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The use of the CapQOL (capacity to report subjective quality of life inventory) with a chronic schizophrenia sample that reside on care facilities.

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Abstract

The capacity to report subjective quality of life inventory (CapQOL) is a brief screening tool designed to evaluate ability to appraise subjective QOL, complete related QOL measures and assess cognitive impairment. The purpose of this study was to assess the CapQOL's test-retest reliability, internal consistency and associations with cognitive impairments (memory and executive functioning) and negative symptoms in a sample of people with chronic schizophrenia that reside on care facilities. The CapQOL, cognitive and schizophrenia symptom assessments were administered to 23 participants (mean age = 43, s.d. = 9.7, male = 13). The CapQOL had good test-retest reliability ($r_s(21) = .868, p < .01$) and internal consistency ($\alpha = .850$). 43% of the chronic schizophrenia sample were identified by the CapQOL as having the ability to complete a subjective QOL measure (a significantly smaller percentage than a prior study with an early psychosis patient

sample). The CapQOL demonstrated a poor agreement with the cognitive assessments ($\kappa < .40$) and a non-significant correlation with negative symptom scores ($p > 0.05$). The main limitation of the study was the sample size that may have affected the range of scores on the measures, the resulting associations with the CapQOL and the number of factors that could be assessed. Further validation studies of the CapQOL are indicated.

Key Words: Cognitive Impairment, Decision making, Psychometrics, Psychosis, Quality of Life, Questionnaires, Schizophrenia

Introduction

Cantril [1] introduced a cognitive element to the conceptualisation of QOL when he proposed that overall life satisfaction could be assessed from the difference between a person's aspirations and satisfactions [2]. He developed a self-anchoring scale on which respondents could place themselves relative to their best or worst life circumstance that they could imagine [1]. Baker and Intagliata [3] developed a multidimensional conceptual model of QOL based on the relationships among individual experience, individual health status, external environments and quality of life responses. They operationalised QOL as both a global measure of well-being and an individual's response to a variety of life domains. Awad [4] proposed a model of QOL in schizophrenia patients that viewed QOL as an interaction between three key determinants: the severity of psychotic symptoms,

side-effects including subjective responses to anti-psychotic medication and psychosocial performance (see appendix 1.1 for an extended description of QOL models).

QOL measures are abundant within the literature and are increasingly being developed and used as screening and outcome measures with schizophrenia patients. They are being designed to assess the diverse range of impairments and consequences that impact on an individual that has schizophrenia. Some of these measures focus on the objective circumstances of a person's life, (e.g. their living situation), others emphasise the subjective experience of satisfaction with those circumstances and others focus on the person's global satisfaction with life as a whole [5] (see appendix 1.2 for an extended discussion of objective and subjective determinants of QOL). In their review of QOL measures for people with schizophrenia, Prince and Gerber [5] acknowledged the usefulness of assessing objective circumstances of a person's life, however, they believed that client-elicited subjective QOL measures were the most appropriate method to assess and monitor changes in QOL.

The credibility of self-reports on subjective QOL measures in select populations (ie. Dementia [6-7], Traumatic Brain Injury [8-9], Learning Disabilities [10]) (see appendix 1.3 for an extended discussion of the validity and reliability of QOL reports in select clinical populations) and especially people with schizophrenia has been questioned [11]. This is not the case in people affected by physical/medical

disorders. It seems that there was a wide spread belief that the self reports given by people with schizophrenia were unreliable. The credibility of their self reports had been raised in the context of history taking, treatment adherence and insight into their illness [12]. This belief appears to have changed, largely due to research that has evaluated the reliability and validity of self-rated QOL estimates in people with schizophrenia. Voruganti et al. [12] found that clinically compliant and stable schizophrenia patients could evaluate and report their QOL with a high degree of reliability and concurrent validity. They concluded that self-report QOL measures were useful tools in clinical trials and outcome studies with this population [12] (see appendix 1.4 for an extended discussion of the validity and reliability of the QOL reporting in schizophrenia).

Andrews and Withey [13] proposed that the subjective experience of QOL includes both a cognitive and an affective element. The cognitive element focuses on the judgement or individual appraisal of the individuals' degree of satisfaction and the affective element measures the degree of happiness or negative affect of the individual [13]. These elements may be less well developed in certain individuals and so they may lack the mental capacity to appraise and report their subjective QOL experience using a subjective QOL measure. Wong et al. [14] described the 'affective' element of QOL as subjective (e.g., another person cannot tell an individual how happy they are about a situation and the appropriateness of how happy they should feel), however the 'cognitive' element which is the capacity to make judgements and appraise an individual's level of satisfaction with their own

life, may be affected by impaired cognition, intellect or reasoning abilities [14]. These problems are more prevalent within certain clinical populations (e.g. people diagnosed with schizophrenia) [14]. Wong et al. [14] therefore developed a measure that claimed to assess these cognitive difficulties objectively (see appendix 1.5 for an extended discussion of the cognitive impairments associated with schizophrenia).

Wong et al. [14] developed the CapQOL (capacity to report subjective quality of life inventory), a brief screening tool, designed for people with a wide range of mental disorders. It consists of 12 questions, which assess five areas that they identified as important in completing subjective QOL measures (see appendix 1.6 for an extended discussion of the QOL measures reviewed by Wong et al., [14]) (see appendix 1.7 for an extended discussion of the development and structure of the CapQOL) (see appendix 1.8 to view a copy of the CapQOL). Wong et al. [14] administered the CapQOL to 442 patients with early psychosis and found it to be reliable and internally consistent. They claimed that the CapQOL had face validity because it was developed according to literature that described the difficulties administering QOL measures, as well as the opinions of experienced professionals who measure QOL [14]. It would appear that the CapQOL also has content validity in that several of its items are depicted in actual QOL measures. Using the CapQOL, Wong et al. [14] found that 89% of their participants were assessed to be able to complete a subjective QOL measure. Wong et al. [14] suggested that the high percentage of participants assessed to have capacity may have been due to

their participant sample being young and in the early stages of a psychotic illness. This would make them less likely to be affected by cognitive impairments and negative symptoms (see appendix 1.9 for an extended discussion of negative symptoms in schizophrenia), which are more characteristic in chronic psychosis patients [14]. Their report suggested further and more extensive validation studies on the CapQOL with people with psychotic disorders (both early and chronic psychoses).

The CapQOL has been shown to be a reliable and internally consistent instrument when used with an 'early psychosis' patient group. It was designed to evaluate the cognitive ability of respondents to appraise and judge their subjective QOL and capability to complete a subjective QOL measure. The CapQOL would therefore be administered before a subjective QOL measure so that respondents that do not have the cognitive ability and/or capability are identified [14].

The primary aim of this study was to assess the CapQOL's reliability and internal consistency with a sample of people with schizophrenia that reside on care facilities. It had also been suggested that this population would be more affected by cognitive impairments and negative symptoms than the early psychosis sample from the Wong et al. [14] study. The secondary aim was therefore to compare the impaired/unimpaired scores from this study with the Wong et al. [14] study, and to assess the associations between the CapQOL, cognitive impairments (memory and executive functioning) and negative schizophrenia symptoms.

The six experimental hypotheses were:

1. The CapQOL will demonstrate reliable and internally consistent properties.
2. There will be a significant difference between the chronic schizophrenia sample's impaired/unimpaired global score on the CapQOL (from this study) and the early psychosis sample's impaired/unimpaired global score on the CapQOL (from the Wong et al. [14] study).
3. There will be a significant association between the impaired/unimpaired global score on the CapQOL and memory impairment.
4. There will be a significant association between the impaired/unimpaired global score on the CapQOL and executive functioning impairment.
5. There will be a significant association between the impaired/unimpaired global score on the CapQOL and both memory and executive functioning impairment (a 'cognitive impairment').
6. There will be a significant association between global scores on the CapQOL and negative schizophrenia symptoms.

Methods

Participants

Sixty-eight people were identified and asked to participate in the study from 7 care facilities in Lincolnshire. Six of the care facilities were psychiatric inpatient wards

and 1 of the care facilities was a residential home (for people with severe and enduring mental illness requiring 24 hour supported care). Forty-five of those people declined to take part in the study. Of the 23 participants, 6 were residents at the residential home. None of the participants dropped out of the study. Thirteen (56%) of the participants were male. The age range of the participants was between 25 and 64 years of age, with a mean age of 43 (s.d. = 9.7) and a mean pre-morbid IQ of 101 (s.d. = 14.2). The participants were selected on the basis of being admitted to the care facility and having received a diagnosis of schizophrenia (identified in their medical notes). Most of the participants had been through multiple psychotic episodes and their condition was described as 'severe and enduring mental illness'. All of the participants were being treated with anti-psychotic medication. There were no age restrictions, however participants were excluded if they did not understand or speak English or give consent.

Measures

Capacity to report subjective quality of life inventory (CAPQOL) [14] (see [appendix 1.8 to view a copy of the CapQOL](#)): the CAPQOL is a 12 item interview questionnaire that assesses an individuals cognitive ability to appraise and make judgements on their subjective QOL and their ability to complete a subjective QOL measure.

National Adult Reading Test 2nd Edition (NART) [15] : the NART is a published measure that has been standardised against the Weschler Adult Intelligence Scale-Revised (WAIS-R) to produce estimates of pre-morbid IQ. It consists of 50 words presented in increasing difficulty. The errors produced by the participant on the NART were used to determine an estimate of their premorbid Full Scale IQ.

The Adult Memory Information Processing Battery (AMIPB): Story Recall Test [16]: the AMIPB is a series of standardised memory tests. The story recall test was used to assess immediate registration of verbal information and retention over time. The test involved the participant being read a short story and then being asked to recall it immediately and after a 30-minute delay. The raw scores for immediate and delayed recall were converted to z-scores for analysis.

The Hayling and Brixton Tests (H&B) [17]: these two tests assess executive functioning, that is the cognitive processes that are supported by frontal lobe structures. Raw scores were derived for each test and age and pre-morbid IQ cut-off scores were used to enable the assessor to identify an executive functioning impairment.

Positive and Negative Syndrome Scale (PANSS) [18]: the PANNS is a published, 30-item scale that measures the degree of positive and negative

symptoms of an individual. The seven positive symptom and seven negative symptom items were rated by the assessor using the PANNS formalised psychiatric interview and the PANNS informant questionnaire (completed by a member of the participants care team).

(see appendix 2.1 for an extended description and justification of the measures that were used)

Procedure

The clinical psychologist responsible for the care facilities approached the identified people to seek permission for the chief investigator to speak to them about the study. The clinical psychologist gave each identified person a copy of an information sheet that explained the study. If the person agreed to be seen, the chief investigator (test administrator) met with them, discussed the information sheet and answered any questions about the study. If the person gave verbal consent, they were asked to sign a consent form. In order to safeguard participants, a member of their nursing team was present to verify that the person had not been coerced into participating in the study and/or lacked the capacity to consent to participate in the study. The study was subject to full NHS ethical and research and design committees (see appendix 2.2 for the NHS Ethics and Research and Design committees' approval letters).

A within subjects design was used with participants completing all of the measures. The order that the measures were presented to participants was randomised. There were two orders of presentation:

1. CapQOL followed by the cognitive and PANNS assessments
2. Cognitive and PANNS assessments followed by the CapQOL

At the first meeting, all of the measures were administered. In order to assess test-retest reliability, the CapQOL was re-administered 7-14 days later (see appendix 2.3 for a rationale for the re-administration interval and sample size).

Analysis

The 'cut-off' (pass/fail) scores on the CapQOL were the same as those used in the Wong et al. [14] study. Those individuals that received a global score of between 4 and 5 on the CapQOL were identified as having the cognitive ability to appraise their subjective QOL and were assigned as 'passing' the CapQOL assessment. Those individuals that received a global score of between 1 and 3 on the CapQOL were identified as not having the cognitive ability to appraise their subjective QOL and were assigned as 'failing' the CapQOL assessment.

The participant's NART score was used to estimate pre-morbid IQ. In order to identify a 'memory impairment', the scores on the AMIPB: Story Recall assessment

and NART were converted to z-scores. If the z-score on the AMIPB: Story Recall was two z-scores below that of the NART, participants were classified as having a 'memory impairment'. In order to identify an 'executive functioning impairment' on the Hayling & Brixton (H&B) Tests, 5% level tables for age and IQ from the Hayling & Brixton (H&B) manual [17] were used.

The statistical analyses were performed using the Statistical Package for Social Sciences: Version 14 (SPSS: 14). The test-retest reliability of the CapQOL was measured by Spearman correlations. The internal consistency of the CapQOL was derived from Cronbach's alpha statistic. Chi-square analysis was used to compare the impaired/unimpaired scores on the CapQOL between this study and the Wong et al. [14] study. The associations between the global score and individual domain scores were measured by Spearman correlation analysis. Screening of the data for principal components analysis with varimax rotation were performed on the domain scores. Cohen's Kappa statistic was used to detect associations between the AMIPB: Story Recall test and the pass/fail global score on the CapQOL and the Hayling and Brixton Tests and the pass/fail score on the CapQOL. Spearman Correlations were used to detect associations between PANNS symptom scores and global scores on the CapQOL.

Results

At the first administration, 10 (43%) of the participants obtained a global score of 4 or 5 on the CapQOL indicating that they were ‘unimpaired’ and had the ability to complete a subjective QOL measure. At the second administration, 13 (57%) of the participants obtained a global score of 4 or 5. There was a significant correlation between the global scores at the first and second administrations ($r_s(21) = .868, p < .01$) indicating good test-retest reliability (see appendix 3.1 for data screening). There was a ‘good’ agreement [19] between impaired/unimpaired global scores at the first and second administrations ($\kappa = .738$) (see appendix 3.2 for an alternative analysis using the Bland & Altman (1995) method). There was a non significant effect for order of presentation of measures ($p > 0.05$) (see appendix 3.3 for χ^2 analysis of order of presentation). The frequency distribution of the domain and global scores at time 1 and time 2 are presented in tables 1 and 2.

