Chapter 7: Patient-reported Health Instruments used for people with epilepsy

Epilepsy comprises a group of disorders in which there are recurrent episodes of altered cerebral function, the clinical accompaniment of which is a seizure. These vary in severity from brief lapses of awareness to prolonged unconsciousness, jerking of limbs and incontinence. Seizures are divided into generalised (arising from a wide area of the brain) or partial (arising from a limited area of damage to the brain). Treatment may be medical or surgical, and aims to control seizures. Surgery does not always prevent seizures from occurring.

About one person in 200 suffers from epilepsy. Many people lead normal lives with no symptoms between seizures. For others, epilepsy can have an adverse impact on everyday life, psychological well-being and feelings of stigma, and can have a slight adverse effect on mental ability. Even within the same group of seizures, differences in seizure frequency and severity can lead to differences in the impact on a person's life. It is an area where multidimensional social, psychological, physical and cognitive patient based outcome assessment is highly relevant.

Search terms and results: identification of articles

At the time of the review, the PHI database contained 12,562 records (up to June 2005). An initial search of record abstracts and titles using the terms 'epilep* *or* seizure*' generated 183 records, as shown in Table 7.1. All records were reviewed. When assessed against the review inclusion criteria, 106 articles were retrieved and reviewed in full. Of these, 71 articles were included in the review.

Table 7.1 Number of articles identified by the literature review

Source	***Results of search***	***No. of articles considered eligible***	***Number of articles included in review***
PHI database: original search (up to June 2005) **Total number = 12,562**	182	82	58
Additional PHI database search (July-December 2005) **Total number = 4021**	1	1	-
Hand searching		23	13
TOTAL	183	106	**71**

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:

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

Identification of patient-reported health instruments
Eight generic and eight epilepsy-specific instruments were included in the review. Instruments targeting paediatric or adolescent populations were excluded, as were those where there was no evidence that an English-language version had been tested. Developmental and evaluative studies relating to the instruments reviewed are listed in Tables 7.2 to 7.15. Table 7.16 provides an overview of records of newly developed epilepsy-specific instruments and single-study reporting of measurement properties and/or evaluation.

RESULTS: GENERIC PATIENT-REPORTED HEALTH INSTRUMENTS

Seven generic instruments were identified which were evaluated with patients with epilepsy. 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 and SF-12
b) EQ-5D
c) HUI
d) Q-TWIST
e) NHP
f) SIP

a) SF-36 and SF-12

Nine published studies (two of which relate to the same study) described the use of the SF-36, as a measure of health status, or quality of life, with patients with diagnosed epilepsy. One study compared the SF-36 and the SF-12. The studies were based on outpatients, convenience samples or mixed groups. In two cases it was not clearly specified whether the patients were in- or outpatients.

Reliability
Jacoby et al. (1999), in their European study, reported that item-scale correlations for each subscale of the SF-36 all exceeded 0.40. Reliability coefficients exceeded the standard recommended for group comparisons. The lowest coefficient reported was for social function ($\alpha = 0.73$) and the highest was for bodily pain ($\alpha = 0.92$). Scaling success was reported to be high at 96% of comparisons made (using a definition of scaling success of any item/same scale correlation exceeding item/other scale correlation by 0.10 or more).

Wagner et al. (1996) reported similar scaling success with their sample of US out-patients, and their reported Cronbach's alpha coefficients similarly ranged from $\alpha =$ 0.73-0.93. Wagner et al. (1995) reported more variable scaling success with UK patients, with correlations varying from 31.3% to 100% (number of hypothesized correlations higher/total number of correlations). They reported modest to high internal consistency coefficients with UK patients (Cronbach's alpha) ($\alpha = 0.43$-0.92) and also high test-retest correlations ($r = 0.55$-0.88).

Validity
Five studies reported evidence of validity. Jacoby et al. (1999) provided the most explicit data for construct validity, reporting on associations between the SF-36 and seizure frequency and type, additional health problems and side-effects, in hypothesised directions. For example, the mean SF-36 scores for the Bodily Pain subscale were 82.7 (SE [standard error] 0.55) for those with no seizures in the past year, to 77.3 (0.77) for those with one per month, and 68.8 (0.70) for those with 1+ per month. Wagner et al. (1995) reported that the Role Physical scale discriminated best among patients' disease severity.

Epilepsy-specific measures of quality of life
SF-36 and SF-12
Two of the nine studies compared the results of the SF-36 and SF-12 with epilepsy-specific measures of quality of life and/or health utilities. Birbeck et al. (2000) compared the SF-36 and SF-12 with the Quality of Life in Epilepsy (QOLIE) shorter and long (31- and 89-item) versions. The QOLIE is an epilepsy-specific measure that includes the SF-36 as a generic core. They reported that the epilepsy-specific measure had larger responsiveness indices than the SF-36 or SF-12, although Wagner et al. (1995) reported stronger results for the generic measures. (See also Wiebe et al., 2002, below.)

Health utilities
Wiebe et al. (2002) compared the SF-36 with the QOLIE-31 and -89, and the Health Utilities Index version 3 (HUI-III). They reported all instruments to be robust, and able to distinguish accurately between different levels of patient-assessed changes in their condition.

Responsiveness
Birbeck et al. (2000) and Wiebe et al. (2002) provided some evidence of responsiveness to change (see earlier). They reported that the epilepsy-specific measure had larger responsiveness indices than the SF-36 or SF-12, although they were comparable in relation to mental and global health. However, Wiebe et al. (2002) reported all instruments to be robust below (see above).

Precision
Jacoby et al. (1999) reported negligible floor effects for all but the two role disability subscales, but substantial ceiling effects for five of the SF-36 subscales. Leidy et al., 1999a (see later in Table 7.7) reported that the SF-36 generic core embedded in the QOLIE-89 had the largest ceiling effects in the instrument: Role limitations-Emotional, Role limitations-Physical, Physical Function and Pain. Wagner et al. (1995) reported noteworthy ceiling effects for Role Functioning and Bodily Pain.

Acceptability
Jacoby et al. (1999) reported high item-completion.

Feasibility
Birbeck et al. (2000) compared scoring methods for the SF-36, using Rand's item response theory-based scoring versus equal weighting and scoring. They reported that the choice of method influenced scale results (overall, the Rand scoring method provided stronger results).

Table 7.2: Evaluative studies relating to the SF-36 and SF-12 *(both Rand MOS and Ware et al. versions)* when completed by patients with epilepsy

Study/ Country	**Population (N) Age (years) Method of administration Setting**	**Measurement and Practical properties**					
SF-36		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Birbeck et al. (2000) USA	Participants in RCT medication for epilepsy (142) Age: range 18.8–66.8, mean 38.2 Mode of administration not specified In- or outpatients not specified		Construct ✓	✓			
*Buck et al. (1999) 8 European countries	Epilepsy (4929) Age: range 16-90, mean 37 Postal Outpatients and support groups		Construct ✓				
Hermann et al. (1996) USA	Epilepsy (271), multiple sclerosis/MS (85), diabetes (555) Age: mean 36.3, 44.6, 58.9, respectively Mode of administration not specified Diabetes patients from medical Outcomes Study, MS patients from neurology referrals, epilepsy centre patients; in- or outpatients not specified		Construct ✓				
*Jacoby et al. (1999) 8 European countries	Epilepsy (4929) Age: range 16-90, mean 37 Postal Outpatients and support groups	Item total ✓	Internal validity ✓ Construct ✓		✓	✓	
Leidy et al. (1999a) USA	Epilepsy (139), Age: 18+ , mean 38.5 Self-completed Convenience sample based on clinic records and outpatients		Construct ✓		✓		

Study/ Country	Population (N) Age (years) Method of administration Setting	Measurement and Practical properties					
SF-36		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Wagner et al. (1995) UK	Epilepsy (136) Age; range 15-78, mean 34.9 Self-administered Outpatients	Internal consistency ✓ Item-total ✓ Test-retest ✓	Construct ✓		✓	✓	
Wagner et al. (1996) USA	Epilepsy (148) Age: 18+, mean 38.5 Self-administered Outpatients	Internal consistency ✓ Item-total ✓	Internal ✓				
Wagner et al. (1997) USA	Participants in RCT medication for epilepsy (163) Age: mean 43 (intervention group), 45 (control group) Self-administered Outpatients					✓	
Wiebe et al. (2002) Canada	Patients with difficult-to-control focal epilepsy investigated for surgery (136) Age: mean 36 Self-administered In- or outpatients not specified		Construct ✓	✓	✓		

***** These papers report on different findings from the same study

c) EuroQoL- EQ-5D

Three studies, all in the UK, used the EQ-5D. Two were studies of in- and outpatients (Remák et al., 2004; Selai et al., 2000), and one was based on a market research database of people with and without epilepsy (Trueman and Duthie 1998).

Reliability
No specific evidence was found.

Validity
Selai et al. (2000) reported that the measure was not valid in detecting changes pre- and post-surgical treatment for epilepsy. They also questioned the scales content validity (see Acceptability). Trueman and Duthie (1998) simply reported significant bivariate associations between the EQ-5D and the HADS (Hospital Anxiety and Depression Scale).

Responsiveness
Selai et al. (2000) reported that, in contrast to the Epilepsy Surgery Inventory-55 (ESI-55), there were no significant changes in the EQ-5D pre- and post-surgery. They concluded that the measure was unable to detect changes pre- and post-surgical treatment for epilepsy, and not valid or responsive. The EQ-5D visual analogue scale (VAS) was, however, responsive to clinically defined outcome. Remák et al. (2004) reported that the EQ-5D had mixed responsiveness to change in patient condition at six months after their commencement of one of five different epilepsy medications (the EQ-5D increased for only two of the medication groups). However, they stated that the lower power of their study might have been the cause.

Precision
No specific evidence was found.

Acceptability
Selai et al. (2000) reported that 42% of their sample queried the EQ-5D VAS, mainly because ‘health does not include epilepsy’ and if it did, the score would be up to 70 points lower.

Feasibility
No specific evidence was found.

