of older adults (156 with complete 6-month follow-up data) Age: mean 63 Face-to-face or telephone interview		Construct ✓					Most widely used and well-tested of the cardiovascular classification scales. There is a large general CVD literature. Re. HF-specific measures: associated with MSAS-HF, but only slight agreement between patient-based KCCQ and clinician-reported NYHA functional class.

Instrument Reference Country	Population (N) Age Method of administration Setting	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
Quality of Life in Severe Heart Failure (QLF-SHF) Wiklund et al. (1987) Reddy and Dunn (2000) USA	Review of medication trial data and comparison with MLHFQ			✓				27 items in 4 domains, designed for self-completion. Includes physical activity (7), somatic symptoms (7), psychological (7), life satisfaction (5), improvement rating (1), all on 6-point Likert scales. Domain scores summed for global score. Inconsistent results. Lack of consistent effect of beta blockers on QoL of HF patients. Little use of the scale in the literature.
Quality of Life Index-Cardiac version (Ferrans and Powers 1985) Grady et al. (2003a, 2003b) USA and Australia Prasun et al. (2005) USA	Post LVAD implantation and heart transplantation patients from medical centres in 2 countries (40) Age: mean 51.1 Inpatients Self-administration Heart failure patients with LVEF \leq 40%, participating in RCT of patient-directed flexible diuretic protocol (66) Age: mean 65 (intervention group), 70 (control group) Outpatients Mode of administration: self-completion		Construct ✓	✓				Greater satisfaction (QLI) at three months noted for heart transplantation versus LVAD implantation Generic cardiovascular instrument. 30 items; domains: psychological state, physical and occupational function, social interaction: 1 = very dissatisfied to 6 = very satisfied

Instrument	Population (N) Age Method of administration Setting	Reliability	Validity	Responsiveness	Precision	Acceptability	Feasibility	Comments
Reference Country								No other records identified unless stated
Utility Based Quality of Life-Heart (UBQ-H) Questionnaire <i>(cardiovascular extension to the Health Measurement Questionnaire)</i> Martin et al. (1999) Australia	Cardiac patients (including HF) (322) Age: mean 60 Outpatients Postal	Internal consistency ✓ Test-retest ✓	Construct ✓	✓				UBQ-H: psychological distress 16 items (response categories 0-10) : self-care 4 items (1-3); social/usual activities 5 items (1-4); physical ability 4 items (1-4.5); overall QoL (1-4/0.0-1.0//0-100) (3 items); Rosser Index (1-7/1-4/-1.486-1) (3 items) Within the QoL domain, this measure includes self-rated health, a time trade-off rating scale, anchored by full health and death, a rating scale; the Rosser Index is a separate domain. Response and item-completion high; high Cronbach's alpha: 0.79-0.91 and test-retest: 0.65-0.82. Correlated significantly with the General Health Questionnaire-30 (symptoms of general psychological morbidity, mainly depression/anxiety).

NB Insufficient information was found on the following:

- 19-item Cardiac Health Profile
- 11-item Heart Condition Assessment Questionnaire
- generic 35-item Multidimensional Index of Quality of Life
- Quality of Life at the End of Life measure/QUAL-E (this is a palliative care instrument, and not heart failure-specific)

SUMMARY - GENERIC INSTRUMENTS

The most frequently used generic measure in patients with heart failure is the SF-36. 21 studies assessed the SF-36, and eight examined the SF-12, in relation to adults with heart failure. Most of these reported construct validity. The studies were based on population surveys and clinical samples of patients. There is less published information about reliability, compared with validity, when used with this population. Of those that examined reliability, internal consistency was good for all the SF-36 scales, except for social functioning (Wolinsky et al., 1998; Green et al., 2000).

Evidence was more mixed for the discriminative ability of the SF-36 in relation to different diagnostic groups of CVD patients. The instrument correlated well with disease-specific measures, including the MacNew and the MLHFQ. The SF-36 was found by some investigators to be less responsive to important clinical change in HF patients than disease-specific instruments such as the MLHFQ (Green et al., 2000). Floor and/or ceiling effects have been found for the SF-36 role-physical, social functioning and role-emotional subscales, which potentially mask patient improvement or deterioration, and reduce scale sensitivity (Wolinsky et al., 1998; Wyrwich et al., 1999).