Table 1. Distribution of domain scores on the CapQOL at time 1 and time 2

		Number of participants (% of score)	
Domain	Score	Time 1	Time 2
Acquiescence	0	5 (22)	6 (26)
	1	18 (78)	17 (74)

	Number of participants (% of score)		
Consistency	0	4 (17)	2 (9)
	1	19 (83)	21 (91)
Understanding of the 5-point scale	0	3 (13)	2 (9)
	1	2 (9)	3 (13)
	2	18 (78)	18 (78)
Understanding of domain: Economic status	0	5 (22)	4 (17)
	1	6 (26)	7 (30)
	2	12 (52)	12 (52)
Understanding of domain: Relationship with others	0	7 (30)	4 (17)
	1	6 (26)	8 (35)
	2	10 (44)	11 (48)
Awareness of situation and comparison: Economic Status	0	10 (43)	11 (48)
	1	2 (9)	2 (9)
	2	11 (48)	10 (43)
Awareness of situation and comparison: Relationship with others	0	8 (35)	6 (26)
	1	5 (22)	3 (13)
	2	10 (43)	14 (61)

Table 2. Distribution of global scores on the CapQOL at time 1 and time 2

Global Score	Number of participants (%)	
	Time 1	Time 2
1	4 (17.4)	2 (8.7)
2	3 (13.0)	6 (26.1)
3	6 (26.1)	2 (8.7)
4	4 (17.4)	6 (26.1)
5	6 (26.1)	7 (30.4)

The internal consistency of the CapQOL of all the items including the global score was $\alpha=.850$ (see appendix 3.4 for analysis of domain/item statistics). The associations between the global score and the domain scores are presented in table 3. The ‘acquiescence’ and ‘consistency’ domains showed a non-significant correlation ($p>0.05$) with the global score (see appendix 3.5 for an alternative analysis of these domains using χ^2 statistics). The other domains showed significant correlations ($p<0.05$) with the global scores. The data was not suitable for principal components analysis (see appendix 3.6 for principal component analysis data screening) and so the factor structure of the domain scores of the CapQOL could not be identified.

Table 3. Spearman correlation between global scores and domain scores on the CapQOL

Domain	Spearman correlation	Significance Value (p)
Acquiescence	0.29	0.175
Consistency	0.41	0.054
Understanding of the 5-point scale	0.44	0.034
Understanding of domain: Economic status	0.62	< 0.001
Understanding of domain: relationship with others	0.87	< 0.001
Awareness of own situation and comparison: Economic status	0.84	< 0.001
Awareness of own situation and comparison: Relationship with others	0.71	< 0.001

There was a significant difference on the impaired/unimpaired global scores between this study and the Wong et al. [14] study ($\chi^2 (1) = 39.995, p < .001$). The levels of agreement of the CapQOL and the cognitive assessments are presented in table 4. Twelve (52%) of the participants were categorised as having a ‘memory impairment’ on the AMIPB: Story Recall. The CapQOL demonstrated a ‘poor agreement’ [19] with memory impairment/unimpairment on the AMIPB: Story

Recall (κ -.128). Fourteen (61%) of the participants were categorised as having an ‘executive functioning impairment’ on the Hayling Test. The CapQOL demonstrated a ‘poor agreement’ [19] with executive functioning impairment/unimpairment on the Hayling Test (κ -.052). Nine (39%) of the participants were categorised as having an ‘executive functioning impairment’ on the Brixton Test. The CapQOL demonstrated a ‘poor agreement’ [19] with executive functioning on the Brixton Test (κ -.298). Four (17%) of the participants were categorised as having both types of cognitive impairment (memory impairment and executive functioning). The CapQOL demonstrated a ‘poor agreement’ [19] with those participant’s with both types of cognitive impairment (κ -.195).

Table 4. Number of participants classified as impaired/unimpaired on the CapQOL and cognitive assessments

		CapQOL	
		Impaired	Unimpaired
AMIPB	Impaired	5	7
	Unimpaired	6	5
Hayling Test	Impaired	7	7
	Unimpaired	4	5
Brixton Test	Impaired	6	3
	Unimpaired	5	9
Both cognitive assessments	Impaired	3	1
	Unimpaired	8	11

PANNS data was only collected for 13 participants (10 participants either became too distressed during the PANNS interview or declined to take part in that section of the assessment due to the time that it took to complete (up to 60 minutes)). The mean PANNS negative score was 19 (s.d. = 6) and mean positive score was 16 (s.d. = 8). There was a non significant correlation between global scores and PANNS negative scores ($r_s(11) = -.471, p = .104$) and PANNS positive scores ($r_s(11) = -.307, p = .307$).

Discussion

The CapQOL demonstrated good test-retest reliability and internal consistency with this sample of people with chronic schizophrenia. As predicted, this chronic schizophrenia sample had more difficulties completing the CapQOL than the early psychosis sample from the Wong et al. [14] study. Approximately 1 in 5 of the participants acquiesced, demonstrated inconsistent responses and lacked ability to understand the 5-point scale. Approximately half of the participants experienced difficulties in understanding, comparing and having an awareness of economic and relationship domains.

This finding suggests that in order to obtain valid and reliable QOL reports in chronic schizophrenia populations, screening should take place using a measure such as the CapQOL. When responding difficulties are identified, the question

and/or response format of the QOL measurement tool would need to be modified accordingly. For example, those individuals that are identified as acquiescing could be further probed for meaning using scripts (see appendix 4.1 for a discussion of additional alterations to QOL measurement). The development of a schizophrenia specific QOL measure that does not contain modifiers, complex question structures, Likert Scales and abstract QOL domains would also be supported by this study's findings (see appendix 4.2 for an extended discussion of condition specific vs. general QOL measurement).

The cognitive testing results from this study were consistent with the literature that reported significant levels of memory and executive functioning impairments in people with schizophrenia, however, the CapQOL was not sensitive to those difficulties. The validity of the CapQOL as a measure of cognitive functioning is questionable given these findings. Additional, independent validation and investigation using other memory (see appendix 4.3 for an extended discussion of memory assessment) and executive functioning measures (see appendix 4.4 for an extended discussion of executive functioning assessment) would be recommended. It is possible that impaired memory and executive function do not affect ability to appraise and report subjective QOL. Perhaps other cognitive impairments associated with schizophrenia (e.g. attention and vigilance) affect this ability, and should be evaluated in future research (see appendix 4.5 for a discussion of attention and vigilance observations and implications for future research).

The global scores on the CapQOL did not demonstrate statistically significant correlations with negative symptomatology and were based on a small ($n = 13$) participant sub-sample. It seems likely that a shorter, more acceptable measure of negative symptomatology would have led to an increased sub-sample and range of negative symptom scores. The correlation value of this study ($r = -.471$) was larger than the Wong et al. [14] study (with $n = 442$), suggesting that a larger sample size would have achieved statistical significance (see appendix 4.6 for an extended discussion of PANNS results and implications for future research).

There are several limitations that need to be considered in relation to the findings. Firstly, the sample size ($n = 23$) was very small and a large number of the people that were identified and approached about the study declined to take part. It seems likely that some of those people that declined were more acutely psychotic than the participant sample. This reduced the possible range of scores on the measures and the resulting associations with the CapQOL. The small sample size also limited the number of factors that could be assessed, for example, residency (i.e. ward / residential-home) factors could not be evaluated (see appendix 4.7 for an extended discussion of recruitment difficulties and declining rates in other studies). Secondly, this study did not include a measure of QOL and so test-retest correlations of the CapQOL could not be compared with test-retest correlations of an actual QOL measure. Thirdly, there was no assessment of inter-rater reliability on the CapQOL and the assessor was not formally 'trained' in its use (see

appendix 4.8 for an extended discussion of inter-rater reliability). Fourthly, it would have been desirable for the PANNS and cognitive assessments to have been completed 'blind' to the CapQOL, however, due to limited resources the order of presentation was 'randomised'. Finally, a limitation of the CapQOL is that it is not based on any theoretical model or process and so cannot be evaluated against them (see appendix 4.9 for an extended discussion of theoretical models) (see appendix 4.10 - 4.12 for additional limitations of the study).

It is important to regularly screen capacity to report subjective QOL because inaccurate reporting of QOL can have significant adverse affects on a patient's rehabilitation care programme. Regular screening should also be aimed at identifying those people whose impaired capacity is temporary and those people that need additional assistance in reporting their subjective QOL. At present, there is no evidence to support Wong et al. [14] claim that the CapQOL 'objectively measures cognitive impairment'. Before the CapQOL is used in clinical settings, repeated independent validation in early psychosis and chronic schizophrenia populations should be conducted. Future studies could validate the CapQOL for other conditions such as mood disorders, learning disabilities, dementia or brain injury (see appendix 4.13 - 4.17 for remaining discussion points).

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Appendix 1.1: Extended description of QOL models

Figure 1 outlines the conceptual model of QOL as presented by Baker and Intagliata (1982). It summarises the differing areas of QOL that are researched.

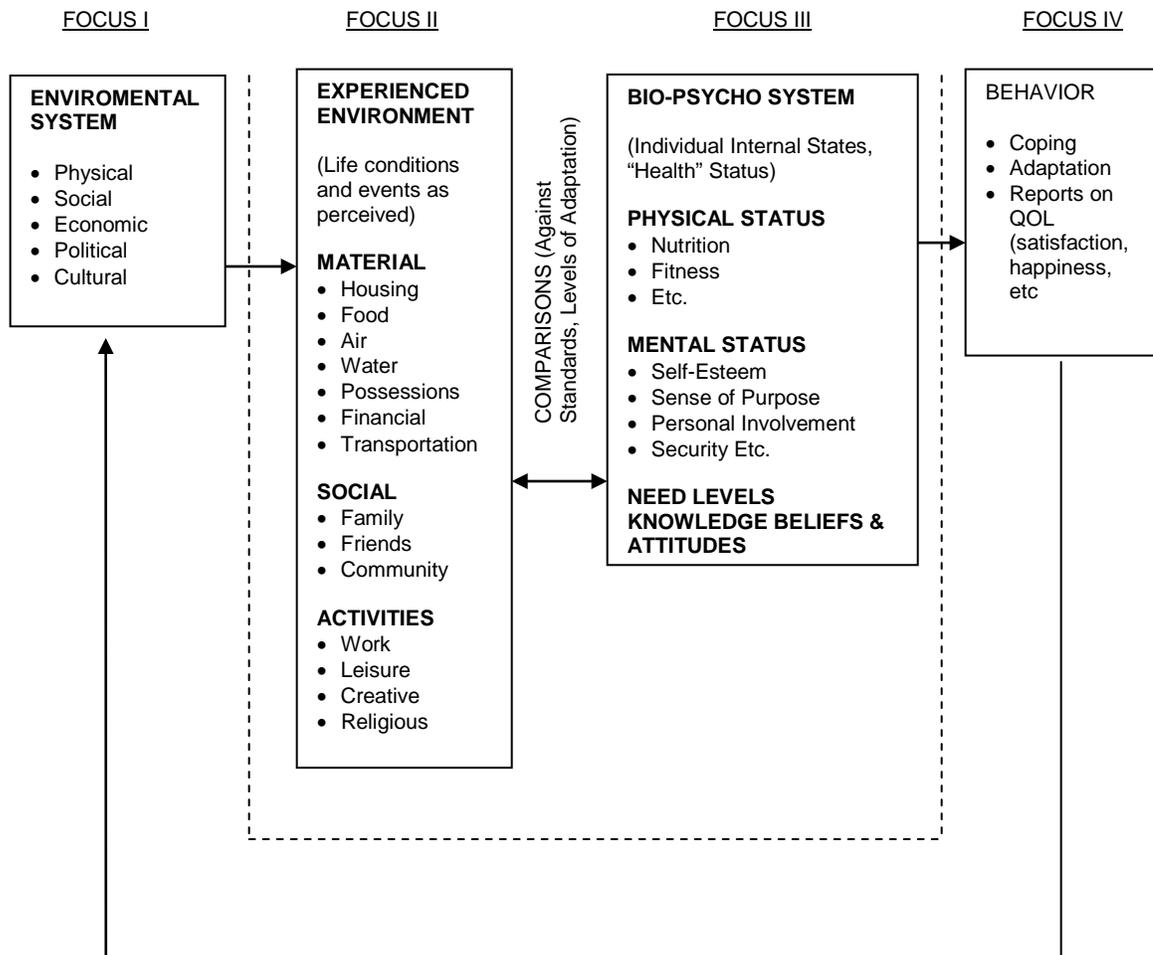


Figure 1. Baker and Intagliata's (1982) conceptual model of QOL (reproduced from Baker & Intagliata, 1982)

Focus 1 is concerned with the objective environment and the counting of social indicators, e.g. physical, social, economic, political and cultural environmental aspects. Focus 2 is concerned with people's perceptions of the physical environment. This focus recognises that people view the world differently. Focus 3 is concerned with the actual state of health and well-being of a person. It covers their 'internal states', e.g. their needs, desires, knowledge, beliefs, values and attitudes. Focus 4 is concerned with the behavioural outcomes of a person's interactions with their environment and how they cope with unpleasant environments. This focus assumes that people try to avoid painful life experiences and increase their skills to alter their environment. Focus 4 suggests that we find out about people's perceived levels of QOL through their responding behaviour on QOL questionnaires and interviews (Baker & Intagliata, 1982).

Awad (1992) developed a conceptual model of QOL that is specific for people with schizophrenia receiving antipsychotic drug treatment. The model proposes that the person's perception of QOL is determined by an interaction between three key determinants: the severity of psychotic symptoms, side-effects including subjective responses to anti-psychotic drugs and the level of psychosocial performance (Awad, 1992). Other influences dynamically influence the perception of QOL and include personality characteristics, pre-morbid adjustment, values and attitudes, resources and opportunities available (Awad, Vorunganti & Heslegrave, 1997).