Table 7.3: Developmental and evaluation studies relating to the EQ-5D

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
EQ-5D		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Remák et al. (2004) UK	Patients with intractable epilepsy on five different medical therapies (125) Age: mean 35.7 to 38 Outpatients Interviews			✓			
Selai et al. (2000) UK	Epilepsy patients (145, 45 followed up) Age: not given Interview Inpatients		Construct ✓	✓		✓	
Trueman & Duthie (1998) UK	Market research database of people of with (289) and without 9389) epilepsy Age: mean 46 Mode of administration: Self-administration		Construct ✓ Concurrent ✓			✓	

d) Health Utilities Index

Wiebe et al. (2001; 2002) examined minimum clinically important change; small, medium, and large changes; and changes needed to exclude chance error in the Health Utilities version III, along with the SF-36, and the Quality of Life in Epilepsy Inventory 31- and 89-item versions (QOLIE-31, QOLIE-89). They reported (2002) that the HUI-III, and the other instruments, all differentiated between no change and minimum important change. Only the two QOLIE instruments distinguished accurately between minimum important change and medium or large change. In 2001, Wiebe et al. reported that threshold values for the HUI-III were larger than expected, due to large between-patient variance, which they attributed to the nature of the instrument. Langfitt and Wiebe (2002) reviewed methodological issues in determining health values in epilepsy.

Table 7.4: Developmental and evaluation studies relating to the Health Utilities Index, version 3

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
HUI-III		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Wiebe et al. (2001) Canada	Stable epilepsy patients, candidates for surgery (40) Age: mean 36 In- or outpatients not specified Mode of adminstration unclear			✓	✓		
Wiebe et al. (2002) Canada	Patients with difficult-to-control focal epilepsy investigated for surgery (136) Age: mean 36 Self-administered In- or outpatients not specified		Construct ✓	✓	✓		

e) Q-TWIST

Schwartz et al. (1995) used the approach of 'quality-adjusted time without symptoms and toxicities' (Q-TWIST) as a hypothetical example. The paper is methodological, and not empirical, and explains their adapted Q-TWIST approach, which includes additional dimensions relevant to epilepsy.

f) The Nottingham Health Profile

The Nottingham Health Profile was used in two trials of medical therapy for epilepsy (Chadwick 1994; Smith et al., 1993) and a study of a patient population (Baker et al., 1993).Chadwick presented no data for the NHP, simply reporting that it gave 'poor information' and 'lacked sensitivity'. Smith et al. (1993) reported there were no differences between control and placebo groups with the NHP subscales post-treatment, despite a significant reduction in seizure frequency among the treatment group. Baker et al. (1993) reported high internal consistency for the NHP, but only the Physical mobility subscale was able significantly to distinguish between patients taking medication or a placebo.

Table 7.5: Developmental and evaluation studies relating to the Nottingham Health Profile

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
NHP		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Chadwick (1994) UK	Epilepsy patients in drug trial (81) Age: range 15-67, mean 33.7 LSSS only In- or outpatients not specified Mode of administration not specified		✓				
Smith et al. (1993) UK	Patients with medically refractory partial seizures (100) Age: range 15-67, mean 32.7 In- or outpatients not specified Self-administration		✓				
Baker et al. (1993) UK	Patients with refractory epilepsy (81) Age: range 15-67, mean 33.7 Self-administration	Internal consistency ✓	✓	✓			

g) Sickness Impact Profile

Langfitt (1995) compared the Sickness Impact Profile with the Epilepsy Surgery Inventory-55 and the Washington Psychosocial Seizure Inventory. All measures were judged to be valid for use with epilepsy patients, and the SIP was preferred in studies of the broad impact of epilepsy on quality of life. All summary scales and most scales exceeded the Cronbach's alpha 0.70 criterion suggested for group comparisons (reliability). Scales with low internal consistency were examined and items generally covaried according to item content. Construct validity was supported by correlations between comparable subscales. Criterion validity was supported by correlations between the scales and disease severity (with the exception of the WPSI family background and interpersonal adjustment subscales). Feasibility analyses showed that the SIP took an average of 34.5 minutes to complete. (WPSI took an average of 15.8 mins to complete; ESI-55 16 mins.

RESULTS: EPILEPSY-SPECIFIC PATIENT-REPORTED HEALTH INSTRUMENTS:

Eight epilepsy-specific instruments were identified which were evaluated with patients with epilepsy. For full details of the development, domains and scoring methods are detailed in Tables 7.6 and 7.7.

The following instruments measurement properties are reported:

a) Epilepsy Surgery Inventory-55
b) Katz Adjustment Scale
c) Liverpool Quality of Life (LQOL) Battery and Seizure Severity Scale
d) Quality of Life in Epilepsy-89
e) Quality of Life in Epilepsy-31
f) Quality of Life in Epilepsy-10
g) Side-Effect and Life Satisfaction (SEALS) Inventory
h) Washington Psychosocial Seizure Inventory

a). Epilepsy Surgery Inventory-55 (ESI-55)

The ESI-55 is a 55-item measure of health-related quality of life, designed to assess outcome of epilepsy surgery. It was constructed after a literature review, and includes the Rand SF-36 as a generic core, plus 19 epilepsy-specific items (Vickrey et al., 1992a). The ESI-55 contains 11 multi-item subscales of health perceptions, energy/fatigue, overall QoL, social functioning, emotional well-being, cognitive functioning, and role limitations due to emotional problems, role limitations due to memory problems, role limitations due to physical health problems, physical functioning and pain. The initial scale was tested on a small sample of epilepsy patients and then reviewed by health-care professionals, before administration to a sample of epilepsy patients to evaluate its reliability and validity (Vickrey et al., 1992a).

Subgroups of these scales can be weighted and summed to form scores for mental health, physical health and role functioning. The scale scores are weighted and summed to produce the overall score. The health perceptions subscale has been reported to have the greatest sensitivity in discriminating between patients varying by seizure type and frequency (Vickrey et al., 1995). The ESI-55 takes an average of 15 minutes to complete. It was reviewed by Devinsky and Vickrey (1994), Selai and Trimble (1995), Jacoby (1996), Leidy et al., (1998), and Buelow and Ferrans (2001).

b) Katz Adjustment Scale

This instrument was originally developed to measure social behaviour and adjustment of people with a diagnosis of schizophrenia (Katz and Lyerly, 1963), but has been extended and adapted for use with people with epilepsy (Vickrey et al., 1992b; see also summary by Trimble, 1994). However the scale is completed by relative/friend proxies and not the patients themselves. Vickrey et al. (1992b) increased the items and supported the scale's validity for use with epilepsy patients. Their tested version contains 126 items (127 items should have been included but one was omitted in error), in 14 rather than 12 subscales. Proxies are asked to rate the patient according to

'how your relative or friend has looked to you during the past few weeks on these things'. For each item there are four response choices ('almost never' to 'almost always'). The revised instrument by Vickrey et al. (1992b) includes 14 subscales: Over-sensitivity/fearfulness, Social, Irritability, Dependency, Acting out, Paranoia, and Abnormal thought process, Withdrawal-R, Emotional liability, Nervousness-R, Sociopathy, Bizarreness-R, Hyperactivity-R, Disorientation. The responses are summed and transformed to a 0-100 point scale. Higher values indicate better functioning. The scale has been reviewed by Hermann (1995).

c) Liverpool Quality of Life (LQOL) Battery and Seizure Severity Scale (LSSS)

The aim of the LQOL was to focus on issues relevant and important to people with epilepsy. The LQOL was initially tested using a wide range of existing and new scales. The final version consists of two epilepsy-specific subscales: adverse drug effects (21 adverse drug effects, rated on a four-point Likert scale; total sum scores are used in analyses) and impact of epilepsy (nine areas of life that can be affected by epilepsy or treatment, rated on four-point Likert scales; mean scores are used in analyses). It also includes three general subscales. The first scale is Affect Balance (an existing, well tested scale encompassing five items describing negative and five items describing positive states, rated dichotomously as present or absent. The second scale is sense of mastery (an existing, well tested, 7-item scale, rated on 4-point Likert scales, summed with higher scores representing higher mastery. Thirdly there is the life fulfilment scale (ten items on areas of life, rated for importance on 4-point rating scales) and then again for satisfaction, on 4-point Likert scales. The scale together with the LSSS takes up to 45 minutes to complete. It was reviewed by Hermann (1995), Leidy et al. (1998), and Buelow and Ferrans (2001).

The LSSS contains 20 clinical features or symptoms of seizures over the previous four weeks, rated on 4-point Likert scales (total scores range from 20-80). Two subscales measure perceived control over seizures and ictal and post-ictal (11 items) symptoms. Scores are computed by summing item scores, with scores ranging from 9-36 for perceptions, and 11-44 for the ictal scale. Higher scores indicate worse severity.

d) Quality of Life in Epilepsy-89 (QOLIE-89)

The QOLIE-89 is an epilepsy-specific measure that includes the seven subscales of the Rand SF-36 as a generic core. It is an extension of a 55-item, QoL questionnaire (the Epilepsy Surgery Inventory, ESI-55) which was designed for use with epilepsy surgery patients. Items judged by the investigators to be missing were included in the QOLIE. It was developed with 304 epilepsy patients and their relative/friend proxies from 25 epilepsy centers in the USA (130 men and 174 women), with a mean age of 36 years (range 17-63). It was repeated two to three weeks later (Devinsky et al., 1995). The questionnaire takes an average of 28.4 minutes (SD [standard deviation] 15.6, range 6-135) to complete.

It contains 17 multi-item subscales comprising 86 items plus three single item measures of change in health, sexual relations, overall health (the SF-36 core is supplemented by 53 items specific to epilepsy) grouped into four factors. It aims to assess physical, mental, and social areas of life. Standardised methods are used to convert each item to a 0-100 score, with higher scores indicating better QoL. Subscale

scores involve averaging across the items in the subscale, with the number of items as the division. The overall score is a weighted sum of the individual subscale scores. Factor-based, standardised regression coefficients (weights) are used to calculate domain scores.

The instrument initially included 99 items at administration, 86 of which, across 17 subscales, were retained after multitrait scaling. Factor analysis of the 17 subscales yielded four underlying dimensions of health: an epilepsy-targeted dimension, cognitive, mental health, and physical health. Construct validity was supported by significant patient-proxy correlations, and correlations between the instrument and seizure frequency over the previous year, neuropsychological tests, and emotional and cognitive function. It was reviewed by Devinsky and Vickrey (1994), Jacoby (1996), Leidy et al. (1998), Leppik (1998), and Buelow and Ferrans (2001).

e) Quality of Life in Epilepsy-31 (QOLIE-31)

The QOLIE-31 was developed, using the original dataset, from the 99 items used to develop the QOLIE-89 by Cramer et al. (1998). They selected the subscales that were reported to be most important by people with epilepsy (as determined by an expert panel), with the result that generic topics (e.g. pain) were excluded.

