

**Quality of life following prolonged critical illness:  
A mixed methods study**

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## **Declaration**

I declare that this thesis is entirely my own work and that it has been submitted only for the degree of PhD.

Pam Ramsay

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## Abstract

Survival following critical illness is associated with a significant burden of physical and psychosocial morbidity and recovery is often protracted and/or incomplete.

Recovery has been measured using, almost exclusively, generic health-related quality of life (HRQoL) questionnaires. There is, however, an inexorable lack of consensus on the conceptual definition of HRQoL, and existing measures have tended to reflect overtly *biomedical* concerns such as morbidity and impairment at *population* level.

Limited empirical or theoretical work has examined the extent to which widely used measures reflect the *individual's* concerns, “health”-related and otherwise.

The primary aims of this PhD are to examine HRQoL among a rarely studied sub group of the critically ill patient population: survivors of prolonged critical illness, and to explore the extent to which professionally endorsed measures capture their experiences of and perspectives on the recovery process. The implications of “patient-centredness” are both diverse and far-reaching in terms of policy, practice and critical care outcomes research, and are discussed throughout.

A review of the literature among a well studied sub group of the patient population (survivors of Adult Respiratory Distress Syndrome) identified the widespread use of generic and ancillary measures which were invariably developed for use among other patient populations. This approach was seen to offer limited insight to the putative relationship between *critical illness*-related morbidity and HRQoL.

Reflecting existing professional recommendations and practice, the Short Form 36 (SF-36) and the EuroQoL were administered by post to 20 survivors of prolonged critical illness at up to 6 months following ICU discharge. Each subsequently participated in a semi-structured interview, the purpose of which was to explore experiences and perceptions of ongoing morbidity within the contexts of the critical illness “journey” and, importantly, everyday life.

A small number (n=5) participated in cognitive interview in order to explore both the everyday logistics of questionnaire completion and the often startling inconsistencies between verbal and questionnaire response. Analysis here revealed the unexpectedly diverse and normally hidden processes through which survivors interpreted and

responded to standardised questionnaire items, challenging traditional (i.e. psychometric) notions of validity.

Data from the semi-structured interviews were “mapped” onto the dimensions of the SF-36, revealing the highly contextualised and complex inter-relatedness of biomedically defined and ostensibly discrete aspects of experience. Morbidity was conceptualised by survivors in terms of the *adaptive* and *interpretive* processes adopted in everyday life (as opposed to a source of loss) and was generally under-reported in questionnaire form. An alternative explanatory framework for HRQoL was subsequently developed.

Data were also analysed with reference to the “biographical narrative” of critical illness, a strategy which revealed the significance of survivors’ own stock of “life experience” (health-related and otherwise) in these interpretive and adaptive processes. The unexpectedly phlegmatic nature of survivors’ accounts directed attention to the narrative form, lending credibility to survivors’ claims that “things weren’t that bad”; accounts of seemingly intolerable morbidity were perceived, for example, as “a lucky escape”. This data also revealed, however, the influence of shortfalls in the processes and delivery of acute hospital rehabilitation upon the efficacy of these interpretive and adaptive processes.

Mixed methods approaches to HRQoL, in summary, offer significant insights into survivors’ conceptualisations of morbidity, recovery, quality of life and the complex inter-relationships therein. Attention to the processes of adaptation also offers significant potential for the development of patient-centred measures of outcome and the expedition of the recovery process in ways which are most meaningful to survivors.

# Contents

<b>Title page</b> .....	<b>i</b>
<b>Declaration</b> .....	<b>ii</b>
<b>Acknowledgements</b> .....	<b>iii</b>
<b>Abstract</b> .....	<b>iv</b>
<b>Contents</b> .....	<b>vi</b>
<b>Background to the study</b> .....	<b>1</b>
<b>Chapter 1: Is Intensive Care “worthwhile” among survivors of prolonged critical illness?</b> .....	<b>4</b>
1.1 Introduction .....	4
1.2 The origins of critical care .....	5
1.3 Contemporary critical care and the long-term patient group .....	5
1.4 Critical care and distributive justice.....	7
1.4.1 Explicit approaches .....	7
1.4.1.1 Prognostic models (mortality).....	8
1.4.1.1.1 Short term mortality .....	8
1.4.1.1.2 Long-term mortality .....	9
1.4.1.2 Economic analyses (cost-effectiveness).....	10
1.4.1.3 Guidelines and protocols.....	11
1.4.1.4 Advance directives .....	12
1.4.2 Implicit approaches .....	13
1.4.2.1 (Health-related) Quality of life (HRQoL) .....	13
1.5 Discussion .....	14
<b>Chapter 2: A Lothian-based prevalence study of prolonged critical illness</b> .....	<b>17</b>
2.1 Introduction.....	17
2.2 Defining “prolonged critical illness” .....	17
2.3 Data collection .....	18