Awad et al. (1997) assessed the validity of the Awad (1992) Multidimensional Model of QOL and found that severity of illness and subjective responses to anti psychotic drugs emerged as key determinants of QOL (Awad et al., 1997). They concluded that the key aspects of the model were endorsed. Limitations to this validation study included the population: predominantly symptomatic but stable psychotic patients. These patients would not be representative of the large spectrum of schizophrenic population (Awad et al., 1997). Criticisms of the model were its narrow focus (i.e. the impact of anti psychotic medications on the QOL of people with schizophrenia) and that it was not broad enough to assess social or vocational interventions (Awad et al., 1997).

Lehman (1983) developed a hierarchical model of QOL using his quality of life interview (QLI) schedule with 278 people with severe and enduring mental illness. This model assumes that QOL is subjective and reflected in a “sense of global well-being” (Lehman, 1983). In common with Awad et al. (1997), Lehman’s (1983) model identified psychosocial factors (e.g. safety, unemployment, financial issues and family and social relations) as primary determinants of QOL (Lehman, 1983).

Appendix 1.2: Objective and subjective determinants of QOL

Objective determinants of QOL

Sullivan, Wells and Leake (1991) found that social relations and finances were the main determinants of QOL. Levitt, Hogan and Bucosky (1990) found that number of readmissions in the previous year, frequency of family contacts, satisfaction with social life, mental health and adult education were key determinants in their sample of people with severe and enduring mental illness.

The most commonly used QOL measures use objective indicators (Lehman, 1983). Lehman (1983) felt that their popularity arose from their apparent objectivity, ease of use and the impression that they represent society's values. He argued that there was an 'implicit belief' that objective QOL measures accurately reflected the values and beliefs of the people being studied (Lehman, 1983). The literature however, does not support this belief with objective life conditions only being marginally related to subjective experience (Andrews & Withey, 1976; Kennedy, Northcott & Kinzel, 1978; Najman & Levine, 1981). Lehman (1983) suggested that it is therefore important to ask people about how they feel about their lives.

Subjective determinants of QOL

Subjective QOL questionnaires appear to measure several related constructs that include “life satisfaction”, “morale”, “happiness”, “positive wellbeing” and “mental health” (Lehman, 1983). It has been argued that even though these constructs are similar, they are not equivalent (Lehman, 1983). This raises the question about conceptual clarity and the comparability of measurement across studies (George, 1979). An example to illustrate this difficulty could be “happiness”, defined as “the affect that people feel toward their current affairs” and “life satisfaction” defined as “a cognitive assessment of progress toward desired goals” (George, 1979). Empirical research has demonstrated that these two constructs differ, with the finding that reported life satisfaction increases with age and happiness decreases (Campbell, Converse & Rodgers, 1976). Lehman (1983) argued that clearer definitions and meanings of subjective QOL determinants are required and how they relate to mental health.

Appendix 1.3: Validity and reliability of QOL reporting in select clinical populations

Older adults with dementia

The ability and point at which older adults with dementia can competently complete subjective QOL measures has been questioned (Lawton, 1994; Rabins, Kasper,

Kleinman, Black & Patrick, 1999). It had been assumed that people with dementia would not be able to rate their own QOL because of the characteristics of the condition (Logsdon, Gibbons, McCurry & Teri, 2002). The ability to understand the QOL questions and communicate subjective experiences had been thought to be influenced by the variety of associated impairments in memory, attention, judgement, insight and communication (Logsdon et al., 2002). The increased risk of agitation, depression and psychosis in this population were also thought to impact on the reliability and validity of the QOL response (Logsdon et al., 2002).

Post (1994) had suggested that what is important for a persons QOL may change as the dementia progresses or the individuals living situation changes (Post, 1994). For example, what seems important in the early stages of the condition (e.g. retaining intellectual capacity) may be less important in the later stages (where comfort and safety are prioritised) (Post, 1994). It would seem that this observation has implications for the type of QOL questions that are used with dementia populations (e.g. retention of intellect vs. comfort and safety) and that the validity and reliability of the responses could be enhanced by considering the individuals 'stage' of dementia and priorities, and tailoring the questions accordingly.

Logsdon et al. (2002) used the Quality of Life-Alzheimer's Disease (QOL-AD) Scale (Logsdon, Gibbons, McCurry & Teri, 1999) to evaluate the impact of cognitive impairment on the reliability and validity of the measure. They found that of the 177 participants that were interviewed, 155 were able to complete the QOL-

AD (Logsdon et al., 1999). They reported that only 22 were unable to understand it sufficiently to provide meaningful responses (Logsdon et al., 2002). The main difference between those who could complete the QOL-AD (Logsdon et al., 1999) and those who could not were related to cognitive and functional status. The mean MMSE score for the participants who could not complete the measure was 4.1 (SD = 3.2, range 0-10) compared with 18.1 (SD= 5.9, range 4-29) who could complete the measure ($F(1,175) = 120.2, p < .001$) (Logsdon et al., 2002). This study concluded that it was possible for people with mild to moderate dementia to reliably and validly rate their own QOL (Logsdon et al., 2002) and that cognitive ability is an important determinant of ability to report QOL. This finding provides support for the development of a cognitive screening tool (e.g. the CapQOL), and a rationale for assessing associations with cognitive impairment in this study (see appendix 1.5 for further descriptions of cognitive impairment in schizophrenia).

Traumatic Brain Injury (TBI)

A significant proportion of people with TBI have cognitive and physical impairments (DePalma, 2001). The length and type of QOL measurement used with this population has been affected by their 'lack of concentration' (DePalma, 2001). It has also been suggested that certain TBI patients are 'emotionally labile' and have difficulty with interactions that ask them to recall their traumatic incident or talk about their feelings (DePalma, Fedorka & Simko, 2003). Another problem with

measures of QOL in TBI are that some of this population may not be able to recall their lives and QOL prior to the trauma (DePalma et al., 2001).

DePalma et al. (2003) studied the QOL experienced by severe TBI survivors. They used the Sickness Impact Profile (SIP) where many patients commented on the length of time and mental fatigue that they experienced. DePalma et al. (2003) criticised the use of standard QOL questionnaires with this population suggesting that they may not be valid or reliable due to insufficient knowledge of the experience of recovering from and/or living with a TBI. They argued that until the major impacts and struggles of TBI are fully explored, the QOL measures may be unreliable and invalid with this population (DePalma et al., 2003). DePalma et al. (2003) suggested that in this population, family members/caregivers should be included in the rating of QOL. This is because there is often a significant disruption in the family life and that in some instances, the person with a TBI reports no problems in coping whereas the family members describe many difficulties coping (DePalma et al., 2003).

Learning Disabilities

Problems with the use of self-report QOL measures in people with learning disabilities are well documented in the literature. The research literature suggests that people with learning disabilities have specific problems with certain types of questioning styles in relation to item content (e.g. quantitative judgements,

generalisations), question phrasing (e.g. modifiers), and response format (e.g. acquiescence, multiple choice questions) (Finlay & Lyons, 2001). Finlay and Lyons (2001) suggested that many QOL self-report measures include these types of questions and that more attention should be paid to establishing the validity and target population that the QOL measures are aimed at. Finlay and Lyons (2001) summarised the types of difficulties with questions in QOL questionnaires and the possible actions that can be taken to alleviate them (reproduced in table 1). These 'actions' are considered in relation to the QOL measurement in schizophrenia in the discussion section of the research paper and appendix 4.1.

Table 1. Summary of difficulties in questioning people with learning disabilities and possible actions to alleviate them (reproduced from Finlay & Lyons (2001))

Problem Area	Specific problems	Possible Action
Question content	Quantitative judgements	Avoid Likert scales and questions of degree and frequency. Use pre-test screening questions about concrete events for which frequency is known.
	Time questions Comparisons Socially reflective questions Abstract or general concepts	Use significant events as markers. Ask about each element separately. Check meaning of answer. Check meaning of answer. Use concrete situations or events. Allow that people may not be able to make generalized judgements.
	Psychiatric symptoms Irrelevant content	Avoid symptoms difficult to understand or describe. Elicit item content from appropriate populations. Beware of basing scales on those for general population.
	Labels Sensitive content	Check understanding. Be aware of the difficulties. Ask about specifics rather than generalities. Stress that information will not be shared with carers.
Question phrasing	Negative wordings	Avoid adding <i>no</i> or <i>not</i> to positive phrasings. Use negative form of words.
	Modifiers	Avoid modifiers, particularly at end of sentences. Check meaning.

Problem Area	Specific problems	Possible Action
	Subject-object confusion and passive phrasings. Question not understood	Be aware of questions where this is possible- check meaning. Keep question structure simple, avoid technical vocabulary. Write alternative phrasings and probes into questionnaires.
Response format	Yes-no questions	Avoid modifiers and complex question structures. Include “don’t know” option. Check meaning by asking for examples and probing further (use scripted probes). Have pre-interview to check how person exhibits uncertainty or responds to false suggestions.
	Multiple-choice format	Break down into two either-or stages. Use picture only if meaning is clear. Avoid Likert scales and offering multiple options.
	Understanding or classifying responses	Tape record interviews. Allow scorer to record “other/uncodeable” responses in questionnaires. Return to question later.
Psychometric properties	Factor structure	Do not assume that this is the same as for the general population.
	Target population	New questionnaires must clearly report sample selection criteria. Use test of verbal ability.

Appendix 1.4: Validity and reliability of QOL reporting in schizophrenia

Research on the subjective QOL of people with schizophrenia has produced mixed conclusions concerning the validity and reliability of the reports. Some of the

studies reported that schizophrenia participants underestimated their psychosocial functioning, whilst others suggested that their QOL estimates were disproportionately high, or just accurate (Weissman, Prusoff & Thompson, 1978; Glazer, Aaronson, Prusoff & Williams, 1980; Sullivan et al., 1991).

The reliability of QOL reports has been assessed on measures such as the Quality of Life Interview (QOLI) (Lehman, 1988). When the QOLI's reliability was assessed on 500 patients with severe and enduring mental illness, internal and test-retest reliability were reported to be 'satisfactory' (Prince & Prince, 2001). Vorunganti, Heslegrave, Awad and Seeman (1998) used correlational analysis in order to assess the reliability and validity of the subjective QOL reports given by schizophrenia patients. Positive and statistically significant correlations were found for the reliability of QOL self reports over consecutive weeks for the Sickness Impact Profile (SIP) (Bergener, Bobbit, Carter & Gibson, 1981) ($r = 0.8 - 0.87$, $p < 0.0001$) and the Gurins Global QOL scale (Gurin, Verhoff & Feld, 1960) ($r = 0.68 - 0.87$, $p < 0.0001$). These findings suggest that schizophrenic patients' subjective QOL reports were highly consistent over repeated measurements on global and multi-dimensional measures (Vorunganti et al., 1998). Inconsistent with other studies (e.g. Wong et al., 2005; Logsdon et al., 2002), the severity of schizophrenic symptoms and cognitive deficits did not influence the reliability of the QOL self reports in their study.

Vorunganti et al. (1998) found that the subjective QOL measures (SIP and Gurin's Global QOL measure) correlated significantly with each other ($r = 0.55-0.89$, $p < 0.0001$) (Vorunganti et al., 1998). They found that the clinicians ratings on global and domain specific measures (Social Performance Schedule (SPS) (Stuart & Wykes, 1987) and Global Assessment Scale of Functioning (GAF) (Endicott, Spitzer, Fleiss & Cohen, 1976) correlated significantly ($r = 0.83-0.86$, $p < 0.0001$) (Vorunganti et al., 1998). They also found that the schizophrenic patients ratings on the multidimensional nature of the SIP correlated with the clinicians rating (with SPS, $r = 0.40-0.52$, $p < 0.0001$; with GAF, $r = 0.35-0.54$, $p < 0.0001$). However, global estimates on Gurin's QOL measure correlated weakly with clinicians ratings (with SPS, $r = -0.15$, $p < 0.28$; with GAF, $r = 0.21-0.28$, $p < 0.03$) (Vorunganti et al., 1998). Vorunganti et al. (1998) concluded that patients and clinicians judgement of QOL concurred more with structured measures than global measures (Vorunganti et al., 1998).

The Vorunganti et al. (1998) study was limited in terms of its sample. The sample was homogeneous in terms of symptom severity, treatment compliance and psychosocial functioning (Vorunganti et al., 1998). This appears to be common problem in schizophrenia research in that the extremely psychotic patients are often non-compliant and not willing to be studied (Schreiber, Breier & Pickar, 1990). Another limitation with the Vorunganti et al (1998) study was that it did not have a control group. Buckley, O'Callaghan, Larkin and Washington (1992) highlighted the difficulty in identifying an appropriate control group in schizophrenia

studies in that it is very difficult to differentiate between the consequences of the condition and the person's pre-morbid characteristics.

Appendix 1.5: Cognitive impairments associated with schizophrenia

Memory impairments

Memory is one of the major impairments that have been associated with schizophrenia. Memory impairments have been demonstrated to be common and disproportionate to the overall level of intellectual impairment (Gold, Randolph, Carpenter, Goldberg & Weinberger, 1992). The specificity of the memory impairment remains unclear; however some aspects of memory may be more affected than others (Aleman, Hijman, De Haan & Kahn, 1999). For example, memory for long-term declarative information has been shown to be significantly more impaired than short-term memory (e.g. digit span exercises) (Koh, Kayton & Peterson, 1980). Heaton et al. (1994) suggested that in people with schizophrenia, it is the encoding of information, rather than recognition and retrieval that is affected. However, other studies that have used multiple memory tasks and assessments have shown that the memory impairments involve many different processes (Landra, Orbeck & Rund 1993; Rund, 1989; Saykin et al., 1991).