Following psychometric and factor analyses of the full scale, variables with loadings of equal to or greater than 0.4 were included in the subscales for the QOLIE-31. This resulted in a 31-item questionnaire, with seven subscales, forming two factors: Emotional/Psychological Effects (seizure worry, overall QoL, emotional well-being, energy/fatigue) and Medical/Social Effects (medication effects, work-driving-social limits, cognitive function). Cross-cultural translations were developed. Analyses supported the reliability and validity of the QOLIE-31. It was reviewed by Leidy et al. (1998), and more briefly by Jacoby (1996) and Leppik (1998).

f) Quality of Life in Epilepsy-10 (QOLIE-10)

This was also developed, using the original dataset, from the 99 items used to develop the QOLIE-89 (Cramer et al., 1996). Items from the QOLIE-89 were selected for inclusion in the QOLIE-10 by an expert panel, which also identified seven domains considered to be important for epilepsy patients. The panel selected items with high item-scale correlations, consistent or appropriate wording and sentence structure. The 10-item questionnaires covers general and epilepsy-specific areas, grouped into three factors: Epilepsy effects (memory, physical effects, mental effects of medication), Mental health (energy, depression, overall QoL), Role functioning (seizure worry, work, driving, social limits).There is some support for its reliability and validity.

g) Side-Effect and Life Satisfaction (SEALS) Inventory

The SEALS is a 50-item self-completion questionnaire designed to measure satisfaction with anti-epileptic drug (AED) therapy. The original also contains an ADL (activities of daily living) subscale with items on frequency of daily activities, from household to social roles. A less diffuse, 38-item version is available (Gillham et al., 2000). The items relate to the patients' feelings and behaviour over the previous week, and were grouped into five subscales, supported by factor analysis: General

cognitive difficulties, Satisfaction/Dysphoria. Fatigue/Tiredness, Temper, Worry, each with 4-point Likert frequency response scales. Answers are summed for each domain and for an overall score. The SEALS was designed by Brown and Tomlinson (1982) with 125 epilepsy patients and 79 people without epilepsy. Fatigue discriminated well between patients and non-patients.

h) Washington Psychosocial Seizure Inventory (WPSI)

The WPSI is the oldest instrument for the evaluation of psychosocial concerns in adults with epilepsy. It was not intended to cover broader health or QoL. The questions are anchored in actual performance in life, and assess adaptation and functioning. It has good reliability and validity when compared to clinical ratings (Dodrill et al., 1980).

The instrument was developed with a group of behavioural scientists, who compiled a list of categories of psychosocial problems they had encountered in this area. These were: Family background, Emotional adjustment, Interpersonal problems, Vocational adjustment, Financial status, Adjustment to seizures, Medicine and medical management, and overall psycho-social functioning. Item development and scaling was constructed next. After two piloting studies, 132 items with Yes/No responses resulted. Professionals then rated 127 adults. Each subscale had to satisfy empirical requirements for inclusion. Inter-rater reliability, retest and internal consistency reliability were established, although patients were not consulted. The resulting scale has 132 items in three validity subscales and the eight clinical subscales (Family background, Emotional adjustment, Interpersonal problems, Vocational adjustment, Financial status, Adjustment to seizures, Medicine and medical management, and overall psychosocial functioning). Later an item measuring QoL was added (Dodrill and Batzel, 1996). There are four profiles: 1) No problems; 2) Possible or slight difficulties; 3) Definite problems; 4) Severe or major problems. Higher scores indicate poorer adjustment. It is a lengthy instrument, taking 15-20 minutes to complete, using a trained interviewer.

The instrument has been reviewed by Hermann (1995), Jacoby (1996) and Selai and Trimble (1995). An overview of its development and widespread use was published by Dodrill and Batzel (1994), who reported 48 published papers on the WPSI.

EPILEPSY-SPECIFIC INSTRUMENTS: RESULTS

Table 7.6: Epilepsy-specific patient-reported health instruments

Instrument	***Domains (no. items)***		***Response options***	***Score***	***Administration/ Completion time***
Epilepsy Surgery Inventory-55 (ESI-55)	*5 subscales/55 items* 1. SF-36* 2. Cognitive function (5) 3. Role limitations (8) 4. Health perceptions (4) 5. Overall QoL (2) ** Includes the 7 subscales of Rand SF-36 as generic core*		Various, including 5- and 6-point scales, dichotomous responses and VAS	Three summary composite scores computed: mental functioning, physical functioning, role functioning	15 minutes to complete
Katz Adjustment Scales (adapted for epilepsy)	Original KAS-R: 12 subscales/76 of 127 potential items 1. General psychopathology (24) 2. Suspiciousness (4) 3. Anxiety (6) 4. Negativism (9) 5. Confusion (3) 6. Belligerence (4) 7. Withdrawal (5) 8. Bizarreness (5) 9. Hyperactivity (3) 10. Helplessness (4) 11. Verbal expansiveness (5) 12. Nervousness (4) Misc. *(not used)* (50)	*Revised by Vickrey et al. (1992b) for epilepsy*: 14 subscales/127 items 1. Oversensitivity/ fearfulness (18) 2. Social (10) 3. Irritability (9) 4. Dependency (15) 5. Acting out (12) 6. Paranoia (5) 7. Abnormal thought process (5) 8. Withdrawal-R (11) 9. Emotional lability (6) 10. Nervousness-R (5) 11. Sociopathy (4) 12. Bizarreness-R (4) 13. Hyperactivity-R (4) 14. Disorientation (5) Misc *(not used)* (13)	4-point scales	Summed. Higher scores indicate better functioning (transformed to 0-100 point scales).	No details

Instrument	*Domains (no. items)*	*Response options*	*Score*	*Administration/ Completion (time)*
Liverpool Quality of Life (LQOL) Battery *and* Liverpool Seizure Severity Scale (LSSS)	LQOL: 1. Adverse drug effects Scale(21) 2. Impact of Epilepsy Scale (8) General: 1. Affect Balance Scale (10) 2. Mastery Scale (7) 3. Life Fulfilment Scale (20) *[Early versions included other existing psychological and health status scales]* LSSS: Seizure Severity Scale (2 subscales): 1. Perceived control over seizures (9) 2. Ictal and post-ictal symptoms (11)	4-point Likert; rating scales, dichotomous Present/Absent	Adverse drug effects summed, with higher scores indicating more problems. Impact: mean scores used. Affect Balance: range 1-9 with higher scores indicating more positive balance; Mastery: range 7-28, with higher scores indicating greater mastery; Fulfilment: computed difference between actual and ideal life satisfaction scores.	30-45 minutes to complete
Quality of Life in Epilepsy-10 (QOLIE-10)	*7 subscales/10 items:* 1. Seizure worry(1) 2. Overall QoL (1) 3. Emotional well-being (1) 4. Energy/fatigue (1) 5. Cognitive functioning (1) 6. Medication effects (2) 7. Social function (3)	5 point Likert; 0-10 QoL rating scale	Summation and domain score (weighted) Higher scores represent better function on all scales Index: 0 = worst QoL, 100 = best QoL Higher scores represent better function on all scales	Self-report 'few minutes to complete'
Quality of Life in Epilepsy-31 (QOLIE-31)	*7 subscales/31 items:* 1. Seizure worry (5) 2. Overall QoL (2) 3. Emotional well-being (5) 4. Energy/Fatigue (4) 5. Cognitive functioning (6) 6. Medication effects (3) 7. Social functioning (5) Health status (1) *[not included in total score]*	5 point Likert; 0-10 QoL rating scale	Summation and domain score (weighted) Higher scores represent better function on all scales Index: 0 = worst QoL, 100 = best QoL Higher scores represent better function on all scales	Self-report 15 minutes to complete

Instrument	*Domains (no. items)*	*Response options*	*Score*	*Administration/ Completion (time)*
Quality of Life in Epilepsy-89 (QOLE-89)	*17 subscales/89 items [SF-36 supplemented by 53 items specific to epilepsy] grouped into four factors:* 1.Seizure-specific effects (seizure worry, health discouragement, medicine effects, work or driving or social function) 2. Cognition (language, memory, attention) 3. Physical health (role limitations/physical pain, health perceptions, or physical function) 4. Mental health (overall quality of life, emotional well-being, role limitations/ emotional, social isolation, social support, and energy or fatigue) *[Original 99 items reduced to 87, two items added on overall health perception and sexual functioning to produce 89 items.]*	4- & 6-point Likert scales; dichotomous Yes/No; 0-10 QoL rating scale, 1-5 VAS scale, 0-100 VAS scale	Summation and domain score (weighted) Overall score = weighted sum of subscale scores Subscale scores = mean scores across items within the subscale Index: 0 = worst QoL, 100 = best QoL Higher scores represent better function on all scales	Self-report 28.4 (±15.6) minutes to complete
Washington Psychosocial Seizure Inventory (WPSI)	*7 subscales/132 items:* 1. Family background (11) 2. Emotional adjustment (34) 3. Interpersonal adjustment (22) 4. Vocational adjustment (13) 5. Financial status (7) 5. Adjustment to seizures (15) 6. Medicine/medical management (8) 7. Overall psychosocial functioning (57) *Later an item measuring QoL was added*	Dichotomous Yes/No	Summation and domain score Higher scores indicate poorer adjustment. There are four profiles: 1) No problems; 2) Possible or slight difficulties; 3) Definite problems; 4) Severe or major problems.	Interviewer 15-20 minutes to complete
Side-Effect and Life Satisfaction (SEALS)	5 subscales/50 *and shorter form versions; Gillam et al. (1996) standardisation:* 1. General cognitive difficulties (17) 2. Satisfaction/Dysphoria (8) 3. Fatigue/Tiredness (5) 4. Temper(4) 5. Worry (4) *[early version included frequency of ADL)*	4-point Likert	Summation and domain scores	

Table 7.7: Summary of epilepsy-specific instruments: health status domains *(after Fitzpatrick et al., 1998)*