2.4 Statistical analyses .....	19
2.5 Findings.....	19
2.5.1 Number and proportion of patients with a prolonged critical illness....	19
2.5.2 Demography and clinical characteristics .....	20
2.5.2.1 Age, gender and illness severity.....	20
2.5.2.2 Duration of ventilation and ICU length of stay.....	20
2.5.3 ICU mortality .....	20
2.5.4 ICU discharge destination .....	21
2.5.5 Acute hospital length of stay.....	22
2.5.6 Additional hospital mortality .....	22
2.5.7 Crude ICU and acute hospital costs .....	22
2.5.8 Hospital discharge destination .....	23
2.5.9 “Long-term” survival .....	23
2.6 The “representativeness” of the study population.....	24
2.7 Discussion .....	24
<b>Chapter 3: The Literature Review .....</b>	<b>25</b>
<b>Section One .....</b>	<b>25</b>
3.1 Introduction.....	25
3.2 The origins of (health-related) quality of life.....	27
3.2.1 Quality of life .....	27
3.2.2 Health-related quality of life (HRQoL).....	28
3.3 Why measure HRQoL? .....	30
3.3.1 Macro level decision-making.....	32
3.3.2 Meso level decision-making .....	32
3.3.3 Micro level decision making.....	33
3.4 Summary .....	35
3.5 How is HRQoL operationalised? .....	35

3.5.1	Nomothetic approaches to HRQoL measurement .....	37
3.5.1.1	Generic profile measures .....	37
3.5.1.2	Generic utility measures.....	37
3.5.1.3	Disease-specific HRQoL measures.....	38
3.5.2	Idiographic approaches to HRQoL measurement.....	38
3.5.2.1	The Patient Generated Index (PGI).....	39
3.5.2.2	Schedule for the Evaluation of Individual Quality of Life ....	40
3.5.2.3	Idiographic disease-specific measures .....	41
3.6	Summary .....	42
3.7	The development of HRQoL instruments .....	43
3.7.1	Generic measures .....	43
3.7.1.1	Generic utility or preference-based measures .....	44
3.7.1.1.1	Visual analogue/direct rating scales.....	44
3.7.1.1.2	Time trade-off (TTO).....	45
3.7.1.1.3	The standard gamble .....	45
3.7.2	Disease specific measures .....	46
3.7.2.1	Individual qualitative interview .....	46
3.7.2.2	Focus group interviews .....	47
3.7.2.3	Ranking exercises and card sorts .....	48
3.7.2.4	Expert panels.....	48
3.7.2.5	Cognitive interview techniques.....	48
3.7.2.6	Frameworks for developing disease-specific measures .....	49
3.7.2.6.1	The “Volkswagen” model.....	49
3.7.2.6.2	“Rolls Royce” models .....	50
3.7.2.6.2.1	<i>A standardised approach</i> .....	50
3.7.2.6.2.2	<i>A modular approach</i> .....	50
3.7.2.6.2.3	<i>A conceptual model approach</i> .....	51
3.7.3	Idiographic measures .....	52
3.8	Summary .....	52

3.9 The validation of HRQoL instruments.....	53
3.9.1 Validity.....	53
3.9.1.1 Face validity.....	53
3.9.1.2 Content validity.....	54
3.9.1.3 Criterion validity.....	54
3.9.1.4 Construct validity.....	55
3.9.2 Reliability.....	55
3.9.2.1 Internal consistency.....	55
3.9.2.2 Reproducibility.....	55
3.9.3 Responsiveness.....	56
3.10 Summary.....	57
3.11 Discussion.....	58
<b>Section Two.....</b>	<b>59</b>
<b>HRQoL in critical care outcomes research.....</b>	<b>59</b>
3.12 Introduction.....	59
3.13 Why measure HRQoL?.....	59
3.14 How is HRQoL operationalised in critical care outcome studies?.....	60
3.14.1 Generic measures.....	60
3.14.2 Disease-specific measures.....	61
3.14.3 Screening tools.....	61
3.14.4 Duration of follow-up.....	62
3.14.5 Caveats to the use of HRQoL data in critical care outcome studies... ..	62
3.14.5.1 Comorbidity.....	62
3.14.5.2 Adaptation and response shift.....	63
3.15 A review of professionally endorsed generic HRQoL measures.....	64
3.15.1 The SF-36.....	64
3.15.1.1 Development.....	64
3.15.1.2 Use and validation in non-ICU populations.....	66
3.15.1.3 Use and validation among survivors of critical illness.....	66