Aleman et al. (1999) conducted a meta-analysis of 70 studies that reported measures of long-term memory (free recall, cued recall, and recognition of verbal

and non-verbal material) and short-term memory (digit span). The results indicated that schizophrenia and memory impairments were significantly associated (Aleman et al., 1999). This meta-analysis suggested that the memory impairments were wide ranging across tasks, such as level of retrieval support (free recall, cued recall, or recognition), stimulus type (verbal versus non-verbal), and retention interval (immediate versus delayed) (Aleman et al., 1999). Heinrichs and Zakzanis (1998) meta analysis compared schizophrenia patients and normal subjects on a range of memory assessments. They found moderate to large effect sizes for memory variables that included verbal and non-verbal long-term memory assessments (Heinrichs & Zakzanis, 1998).

Several researchers (Baddeley, Thornton, Chua & McKenna, 1996; Feinstein, Goldberg, Nowlin & Weinberger, 1998; Riutort, Cuervo, Danion, Peretti & Salame, 2003) have suggested that autobiographical memory disturbances contribute to the symptoms of schizophrenia. Autobiographical memory includes personal semantic memory (knowledge of personal facts) and episodic memory (recall of specific events). It is not known whether this is a specific deficit, due to a co-morbid depression or is part of a general long-term memory impairment in people with schizophrenia (Wood, Brewin & McLeod, 2006).

Research into brain pathology has shown that encoding and consolidation difficulties may be associated with hippocampus and temporal lobe dysfunction (Squire, 1992; Hijaman, 1996). Brain imaging techniques have shown reduced

volume or pathology in those areas (Lawrie & Abukmeil, 1998). The frontal lobe systems, which may be affected in schizophrenia, have been shown to be involved in active retrieval of declarative memories (Wheeler, Stuss & Tulving, 1995; Ungerleider, 1995).

Frith (1984) suggested that the memory impairments seen in schizophrenia patients are a consequence of the anticholinergic drugs that they are treated with. He reported that when Hyoscine (an anticholinergic medication) was intravenously administered, it impaired retention of word lists and delayed testing (Frith, 1984). He found that the ability to learn new material was impaired, but material acquired before drug administration was not affected (Frith, 1984). Frith (1984) also reported that Benzodiazepines (e.g. Diazepam, Nitrazepam) affect memory in a similar way to the anticholinergic medications. Sydulko et al. (1981) found that 10 weeks of treatment with Benztropine Mesylate (CogentinTM), four times a day significantly impaired word-list acquisition in comparison to placebo patients. Tune, Strauss, Lew, Breitlinger and Coyle (1982) compared schizophrenia patients receiving a typical regime of neuroleptics plus anticholinergics. They found a significant inverse correlation between word-list recall and serum levels of anticholinergic drug: high levels of serum were associated with poor performance (Tune et al., 1982).

Aleman et al. (1999) meta-analysis compared the memory performance of unmedicated with medicated groups. They found that medication status was not

associated with memory impairment, however, these analyses only considered conventional neuroleptics. Further support for neuroleptic medication not impairing the cognitive performance of people with schizophrenia has been provided (Goldberg & Weinberger, 1996; Mortimer, 1997; Riley et al., 2000). Some of the atypical antipsychotics (e.g. Risperidone and Clozapine) have shown beneficial effects on memory (Green et al., 1997; Keefe, Silva, Perkins & Lieberman, 1999).

Executive functioning impairments

Most studies of people with schizophrenia have shown impaired ability on executive functioning tasks when compared with normal healthy controls (Blanchard & Neal, 1994; Kinney, Yurgelm-Todd, Waternaux & Mattysee, 1994). Blanchard and Neale (1994) found that compared with the normal healthy controls, patients with schizophrenia were significantly impaired ($t=2.87$, $df\ 41$, $p<0.01$) on executive functioning assessments that included the Wisconsin Card Sorting Test (WCST) (Heaton, 1981) and the Controlled Word Association Test (Benton & Hamsher, 1976). Kinney et al. (1994) found significant impairments in their schizophrenic sample on the Trail Making Test (Reitan & Wolfson, 1985) when compared to normal controls. The Trail Making Test (Reitan & Wolfson, 1985) purports to assess alternate mental sets and attention, a higher cortical function associated with frontal lobe activity (Kinney et al., 1994).

Johnson-Selfridge and Zalewski (2001) conducted a meta-analysis and found that on a range of executive functioning tests, people with schizophrenia performed one and a half standard deviations below normal control participants. They also found that schizophrenic groups performed about 0.40 standard deviations lower than other psychiatric groups on executive functioning measures, a moderately large effect size (Johnson-Selfridge & Zalewski, 2001). Johnson-Selfridge and Zalewski (2001) found that the magnitude of the impairment depended on the measure used (i.e. the variation in the measures psychometric properties and multifactorial constructs). On the executive functioning measures, duration of illness was not related to effect size, but number of hospitalisations was. Johnson-Selfridge & Zalewski (2001) suggested that this relationship may be due to the people that require more hospitalisations having more severe symptomatology and impaired functioning. A limitation of this meta-analysis was that the impact of anticholinergic medication on executive functioning could not be assessed (Johnson-Selfridge & Zalewski, 2001). This was due to the numbers of people and dosages given, rarely being reported in the literature.

Heinrichs and Zakzanis (1998) found similar effect sizes (when compared to normal control participants) on their measures of executive functioning assessments. Heinrichs and Zakzanis (1998) reported effect sizes of 0.95 and 0.88 (absolute effect size and corrected for sample size, respectively) based on the WCST (Heaton, 1981) variables, as well as corrected effect sizes based on the

Trail Making Test - B (Reitan & Wolfson, 1985) (0.80), the Stroop Test (Golden, 1978) (1.11), and the Chicago Word Fluency Test (Milner, 1964) (1.15).

Appendix 1.6: QOL measures reviewed by Wong et al. (2005)

Wong et al. (2005) reviewed three of the 'most commonly used' health-related QOL measures in order to develop the CapQOL: Short Form 36 Item Health Survey (SF-36) (Ware, Kosinsky & Dewey, 2000); Quality of Well-Being Scale – Self Administered (QWB-SA) (Kaplan, Sieber & Ganiats, 1997); EORTC Quality of Life Questionnaire C-30 (EORTC QLQ C-30) (Aaronson, Ahmedzai, Bergman & Bullinger, 1993).

SF-36 (Ware et al., 2000)

The SF-36 (Ware et al., 2000) is a multi purpose short-form health survey that has 36 items. It produces an 8-scale profile of functional health and well-being scores, physical and mental health summary measures and a preference based health utility index (Ware et al. 2000). The SF-36 is a generic measure, that does not target a specific condition and has been used in general and specific populations. It has been used to compare the relative 'burden' of diseases and/or disorders (Ware et al. 2000).

The SF-36 can be administered in 5-10 minutes with a high degree of acceptability and data quality (Ware, Snow, Kosinsky & Gandek, 1993). Alternative long-form measures are reported to take 5-10 times longer to complete due to the number of questionnaire items that must be administered (Ware et al. 2000). Empirical studies have suggested that the SF-36 provides a practical alternative to longer measures, and that the 8 scale profile and summary scales rarely fail to identify differences in physical and/or mental health status (Ware et al., 1993; Ware, Kosinsky & Keller, 1994; Katz, Larson, Phillips, Fossel, & Liang, 1992).

QWB-SA (Kaplan et al., 1997)

The QWB-SA (Kaplan et al., 1997) is another generic measure of health status. It includes five parts that assess acute and chronic symptoms, self-care, mobility, physical functioning and performance of usual activity. The output is a quality-adjusted index score between 0.0 (death) and 1.0 (perfect health). The QWB-SA includes 58 symptoms whereby respondents answer 'yes' or 'no' if they have had each of the chronic, acute and mental health symptoms over the previous three days. The QWB-SA is reported to take approximately 10 minutes to complete (Kaplan, Ganiats, Sieber & Anderson, 1998) and has demonstrated stable test-retest reliability in 'relatively healthy adults' (Kaplan et al., 1997).

EORTC QLQ C-30 (Aaronson et al., 1993)

The EORTC QLQ-C30 is a cancer-specific, self administered questionnaire for use in clinical trials. It contains 30 questions: 9 are multi-item scales representing aspects of health related QOL: 5 represent functional scales (physical, role, emotional, cognitive and social), 3 are symptom scales (fatigue, pain and nausea) 6 are mono-item scales describing relevant cancer-orientated symptoms (dyspnae, insomnia, appetite, constipation, diarrhoea, financial difficulties) and one item forms a global scale (Sneeuw et al., 1998). Apolone, Filberti, Cifani, Ruggiata and Mosconi (1998) evaluated the EORTC QLQ-C30 and found 'substantial correlations' with scales from the SF-36. They reported that the EORTC QLQ-C30 met all the standards for convergent and discriminant validity and had 'very high' internal consistency (as measured by Cronbach's alpha) (Apolone et al. 1998).

Appendix 1.7: The development and structure of the CapQOL

Wong et al. (2005) identified five key areas important in completing subjective QOL measures. The areas were identified by a review of the 'most commonly used' health-related QOL measures (to understand the process of completing items on the measures) and subjective QOL measures, and discussion and 'brainstorming' sessions with professionals who were experienced in QOL, mental capacity research and administration. The five areas that were identified as important in

addressing whether an individual can complete a self-rated subjective measure are detailed below along with a description of how the CapQOL assesses those areas:

Acquiescence

In self-reporting measures, acquiescence is a response bias whereby an individual tends to agree with items, despite their content (Rust & Golombok, 1999). The CapQOL assesses if an individual is acquiescent by asking questions about two situations that are mutually exclusive ('Do you live alone now?' and 'Do you live with other people now?'). If the individual answers 'yes' to both questions, they are judged to be 'acquiescent' (Wong et al., 2005).

Consistency

This area evaluates whether an individual gives consistent answers to any QOL measure and is used to assess the validity of responses. The CapQOL uses two open-ended questions to assess if an individual gives inconsistent responses. Close-ended questions were not included because it was thought that they might elicit consistent, but acquiescent responses (Wong et al., 2005). The open-ended questions are concerned with an individual's favourite singer and the amount of television they watch each day. The same question is presented again at the end of the CapQOL and if the individual gives a different answer, they are identified as inconsistent responders (Wong et al., 2005).

Understanding of the 5-point scale

Many QOL measures use a 5-point likert scale, therefore an individual needs to understand how it works (Wong et al. 2005). The CapQOL asks respondents to rate two scenarios on a 5-point scale that ranges from 'very unhappy' to 'very happy'. The two scenarios differ in that one is favourable (being given their favourite food), whilst the other scenario is relatively neutral (watching the weather report). The different scenarios attempt to 'prime' an individual toward expressing positive and neutral feelings respectively. The neutral scenario assesses recency and primacy biases, whereby an individual chooses either the first or last option (Perry & Felce, 2002). The two scenarios assess if an individual can imagine and appraise different feelings on a 5-point scale. If they do not respond to the favourable scenario with a positive response, or the neutral scenario with a neutral response, without a good reason, they are regarded as not having an understanding of a 5-point scale (Wong et al., 2005).

Understanding of and values attached to each domain

Wong et al. (2005) argued that a respondent needs to be able to understand what a domain is and what is considered desirable within a domain if they are to complete a subjective QOL measure validly. The CapQOL uses two domains that are often used in subjective QOL measures: economic status and relationship to

others. According to their own standards, respondents are asked what would be the best and worst situations they could imagine within each domain. Those respondents that give vague or irrational/delusional answers are considered to have impaired understanding of QOL domains (Wong et al., 2005).

Awareness of own situation and comparison with standard/desirable

Wong et al. (2005) argued that a respondent needs to be able to appraise their own situation and evaluate it within the context of the continuum between their 'worst imaginable state' to the 'best imaginable state'. After the respondent has described their 'best' and 'worse' extremes on the economic status and relationship with others domains, they are shown a 9-point scale on a continuum from 'worst imaginable' to 'best imaginable' situation. The respondent is asked to select which number represents their situation within the domains and then to explain their choice. This gives the assessor the opportunity to understand the reason behind the respondent's judgement, their awareness of their own situation and ability to compare their current situation with their subjective 'best' and 'worst' extremes (Wong et al. 2005). Those respondents that answer with vague or irrational/delusional thinking are considered to lack the ability to compare their current situation with their subjective best and worst situations.

In addition to assessing the five areas, the CapQOL includes a final 'global score'. This uses a 5-point scale and is scored by the assessor on their impression of the

respondents' ability to complete the CapQOL, based on how they performed on the previous five areas. A score of 4 or 5 would indicate that they believe the respondent has the capacity to give valid and reliable answers on a QOL measure. A score of 1 or 2 would indicate that they believe the respondent lacks the capacity to give valid and reliable answers on a QOL measure. A score of 3 would indicate borderline ability.

Appendix 1.8: The capacity to report subjective quality of life inventory
(CapQOL) (Wong et al. (2005))

Capacity to Report Subjective Quality of Life Inventory
(CapQOL)

1. Do you live on your own now?	<input type="text"/>
---------------------------------	----------------------

2. Who is your favorite singer?	<input type="text"/>
3. How much TV do you watch each day?	<input type="text"/>

4. What is your favorite food?	<input type="text"/>			
If I give you _____ (<i>fill in the favorite food</i>) now, please describe how you feel by choosing one of the five boxes below.				
very unhappy	unhappy	neither unhappy nor happy	happy	very happy
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If you switch on the TV and the weather report is on, how would you feel? Please describe how you feel by choosing one of the five boxes below.				
very unhappy	unhappy	neither unhappy nor happy	happy	very happy
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Output

0 1 2

For the question on favorite food (supposed to induce positive feelings), the expected range of output is: (neither happy nor unhappy, happy, very happy)

For the question on weather report (a supposedly neutral event), the expected range of output is: (unhappy, neither happy nor unhappy, happy)

- 0 Answers beyond the expected range are given to both questions, without a reasonable explanation (Example of a reasonable explanation: 'very unhappy' about the weather report because there are thunder storms and an outing has to be cancelled.)
- 1 An answer beyond the expected range is given to one question only; the answer given to another question is within the expected range.
- 2 Answers within the expected range are given to both questions.