Instrument	***Instrument domains***								
	Physical function	**Symptoms**	**Global judgement of health**	**Psychol. well-being**	**Social well-being**	**Cognitive functioning**	**Role activities**	**Personal construct***	**Treatment satisfaction**
Liverpool Quality of Life (LQOL) Battery		x	x	x	x		x	x	
Epilepsy Surgery Inventory-55 (ESI-55)	x	x	x	x	x	x	x	x	
Katz Adjustment Scale				x		x			
Quality of Life in Epilepsy-10 (QOLIE-10)		x		x	x	x	x	x	
Quality of Life in Epilepsy-31 (QOLIE-31)		x	x	x	x	x	x	x	
Quality of Life in Epilepsy-89 (QOLE-89)	x	x	x	x	x	x	x	x	
Washington Psychosocial Seizure Inventory (WPSI)				x	x		x	x	x
Side-Effect and Life Satisfaction (SEALS)	x	x		x		x	x	x	

*** Includes global (HR) QoL ratings**

EPILEPSY-SPECIFIC PATIENT-REPORTED HEALTH INSTRUMENTS

a) Epilepsy Surgery Inventory-55 (ESI-55)

The seven studies included contained cohorts of patients who has undergone surgery, those who had undergone or been assessed for surgery, a cohort eligible for surgery, and mixed groups of patients (Langfitt, 1995; McLachlan et al., 1997; O'Donogue et al., 1998; Selai et al., 2000; Vickrey et al., 1992a, 1995; Wiebe et al., 1997). Both males and females were included. Mean ages ranged from 28 to 34 (actual age-ranges not given).

Reliability
Vickrey et al. (1992a) reported internal consistency reliability coefficients for the ESI-55 (Cronbach's alpha: 0.68–0.88). Multi-trait scaling supported item discrimination across subscales. Good internal consistency correlation coefficients and Cronbach's alphas of 0.62 to 0.94 were also reported by Langfitt (1995). In addition, high inter-rater agreement (kappa 0.91) has been obtained (Langfitt, 1995).

Validity
Factor analysis has confirmed mental and physical health factors, and a third defined by cognitive function and role limitations (Vickrey et al., 1992a).

Epilepsy-specific patient-reported health instruments
Selai et al. (2000) reported that the measure correlated well with the QOLAS. Construct validity was further supported by correlations between the ESI-55 and the WPSI emotional adjustment domain (Langfitt, 1995).

Measures of epilepsy function
O'Donoghue et al. (1998) reported that only some ESI-55 subscales were associated with seizure frequency, and the ESI-55 was less sensitive to outcome after surgery than the SHE (Subjective Handicap of Epilepsy scale), which measures subjective evaluations of handicap in epilepsy. The health perceptions subscale has been reported to have the greatest sensitivity in discriminating between patients varying by seizure type and frequency (Vickrey et al., 1995). Vickrey et al. (1992a) reported that patients who were seizure-free following surgery were significantly more likely to have higher ESI-55 scores than patients who continued to have seizures. The ESI-55 was able to discriminate between patients having only auras and seizure-free patients, but not between aura-only and seizure-free patients (Vickrey et al., 1995). (See also 'Responsiveness'.)

Generic heath status
Construct validity was supported by correlations between the ESI-55 and comparable functioning domains on the SIP; and by correlations between the ESI-55 and measures of mood (Vickrey et al., 1992a).

Responsiveness
McLachlan et al. (1997) reported that seizure-free patients and those with at least a 90% reduction in seizure frequency, reported improved QoL on five of 10 ESI-55 subscales and overall score at 24 months. The ESI-55 was also sensitive to < 90% seizure reduction. But only one ESI-55 subscale at six months and two at 12 months

showed significant differences between groups. Selai et al. (2000) reported that the ESI-55 scales for Mental health and Physical health showed improvements at one-year patient follow-up, although Role functioning did not achieve significance. Wiebe et al. (1997) examined the responsiveness at one year of the ESI-55, and supported the responsiveness of the ESI-55.

Expert consensus
Review of piloted instrument by panel of nine health professionals (Vickrey et al., 1992a). No further details given.

Precision
No specific evidence was found.

Acceptability
No specific evidence was found.

Feasibility
The ESI-55 takes an average of 15-16 minutes to complete, compared with 15.8 for the WSPI and 34.5 for the SIP (Langfitt, 1995).

Table 7.8: Developmental and evaluation studies relating to the Epilepsy Surgery Inventory-55 (ESI-55)

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
Epilepsy Surgery Inventory-55 (ESI-55)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Langfitt (1995) USA	Patients with intractable epilepsy grouped into complex partial seizures with secondary generalization, complex partial seizures only, having undergone anterior temporal lobectomy 6 months+ earlier (71) Age: mean 34.6, 34.3, 31.2, respectively Postal Inpatients	Internal consistency ✓ Inter-rater ✓	Face ✓ Content ✓ Construct ✓ Concurrent ✓				✓
McLachlan et al. (1997) Canada	Epilepsy patients, eligible for temporal lobectomy, who had surgery or medical therapy (81) Age: mean 31.9, 34.2, respectively Self-administered Inpatients		Construct ✓	✓			
O'Donogue et al. (1998) UK	Epilepsy patients (287) Age: median 34 Outpatients		Construct ✓				
Selai et al. (2000) UK	Epilepsy patients (145, 45 followed up) Age: not given Interview Inpatients		Construct ✓ Concurrent ✓	✓			
Vickrey et al. (1995) USA	Cohort of patients who had undergone surgery for intractable epilepsy (133) Age: mean 28 Postal		Construct ✓				

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
Epilepsy Surgery Inventory-55 (ESI-55)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Vickrey et al. (1992a) USA	Cohort of patients who had undergone surgery or assessed without having surgery (200) Age: mean 34 Postal	Internal consistency ✓	Construct ✓		✓		
Wiebe et al. (1997) Canada	Surgically and medically treated epilepsy patients (57) Age: mean 32.6 and 36.7, respectively		Construct ✓	✓			

b) Katz Adjustment Scales

The Katz Adjustment Scale was developed to assess social behaviour and adjustment among patients with schizophrenia (Katz and Lyerly, 1963) and most of the validation studies are with mental health patients. The measure was revised and tested for use with epilepsy patients by Vickrey et al. (1992b). The revisions to the scale improved its scaling success, comparing item-scale correlations, and also increased the number of Cronbach's alpha reliability coefficients equalling or exceeding 0.70 from five out of 12 to 12 out of 14 scales. Their analyses overall supported construct validity. Nervousness, Dependency, Oversensitivity/fearfulness, and Withdrawal subscales were the most sensitive to seizure status, while Sociopathy and Hyperactivity were the least sensitive.

Table 7.9: Developmental and evaluation studies relating to the Katz Adjustment Scales

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
Katz Adjustment Scales		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Vickrey et al. (1992b) USA	Epilepsy patients (328 and 193 cross-validation sample) Age: 328 patients - range 12-63, mean 30; 193 patients - range 16-66, mean 34 Self-completion by relative/close friend proxy Postal Outpatients, proxies	Internal consistency ✓	Construct ✓				

c) Liverpool Quality of Life (LQOL) Battery and Seizure Severity Scale (LSSS)

The nine studies examining these instruments studies included both men and women, and mainly outpatients (where specified) with ages ranging from 15 to 78 years (Baker et al., 1993, 1994; Buck et al., 1999; Chadwick 1994; Jacoby et al., 1993; Rapp et al., 1998; Smith et al., 1991; Wiebe et al., 2001; Wagner et al., 1995). Overviews of the scales have been published by Baker (1998); Baker et al. (1994) Cramer and French (2001).

Reliability

Tests of internal consistency of an early LQOL model showed Cronbach's alphas ranging from weak to strong (0.35 to 0.84) and from 0.69 to 0.85 for the two subscales of the LSSS (Baker et al., 1993). Cronbach's alphas for Personal and Material Fulfilment were later reported to be 0.68-0.77 (Baker et al., 1994). Jacoby et al. (1993) tested the Impact subscale within the LQOL and reported the Cronbach's alpha to be 0.65, but increasing to 0.82 if the work item was removed. With the exception of the Perceptions subscale, the minimum criterion for internal consistency for scales under early evaluation (> 0.50) were met for all scales (Wagner et al., 1995). The internal consistency of the LQOL has since been found to be adequate, although test-retest correlations are more variable (Rapp et al., 1998).

Validity

Smith et al. (1991) tested an early version of the LQOL model, and found that while no associations were found between seizure frequency and psychological factors, seizure severity was the most significant predictor of self-esteem, control and anxiety. Baker et al. (1993) also tested an early version of the model, and reported that the happiness and mastery subscales of the LQOLS and the subscales of the LSSS were able to detect treatment effects, supporting the construct validity of both.

Baker et al. (1994) reported moderate to high correlations for the Impact subscale of the LQOL and affect balance, anxiety, self-esteem and mastery (> 0.4) depression and perceived QoL (> 0.6). The only significant correlations for the Material fulfilment subscale were with Impact of epilepsy and Perceived QoL. The revised Impact subscale correlated significantly with the other psychological subscales in the battery by -0.21 to 0.6, with the exception of the partner item which failed to correlate significantly with three of the seven subscales tested. The total Impact score was significantly correlated with all psychological subscales (r = 0.45-0.66), supporting construct validity (Jacoby et al., 1993).

Epilepsy-specific patient-reported health instruments

Rapp et al. (1998) reported that the LSSS and the LQOL instrument correlated well with the ESI-55.

Measures of epilepsy function

There is some inconsistency of results in this area. The Ictal subscale, but not the Perceptions subscale, has been found to discriminate between seizure types (Baker et al., 1993). Rapp et al. (1998) reported that most of the LQOL subscales were significantly associated with seizure severity (LSSS), although none distinguished between patients with different seizure types. But both seizure type and frequency have also been found to be key predictors on all items of the Impact subscale (Buck et al., 1999). Wagner et al. (1995) found that the scales varied widely in their ability to discriminate between groups of patients known to differ clinically. Chadwick (1994) did find that seizure frequency was reduced with medication, compared with a placebo group. Differences with seizure severity and seizure ratings were small but significant. A critical review of the LSSS can be found in Cramer and French (2001).