3.15.1.4 Criticisms of the SF-36 .....	67
3.15.1.4.1 “Floor” and “ceiling” effects.....	67
3.15.1.4.2 Use among the elderly.....	68
3.15.2 The EuroQoL (EQ-5D) .....	69
3.15.2.1 Development .....	69
3.15.2.2 Use and validation in non-ICU populations.....	70
3.15.2.3 Use and validation in ICU populations .....	70
3.16 Summary .....	71
3.17 Exemplar; HRQoL among survivors of ARDS .....	72
3.17.1 The SF-36 and decrements in HRQoL dimensions.....	72
3.17.2 The SF-36 and disease-specific measures of HRQoL.....	73
3.17.3 The SF-36 and functional ability.....	73
3.17.4 The SF-36 and psychological morbidity .....	75
3.17.4.1 Anxiety .....	75
3.17.4.2 Depression.....	75
3.17.4.3 Post Traumatic Stress Disorder (PTSD) .....	76
3.17.4.4 Neurocognitive impairment .....	76
3.18 Summary .....	77
3.19 Discussion .....	79
<b>Chapter 4: Methods .....</b>	<b>81</b>
<b>Section One .....</b>	<b>81</b>
<b>4.1 Introduction .....</b>	<b>81</b>
4.2 A brief clarification of terms.....	84
4.2.1 Theory and health services research methodology .....	85
4.2.2 Epistemology and health services research methodology.....	86
4.2.3 Summary .....	86
4.3 Quantitative approaches to HRQoL .....	87
4.3.1 Evaluating quantitative approaches to HRQoL.....	87

4.4 Qualitative approaches to HRQoL .....	88
4.4.1 Evaluating qualitative approaches to HRQoL.....	89
4.5 The over-arching research strategy: mixed methods .....	91
4.5.1 Evaluating mixed methods approaches to HRQoL.....	93
4.6 Summary .....	93
4.7 Quantitative methods used in this thesis .....	93
4.7.1 A prevalence study of prolonged critical illness.....	93
4.7.2 The administration of generic HRQoL questionnaires .....	94
4.8 Qualitative methods used in this thesis .....	95
4.8.1 “Any comments?” .....	95
4.8.2 Cognitive interview techniques.....	95
4.8.3 The semi-structured interview.....	96
4.9 Summary .....	97
<b>Methods: Section Two .....</b>	<b>98</b>
4.10 Introduction.....	98
4.11 The setting(s).....	98
4.12 The research ethics.....	98
4.12.1 Ethical approval .....	98
4.12.2 Ethical conduct.....	99
4.13 The recruitment strategy .....	99
4.13.1 Access to patient data.....	99
4.13.2 Eligibility .....	100
4.13.3 Sampling .....	100
4.13.4 Recruitment.....	100
4.13.4.1 Alternative strategies for recruitment.....	101
4.14 The research venue.....	102

4.15 Conducting the interviews .....	102
4.16 Conducting the post-interview ICU visits.....	103
4.17 Confidentiality .....	104
4.17.1 The prevalence study.....	104
4.17.2 The semi-structured interview.....	104
4.17.3 Ongoing engagement with participants.....	105
4.18 Funding .....	105
<b>Chapter 5: A “quasi-qualitative” exploration of the .....</b>	<b>106</b>
<b>SF-36.....</b>	<b>106</b>
5.1 Introduction.....	106
5.2 Data Collection.....	106
5.3 Data analysis .....	106
5.4 Data quality and implications.....	107
5.4.1 Missing data .....	107
5.4.2 Ambiguous or contradictory data.....	108
5.4.3 Respondent comments .....	108
5.5 Findings.....	110
5.5.1 HRQoL scores (individual level analyses).....	110
5.5.2 Physical Function.....	110
5.5.3 Role Physical.....	111
5.5.4 Energy/vitality.....	112
5.5.5 Mental Health and Role Emotion.....	112
5.5.6 General Health Perception .....	113
5.5.7 Others .....	113
5.6 Discussion .....	113