The internal consistency of the SF-12 was also good reportedly good, although Bennett et al. (2003) reported that the SF-12 was less reliable than the CHQ or the MLHFQ. Results for validity were generally good. Correlations between the SF-12 and the CHQ and MLHFQ were moderate to high, although results for responsiveness were more mixed. No floor or ceiling effects were reported.

Other generic measures used in heart failure, but in a smaller number of studies, included the SIP, which had generally good results for validity. The EuroQoL/EQ-5D was used in a very small number of studies, and with mixed results for responsiveness, although it correlated significantly with disease-specific indicators.

Overall, the SF-36 is the most widely used and well-tested generic instrument for use with patients with heart failure, although, unlike the shorter SF-12, it has floor and ceiling effects. More evidence of the reliability of these instruments is needed when used with this group of patients.

SUMMARY – HEART FAILURE-SPECIFIC INSTRUMENTS

While several general cardiovascular disease instruments were identified, four main heart failure-specific instruments were identified: three papers examined the MacNew (ex-QLMI – Quality of Life after Myocardial Infarction) (Lim et al., 1993); ten papers examined the Chronic Heart Failure Questionnaire (CHQ) (Guyatt et al., 1989); 13 examined the Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green et al., 2000); and most, 28, examined the Minnesota Living with Heart Failure Questionnaire (MLHFQ) (Rector et al., 1987). The Duke Activity Status Index (DASI - see Table 8.12) (Hlatky et al., 1989) is a short but narrow measure of activity performance. It does have some attractive features with promising measurement properties.

The MLHFQ, followed by the KCCQ, then, was the most commonly used and tested disease-specific instrument. The psychometric properties of the KCCQ were generally

good but more mixed than those for the MLHFQ. The KCCQ was more responsive to clinical change than generic measures.

The MLHFQ has been shown to have high internal consistency, and satisfactory results for test-retest reliability. It correlates highly with other heart failure-specific measures (MacNew, CHQ) (Bennett et al., 2002; Oldridge et al., 2002), and most studies supported its sensitivity to NYHA classes, and responsiveness to change. However, not all results were consistent or good. Some items on the MLHFQ have lower item-response: difficulty with sexual activities, difficulty with recreational pastimes, sports or hobbies (Bennett et al., 2002), indicating that further revision is needed.

DISCUSSION AND RECOMMENDATIONS

This review was based on generic and heart failure-specific instruments. Most studies were carried out in North America. Johansson et al. (2004), from their systematic review, identified 32 different generic, disease-specific and domain-specific HRQoL questionnaires used in 33 articles on HF. However, the number of commonly used generic and heart failure-specific measures is relatively small, comprising mainly the SF-36; the SF-12; the Chronic Heart Failure Questionnaire (CHQ); the Kansas City Cardiomyopathy Questionnaire (KCCQ); the MacNew (ex -QLMI – Quality of Life after Myocardial Infarction); and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The most popularly used measure is the MLHFQ. There was relatively little use of utility measures.

The generic instruments reviewed were multidimensional indicators of health status or health-related quality of life. Acceptability was examined only for the SF-12, and no study examined feasibility. For the disease-specific instruments, feasibility was not assessed. While the MLHFQ is the most popular and well-tested disease-specific instrument, two MLHFQ items were reported to be missing for large numbers of respondents in one study: difficulty working to earn a living (27%) and difficulty with sexual activities (22%) (Bennett et al., 2002).

The SF-36 and SF-12 have been tested against heart failure-specific questionnaires, with overall moderate to high significant correlations, although with some inconsistency between studies. The heart failure-specific instruments have been tested for concurrent validity, and most results show that the different instruments correlate highly, except between the GHFQ and the KCCQ where correlations were weak to modest. There was relatively little information on the distribution of scale items, or variation, by socio-demographic characteristics.

Recommendations

This review supports the use of the SF-36 and the SF-12 as generic instruments, and the MLHFQ as a heart failure-specific instrument with people with heart failure. However, there was some indication that the wording of some of the MLHFQ items needs revision and retesting, and the narrow scope of the instrument suggests that it may not have full content validity. The development and use of broader, generic and disease-specific patient-based indicators has been slow in the field of cardiovascular disease compared to other areas (e.g. respiratory conditions), and this is reflected in the range and development of instruments included here.

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