Generic heath status

The NHP, and a range of generic psychological scales (HADS [Hospital Anxiety and Depression Scale], POMS [Profile of Mood States], Rosenberg Self-Esteem Scale [RSES]) as well as the SEALS ADL measure, were included in an early LQOL battery. The Cronbach's alpha of the NHP was reported to be 0.76 (Baker et al., 1993). No treatment effects were found for the NHP, nor for the HADS, RSES and POMS. The NHP, along with the Social Problems Questionnaire (SPQ), ADL scale of the SEALS inventory and the POMS, were excluded in later versions.

Wagner et al. (1995) used the LQOL and LSSS with the SF-36, and reported that, although the SF-36 had large ceiling effects, it discriminated better than epilepsy-specific scales among different disease severity groups. Buck et al. (1999) reported that the SF-36 subscales were all significantly correlated with seizure type and frequency.

Responsiveness

Threshold values for detecting clinically important changes were small for the LSSS and for the Impact of Epilepsy and Adverse drug events subscales of the LQOL (Wiebe et al., 2001).

Precision

Floor and ceiling effects were small in one study of the Impact subscale of the LQOL and the LSSS (Wiebe et al., 2001), although larger ceiling effects were reported for both LQOL and LSSS by Wagner et al. (1995).

Acceptability

Smith et al. (1991) commented on the high completion rate of the LSSS and an early version of the LQOL, and the acceptability of the battery of questionnaires to patients.

Feasibility

No evidence reported.

Table 7.10: Developmental and evaluation studies relating to the Liverpool Quality of Life (LQOL) Battery and Liverpool Seizure Severity Scale (LSSS)

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
Liverpool Quality of Life (LQOL) Battery and Liverpool Seizure Severity Scale (LSSS)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Baker et al. (1993) UK	Patients with refractory epilepsy (81) Age: range 15-67, mean 33.7 Self-administration	Internal consistency ✓	Construct ✓	✓			
Baker et al. (1994) UK	Patients with epilepsy (75) Age: range 15-68, mean 33.3 Self-administration Outpatients	Internal consistency ✓	Construct ✓ Concurrent ✓				
Buck et al. (1999) Eight European countries	Epilepsy (4929) Age: range 16-90, mean 37 Postal Outpatients and support groups		Construct ✓				
Chadwick (1994) UK	Epilepsy patients in drug trial (81) Age: range 15-67, mean 33.7 LSSS only In- or outpatients not specified Mode of administration unclear		Construct ✓ Concurrent ✓				
Jacoby et al. (1993) UK	Epilepsy patients (75) Age: range 15-68, mean 33 Self-administration Outpatients	Internal consistency ✓	Construct ✓				

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
Liverpool Quality of Life (LQOL) Battery and Liverpool Seizure Severity Scale (LSSS)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Rapp et al. (1998) USA	Epilepsy patients experiencing seizures in previous 4 weeks (92) Age: mean 39.04 Self-administered Outpatients	Internal consistency ✓ Test-retest ✓	Construct ✓ Concurrent ✓				
Smith et al. (1991) UK	Patients with medically refractory partial seizures (100) Age: range 15-67, mean 32.7 Self-administration In- or outpatients not specified		Construct ✓			✓	
Wagner et al. (1995) UK	Epilepsy patients on AED therapy in multicentre study (136) Age: range 15-78, mean 34.9 Self-administration Outpatients	Internal consistency ✓	Construct ✓		✓		
Wiebe et al. (2001) Canada	Stable epilepsy patients, candidates for surgery (40) Age: mean 36 In- or outpatients not specified Mode of administration unclear			✓	✓		

QUALITY OF LIFE IN EPILEPSY 10-, -31-, & 89-ITEM VERSIONS (QOLIE)

The early development of the QOLIE as a test battery of 98 items, constructed using the Rand SF-36 as a generic core, was described by Perrine (1993). This version was reported to have good reliability and validity. Two studies were identified which evaluated the Quality of Life in Epilepsy 10-item version, eight which evaluated the 31-item version, and 13 which evaluated the 89-item version.

d) Quality of Life in Epilepsy-89 (QOLIE-89)

13 studies of the QOLIE-89 were identified (Birbeck et al., 2000; Breier et al., 1998; Devinsky et al., 1995; Fargo et al., 2004; Hays et al., 1995; Kim et al., 2003; Leidy et al., 1999b; Loring et al., 2004, 2005; Perrine et al., 1995; Vickrey et al., 2000; Wiebe et al., 2001, 2002). Of these, most were observational, based on convenience, epilepsy clinic or centre out- or inpatients (the latter was not always specified), and one study involved randomisation of patients to telephone interview or self-completion questionnaire. All involved self-completion of the questionnaire. The studies included both adult men and women, with an age-range (where given) of 16-90 years.

Reliability

Devinsky et al. (1995), in the development phase of the instrument, reported the Cronbach's alpha for the subscales as high, ranging from 0.78 (medication effects) to 0.92 (attention/concentration), and 0.97 for the overall score. These exceeded the generally accepted criterion for acceptability of 0.70. Leidy et al. (1999b) also reported on internal consistency in their study comparing self- and telephone completion. For both methods they reported Cronbach's alpha for the 17 subscales to be high, ranging between 0.76 and 0.95.

Devinsky et al. (1995) reported test-retest reliability (up to 91 days) to be good overall, with product moment correlations ranging from $r = 0.58$ to $r = 0.86$ for the 17 scales. Apart from the two role limitations, pain and medication effects subscales, the remaining subscales exceeded the generally accepted criterion for acceptability for group comparisons of 0.70. Leidy et al. (1999b) reported high test-retest correlations at two weeks.

Devinsky et al. (1995) reported patient-proxy agreement product moment correlations to be low to modest, although significant, ranging from $r = 0.29$ (role limitations, emotional) to $r = 0.57$ (work/social function). Hays et al. (1995), however, reported that while proxy ratings can be substituted for patients' ratings in group comparisons with adequate reliability and validity, caution is needed for individual comparisons given the discrepancies for more subjective measures (cognitive functioning, health perceptions, seizure distress).

The instrument included 99 items at initial administration, 86 of which, across 17 subscales, were retained after multitrait scaling. Factor analysis of the 17 subscales yielded four underlying dimensions of health: an epilepsy targeted dimension (seizure worry, health discouragement, medicine effects, work/driving/or social function), cognition (language, memory, attention), mental health (overall QoL, emotional well-being, role limitations-emotional, social isolation, social support, energy/fatigue), and

physical health (role limitations-physical, pain, health perceptions, physical function) (Devinsky et al., 1995).

Leidy et al. (1999b) reported that the mode of administration (telephone interview or self-completion) did not influence the reliability or validity of results.

Validity

Initial testing was conducted by Devinsky et al. (1995), with 304 epilepsy patients and their relative/friend proxies from 25 epilepsy centers in the USA (130 men and 174 women), with a mean age of 36 years (range 17-63). The authors reported that construct validity was supported by significant patient-proxy correlations (although these were low to modest and significant correlations between the instrument and seizure frequency over the past year, neuropsychological tests and emotional and cognitive function. Hays et al. (1995) have reported caution in interpretation – see 'Reliability').

Loring et al. (2004) reported significant associations between the QOLIE-89 and measures of depressive symptoms (using the Beck Depression Inventory) as well as seizure worry (using the EFA [Epilepsy Foundation of America] Concerns Index), supporting construct validity. The EFA Concerns Index, a measure of the experience of epilepsy in relation to everyday activities, correlated variously with QOLIE-89; the strongest correlations were with the Work/Driving/Social Function subscale (Loring et al., 2005). Breier et al. (1998) reported that the QOLIE-89 Memory, Language and Attention/Concentration scales correlated significantly with the Minnesota Multiphasic Personality Inventory-2, supporting construct validity.

Socio-demographic variables

Reporting of results by socio-demographic variables was rare. Loring et al. (2004) reported linear regression analyses showing that older patients developing seizures had lower QOLIE-89 scores than those developing epilepsy at younger ages. Higher years of education were also an independent influencer of higher QOLIE-89 scores.

Measures of epilepsy function

Devinsky et al. (1995) reported significant correlations between the instrument and seizure frequency over the past year, as well as neuropsychological tests, emotional and cognitive function. Vickrey et al. (2000) reported weak, but significant, associations between seizure severity score (National Hospital Seizure Severity Scale-3) and the QOLIE-89 subscale and overall scores, although not all items on either scale achieved significant correlations. However, Fargo et al. (2004) reported that, in patients with epilepsy or psychogenic non-epileptic seizures, while the self-reports of neurocognitive functioning (memory, language, attention/concentration) with the QOLIE-89 correlated significantly with mood, not all self-reports of neuro-psychological functioning were accurate when tested against neuropsychological tests. But Perrine et al. (1995) reported the QOLIE-89 correlated adequately with a wide range of tests of neuropsychological measures, and supported the validity of the QOLIE-89.

Generic heath status

Birbeck et al. (2000) compared the SF-36 and SF-12 with the Quality of Life in Epilepsy (QOLIE) shorter and long (31- and 89-item) versions. They reported that the

epilepsy-specific measure had larger responsiveness indices than the SF-36 or SF-12, although they were comparable in relation to mental and global health for change in seizure frequency. Wiebe et al. (2002) compared the QOLIE-31 and QOLIE-89 with the SF-36 and the Health Utilities Index version 3 (HUI-III). They reported all instruments to be robust, and able to distinguish accurately between different levels of patient-assessed changes in their condition

Responsiveness
Kim et al. (2003) examined responsiveness in the QOLIE-89 at baseline and 28-week follow-up and reported mixed results. Wiebe et al. (2001) reported that the threshold values for QOLIE-31 and QOLIE-89 were similar. The additional 58 items in QOLIE-89 did not significantly improve its ability to detect real (clinically important) change.

Interpretation
Wiebe et al. (2001, 2002) examined minimum clinically important change, small, medium and large changes, and changes needed to exclude chance error in the Health Utilities version 3, along with the SF-36, and the Quality of Life in Epilepsy Inventory 31- and 89-item versions (QOLIE-31, QOLIE-89). They reported (2002) that the HUI-III, and the other instruments, all differentiated between no change and minimum important change. Only the two QOLIE instruments distinguished accurately between minimum important change and medium or large change.