<b>Chapter 6: Cognitive Interview Techniques.....</b>	<b>115</b>
6.1 Introduction.....	115
6.2 The evolution of cognitive interview techniques.....	115
6.3 The cognitive interview process.....	116
6.3.1 Think aloud.....	117
6.3.2 Verbal probing.....	117
6.3.3 The Three Step Test Interview (TSTI).....	118
6.4 Analysis of cognitive interview data.....	118
6.5 CASM and HRQoL research.....	119
6.5.1 Adaptation of the “generic” cognitive model.....	119
6.5.1.1 Responsiveness to change.....	121
6.5.1.2 Response shift.....	122
6.5.1.3 Validity.....	124
6.5.1.4 Social desirability bias.....	125
6.5.1.5 Sensitivity and specificity.....	126
6.6 Summary.....	126
6.7 The use of cognitive interview techniques in this study.....	129
6.7.1 Questionnaire administration.....	129
6.7.2 Methods.....	129
6.7.3 Analysis.....	129
6.7.4 Findings.....	130
6.7.4.1 Motivation and social desirability bias.....	130
6.7.4.2 Cognitive burden.....	131
6.7.4.3 Physical Function.....	132
6.7.4.4 Mental Health and Role Emotion.....	133
6.7.4.5 General health perception.....	135
6.7.4.6 Bodily pain.....	136
6.7.4.7 Energy/vitality.....	137
6.8 Discussion.....	137

<b>Chapter 7: A qualitative exploration of the dimensions of</b> .....	<b>139</b>
<b>the SF-36</b> .....	<b>139</b>
7.1 Introduction .....	139
7.2 Data collection .....	139
7.3 The complexities of the analytical process .....	140
7.3.1 The inter-relatedness of data and dimensions of experience .....	140
7.3.2 The development of qualitative themes .....	140
7.3.3 Unraveling aspects of experience; “strategy” and “coping” .....	141
7.3.4 Capturing temporality .....	142
7.4 The Physical function, Role Physical and Energy/Vitality dimensions.....	142
7.4.1 Physical function.....	142
7.4.2 Role physical.....	143
7.4.3 Energy/vitality.....	144
7.5 An alternative Physical Dimension.....	144
7.5.1 “Getting by” .....	145
7.5.1.1 Organising material resources.....	145
7.5.1.2 Organising (informal) support.....	145
7.5.1.3 Finding new ways of doing things .....	146
7.5.1.4 Summary .....	147
7.5.2 “Moving on” .....	148
7.5.2.1 Pacing (managing weakness and fatigue) .....	148
7.5.2.2 Resistance.....	149
7.5.2.3 Marking progress and setting goals.....	150
7.5.2.4 Summary .....	151
7.6 The Mental Health and Role Emotion dimensions .....	151
7.6.1 Mental Health.....	151
7.6.2 Role emotion .....	152

7.7 An alternative Mental Health Dimension .....	153
7.7.1 “Making sense of the ICU experience” .....	153
7.7.1.1 “Filling in the memory gap” .....	153
7.7.1.2 “Making sense of bizarre dreams and experiences” .....	155
7.7.1.3 Summary .....	157
7.7.2 “Putting things in perspective” .....	157
7.7.2.1 “It’s better than being six feet under” .....	158
7.7.2.2 “There’s always somebody else worse off” .....	159
7.7.2.3 Summary .....	160
7.8 The Social Function dimension.....	160
7.9 An alternative Social Function dimension.....	161
7.9.1 Leaning on family and friends .....	161
7.9.2 Getting back to normal.....	163
7.9.4 Summary .....	165
7.10 Bodily pain.....	166
7.10.1 Summary .....	167
7.11 General health perception .....	168
7.12 An alternative General Health Perception.....	168
7.12.1 “I was fine, really” .....	168
7.12.2 “Since all this...”.....	170
7.12.3 “I’m probably healthier now” .....	171
7.12.4 Summary .....	172
7.13 Discussion .....	172
<b>Chapter 8: Biographical disruption following critical illness .....</b>	<b>175</b>
8.1 Introduction.....	175
8.2 Illness narratives.....	175