6. Do you live with other people now?

Acquiescence (Refer to Q1)

0 1

- 0 Identical answers are given to the two mutually exclusive questions.
- 1 Different answers are given to the two mutually exclusive questions.

7. People have different standards and views about one's economic status. According to your own standard, what would be the best economic status you can think of? What would be the worst economic status you can think of?

the worst:

the best:

Understanding of Domain: Economic Status

0 1 2

- 0 No subjective description of the best and worst expectations of the domain given; or the patient can describe own expectations of the domain, but which seem to be based on delusional beliefs or psychotic experiences.
- 1 Patient seems ambivalent, gives only vague descriptions of own expectations of the domain; or answers given cannot allow the examiner to determine whether they represent delusional beliefs or psychotic experiences.
- 2 Patient gives clear descriptions of own expectations of the domain, which are not based on any delusional belief or psychotic experience.

12. Could you tell me once again how much TV you watch each day?

Consistency (Refer to Q2, Q3)

0 1

- 0 Inconsistent answers are given to the two sets of questions.
- 1 Consistent answers are given to the two sets of questions.

Global Score 1 2 3 4 5

- 1 Patient seems to be unable to understand any QoL domain. Despite the provision of maximum assistance and guidance from the examiner, no description or explanation of each QoL domain can be given; or it is clearly based on delusional beliefs or psychotic experiences. Any answer given by the patient when administering the QoL assessment tools is expected to be highly invalid and unreliable.
- 2 Patient shows only a limited understanding towards the QoL domains. Although the patient can give some descriptions and explanations of each domain, they do not allow the examiner to determine whether the patient's reasoning process represents delusional beliefs or psychotic experiences. Patient's ability and capacity to complete the QoL assessment tools would be questioned.
- 3 Patient only has a fair understanding of the QoL domains. Despite the examiner's effort to provide appropriate assistance and guidance, only vague descriptions and explanations concerning each domain can be given. Patient may not have the ability and capacity to be administered the QoL assessment tools.
- 4 Patient shows a good understanding of the QoL domains. Reasons and explanations are given only with some assistance and guidance from the examiner. The patient would still be able and capable to complete the QoL assessment tools.
- 5 Patient understands and describes all QoL domains very well. No unclear description or explanation is given. Minimum assistance or guidance is required from the examiner. The patient clearly has the ability and capacity to successfully complete the QoL assessment tools.

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Appendix 1.9: Negative symptoms in schizophrenia (and their associated problems)

The associations between negative symptoms and cognitive impairments in schizophrenia are widely reported in the research literature (e.g. Buchanen et al., 1994; Liddle, 1987; Liddle & Morris, 1991; Perlick, Mattis, Stasny & Silverstein, 1992). Negative symptoms have been linked with deficits involving intelligence,

executive function and memory (Berman, et al., 1997; Cuesta & Peralta, 1995; Himelhoch, Taylor, Goldman & Tandon, 1996). Positive symptoms have not been associated with cognitive impairments (Basso, Nasrallah, Olson & Bornstein, 1998).

There are inconsistencies in the research literature with some studies suggesting that executive function deficits are not related to negative symptomatology (Basso et al., 1998; Van der Does, Dingemans, Linszen, Nugter & Scholte, 1993). These inconsistencies in the research have been attributed to differences between patient samples and the differing types of neuropsychological assessments used across studies (Basso, Bornstein & Lang, 1999). Lezak (1995) suggested that different measures of executive function have differential sensitivity in detecting impairments across a variety of brain regions.

Studies of brain pathology have found that negative symptoms are related primarily to fronto-temporal abnormalities (Schroeder, Buchsbaum, Siegel, Geider & Niethammer, 1995), suggesting that negative symptoms may be related to higher-cognitive functioning deficits such as attention, intellect and concept formation (Basso et al., 1999). Basso et al. (1999) studied correlations of positive and negative symptomatology across a range of neuropsychological tests and found that increasing severity of negative symptoms were related to decreased performance across a broad range of neuropsychological functioning (Basso et al., 1999). Negative symptoms tended to achieve moderate to large correlations with

neuropsychological function and were related to intelligence, conceptual reasoning, attention span, sustained attention, memory and sensory motor function (Basso et al., 1999).

The Basso et al. (1999) study contradicted previous research that negative symptoms are associated primarily with executive dysfunction (Berman et al., 1997). Basso et al. (1999) concluded that because their findings indicated that negative symptoms were associated with poor performance on most measures of higher cognitive function, negative symptoms were associated with wide spread cerebral dysfunction rather than being restricted to the left hemisphere (Basso et al., 1999).

It has been suggested that with negative symptoms being associated with frontal lobe dysfunction, this may account for retrieval deficits (Liddle & Morris, 1991). In the Aleman et al. (1999) meta-analysis, the only potential moderator variable that they found for a schizophrenia-memory association was negative symptoms. They found a small effect size, however this finding is consistent with previous research that had examined the relationships between negative symptoms and cognitive function in schizophrenia (Basso et al., 1999; Liddle, 1987; Liddle & Morris, 1991).

Appendix 2.1: Description and justification of the measures that were used

National Adult Reading Test 2nd Edition (NART) (Nelson & Willison, 1992)

Nelson et al. (1990) concluded that word reading ability is unaffected in chronic schizophrenia. The most commonly used word reading test to predict pre-morbid IQ levels in people with schizophrenia is the NART (Russell et al., 2000). The validity of the NART as an estimate of premorbid IQ was assessed in 62 patients (35 long-stay hospitalised, 29 community-based) who were administered both the NART and WAIS-R (Crawford et al., 1992). They found a significant discrepancy between scores on the NART and WAIS-R, with the NART estimating IQ higher than the WAIS-R. Crawford et al. (1992) concluded that a decline had occurred in the patients that were assessed and recommended that the NART was therefore a valid and useful assessment of pre-morbid IQ (Crawford et al., 1992).

O'Carroll, Mofoot, Ebmeir and Goodwin (1992) replicated Crawford et al. (1992) finding in that NART scores were higher than WAIS-R in their schizophrenia sample. They also compared NART performance between acutely ill unmedicated schizophrenics and non-schizophrenic psychotics with controls (with similar demographics thought to affect NART performance) (O'Carroll et al., 1992). No significant differences were found between the three groups. O'Carroll et al. (1992)

concluded that the pronunciation of irregular words is unaffected in the acute phases of psychosis.

Smith, Roberts, Brewer and Pantelis (1998) examined the test-retest reliability of the NART in a schizophrenia sample over a six-month period. Their sample was assessed on the NART at baseline, six weeks and six months. No significant differences between the scores were found (Smith et al., 1998). Smith et al. (1998) concluded that NART-estimated premorbid IQ scores were stable over time.

Russell et al. (2000) selected a sample of adults with schizophrenia who had their IQ assessed as children using the Weschler Intelligence Scale for Children (WISC) (Weschler, 1949) or the Revised Version (WISC-R) (Weschler, 1974). They found no significant differences between their childhood (WISC or WISC-R) and adult (WAIS-R) estimates of IQ, but they did find a significant difference between those indices and NART estimates of IQ, especially when participants IQ deviated from general population means (Russell et al., 2000). Russell et al. (2000) suggested that NART estimates should be interpreted with caution when IQ scores do not fall in the 'average' category and that ideally, more than one measure of premorbid functioning should be used.

Adult Memory Information Processing Battery (AMIPB): Story Recall (Coughlan & Hollows, 1985)

The AMIPB is particularly popular in schizophrenia rehabilitation settings due to each test having parallel forms. This minimises practice effects if repeated testing is required (Allen, Brechin, Skilbeck & Fox, 2007). The Story Recall test is designed to assess immediate registration of verbal information and retention over time (Coughlan & Hollows, 1985). The test involves the person being read a short story, then being asked to recall it immediately and 25-35 minutes later. This procedure was derived from the Logical Memory passages of the Weschler Memory Scales (WMS) to assess immediate and delayed recall after one hour (Coughlan & Hollows, 1985). Coughlan and Hollows (1985) reduced the delay recall period of the AMIPB in order to ease administration.

Wood et al. (2006) used the AMIPB to assess memory impairments in their schizophrenia sample. They assessed the difference in immediate and delayed memory when comparing people diagnosed with schizophrenia and matched normal controls. They found that the two groups differed significantly on both the immediate and delayed recall tasks with the schizophrenia group performing worse (Wood et al., 2006).

The Story Recall Test appears to have face validity and is a procedure commonly used in clinical psychology (Lezak, 1995). Coughlan and Hollows (1985) suggested

that the Story Recall Test has a clinical rather than theoretical orientation, and assesses broad aspects of memory (e.g. retention and learning), not specific memory system components. Despite the verbal presentation of the test, it does not necessarily mean that it is reflective of verbal memory systems (Coughlan & Hollows, 1985).

The inter-test correlations within the AMIPB are mostly highly significant ($p < 0.001$), but small (Coughlan & Hollows, 1985). This small correlation may be due to the different tests focusing on differing aspects of memory skills (Coughlan & Hollows, 1985). The sensitivity of the Story Recall Test has been assessed when comparing neurological patients with generalised cerebral dysfunction, with normal healthy controls. At the 10th and two standard deviation cut-off, the incidence of neurological patients' poor performance was significantly higher than normal healthy controls (Coughlan & Hollows, 1985).

Hayling & Brixton (H&B) Tests (Burgess & Shallice, 1997)

The H&B Tests are an example of the newer type of executive functioning assessments that are designed to predict social and functional ability (ecological validity) and are less focused on discriminative ability for diagnosis (Wood & Liossi, 2006). The H&B Tests involve procedures that are sensitive to executive functioning, thought to be impaired after damage to the frontal lobes (Wood & Liossi, 2006). The Hayling Test measures initiation speed and response

suppression, while the Brixton Test measures rule detection (Wood & Lioffi, 2006).

The Dysexecutive Questionnaire (DEX), a supplementary measure of the Behavioural Assessment of Dysexecutive Syndrome (BADS) (Wilson, 1996), is considered to be an ecologically valid measure of dysexecutive symptoms (Wood & Lioffi, 2006). Bajo and Nathaniel-Jones (2001 as cited in Wood & Lioffi, 2006) found that Hayling part 1 (initiation) correlated weakly (.21-.28) with all three DEX factors (response suppression, intentionality, and executive memory) and that the Brixton Test correlated significantly with the executive memory factor (.40). Hayling part 2 (response suppression) did not correlate with scores on any of the three DEX factors (Wood & Lioffi, 2006).

Stokes and Bajo (2003) evaluated the associations between the H&B, BADS and DEX. They found that when IQ was not partialled out, the H&B Tests did not correlate with any factors on the DEX (Stokes & Bajo, 2003). However, when WAIS-III (Wechsler, 1999) correlations were partialled out, the BADS did not correlate with the DEX, however, a number of parts of the H&B Tests parts correlated with DEX measures. Stokes and Bajo (2003) concluded that the H&B Tests showed a greater specificity than the BADS in the measurement of executive functioning when IQ was partialled out. Marczewski, Van der Linden & Laroi (2001) demonstrated moderate bivariate correlations between the Hayling Test and other measures of executive functioning.

There is evidence that areas other than the frontal lobes contribute to performance on the Hayling Test (Andres & Van der Linden, 2000; Collete et al., 2001). Functional imaging has demonstrated a left hemisphere bias for the Hayling Test; the cortical areas for verbal initiation and suppression have shown higher activation in the left frontal areas (Collete et al., 2001).

Marczewski et al. (2001) demonstrated moderately strong bivariate correlations between the Brixton Test and the Tower of London Tests in their schizophrenia sample. Patients with anterior lesions have produced more errors on the Brixton Test than posterior lesions and controls (Burgess & Shallice, 1997). De Frias, Dixon and Strauss (2006) argued that evidence for construct validity was found when they discovered that the Brixton Test loaded with other executive functioning tasks on the same factor.

Reverberi, Lavaronni, Gigli, Skrap and Tim (2005) demonstrated that the Brixton Test is more sensitive to left than right hemisphere damage. Their patient sample with left frontal lesions were significantly impaired on the Brixton Test, but right lateral lesion patients made the same number of errors as controls (although they made three times more 'capture errors', a sign of impaired monitoring processes) (Reverberi et al., 2005). These findings indicate that performance on the Brixton Test may differentiate between processes mediated by the left lateral frontal cortex

(inductive reasoning, monitoring, and working memory), and processes for the right lateral cortex (monitoring and checking) (Reverberi et al., 2005).

Chayton and Schmitter-Edgecombe (2003) have argued that the ecological validity of executive functioning tests varies according to the seriousness of the neurological problem and the clinical population. IQ appears to contribute strongly to performance on executive functioning tests. This is supported by significant correlations between tests of executive functioning (i.e. Hayling Test, Zoo Map, Key Search) and WAIS-III (Wood & Lioffi, 2006). Rabbit (1997) suggested that executive functioning may represent a cluster of components that have not been successfully linked together and have no obvious hierarchy. It also seems likely that existing tests involve several executive and non-executive processes. Wood and Lioffi (2006) suggested that it may be impossible to develop a pure test of executive functioning, because executive function involves the coordination of several cognitive domains at the same time.