Precision
Floor and ceiling effects were reported for the QOLIE-89 by Leidy et al. (1999b). The subscales with the largest ceiling effects (> 25%) were generic SF-36 subscales: role limitations-emotional, role limitations-physical, physical function and pain. Breier et al. (1998) stated that there was evidence of possible floor effects in some subscales but did not produce the full data to illustrate this comment. Wiebe et al. (2001) found no floor and ceiling effects.

Acceptability
Devinsky et al. (1995) analysed patients' responses to an open-ended question on QoL. The analyses showed that patients had additional concerns not captured in the QOLIE questionnaire (e.g. about finances, athletic activities, pregnancy, birth defect, stigma, bother with medication and insomnia). However, the authors justified the questionnaire as it covered the areas raised by 'many other responses'. Devinsky et al. (1995) reported that the questionnaire took an average of 28.4 minutes (SD 15.6, range 6-135) to complete.

Feasibility
Devinsky et al. (1995) reported that the questionnaire took an average of 28.4 minutes (SD 15.6, range 6-135) to complete. No estimation of costs was provided.

Table 7.11: Developmental and evaluation studies relating to the Quality of Life in Epilepsy-89 (QOLIE-89) instrument

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
Quality of Life in Epilepsy-89 (QOLIE-89)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Birbeck et al. (2000) USA	Participants in RCT medication for epilepsy (142) Age: range 18.8- 66.8, mean 38.2 Mode of administration not specified In- or outpatients not specified		Construct ✓	Time period ✓ [responsiveness indices for SF-36 and SF-12 also compared]			
Breier et al. (1998) USA	Patients with seizures and pseudo-seizures (68) Age: mean 35.1 (pseudo-seizure), 35.7 (epileptic) Self-administered Inpatients		Construct ✓		✓		
Devinsky et al. (1995) USA	Epilepsy patients (seizure-free for one year) and their accompanying friend/relative proxies (304) Age: range 17-63, mean 36 Self-administered Outpatients	Internal consistency ✓ Test-retest ✓ Inter-rater ✓	Content ✓ Construct ✓			✓	✓
Fargo et al. (2004) USA	Patients with epilepsy (45) or psychogenic non-epileptic seizures (37) Age: median 34.66 and 37, respectively Inpatients Self-administered		Construct ✓				

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
Quality of Life in Epilepsy-89 (QOLE-89)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Hays et al. (1995) USA	Epilepsy patients and their and their accompanying friend/relative proxies (292) Age: range 18-64, mean 36 Outpatients Self-administered	Internal consistency ✓ Inter-rater ✓ Test-retest ✓	Construct ✓				
Kim et al. (2003) USA	Patients in anti-epileptic drug trial (147) Age: mean 38.2 Self-administered			✓			
Leidy et al. (1999b) USA	Patients with epilepsy identified with patient records and clinic visits (139) Age: mean 38 Self- and telephone-administered	Internal consistency ✓ Test re-test ✓	Construct ✓		✓	✓	✓
Loring et al., (2004) USA	Patients with epilepsy undergoing evaluation for surgery (115) Age: mean 34.2 Self-administered within cognitive assessments		Construct ✓				
Loring et al. (2005) USA	Epilepsy patients assessed for surgery (189) Age: mean 34		Construct ✓				

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
Quality of Life in Epilepsy-89 (QOLIE-89)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Perrine et al. (1995) USA	Epilepsy patients across epilepsy centres and clinics (304) Age: mean 36.1 Self-administered		Construct ✓				
Vickrey et al. (2000) USA	Epilepsy patients enrolled in seven centre prospective study (340) Age: range 18-66, mean 37.3 Self-administered within interview study		Construct ✓				
Wiebe et al. (2001) Canada	Stable epilepsy patients, candidates for surgery (40) Age: mean 36 Self administered In- or outpatients not specified			✓	✓		
Wiebe et al. (2002) Canada	Patients with difficult-to-control focal epilepsy investigated for surgery (136) Age: mean 36 Self-administered In- or outpatients not specified			✓			

e) Quality of Life in Epilepsy -31 (QOLIE-31)

Seven studies were identified that examined the QOLIE-31 (Cramer et al., 1998; 2000, 2004; Gunter, 2004; Wiebe et al., 2001, 2002). Of these, one was based on the dataset to develop the parent measure (QOLIE-89). The studies included both men and women, with an age-range of 17-92 years (range not always provided).

Reliability

Cramer et al. (1998) used the original QOLIE-89 developmental dataset to assess the reliability and validity of the 31-item version. Internal consistency was high, and Cronbach's alpha ranged from 0.77 (social functioning) to 0.85 (cognitive functioning). Test-retest results were good, and correlations ranged from r = 0.64-0.85. In every instance, individual scale items correlated more significantly with the scale on which that item loaded than with other scales, and item-scale correlations were uniformly high: (seizure worry (r = 0.68-0.79), overall QoL (r = 0.90-0.92), emotional well-being (r = 0.71-0.82), energy/fatigue (r = 0.81-0.85), cognitive functioning (r = 0.66-0.81), medication effects (r = 0.75-0.89), and work/driving/social functioning (r = 0.68-0.80).

Factor analysis of the 30 items yielded seven factors, paralleling the QOLIE-31 scale structure, with the exception of broader QoL. Factor analysis of the seven subscales yielded two factors: emotional and psychological issues (seizure worry, overall QoL, emotional well-being, energy/fatigue subscales) and mental efficiency (medical/social effects, work/driving/social and cognitive functioning subscales).

Validity

The QOLIE-31 correlated significantly with seizure frequency, supporting its construct validity. It was reported by Cramer et al. (2000) to discriminate between treatment groups in relation to seizure worry, cognitive functioning and total scores, and to detect a difference in the overall QoL subscale. Cramer et al. (2004) reported that the QOLIE-31 emotional well-being subscale correlated significantly with the Profile of Mood States (POMS), among patients in a drug trial, supporting its construct validity. All seven subscales (especially energy and well-being) correlated well with each of the six POMS subscales (tension, depression, anger, vigour, fatigue, confusion) (Cramer et al., 1998).

Socio-demographic variables

Cramer et al. (1998) reported that the overall QOLIE-31, the cognitive and the work subscales correlated with employment status.

Measures of epilepsy function

Cramer et al. (1998) reported that the QOLIE-31 subscales correlated significantly with neurotoxicity scores, but not with systematic toxicity scores.

Generic heath status

Birbeck et al. (2000) compared the SF-36 and SF-12 with the Quality of Life in Epilepsy (QOLIE) shorter and long (31- and 89-item) versions. They reported that the epilepsy-specific measure had larger responsiveness indices than the SF-36 or SF-12, although they were comparable in relation to mental and global health for change in seizure frequency. Wiebe et al. (2002) compared the QOLIE-31 and -89 with the SF-

36 and the Health Utilities Index version 3 (HUI-III). They reported all instruments to be robust, and able to distinguish accurately between different levels of patient-assessed changes in their condition.

Responsiveness

Gunter et al. (2004) reported results from a study of a disease management programme, showing that the patients in the intervention group significantly improved their scores at 6-8 weeks post-baseline, on the QOLIE-31 for Seizure worry and Emotional well-being subscales, while there were no changes in the control group. Cramer et al. (2000) also reported evidence of responsiveness to change (baseline and 18 weeks) among respondents in a medication trial. Wiebe et al. (2001) reported that the threshold values for QOLIE-31 and -89 were similar, and the additional 58 items in QOLIE-89 did not significantly improve its ability to detect real (clinically important) change.

Interpretation

Wiebe et al. (2001, 2002) examined minimum clinically important change, small, medium and large changes, and changes needed to exclude chance error in the Health Utilities version 3, along with the SF-36, and the Quality of Life in Epilepsy Inventory 31- and 89-item versions (QOLIE-31, QOLIE-89). They reported (2002) that the HUI-III, and the other instruments, all differentiated between no change and minimum important change. Only the two QOLIE instruments distinguished accurately between minimum important change and medium or large change.

Expert consensus

The subscales were selected from the full QOLIE, on the basis of those believed to be the most important to people with epilepsy, as determined by an expert panel; no further details were provided (Cramer et al., 1998).

Precision

Wiebe et al. (2001) found no floor and ceiling effects.

Acceptability

No specific evidence was found.

Feasibility

No specific evidence was found.

Table 7.12: Developmental and evaluation studies relating to the Quality of Life in Epilepsy-31 (QOLIE-31) instrument

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
Quality of Life in Epilepsy-31 (QOLIE-31)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Birbeck et al. (2000) USA	Participants in RCT medication for epilepsy (142) Age: range 18.8-66.8, mean 38.2 Mode of administration not specified In- or outpatients not specified		Construct ✓	✓ [responsiveness indices for SF-36 and SF-12 also compared]			
Cramer et al. (1998) USA	Patients recruited from epilepsy clinics (304) Age: range 17-60, mean 36 Self-administered Outpatients	Internal consistency ✓ Test re-test ✓	Construct ✓				
Cramer et al (2000) USA	Patients in RCT epilepsy medication therapy (246) Age: range 16-70 Self-administered		Construct ✓	✓			
Cramer et al. (2004) USA	Epilepsy patients with poorly controlled seizures or experiencing unacceptable adverse effects from current medication before and after changes to medication (two comparative treatment arms) (196) Age: mean 43.4 and 44.9 in two arms Self-administered		Construct ✓				

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
Quality of Life in Epilepsy-31 (QOLIE-31)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Gunter et al. (2004) USA	Patients in pre-and post-intervention evaluation of management of epilepsy (225) Age: range 18-92, mean 92 Self-administered		Construct ✓				
Wiebe et al. (2001) Canada	Stable epilepsy patients, candidates for surgery (40) Age: mean 36			✓	✓		
Wiebe et al. (2002) Canada	Patients with difficult-to-control focal epilepsy investigated for surgery (136) Age: mean 36 Self administered In- or outpatients not specified			✓			

f) Quality of Life in Epilepsy-10 (QOLIE-10)

Two studies reported psychometric properties of the QOLIE-10 (Cramer et al., 1996, 2000). One was based on patients recruited from seizure clinics (the same dataset used for the development of the full QOLIE-89 and the QOLIE-31) and the other was based on patients participating in a medication trial. All were adults, with mean ages of 36 and 38.7 years.