8.3 Defining biographical disruption .....	177
8.3.1 The disruption of taken-for-granted assumptions .....	177
8.3.2 Disruption in explanatory systems .....	177
8.3.3 The response to disruption .....	178
8.4 Critiques of biographical disruption.....	179
8.5 Biographical disruption following critical illness .....	180
8.5.1 Data analysis .....	180
8.5.1.1 The development of qualitative themes .....	180
8.5.1.2 Capturing complex temporal processes .....	180
8.6 Disruptions in taken-for-granted assumptions .....	181
8.6.1 “You have to be well to be ill” .....	183
8.6.2 “What were they doing for me, really?” .....	184
8.6.3 “I was a bit disappointed with physio” .....	185
8.6.4 “Nobody really spoke to me about getting home” .....	189
8.6.5 Summary .....	192
8.7 Disruptions in explanatory systems .....	193
8.7.1 “I still don’t know what happened to me” .....	193
8.7.2 “How on <i>Earth</i> did I become so ill?.....	196
8.8 The cognitive response to disruption .....	198
8.8.1 “Well, what else can you do?” .....	198
8.8.2 “Everything happens for a reason” .....	199
8.9 Discussion .....	202
<b>Chapter 9: Summary, discussion and implications.....</b>	<b>204</b>
9.1 Introduction.....	204
9.2 Background to this research.....	204
9.3 The “unfolding story” of this research.....	205
9.4 Summary of the main findings.....	206

9.4.1 The current state of knowledge in critical care research.....	206
9.4.2 The prevalence of prolonged critical illness .....	207
9.4.3 A “quasi-qualitative” exploration of the SF-36 .....	207
9.4.4 Cognitive interview and the SF-36 .....	208
9.4.4.1 The Physical Function and Role Physical dimensions.....	208
9.4.4.2 Mental Health and Role Emotion.....	209
9.4.4.3 General Health Perception .....	209
9.4.4.4 An alternative cognitive response model .....	210
9.4.5 A qualitative exploration of the dimensions of the SF-36 .....	210
9.4.6 Biographical disruption following critical illness.....	212
9.5 What this research contributes to existing knowledge.....	213
9.6 A word about method(ology).....	214
9.7 Implications for practice .....	216
9.8 Contribution to future research .....	217
9.9 Implications for HRQoL measurement in critical care outcomes research .....	218
<b>Appendices.....</b>	<b>221</b>
Appendix 1: Admissions to a Scottish ICU (1996 to 2006).....	222
Appendix 2: Admissions to a Lothian ICU (1996 to 2006).....	222
Appendix 3: Data fields and attendant issues .....	223
Appendix 4: Demography and clinical characteristics of the study cohort and patient population from whom they were recruited (1.1.2006-21.11.07).....	224
Appendix 5: Demography, clinical and resource-related characteristics of the 5 year Lothian cohort, by site .....	225
Appendix 6: Differences between ICU survivors and non-ICU survivors .....	226
Appendix 7: Differences between hospital survivors and non-hospital survivors...	227
Appendix 8: The number of publications reporting upon HRQoL (1996-2005).....	228
Appendix 9: Morbidity associated with survival following critical illness .....	229
Appendix 10: The SF-36.....	230

Appendix 11: The SF-36 in critical care outcome studies .....	235
Appendix 12: The EQ-5D .....	244
Appendix 13: The EQ-5D in critical care outcome studies .....	246
Appendix 14: Use of the SF-36 among survivors of ARDS .....	249
Appendix 15: Decrements in HRQoL (by dimension) among survivors of ARDS.	251
Appendix 16: Strengths and weaknesses of the quantitative approach to HRQoL measurement .....	253
Appendix 17: Attributes and criteria for reviewing HRQoL instruments.....	254
Appendix 18: Checklist for reporting the results of QoL assessments in clinical trials .....	258
Appendix 19: Strengths and weaknesses of qualitative approaches to HRQoL .....	260
Appendix 20a: Criteria for evaluating qualitative research (methods) .....	261
Appendix 20b: Criteria for evaluating qualitative research (analysis).....	262
Appendix 20c: Criteria for evaluating qualitative research (presentation) .....	263
Appendix 21: Strengths and weaknesses of mixed methods approaches to HRQoL .....	264
Appendix 22: Eligibility of patients for study inclusion at RIE and WGH .....	265
Appendix 23: Copy of GP letter .....	266
Appendix 24: Copy of Patient Information Sheet.....	268
Appendix 25: GP checklist .....	273
Appendix 26: A “potted history” of the research participants .....	274
Appendix 27: The interview topic guide.....	277
Appendix 28: Individual level HRQoL data .....	279
Appendix 29: Structured probes in cognitive interviewing .....	283
References .....	286

## Background to the study

My interest in patients experiencing prolonged critical illness evolved from many years' clinical practice as a staff nurse in Intensive Care and from subsequent experience as a Research Co-ordinator in the specialty.