Positive and Negative Syndrome Scale (PANNS) (Kay, Fiszbein & Opler, 2000)

The Positive and Negative Scales of the PANNS are reported to be internally consistent and highly reliable when assessed by test-retest, split-half and coefficient alpha (Kay et al., 2000). PANNS ratings have been shown to be highly correlated with the Andreasen method for evaluating positive ($r = .77$) and negative ($r = .77$) symptoms (Kay, Fiszbein & Lindenmayer, 1988). The inter-rater reliability

of the PANNS has been reported in the range of .83 to .87 (Kay et al., 2000). Kay and Singh (1989) demonstrated test-retest correlations of $r=.37$ (positive scale) and $r=.43$ (negative scale) in their 'subacute' schizophrenia sample after a 3-4 month delay. Kay et al., (1987) demonstrated test retest coefficients of $r=0.8$ (positive scale) and $r=0.68$ (negative scale) over 3-6 months in their chronic schizophrenia sample.

The PANNS manual presents a five factor, 'pentagonal' model of schizophrenia. The five factors are: Positive, Negative, Dysphoric Mood, Activation, and Autistic Preoccupation (Kay et al., 2000). External validity of the PANNS and the five factor-model have been assessed by correlations with socio-demographic variables, DSM-IV (subtype) diagnoses, clinical characteristics and drug use (Van der Oord et al., 2006). Van der Oord et al. (2006) demonstrated significant correlations with the five PANNS scales, suggesting that they measure meaningful aspects of schizophrenia. These correlations varied, suggesting that the scales assessed differing aspects of the schizophrenia condition (Van der Oord et al., 2006). Internal consistency on the scales, apart from the Dysphoric Mood scale, were reported to be 'satisfactory' using Cronbach's Alpha and in the range of 0.70 to 0.85 (Van der Oord et al., 2006).

Appendix 2.2: NHS Ethics and Research and Design committees' approval letters

Nottingham Research Ethics Committee 1
Standard Court
Park Row
Nottingham
NG16GN

Telephone: 01159123344 Facsimile: 01159123300 22 September 2006

Mr N McGrath
Trainee Clinical Psychologist
Lincolnshire Partnership (NHS) Trust
Mid-Trent Doctorate in Clinical Psychology, University of Lincoln
Brayford Pool
Lincoln, LN6 7TS

Dear Mr McGrath,

Full title of study: The use of the CapQOL (capacity to report subjective quality of life inventory) with an inpatient population of people with Severe and Enduring Mental Illness (SEMI).
REC reference number: 06/Q2403/127

Thank you for your letter of 10 September responding to the committee's request for information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice Chair.

Conformation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the bases described in the application form, protocol and supporting documentation as revised.

Conditions of approval

The favourable opinion is given provided that you comply with the condition set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	1	16 July 2006
Investigator CV		16 July 2006
Investigator CV	1	01 January 2006
Protocol	3	16 July 2006
Letter from sponsor		06 September 2006
Peer review		
Questionnaire: CapQOL		
Questionnaire: NART		
Questionnaire: Hayling and Brixton Tests		
Questionnaire: AMIPB		
Questionnaire: SCI-PANSS		
Participant Information Sheet	4	10 September 2006
Participant Consent Form	4	10 September 2006
Response to Request for Further Information		10 September 2006
Supervisors Signature Page		07 August 2006

Research governance approval

You should arrange for R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q2403/127

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



Dr K Pointon / Ms L Ellis
Chair / Co-ordinator

Email:linda.ellis@rushcliffe-pct.nhs.uk

Enclosures: Standard approval conditions

Copy to:

Judith Tompkins
University of Lincoln
Mid-Trent Doctorate in Clinical Psychology, University of Lincoln
Health, Life and Social Science
Brayford Pool, Lincoln

R&D Department for NHS care organisation at lead site - -LPT

Your ref:
NM/AL/18.10.05
Our ref:

Research and Effectiveness Unit
Lincolnshire Partnership NHS Trust
Faculty of Health, Life and Social Sciences
University of Lincoln
Brayford Pool
Lincoln
LN6 7TS

Date: 18th October 2006

Mr Noel McGrath
Trainee Clinical
Psychologist
Lincolnshire Partnership
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Lincoln
LN6 7TS

Tel: 01522 837030

Email: Gill.Thompson@lpt.nhs.uk

Dear Noel

Re: **Project Reference: 06/Q2403/127**
Title of Study: **The use of the CapQOL (capacity to report subjective quality of life inventory) with an inpatient population of people with Severe and Enduring Mental Illness (SEMI).**

Trust approval has now been granted for the above study. In addition to your ethics approval we are pleased to notify you that you may now commence your research. Please retain this letter to verify that you have Trust approval to proceed.

We may contact you from time to time to monitor progress with your work. If the research is terminated or you complete this work, please let the research and effectiveness office know so they can amend their records.

Do contact us if you require any further advice. We wish you every success with your work.

Yours sincerely



Gill Thompson
Research and Audit Assistant

Appendix 2.3: Rational for re-administration interval and sample size

Re-Administration interval

A 1-2 week interval was chosen for re-administration of the CapQOL. This is consistent with the spacing of evaluations in clinical practice and research (Vorunganti et al., 1998). Over a 1 week period, Vorunganti et al. (1998) found a correlation co-efficient of 0.86 in their stabilised schizophrenia sample. Vorunganti et al. (1998) argued that stabilised schizophrenic patients were therefore as reliable as patients from general practice studies (e.g. Bergener et al., 1981).

Sample size

The required number of participants was estimated at 28, using a power calculation and through consulting the literature. With an effect size (Pearson's R) of 0.5 (large), an alpha of 0.05 and a power of 0.8, Barker, Pistrang and Elliott (2002) suggested a sample size of 28 would be needed. The literature suggested that 1 in 10 young, first episode psychosis patients lacked the capacity to appraise their subjective QOL according to the CapQOL (Wong et al., 2005). Due to the expected greater cognitive impairments present in this study's population, it was predicted that there would be a much higher percentage of participants assessed as lacking capacity on the CapQOL (e.g. 30-40%). Therefore a sample size of 28 would

produce enough participants that had and had not the capacity as assessed by the CapQOL.

Appendix 3.1: Data Screening

The histograms presented in figures 2 and 3 indicate that the data was not normally distributed. However, the data was obtained from a clinical sample and the scale is only designed to detect impaired ability so you might expect the data to not be normally distributed.

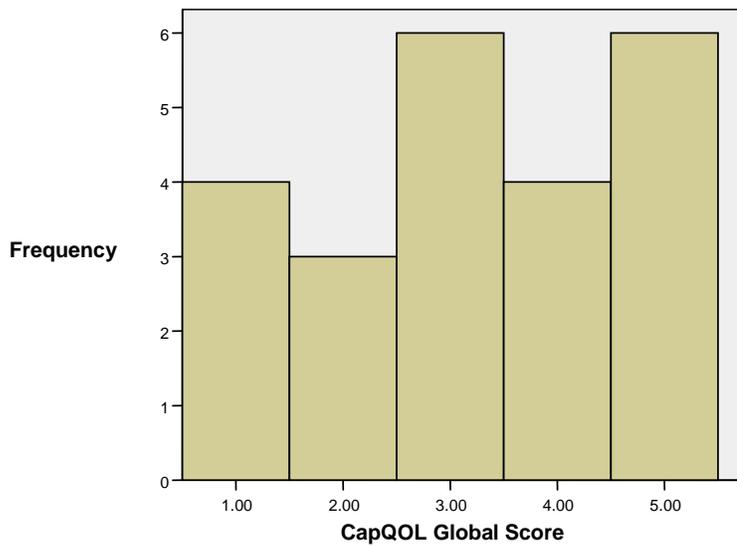


Figure 2. Histogram of CapQOL global scores at time 1

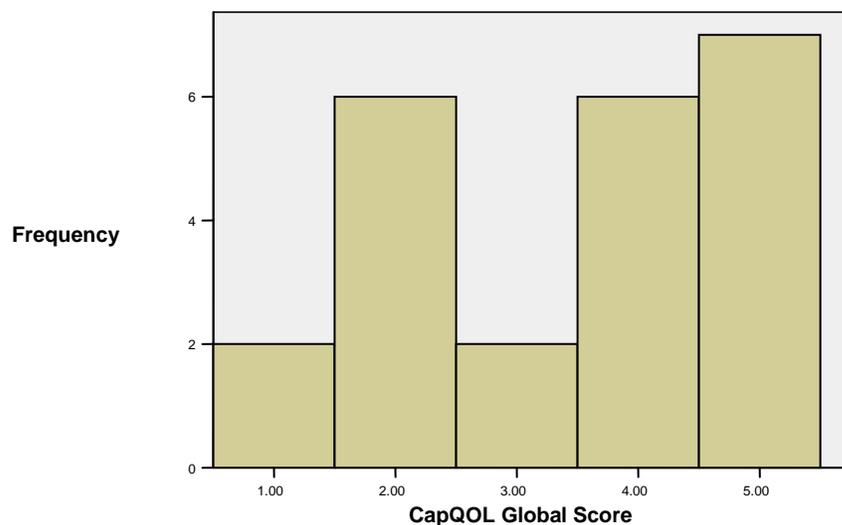


Figure 3. Histogram of CapQOL global scores at time 2

The Shapiro Wilk test (presented in table 2) was significant indicating again that the data was significantly different from a normal distribution at time 1 and time 2.

Table 2. Shapiro Wilk Tests of Normality

	Shapiro-Wilk		
	Statistic	df	Sig.
Global Scores: Time 1.	.886	23	.013
Global Scores: Time 2.	.858	23	.004

The descriptive statistics of the CapQOL global scores at time 1 and time 2 are presented in table 3. The Zskew's were within the range -1.96 - 1.96 (Time 1 = 0.45, Time 2 = 0.70). This test indicated that data transformation was not required.

Table 3. Descriptive statistics for the CapQOL global scores (at time 1 and time 2)

Statistic	Time 1	Time 2
Median	3	4
Variance	2.087	1.984
Range	1 – 5	1 – 5
Interquartile range	3	3
Skewness	-.218 (s.e. = .481)	-.335 (s.e. = .481)

Due to the small sample size (n = 23) and the histograms and Shapiro Wilk Tests indicating that the data was not normally distributed, non-parametric correlations (Spearman's rho) were used.

Appendix 3.2: Bland and Altman (1995) method

Bland and Altman (1995) have argued that the correlation coefficient is an inappropriate method to analyze the repeatability of a single measurement tool.

They suggested an alternative approach based on graphical representations (in the form of scatter plots) and simple calculations (Bland & Altman, 1995). The Bland and Altman (1995) plot for the CapQOL domain scores at time 1 and 2 is presented in figure 4. The plot indicates 'good' repeatability of the CapQOL at time 1 and 2, with only one of the scores (participant no. 12) falling outside the 95% confidence interval range.

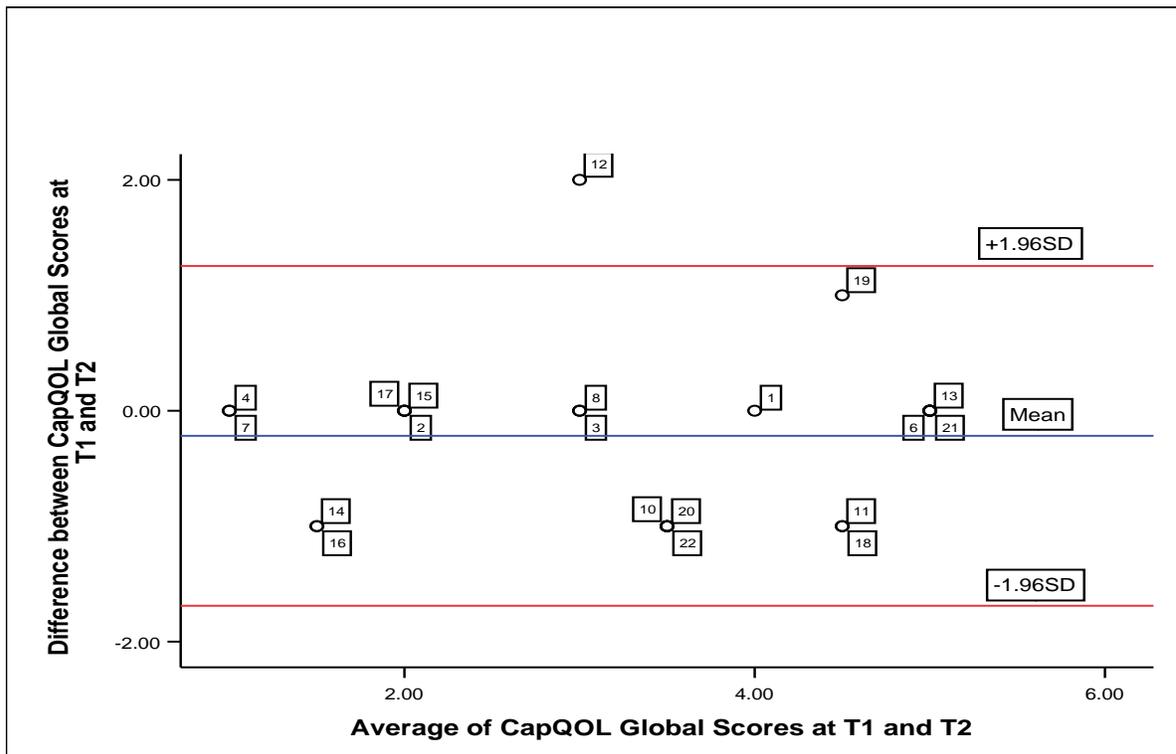


Figure 4. Difference against average global scores on the CapQOL at time 1 and 2, with 95% limits of agreement (red lines)

Appendix 3.3: χ^2 analysis of order of presentation

There was a non-significant effect for order of presentation of the assessments and impaired/unimpaired scores on the CapQOL ($\chi^2 (1) = .381, p = .537$). All of the expected frequencies were above 5. The count and expected count frequencies are presented in table 4.