Reliability

Cramer et al. (1996) reported that test-retest correlations for all items and subscales were significant, and were moderate to high (Pearson's r = 0.48-0.81). Cronbach's alphas for the three subscales ranged from 0.48 to 0.51.

Validity

Three subscales were confirmed by factor analyses: Epilepsy effects, Mental health and Role function. The three resultant QOLIE-10 subscales correlated well with their QOLIE-89 counterpart subscales (r -0.78-0.92) (Cramer et al., 1996).

Measures of epilepsy function

Cramer et al. (1996) reported that measures of systemic toxicity and neurotoxicity scores correlated best with different QOLIE-10 subscales. Correlations were weak to modest. The authors interpreted these variations as suggesting that patients' perceptions approximately reflected clinical test results. Scales also varied by seizure frequency. Patients with low seizure frequency had better Role function scores (driving, work, social issues) than patients with moderate or high seizure frequency. The authors stated this supported the discriminant validity of the QOLIE-10.

Responsiveness

Cramer et al. (2000) reported evidence of responsiveness to change (baseline and 18 weeks) among respondents in a medication trial.

Precision

No specific evidence was found.

Acceptability

No specific evidence was found.

Feasibility

Cramer et al. (2000) reported that, while the QOLIE-10 was able to detect changes over time among patients in a drug trial, the longer QOLIE-31 is preferred as it provides more detailed information.

Table 7.13: Developmental and evaluation studies relating to the Quality of Life in Epilepsy-10 (QOLIE-10) instrument

Study/ Country	Population (N) Age Method of administration Setting	Measurement properties					
Quality of Life in Epilepsy 10 (QOLIE-10)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Cramer et al. (1996) USA	Patients recruited from epilepsy clinics (304) Age: range 17-60, mean 36 Self-administered Outpatients	Internal consistency ✓ Test-retest ✓	Construct ✓				✓
Cramer et al. (2000) USA	Patients in RCT epilepsy medication therapy (246) Age: range 16-70 Self-administered		Construct ✓	✓			

g) Washington Psychological Seizure Inventory (WPSI)

Four studies were identified on the WPSI, based on outpatients where specified. The age-range of patients included was 18-69, where given. Men and women were included. It was not always clear whether the instrument was adapted for self-completion, rather than being administered during an interview.

Reliability

Dodrill et al. (1980) reported on the development of the WPSI. Internal consistency, evaluated by split-half reliability, was modest to good, with most correlations ranging from 0.68 to 0.95, and one was 0.37. Test-retest correlations ranged from 0.58 to 0.58 to 0.84, with one at 0.28. Ratings by professionals showed good reliability, but ratings of patients' 'significant others' were less good.

Chang and Gehlert (2003) used item-response theory to evaluate how items in each clinical scale performed in relation to representing the underlying constructs being measured. They reported that most items within each scale fitted the measurement model well. All subscales were found to be acceptably unidimensional.

Validity

The WPSI was independently associated with preoperative adjustment and seizure-free outcomes, supporting its construct validity (Hermann et al., 1992).

Responsiveness

Wiebe et al. (1997) examined the responsiveness at one year of the WPSI and the ESI-55. They reported that all instruments registered some change, and supported the responsiveness of the ESI-55. But the WPSI was relatively unresponsive to small or medium changes.

Precision
No specific evidence was found.

Acceptability
No specific evidence was found.

Feasibility
No specific evidence was found.

Table 7.14: Developmental and evaluation studies relating to the Washington Psychosocial Seizure Inventory (WPSI)

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
Washington Psychosocial Seizure Inventory (WPSI)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Dodrill et al. (1980) USA	Epilepsy patients (127) Age: range 18-56, mean 29.16 Outpatients Interview	Internal consistency ✓ Test-retest ✓ Inter-rater reliability ✓					
Chang and Gehlert (2003) USA	Epilepsy patients (145) Age: range 18-69, mean 39.6 Outpatients Interview	Item-response theory ✓					
Hermann et al. (1992) USA	Epilepsy patients with complex partial seizures, seizure-free or significantly improved post-surgery (97) Age: mean 30.6 and 30.4, respectively		Construct ✓				
Wiebe et al. (1997) Canada	Surgically and medically treated epilepsy patients (57) Age: mean 32.6 and 36.7, respectively			✓			

Other epilepsy-specific instruments

Less well-known and well-tested seizure severity and other epilepsy-specific scales can be found in reviews by Cramer and French (2001), and Trimble and Dodson (1994). The section below includes better known scales, but with relatively little evidence of testing with epilepsy patients than the scales reviewed above.

h) Side-Effect and Life Satisfaction Inventory (SEALS)

The SEALS, a measure of side-effects and satisfaction with drug therapy, has undergone some limited testing since its early development, with larger numbers of male and female patients, and ages ranging from 15-60 years. While five factors were confirmed, their structure is slightly different to the original (Gillham et al., 1996). Split-half coefficient of test-retest reliability was 0.792; while less than perfect, it was regarded as adequate. The SEALS is able to discriminate in the expected direction between patients taking two or more drugs compared with those taking none. It was also able to detect expected changes in patients' condition.

The initial version included a frequency of ADL subscale, but Baker et al. (1993) reported that it was unable to discriminate between patients taking medication or a placebo. Gillham et al. (2000) reported that a 38-item version of SEALS (subscale scores and the total score) did correlate significantly with generic psychological measures (POMS, HADS, Rand Medical Outcomes Study Cognitive Functioning Scale) (r = 0.53-0.84).

Table 7.15: Developmental and evaluation studies relating to the Side-Effect and Life Satisfaction Inventory

Study/ Country	**Population (N) Age Method of administration Setting**	**Measurement properties**					
Side Effect and Life Satisfaction Inventory (SEALS)		**Reliability**	**Validity**	**Responsiveness**	**Precision**	**Acceptability**	**Feasibility**
Baker et al. (1993) UK	Patients with refractory epilepsy (81) Age: range 15-67, mean 33.7 Self-administration		Construct ✓				
Gillham et al. (1996) UK	Epilepsy patients from 5 centres (45 for test-retest and 923 for validity) Age: 923 -range 15-60, mean 33.43	Test-retest ✓ Split half ✓	Construct ✓				
Gillham et al. (2000)	Epilepsy patients Age: range 18-71, mean 37.82 Self-administration Outpatients		Construct ✓				

Table 7.16: Other epilepsy-specific instruments identified from the review

The following table provides an overview of other records of epilepsy-specific instruments identified of either newly developed instruments or single-study reporting of measurement properties and/or evaluation.

Instrument/reference	Population (N) Age Method of administration Setting	Reliability	Validity	Responsive-ness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
Epilepsy Foundation of America (EFA) Concerns Index **Loring et al. (2005)** **USA**	Epilepsy patients assessed for surgery (189) Age: mean 34 In- or outpatients not specified nor mode of administration		✓					EFA Concerns Index aims to measure the experience of epilepsy in relation to everyday activities. Modest correlations between EFA Concerns Index and cognitive measures, and varying correlations with QOLIE-89 reported - the strongest correlations were with the Work/Driving/Social Function subscale. Five factors identified: affective impact on enjoyment of life, general autonomy concerns, fear of seizure recurrence, concern of burdening family, perceived lack of understanding by others.

Instrument/reference	Population (N) Age Method of administration Setting	Reliability	Validity	Responsive-ness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
Epilepsy Social Effects Scale **Chaplin et al. (1990)** **UK**	Epilepsy patients in two centres No further details provided In- or outpatients not specified Interview	Internal consistency ✓	✓					The questionnaire was developed to investigate the social effects of epilepsy. Developmental work reported with patients who were asked to generate statements, which were compared with existing questionnaires. Following piloting, the areas included were: Attitudes towards accepting attacks, Attitude to label Epilepsy, Fear of having seizures, Fear of stigma in employment, Lack of confidence about the future, Concern about performance at work, Concern about sexual relationships, Concern about platonic relationships, Concern about housing, Lack of confidence travelling, Adverse reaction on social life, Adverse reaction on leisure pursuits, Change of outlook on life, Difficulty communicating with family, Problems taking medication, Distrust of medical profession, Misconceptions about epilepsy, Depression or emotional reactions, Feeling increased social isolation,, Lethargy/lack of energy, Sleep disturbance. The response format was Yes/No answers, which, during piloting, some respondents found difficulty with, thus these were changes to levels of agreement/disagreement. Some statements were weighted. Validity was assessed against staff ratings of patients' behaviour which led to weak or modest correlations. Inter-scale correlations were generally high.

Instrument/reference	Population (N) Age Method of administration Setting	Reliability	Validity	Responsive-ness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
Glasgow Epilepsy Outcome Scale (GEOS-90) **Espie et al. (1998, 2001)** **Scotland, UK**	1998: epilepsy patients (39), carers 2001: family of epilepsy patients (384), clinicians and staff Outpatients and in care Age: 39 in care environments, 31 living with family	Internal consistency ✓	✓					The scale measures types and degrees of concern in the treatment of people with epilepsy and mental retardation. The final scale, tested for factor structure, contains four subscales of Concerns about seizures (30 items), Concerns about treatment (26), Concerns about caring (14), and Concerns about social impact (20). Internal consistency was reported as high, and the scale could discriminate between patient groups. A short 35 item version was also developed (2001).
National Hospital Seizure Severity Scale (SSS) **Vickrey et al. (2000)** **USA**	Epilepsy patients enrolled in 7-centre prospective study (340) Age: range 18-66, mean 37.3 Interview		✓		✓			This was a refinement of a previously developed measure, containing 7 items on seizure severity. Instructions recommend completion by a witness to seizures in addition to the person with epilepsy. SSS was significantly, although weakly, associated with QoL. There were no floor, and few ceiling effects.