Routine clinical practice in a busy Intensive Care Unit (ICU) provides limited opportunities for discourse with patients either during or after their ICU stay. The nature and severity of critical illness, the frequent requirement for endotracheal intubation, mechanical ventilation and sedation severely constrains the didactic process of communication. Many patients, once extubated, suffer from "ICU delirium"; a state characterised by acute confusion, disorientation and dissociation from reality. Among "awake" (i.e. cognisant) patients, communication is often limited to the practicalities of routine, technically oriented care and related issues such as pain, anxiety or discomfort. Due to the rapid turnover of patients, the vast majority of survivors are discharged from ICU once the requirement for advanced respiratory and other organ support abates and a cautionary (and often alarmingly brief) "period of grace" has passed. The vast majority of patients, in short, pass rather anonymously through our doors.

Patients experiencing *prolonged* critical illness and mechanical ventilation are somewhat anomalous in many aspects of routine clinical practice. These patients are often the most severely ill upon ICU admission, or require prolonged critical care intervention as a consequence of a complex illness trajectory which may include, for example, failure to wean from mechanical ventilation or the acquisition of secondary systemic infection. A clinical emphasis upon "continuity of care" is both espoused and apparent, and these patients in particular evoke significant emotional investment among clinicians by virtue of this sustained interaction and, despite the often profound debilitation they experience, by their often remarkable "will to live". Very little is known about what happens to patients *after* ICU, however, and clinicians are often left to wonder whether our interventions and the associated suffering were "worth it".

The long-term patient group often spend a significant proportion of their ICU stay “awake”, recovering, and requiring minimal or “low tech.” care once the acute illness has resolved. Routine care is often provided by junior or inexperienced staff and, tempered with the affinity previously described, is perhaps an implicit bias towards this patient group among the more “elite” or “technocratic” of clinicians. This implicit bias (whether real or imagined) is somewhat reminiscent of Becker and Geer’s (1982) classic description of a “crock”; a somewhat jaded descriptor for a patient who offers limited opportunity for clinical learning or the assumption of clinical responsibility.

There is a paucity of research and evidence-based practice across many aspects of routine care among this patient group. My subsequent research experience (in the exploration of weaning strategies among patients requiring prolonged mechanical ventilation) revealed the inadequacy of existing protocols and clinical guidelines in their management and a reluctance or inability among clinicians to engage in individualised care planning. My interest in the long-term patient group, at this stage of my career, was borne out of a sense of disquiet regarding inherent inconsistencies in their care and management.

Several years later, marginal involvement in a longitudinal follow-up study (among anaemic survivors of critical illness) provided unique insights into the complexities and protraction of the recovery process. Home based visits in particular proved revelatory in terms of the continuing difficulties survivors experienced in their everyday lives. Several patients, for example, alluded to the prohibitive and cumulative effects of fatigue, generalised weakness and impaired mobility in their attempts to “get back to normal”. Our quality of life measures, however, provided only limited recognisance of their effects upon everyday life and their complex interaction.

The coalescence of these insights and experiences into a “researchable” question was founded upon a chance remark made by a colleague in relation to a subsequent follow-up study in which HRQoL was an outcome of interest. He had described, with some bemusement, a visit to an elderly and profoundly impaired survivor who, despite marked dependence upon her husband and adult children described her

quality of life as “pretty good, thanks very much”. She was, in her own words, “as happy as Larry” to have survived and to be at home among her family.

Subsequent discussions with my colleague centred around the unanticipated difficulty survivors expressed in response to seemingly straight-forward items in the HRQoL questionnaires used, their apparent irrelevance in everyday life, and the relative redundancy (i.e. entirely descriptive nature) of the information gathered. Intriguingly, despite the revelatory nature of informal discussion and the inherent utility of the information gained (in terms of potential interventional strategies), this rich “data” seemed somehow *inferior* to that provided by questionnaire. A cursory review of the professional literature revealed the pervasiveness of the questionnaire in the characterisation of critical illness-related morbidity-an approach which now seemed rather anonymous and disembodied. The preliminary research questions emerging, finally, from these multiple perspectives comprised;

1. What is meant by “quality of life”?
2. What is quality of life “like” among survivors of prolonged critical illness?
3. What can generic questionnaires *really* tell us about the “quality” (or nature) of these patients’ lives following discharge home?
4. How can we more fully capture the patient experience in order to improve care and expedite recovery?