Table 4. Frequency and expected count of order of presentation and impairment on the CapQOL

		Order 1	Order 2
Impaired	Count	5	6
	Expected Count	5.7	5.3
Unimpaired	Count	7	5
	Expected Count	6.3	5.7

Appendix 3.4: Analysis of domain/item statistics

The internal consistency of the CapQOL as measured by Cronbach's alpha (.850) is in the 'good' range (values around .8) (Field, 2000). The domain/item analysis if an item were deleted (see table 5) indicated that there would only be marginal improvements in the reliability of the CapQOL if three domains/items were deleted (acquiescence, consistency and understanding of the 5 point scale). Domain/item deletion would therefore not substantially improve the reliability of an already internally consistent questionnaire.

Table 5. Cronbach's alpha scores if a domain/item were deleted

Domain/Item	Cronbach's Alpha if Item Deleted
Global Score	.777
* Acquiescence	.862
* Consistency	.855
* Understanding of 5-point scale	.856
Understanding of domain: economic status	.834
Understanding of domain: relationship with others	.798
Awareness of economic status	.810
Awareness of relationship with others	.823

Appendix 3.5: Alternative analysis of the acquiescence and consistency domains using the χ^2 statistic

As opposed to the other domains, the acquiescence and consistency domains are not scored on a continuum and are scored as 'fail' (0) or 'pass' (1). Therefore the associations between the global domain scores and acquiescence and consistency domains should be analyzed using the χ^2 statistic. The research paper reports Spearman's Correlation Statistics so that the data can be compared to the original Wong et al. (2005) study (that used Pearson's Correlations), however, χ^2 statistics for the acquiescence and consistency domains should have been used.

Due to the small sample size, one of the assumptions of the χ^2 Test (that the expected frequencies are greater than 5) (Field, 2000) was not met. A non-significant effect for the association between global scores and acquiescence (χ^2 (4) = 3.407, p = .587) and consistency (χ^2 (4) = 7.339, p = .129) was computed.

This non-significant effect may be accounted for by the 'loss of statistical power' resulting from all of the expected frequencies being lower than 5 (Field, 2000).

Appendix 3.6: Principal component analysis data screening

Wong et al. (2005) conducted principle component analysis with varimax rotation on their domain scores in order to identify factor structures of the domain scores. Screening of the data from this study highlighted that this type of analysis was not appropriate. The variable to participant ratio for this study was 1 : 3.3. Kass and Tinsley (1979 as cited in Field, 2000) recommend having between 5 and 10 participants per variable. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was calculated at .598. This indicated that the data was only just above the 'bare minimum' (.5) and in the 'mediocre' range' for sampling adequacy (Kaiser, 1974 as cited in Field, 2000). Finally, the correlation matrix indicated that many of the domains did not correlate significantly with each other (see table 6).

Table 6. Correlation matrix of domain (D) scores

		D1	D2	D3	D4	D5	D6	D7
Spearman Correlation	D1	1.000	.036	-.055	.183	.132	.162	.323
	D2	.036	1.000	-.240	.133	.500	.436	.324
	D3	-.055	-.240	1.000	.237	.141	.429	.343
	D4	.183	.133	.237	1.000	.550	.250	.575
	D5	.132	.500	.141	.550	1.000	.459	.733
	D6	.162	.436	.429	.250	.459	1.000	.563
	D7	.323	.324	.343	.575	.733	.563	1.000
Sig. (1-tailed)	D1		.435	.401	.202	.273	.230	.066
	D2	.435		.135	.273	.008	.019	.066
	D3	.401	.135		.138	.260	.021	.054
	D4	.202	.273	.138		.003	.125	.002
	D5	.273	.008	.260	.003		.014	.000
	D6	.230	.019	.021	.125	.014		.003
	D7	.066	.066	.054	.002	.000	.003	

Appendix 4.1: Alterations to QOL measurement

The actions suggested by Finlay and Lyons (2001) for QOL measurement in learning disabilities populations may generalise to chronic schizophrenia populations and enable more of this population to reliably complete QOL measures. For example, the CapQOL assesses 'acquiescence' using a 'yes/no' format. 22% of the participant's failed this domain at the first administration. Finlay and Lyons (2001) suggested conducting a pre-interview to check how a person exhibits uncertainty and responds to false suggestions. They also suggested deleting modifiers and complex question structures in the QOL measure. They suggested adding a 'don't know' option to the QOL measure and that assessors should check the meaning by asking for examples and probing further using scripts.

22% of the participant's exhibited difficulties using the 5-point Likert scale on the CapQOL. Finlay and Lyons (2001) suggested that Likert scales and degrees of frequency should be avoided in QOL measurement. The understanding of economic status and relationship domains in the CapQOL and in QOL are very general/abstract concepts. Respectively, 48% and 57% of the participants had difficulties with these domains at the first administration. Finlay and Lyons (2001) suggested the inclusion of concrete situations and events in the measures and to allow for the possibility that people may not be able to make generalized judgements.

The awareness of own situation and comparison with standard/desirable domains in terms of economic status and relationship with others were problematic for 52% and 57% respectively for the participant's at the first administration. For these types of questions/items, Finlay and Lyons (2001) suggested that elements (i.e. own situation, standard/desirable) should be rated separately, using a method other than the traditional Likert Scale.

Appendix 4.2: Condition specific vs. general QOL measurement

Two of the health-related QOL measures (the SF-36 and QWB-SA) that were reviewed by Wong et al. (2005) in order to develop the CAPQOL were designed to be used with any adult population. The other health related QOL measure (e.g. EORTC QLQ-C30) that was reviewed was designed for a specific cancer population. Some investigators believe that it is necessary to develop QOL measures for specific conditions/diseases. It could be argued that schizophrenia has very specific outcomes that affect QOL. The types of impaired responding (e.g. acquiescence, consistency, understanding and awareness of domains) would provide further support for the development of schizophrenia specific QOL measures that take into account the responding style of the population.

The counter argument to developing schizophrenia specific QOL measures is that all severe and enduring conditions affect overall QOL by affecting functioning

and self perceptions of health status. Also, measures that are condition specific might fail to capture the unanticipated effects of the condition or its treatment/s. The investigator that adopts this argument would therefore be interested in understanding the impact of the condition on general function.

Appendix 4.3: Extended discussion: Memory assessment

Just over half (52%) of the participants were identified as having a 'memory impairment' on the AMIPB: Story Recall. This finding is consistent with the research that suggests that memory is one of the major impairments in schizophrenia (e.g. Gold et al., 1992; Landra et al., 1994; Rund, 1989; Saykin et al., 1991) and that this clinical population differs significantly from the 'normal' population on immediate and delayed verbal memory recall tasks (Wood et al., 2006). Memory impairments have been reported to encompass a broad range of processes and so the AMIPB: Story Recall was a good measure to use because despite being verbally presented, it is thought to assess broad aspects of memory (e.g. retention and learning) and not specific memory system components (Coughlan & Hollows, 1985).

Despite a significant proportion of the participants being identified as having a 'memory impairment', there was a poor agreement with impairment on the CapQOL. This may be because the CapQOL was not sensitive to the memory skills that are assessed on the AMIPB: Story Recall subtest. A limitation of this

study was that only one of the AMIPB tests (ie. Story Recall) were used. Coughlan and Hollows (1985) have suggested that their memory tests focus on differing aspects of memory. The reasons that only one test was administered were testing time constraints and that most of the sub-tests of the AMIPB correlate highly significantly with each other (Coughlan & Hollows, 1985).

Future research may evaluate the associations between the CapQOL and the other sub-tests of the AMIPB (list learning, figure recall, design learning and number-cancellation tasks) and/or other memory assessment tools (e.g. Weschler Memory Scales (3rd ed.), Weschler, 1999; Rivermead Behavioural Memory Test (3rd ed), Wilson, Cockburn & Baddeley, 2007; Rey Complex Figure Test and Recognition Trial, Meyers & Meyers, 1995).

Another limitation of the memory assessment component of this study is that autobiographical memory impairments were not assessed and compared with the CapQOL, despite the literature suggesting that they may contribute to the symptoms of schizophrenia (Baddeley et al., 1996; Feinstein et al., 1998; Riutort et al., 2003). Future research may therefore evaluate the associations between the CapQOL and a measure of autobiographical memory (e.g. the Autobiographical Memory Interview, Kopelman, Wilson & Baddeley, 1990), however, it is not known whether this is a specific deficit, due to a co-morbid depression or is part of a general long-term memory impairment in schizophrenia (Wood et al., 2006). Therefore, another addition to a future research study that

includes a measure of autobiographical memory would be the assessment of depressive symptomatology using measures such as the Beck Depression Inventory-II (BDI-II) (Beck, Steer & Brown, 1996) and/ or the Hamilton Depression Inventory (HDI) (Williams, 1988).

Appendix 4.4: Extended discussion: Executive functioning assessment

The CapQOL demonstrated a poor agreement with executive functioning impairment/unimpairment. This finding would suggest that in its present form, the CapQOL does not detect executive functioning difficulties. However, the finding that many people with executive functioning impairments were able to 'pass' the CapQOL suggests that executive functioning skills may not be an essential requirement for completing QOL measures validly and reliably.

There were variable overall levels of executive functioning impairments on the Hayling (61%) and Brixton (38%) Tests. These findings are consistent with most studies that suggest that people with schizophrenia show impaired ability on executive functioning tasks compared to normal healthy controls (e.g. Blanchard & Neal, 1994; Kinney et al., 1994) and that the magnitude of impairment is dependent on the measure used (Johnson-Selfridge & Zalewski, 2001). The Hayling Test detected more impaired participants than the Brixton Test. This may be because the Hayling Test purports to measure initiation speed and response

suppression whilst the Brixton Test measures rule detection (Wood & Lioffi, 2006).

A criticism of executive functioning tests are that they probably involve several executive and non-executive processes (associated with brain areas outside the frontal lobes), and so no test can claim to be a 'pure' test of executive functioning (Wood & Lioffi, 2006). Until such a test is developed (and that may never be the case), an improvement to this study would be to use a wider battery of executive functioning assessments (e.g. Behavioural Assessment of Dysexecutive Syndrome, Wilson et al., 1996; Wisconsin Card Sorting Test, Heaton, 1981; Controlled Word Association Test, Benton & Hamsher, 1976; Trail Making Test, Reitan & Wolfson, 1985) and assess their associations with the CapQOL.

Appendix 4.5: Attention and vigilance observations: Implications for future research

There were occasions during testing when some of the participant's attention and vigilance on assessments appeared to be distracted. The distraction may have been a response to internal stimuli (e.g. auditory hallucinations), external stimuli (e.g. conversations outside the testing room) or 'information overload' (Seidman et al., 1998). This observation is consistent with research that has found that people with schizophrenia are significantly impaired to normal controls on attention and vigilance tasks (Seidman et al., 1998). People with schizophrenia

have often reported that these types of tasks involve 'considerable effort' (Seidman et al., 1998).

Attention involves a series of processes that include focusing on a target, sustaining that focus and minimising distractibility to unimportant stimuli (i.e. vigilance), encoding stimulus properties and disengaging and shifting focus (Mirsky, Anthony, Duncan, Ahearn & Kellam, 1991). It has been proposed that people with schizophrenia have a deficit in information-processing resources that are required to undertake these higher processing demands and this results in 'information overload' (Nuechterlein & Dawson, 1984). In order to assess the impact of attention and vigilance difficulties, a future study could use Continuous Performance Tests (CPT) (Seidman et al., 1998) in order to investigate if these types of difficulties are associated with impaired performance on the CapQOL and other cognitive assessments.

Appendix 4.6: PANNS results and implications for future research

The PANNS was chosen as a measure of positive and negative symptoms because of its psychometric properties (Kay, Fiszbein & Opler, 1987; Kay et al., 1988; Kay et al. 2000) and so that comparisons could be made with the Wong et al. (2005) study. It was not possible to calculate positive and negative scores for 10 of the participants. This was because those participants either became too

distressed during the PANNS interview or declined to take part in that section of the assessment due to the time that it took to complete (up to 60 minutes).

The clinical observation of those people that did not complete the PANNS interview were that they generally displayed more overt symptomatology during testing. For example, some of the participants displayed significant levels of negative symptomatology, such as blunted affect, emotional withdrawal or poor rapport. Other participants displayed significant levels of positive symptomatology in the form of suspiciousness, delusions and hallucinations. It seems likely that the participants where PANNS data was collected were less symptomatic than those that did not complete the PANNS interview. It is interesting to note that the mean PANNS scores for this sub sample were in a similar range to the early psychosis sample from the Wong et al. (2005) study, i.e. Wong et al. (2005) mean PANNS negative symptom score was 16 (s.d. = 7) compared to this study's mean PANNS negative score of 19 (s.d. = 6). This would indicate that the lack of significant correlation with the CapQOL was not due to this study's smaller distribution of negative symptom scores.

On reflection, it would have been preferable to have used a more acceptable, shorter symptom rating scale with this sample. The Clinical Global Impression Scale – Schizophrenia (Haro et al., 2003) is a scale that may have been more appropriate. It takes less time to complete and has demonstrated good reliability

and validity when evaluating the severity of positive, negative, depressive and cognitive symptoms in schizophrenia populations (Mortimer, 2007).

Appendix 4.7: Recruitment difficulties and declining rates

62% of the people that were identified and approached about the study did not consent to take part. A review of 18 studies published between 2003 and 2007 was undertaken to determine the research consent rates of schizophrenia populations. The main finding from this review was that very few studies reported the number of people that had not consented (despite the research being identified as 'high quality' by Cochrane reviews). Two studies did identify their rates of non-consenters to research. Durham, Guthrie, Morton, Reid & Treliving (2003) reported that in their study of CBT in a medication resistant schizophrenia sample, 44% did not consent to take part in their study. Greig, Zito, Wexler, Fizdon and Bell (2007) reported that in their study of the impact of cognitive training and vocational services on cognitive function, 48% did not consent to take part in their study.