Instrument/ reference	Population (N) Age Method of administration Setting	Reliability	Validity	Responsive-ness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
Quality of Life Assessment Schedule (QOLAS) **Kendrick and Trimble (1994)** **UK**	Patients with chronic epilepsy (50) and undergoing surgery (11) Age: not given In- or outpatients not specified Mode of administration not specified	Test-retest ✓	✓					QOLAS uses repertory grid techniques, to elicit epilepsy patients' own constructs and concerns. Patients are first asked to define what aspects of their life are important to their QoL. The method permits an objective assessment of subjective feelings. Initial test-retest results were good; construct validity was partly supported. Lack of standardisation is likely to limit its appeal in clinic settings.
Selai et al. (2000) **UK**	Epilepsy patients (145, 45 followed up) Age: not given Interview Inpatients	Internal consistency ✓	✓	✓				Coefficient alpha 0.7; correlated well with ESI-55.
Quality of Life Index Epilepsy Version III **Ferrans and Powers (1985, 1992)**	No specific evidence was found							This scale was developed for use with haemodialysis patients, and a version was developed for use with epilepsy patients. Other versions exist – e.g. for cardiac and cancer patients. It consists of satisfaction and importance ratings of various areas of life. It is a well known (in cancer) but little used scale.

Instrument/reference	Population (N) Age Method of administration Setting	Reliability	Validity	Responsive-ness	Precision	Acceptability	Feasibility	Comments No other records identified unless stated
Quality of Life in Newly Diagnosed Epilepsy Instrument (NEWQOL) **Abetz et al. (2000)** **UK and USA**	Patients with new-onset epilepsy (48 UK, 60 USA) Age: mean 35.3 UK, 36.5 USA Self-administration Outpatients Self-completion, followed by interviews	Internal consistency ✓ Test-retest ✓	✓					The NEWQOL includes a battery of previously validated multi-item scales and items, containing 93 items, 81 of which form eight multi-item subscales. It aims to measure epilepsy-specific QoL, and includes 13 subscales which measure: Anxiety, Depression, Social activities, Symptoms, Locus of Control/Mastery, Neuropsychological Problems, Social Stigma, Worry and Work Limitations. Single items measure general Health, Number of Seizures, Social Limitations, Social Support, Self-Concept, Ambition Limitations, Health Transition, and General Limitations. Five additional items measure supportive networks. All use Likert scaling and scores are summed. All multi-item scales had good test-retest reliability, acceptable internal consistency, and high item discriminant validity. The NEWQOL was able to discriminate between patient groups (particularly symptoms, psychological problems).
Subjective Handicap of Epilepsy (SHE) **O'Donoghue et al. (1998)** **UK**	Epilepsy patients (287) Age: median 34 Outpatients Postal	Internal consistency ✓ Test-retest ✓	✓			✓		SHE, measures subjective evaluations of handicap in epilepsy. It contains 32 items in 6 subscales: Work and activities, Social and personal, Self-perception, Physical, Life satisfaction, and Change. It takes 10 mins to complete. Cronbach's alphas were high (0.79-0.88), and test-retest results satisfactory. SHE was sensitive to seizure frequency and was more sensitive than the ESI-55 to outcome after surgery.

SUMMARY - GENERIC INSTRUMENTS

Seven generic instruments were included in the review. The SF-36 was the most used and well-tested patient-based generic measure for use with patients with epilepsy. It was recommended by Vickrey et al. (1992a) and is the generic core in the most established and well-tested epilepsy-specific measures. One study compared the SF-36 and the shorter form SF-12. Other generic instruments included the EuroQoL/EQ-5D, the Health Utilities Index, the Nottingham Health Profile, and the Sickness Impact Profile. The instruments were tested on a wide range of patient types and severities. Not all studies specified whether they included in- or outpatients. The content of the generic instruments are detailed in Chapter 3.

Most SF-36 studies tested this instrument for construct validity, and reported satisfactory results (Buck et al., 1999; Hermann et al., 1996; Jacoby et al., 1999; Leidy et al., 1999a; Wagner et al., 1995, 1996). Jacoby et al. (1999) reported the most explicit data for construct validity, and reported associations in the expected directions between the SF-36 and seizure frequency and type, other health problems and side-effects.

Three studies reported good results for internal consistency (Jacoby et al., 1999; Wagner et al., 1995, 1996), two for time-period responsiveness (Birbeck et al. 2000; Wiebe et al. 2002), three for precision (Jacoby et al., 1999; Leidy et al., 1999a; Wagner et al., 1995), and one reported patients' and doctors' preferences (Wagner et al., 1997). Overall, US results for internal consistency reliability were high (Cronbach's alpha = 0.73-0.93), although they were lower among UK patients (0.43-0.92) Wagner et al. (1996). Other tests for reliability have indicated that they are satisfactory, except in Germany, for unknown reasons (Jacoby et al., 1999). Floor and ceiling effects were evident in many of the SF-36 subscales (Jacoby et al., 1999; Leidy et al., 1999a; Wagner et al., 1995). Overall, the evidence supports the use of the SF-36 as a generic instrument with people with epilepsy. But it is less responsive than epilepsy-specific measures, such as the QOLIE (Birbeck et al., 2000).

The evidence is limited for the other instruments reviewed. Three studies used the EQ-5D on community, market research and hospital samples. Selai et al. (2000) found that it was not valid in detecting changes pre-and post-treatment for epilepsy. They reported that 42% of their sample questioned the EQ-5D VAS, and thus questioned the scale's content validity. There was less evidence for the HUI-III. Compared with the QOLIE, the HUI-III was not able to distinguish accurately between minimum important changes. One paper commented only on the Q-TWIST, generally poor results were reported for the NHP, and one study reported good results for reliability and validity for the SIP.

In conclusion, the SF-36 is the best tested generic instrument for use with epilepsy patients, although it has floor and ceiling effects. There is little evidence in relation to other generic or utility instruments.

SUMMARY - EPILEPSY-SPECIFIC INSTRUMENTS

Eight epilepsy-specific instruments were reviewed, and a small number of others were summarised. The most extensively used and tested specific instruments are the Epilepsy Surgery Inventory, the QOLIE-31 and QOLIE-89, the Washington Psychosocial Seizure Inventory, and the Liverpool QoL Battery and Seizure Severity Scale. Overall, there was good evidence of concurrent validity, when compared with generic measures.

The Washington Psychosocial Seizure Inventory was the most popular measure in the past. Four studies were identified. But it does not cover all important areas in relation to cognition, physical functioning, energy and overall QoL. An improvement on the scale is the Epilepsy Surgery Inventory which has been shown to be reliable and valid (Vickrey et al., 1992a). Seven studies were identified for the ESI. It includes the SF-36 as a generic core, and supplements it with epilepsy-specific items. Although it contains 55 items, the completion time is about 15 minutes. Vickrey et al. (1992a) reported acceptable to high internal consistency reliability coefficients (Cronbach's alpha: 0.68-0.88). Cronbach's alphas of 0.62 to 0.94 were also reported by Langfitt (1995). Selai et al. (2000) reported that the ESI-55 scales for Mental health and Physical health showed improvements at one year patient follow-up, although Role functioning did not achieve significance.

The Liverpool Battery aimed to focus on issues important to people with epilepsy, although it is lengthy and time-consuming. Nine studies were identified. The studies relating to these are not all easily identified as the measures were unlabelled during their early development. Internal consistency reliability coefficients have generally been reported to be just adequate to good (Cronbach's alpha: 0.68-0.88) (Rapp et al., 1998). Most of its subscales have been reported to be associated with seizure severity, although not all with seizure type (Baker et al., 1993; Rapp et al., 1998). Wagner et al. (1995) reported that the SF-36 discriminated better between different disease severity types.

An increasingly more popular measure is the QOLIE, particularly the 31- and 89-item versions. The 89-item version includes the Rand SF-36 as a generic core. 13 studies were identified for the QOLIE-89, eight for the QOLIE-31, and two for the QOLIE-10. The QOLIE has also been tested on a wide range of patients (whether in- or outpatients was not always clearly specified). Cronbach's alphas were high for the QOLIE-89 (Cronbach's alpha: 0.76-0.97) (Devinsky et al, 1995; Leidy et al., 199b). Other tests for reliability were generally good. Caution is needed if substituting proxy for patient assessments, as concordance is not always good (Devinsky et al., 1995; Hays et al., 1995). More mixed results for validity have been reported, although construct validity was generally supported. One problem is that not all self-reports of neuropsychological functioning correlate well with neuropsychological measures (Fargo et al., 2004), although others have reported the correlations to be adequate (Perrine et al., 1995). While 12 studies evaluated the QOLIE-89, just eight were included for the shorter form QOLIE-31. Overall, the reliability and validity of the QOLIE-31 was reported to be good.

In sum, the most robust and popular measures are the ESI-55 and the QOLIE-89, although all require further evidence and many need better clarification of sample sources and types.

DISCUSSION AND RECOMMENDATIONS

A large number of studies were reviewed, the majority of which were based in North America, with the exception of the Liverpool Battery which was developed in the UK.

The SF-36 is the most widely applied and tested generic instrument. The most psychometrically sound and popular measures epilepsy-specific measures are the ESI-55 and the QOLIE-89. One possible limitation of the ESI-55 is that it was developed for use in the context of surgery for epilepsy and the majority of evidence derives from that context. It would be helpful to have evidence from more general contexts. There was little evidence in support of the use of the utility measures.

The generic instruments were multidimensional indicators of broader health or health-related quality of life. Few examined acceptability in any depth, or feasibility with this patient population. The SF-36 is a popular core in some of the epilepsy-specific measures reviewed, and many indicators built on earlier scales, the views of expert panels, professionals and behavioural scientists. More information on how relevant and important the items are to patients themselves is needed.

Relatively few investigators examined the performance of measurement scales against each other. The SF-36 and SF-12 have been tested against the QOLIE scales, with some inconsistent results. More comparisons have been made between the epilepsy-specific measures and domain-specific measures (e.g. psychological mood). The lack of information on scale distribution and variation by patients' socio-demographic variables was also noticeable.

Recommendations

The evidence summarised here supports the use of the SF-36 as a generic tool, with patients with epilepsy. Indeed, popular epilepsy-specific instruments have included this instrument within their generic core. The most extensively used and tested epilepsy-specific instruments are the Epilepsy Surgery Inventory, the QOLIE-31 and QOLIE-89, the Washington Psychosocial Seizure Inventory, the Liverpool QoL Battery and Seizure Severity Scale. The measures which are recommended are the ESI-55 and the QOLIE-89, although they require further evidence, especially with European populations, and, for ESI-55 testing outside of the specific surgical context. It also should be noted that the QOLIE family of questionnaires was originally derived, in item content, from the SF-36. Given that it is often recommended that a disease-specific and generic measure be used in conjunction, it may not be sensible to combine the QOLIE with the SF-36 in this way.

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