# Chapter 1: Is Intensive Care “worthwhile” among survivors of prolonged critical illness?

## 1.1 Introduction

Critical care intervention undoubtedly saves lives. The associated costs, however, are both diverse and extraordinary. A major criticism of the specialty is that its rapid development has not been accompanied by adequate evaluation of efficacy (Gunning and Rowan (1999), Eddleston et al (2000)). Experimental approaches or randomised controlled trials, widely regarded as the “gold standard” for the evaluation of healthcare intervention are rarely applicable or available in critical care, and evaluation is therefore heavily reliant upon *observational* approaches to measuring patient outcome (Gunning and Rowan, 1999). It is perhaps unsurprising that the “worthwhileness” of critical care intervention has repeatedly been called into question (Jennett, 1990).

The notion of worthwhileness is of inherent relevance and importance to the multiple stakeholders in a publicly funded critical care service. Questions remain, nonetheless, as to how that notion is measured, by whom, and for what intended purpose (Devlin et al, 2003). The notion of worthwhileness is predominantly reported in the critical care literatures in terms of *explicit*, readily measurable outcomes such as short-term mortality and ICU length of stay (as the primary determinant of cost). These measures, somewhat predictably, have been utilised in attempts to rationalise scarce critical care resource and contain cost under the rubric of distributive justice; “the greatest good for the greatest number”. Patients requiring prolonged critical care intervention, as this chapter will demonstrate, present a unique challenge to these notions.

It is increasingly acknowledged that existing approaches, which are largely organisationally, biomedically and societally defined, should be augmented by those which focus upon the concerns of *patients* (Fitzpatrick et al, 1998). As this chapter and indeed thesis will demonstrate, the “patient’s voice” is largely absent from contemporary debates around the worthwhileness of critical care intervention and is, to all intents and purposes, *implicitly* recognised. In this opening chapter, the scene is

set for the exploration of quality of life as means through which to examine and render more explicit its value from the patient's perspective.

In the first instance, a review of the origins and evolution of critical care is provided, followed by a critique of "explicit" and "implicit" approaches to estimations of worthwhileness "at the coalface" i.e. in routine clinical practice. As this critique will demonstrate, singularly explicit approaches invariably fail to take into account the complexity of the decision making processes, the ethical tensions therein, or the longer term "costs" associated with critical care intervention. Given the inherent relevance and importance of quality of life to its recipients, a case is made for its development as a more transparent means of evaluating its worth.

## **1.2 The origins of critical care**

Critical care is a relatively new clinical specialty whose origins are widely attributed to the anaesthetist Bjorn Ibsen and his novel management of patients with severe respiratory complications during the Danish poliomyelitis epidemic of 1952-3 (Trubuhovich, 2004). In the absence of effective treatment strategies, the vast majority (some 80%) of patients died. The transferral of techniques normally employed in the operating theatre (anaesthesia and mechanical ventilation) and their adoption by medical students and nursing personnel (given the vast numbers of individuals affected) is estimated to have saved 100 lives at Blegdam Hospital in the first 3 months of its use. Many survivors, however, suffered mild to disabling paralysis.

## **1.3 Contemporary critical care and the long-term patient group**

The provision of advanced respiratory and circulatory support to a patient group with high illness severity and high short-term mortality continues to underpin modern critical care practice. Monitoring and treatment modalities are increasingly technologically sophisticated and are delivered by a highly skilled multidisciplinary team including, traditionally, a 1:1 nurse-patient ratio. Increasing numbers of patients survive a critical illness to which they would previously have succumbed. Survival,

however, is associated with a broad spectrum of physical and psychosocial morbidity.

Both the origins of critical care and contemporary clinical practice exemplify the “Rule of Rescue”; the human proclivity to rescue individuals facing imminent and avoidable death with little thought to the costs or consequences (McKie and Richardson, 2003). Closely allied is the notion of the “technological imperative”; broadly understood as the pervasive, self-propagating nature of medical technology and “the impossibility of saying no” to life sustaining interventions (Kaufman et al, 2004). Their coalescence has resulted, paradoxically, in a growing population of patients with prolonged dependence upon life sustaining therapies.