The consent rates for the Durham et al. (2003) and Greig et al. (2007) studies were higher than this study, however, the participants in the Greig et al. (2007) study had already been approached by clinicians and declared an initial interest in the study. This suggests that that consent rates would have been much lower than the 52% that they obtained. Making comparisons regarding consent rates is

difficult given that many of the research studies potential participants were 'referred' to the study, suggesting that there was already some form of informal consent process undertaken by the referrer.

There were significant difficulties in recruiting for this study. The original research sites were identified as two inpatient wards in Lincolnshire where the recruiter undertook the majority of his work. From these wards, only 6 out of the 18 people that were identified agreed to participate in the study. The number of beds (i.e. capacity) on the wards had also reduced since ethical approval had been sought; therefore the number of inpatient wards that were approached had to be increased.

The observations of the recruiter recruiting at wards where he had limited involvement were that the patients on those wards were much more difficult to engage with and were more likely to be suspicious of his intentions. This appeared to have led to a higher ratio of people declining to take part in the study. This problem was also applicable to the nursing teams who were less facilitative in identifying participants and helping with the recruitment process.

In order to improve recruitment levels for studies of this type, it appears to be important that potential participants know of and/or trust the recruiter. Of course, the strength of this relationship should never be exploited as a means to recruit people into a study. Recruitment may have been improved if recruiters were

based at specific sites, however the scarcity of Clinical Psychologists in Lincolnshire means that there is very limited input from Clinical Psychologists on some inpatient wards.

It seems that the Wong et al. (2005) study had such a large sample size because the assessments were part of the admission procedure to the service. This would not be possible for chronic schizophrenia populations who are often long-term residents on inpatient wards or residential-homes. Nor would it be ethically acceptable for people to be denied admission to a ward if they declined to complete the assessments.

This study was limited by the time available to collect participant data. Ethical approval (from COREC, Trust Research & Design and University Departments) was finally obtained in October 2006. The data had to be collected by August 2007 in order that it could be analysed for submission in November 2007. This meant that there was a 10 month period where data could be collected. It appears that other schizophrenia research studies collect participant data over longer periods (e.g. several years). It seems likely that more time to collect data would have resulted in a larger sample size due to new patients being admitted to the inpatient wards and care home.

Further delays in approaching participants occurred when contacting Responsible Medical Officers (RMO's) regarding patient's ability to consent (a

condition of COREC), arranging meetings with ward managers to discuss the research and agreeing suitable times to visit the inpatient wards and residential home. The tight deadline meant that only a limited amount of preparatory work could be done on the wards (i.e. meetings with ward managers). Oral presentations about the research to the ward staff and patients may have improved consent rates, due to a greater awareness and appreciation of the study.

The sample in this study turned out to be more heterogeneous than had been anticipated, i.e. people were recruited from 6 inpatient wards and 1 residential home as opposed to the planned recruitment from 2 inpatient wards. Participants were under the care of differing RMOs, ward regimes and care teams. However, this sample appeared to be similar in many ways to the type of sample that are admitted to schizophrenia research units as described by Schreiber et al. (1990). For example, in both samples symptomatology is persistent and they have often had repeated hospitalisations. This study did not screen for 'episodes of aggressive and flagrantly uncooperative behaviour', a characteristic that often leads to exclusion from schizophrenia research units (Schreiber et al., 1990). Screening for these types of behaviour is undertaken because the units are looking for cooperative patient samples with whom a research and therapeutic alliance can be built (Schreiber et al., 1990). There are several known patients on Lincolnshire inpatient wards that demonstrate 'aggressive and uncooperative

behaviours', however when approached by the recruiter, they declined the opportunity to take part in the study, in effect excluding themselves.

Clinical observations of the participants were that only a small minority would be described as acutely psychotic. The recruiter felt that those individuals that presented as paranoid or mistrustful would often decline the opportunity to take part in the study. These observations are consistent with Schreiber et al. (1990) suggestion that the acutely psychotic often decline treatment and research studies. The impact on this study (and other cognitive testing studies in schizophrenia populations) would be that the strength of associations between measures are reduced because of restricted score ranges on some measures.

Appendix 4.8: Inter-rater reliability

A limitation of this study is that the inter-rater reliability of the CapQOL was not assessed. Inter-rater reliability was beyond the scope (and resources) of this study. Another reason that this type of reliability was not assessed was that the CapQOL had already demonstrated good inter-rater reliability (0.92 for global scores) with the early psychosis sample (Wong et al., 2005). The danger of accepting that the CapQOL has good inter-rater reliability, based on the Wong et al. (2005) study is that the raters probably worked together on the development of the instrument. If this were the case, fairly consistent ratings would be expected, irrespective of the properties of the measure. In clinical use, raters do

not have this level of knowledge, training or expertise regarding the tools that they use. Therefore, independent, inter-rater reliability studies of the CapQOL with early psychosis and chronic schizophrenia populations would be recommended.

Appendix 4.9: Theoretical models

A criticism of the CapQOL is that the authors did not propose any theoretical models to explain the processes involved in making a decision about subjective QOL. Experts in legal and bioethics generally agree that there are a least four components that are important for the capacity to make a decision: understanding information relevant to the decision; appreciating the information (applying the information to one's own situation); using the information in reasoning; and expressing a consistent choice (Roth, Meisel & Lidz, 1977; Grisso & Appelbaum, 1998a).

Decisional capacity for informed consent in schizophrenia research has been the focus of recent professional debate (Dunn, Nowrangi, Palmer, Jeste & Saks, 2006). The four components of decisional capacity have been assessed in relation to informed consent using a structured instrument, the MacArthur Competence Assessment Tool (Mac-CAT) (Grisso & Appelbaum, 1998b). Carpenter et al. (2000) found that their schizophrenia sample did not perform as well as controls on an initial administration of the Mac-CAT. They found that poor performance was moderately related to symptomatology and strongly related to

cognitive impairment (Carpenter et al., 2000). However, when they applied a programme that consisted of two 30 minute educational sessions on the study described in the Mac-CT, provided prompts to 'master' the material and the option of using a computerised interactive programme, they found that the performance of their schizophrenia sample was equal to their control group (Carpenter et al., 2000).

This finding has relevance to the CapQOL in that if people are educated and prompted in how to complete QOL measures, they may give more valid and reliable responses on the CapQOL and QOL measures. The CapQOL may be changed to include prompts to assist participants in completing the domains of its scales. Those prompts that were useful for a particular participant on the CapQOL could then be used when a QOL measure is administered.

Appendix 4.10: Limitation: Estimate of pre-morbid IQ

In order to partial out the effects of IQ on the memory and executive functioning assessments, the NART (Russell et al., 2000) was used as an estimate of pre-morbid IQ. A limitation of this study is that only one measure of pre-morbid IQ was used. Russell et al. (2000) recommended that ideally, more than one measure of pre-morbid IQ should be used. A future study might only include adults with schizophrenia who had been assessed as children using the Weschler Intelligence Scales for Children (either WISC or WISC-R). The

disadvantage of doing this in practice would be a large proportion of the adult schizophrenia population would be excluded.

Another reason for using multiple sources to identify pre-morbid IQ is that Russell et al. (2000) suggested that NART scores that do not fall in the 'average' categories should be 'interpreted with caution'. Three participants from this study were below the 'average' category range and so the accuracy that could have been attributed to their pre-morbid IQ estimates could have been enhanced with the collection of additional measurement data.

Appendix 4.11: Limitation: Duration of illness

The duration of illness was not measured despite Wong et al. (2005) suggesting that chronicity is associated with increased cognitive impairment. On the other-hand, Johnson-Selfridge and Zalewski (2001) have demonstrated that duration of illness does not significantly affect executive functioning. The main reason for not considering duration of illness was the difficulty in assessing the onset of an 'illness' such as schizophrenia from medical records that are incomplete and/or inconsistent in their descriptions of a patient's onset and pre-morbid presentation. However, the duration of illness would appear to be more chronic in this study's population when you consider their age range (25 - 64 years) and mean (43 years), in comparison with the Wong et al. (2005) study (range = 18 – 29 years, mean = 22 years).

The number of hospitalisations has been related to executive functioning impairments (Johnson-Selfridge & Zalewski (2001), and may have been an easier factor to quantify. This factor would give an indication of duration and severity of illness (possibly because people with more symptoms require more hospitalisations). However, reviewing each participant's medical notes (often with this population, multiple volumes) would be beyond the capacity of a project of this size. The accuracy and completeness of the records would also affect the validity and reliability of the data.

Appendix 4.12: Limitation: diagnostic classification system

The initial research proposal had stated that participants would be identified from DSM-IV diagnoses of Schizophrenia in their medical notes. The reality when reviewing participants' medical notes was that the diagnostic classification system that was used was rarely cited or the Schizophrenia diagnosis was based on various versions (8-10) of the ICD classification system. In order to improve identification of participants' diagnoses, future studies may request that the Responsible Medical Officer undertakes an up-to-date diagnostic classification based on an agreed classification system. Also, the diagnosis of schizophrenia and presence of persistent hallucinations and/or delusions could be confirmed using diagnostic checklists.

Appendix 4.13: Future study: Effect of medication

All of the participants were being treated with anti-psychotic medications. This appears to be the 'norm' for inpatient and residential home chronic schizophrenic populations. Frith (1984) suggested that memory impairments are associated with the use of anticholinergic drugs and Benzodiazepines in the medical treatment of schizophrenia. Alternatively, memory improvements have been demonstrated in individuals that were prescribed the newer anti-psychotic medications such as Risperidone and Clozapine (Green et al., 1997; Keefe et al., 1999). A future study could therefore evaluate the associations between medicated and unmedicated schizophrenic samples, CapQOL performance and cognitive testing performance. This study would identify if medication affects both cognitive testing and CapQOL performance, or cognitive tests but not CapQOL performance, or vice versa. The average chlorpromazine-equivalent neuroleptic daily dose could be calculated for the medicated groups in this proposed study, as described by Seidman et al. (1998).

Appendix 4.14: Face validity

The authors of the CAPQOL claimed that it had face validity because it was developed from a review of the 'most commonly used' health related QOL measures and had questions that are depicted in QOL measures.

Correspondence with Dr Wong revealed that only three health-related QOL measures were reviewed (SF-36, QWB-SA, EORTC QLQ-C30). The CapQOL's face validity may therefore be questionable given the extensive number of QOL measures that have been developed.

Appendix 4.15: Proposed alterations to CapQOL terms and instructions

On question 7, the term 'economic status' needed clarification by several participants. This term could be replaced with 'wealth' or 'amount of money' in order to ease comprehension. On question 9, several participants required clarification on the 'type' of relationship that was being asked about. For example, did the question mean a romantic, platonic or both 'types' of relationship? Either types of relationship that were described by participants were regarded as acceptable; however this was not specified in the instructions. The 'type' of relationship could therefore be inserted in the question in order to lower confusion for participant and assessor.

An administrative difficulty with the CapQOL was that it was rather unclear about the amount of 'assistance and guidance' that should be offered to participants that encounter difficulties. For example, a global score of 1 is assigned when the 'maximum assistance and guidance' is provided to a participant. This is a very subjective description and clear instructions should be provided about what can and cannot be provided. Objective descriptions and instructions about the

amount of assistance and guidance that could be offered may have been given to the 'trained' assessors from the Wong et al. (2005) study.

Appendix 4.16: Cut-off scores

Consideration was given to whether the cut-off scores on the cognitive assessments were too lenient and if this then affected the sensitivity of the CapQOL. For example, was a 2 z-score cut-off for the AMIPB (in comparison to the NART) too lenient? Examination of the AMIPB raw scores indicated that those individuals that were identified as being impaired had very low raw scores that were in a similar range. This indicated that the cut-off scores were not too lenient.

It was also considered if the cut-off score for impairment on the CapQOL were too stringent. For example, this study and the Wong et al. (2005) study classified 'impairment' on the CapQOL as global scores ≤ 3 . However, a score of 3 indicated that the person 'only has a fair understanding of QOL domains' and 'may not have the ability and capacity'. Given that 43% (time 1) and 57% (time 2) of the participants were identified as unimpaired on the CapQOL, and the high rates of cognitive impairment, it would seem that the cut-off scores were not too stringent.

Appendix 4.17: Capacity to consent vs. capacity to appraise subjective QOL

57% of the sample failed the CapQOL at time 1, indicating that they did not have the capacity to report their subjective QOL. However, the sample were all judged to have the capacity to make an informed decision (consent) regarding taking part in the study by four people: their Responsible Medical Officer (RMO), a member of their nursing team, the Clinical Psychologist (recruiter) responsible for their inpatient ward or care home and the chief investigator (test administrator).

The consent process was designed so that people had sufficient information and understanding about the study in order to make an informed decision. The first stage involved the recruiter meeting the identified person and giving a verbal explanation of the study, a typed 'layperson' information sheet (agreed by Ethics committees) and the opportunity to ask questions. This initial meeting lasted from 5 minutes to 60 minutes, dependent on the comprehension and/or interest of the identified person. If the identified person agreed to meet the chief investigator (test administrator), the second stage of the consent process involved them meeting (with a member of the nursing team present) 24 hours later. At this meeting, the identified person was asked about their understanding of the study and any misunderstandings were clarified. The person was again given the opportunity to ask questions. Having a second meeting meant that as well as a second opportunity to increase and assess understanding, the identified persons'

ability to express consistent choices were sought (Roth et al., 1977; Grisso, 1998a).

This consent process gave information in different formats (i.e. verbal and written) by two different people, checked understanding and clarified information, and assessed consistency of responses (over a 24 hour period). This detailed and time consuming process is not part of the CapQOL administration procedure and may account for the number of participants that were identified as 'impaired' and lacking capacity on the CapQOL.

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