“The patient arrives in intensive care critically ill and in crisis...intubated and mechanically ventilated. The time frame is in minutes, hours, or days: the focus is life or death. Days pass. The acute crisis wanes, but improvement stalls. Although no longer in immediate danger of death, the patient still requires mechanical ventilation to survive. Hopes for a rapid recovery fade. The time frame stretches into weeks...Care providers shift the focus of family discussions to long-term goals of care, quality of life, and hoped for best outcomes. A critical decision point is reached. Which direction to go toward? Should care shift to comfort care, perhaps a compassionate extubation (i.e. the facilitation of death)? Or should it continue to push ahead?” (Nierman, 2007: 1994)

Ethical and clinical concerns regarding the worthwhileness of prolonged critical care intervention are increasingly augmented by fiscal and resource limitations (Heyland et al, 1998) and by the implicit presence of “dispassionate others” (policy-makers, health economists and the like) at the margins of the decision making processes (Skowronski, 2001). As the following chapter will demonstrate, this patient group in particular utilise an extraordinary and disproportionate amount of scarce critical care and acute hospital resource (Heyland et al (1998), Chelluri et al (2003), Cox et al (2007)) and accrue the highest costs in terms of ICU bed days used (Hughes et al, 2003). Despite such investment, they also have an increased risk of both short and long-term mortality.

There are, in addition, significant “opportunity costs” for the wider patient population. The consequences of limited bed availability include, for example: clinician refusal of patients who might otherwise have benefited from critical care intervention (Metcalf et al, 1997), increased illness severity (Sinuff et al, 2004),

reduced ICU length of stay (Walther et al, 2001) and untimely or premature ICU discharge (Goldfrad and Rowan, 2000) among those admitted, all of which have demonstrable effects for the individuals concerned upon the probability of survival.

## **1.4 Critical care and distributive justice**

The rationing of critical care resource is therefore both commonplace and inevitable, as is the requirement to demonstrate its fair and judicious use. The principle of (utilitarian) distributive justice; broadly understood to mean “the greatest good for the greatest number” is pervasive throughout the burgeoning healthcare and critical care literatures and provides a useful framework within which to examine these processes. A review of the literature reveals (i) a seemingly intractable tension between “explicit” approaches and the “implicit” (i.e. value or judgement based) processes which would appear to prevail in routine clinical practice and (ii) the complex inter-relationship between the use of implicit approaches in the *allocation* (i.e. the initiation, limitation or withdrawal) of critical care resource and their use as a measure of *outcome*. In the following sections, a review of their applicability and limitations is provided.

### **1.4.1 Explicit approaches**

Explicit approaches are generally concerned with making clear the basis upon which decisions about resource allocation are made. Proponents argue that this approach may assuage the burden of responsibility upon clinicians and increase the consistency with which decisions are made (Coast, 2001). Prevalent strategies within the context of critical care in the United Kingdom comprise the use of prognostic models of short term mortality and economic analyses. The North American community has developed, in addition, clinical guidelines and protocols for the initiation and withdrawal of critical care intervention. Also relevant in the United States, based on respect for patient autonomy, is the statutory requirement to observe patient preferences for life-sustaining therapies.

### 1.4.1.1 Prognostic models (mortality)

#### 1.4.1.1.1 Short term mortality

Given the high illness severity among the critically ill, short-term mortality (i.e. ICU, hospital and the 28 day “all cause” mortality traditionally reported in clinical trials) is an important measure of outcome among this patient group. Prognostication is largely based upon illness severity scoring on ICU admission, and early models were developed exclusively for the purposes of comparison and evaluation. Comparison of mortality rates, for example, between and within patient groups, between “predicted” and actual mortality rates or across health care organisations provides a useful benchmark against which to evaluate the efficacy of interventional and organisational strategies.

Subsequent models have been promoted as an adjunct to clinical decision making i.e. in the prospective stratification of patients by risk of death in order that scarce and expensive ICU resource might be more “efficaciously distributed” i.e. withheld or withdrawn from those identified as least likely to survive (Schultz et al, 2006). The limitations of existing models are well recognised, however, and include: the generation of *probabilities* (which often fail to take into account the unpredictable and complex nature of the critical illness trajectory) (Gunning and Rowan, 1999) and concerns around the sensitivity, specificity and generalisability of data among both specific sub-sets of the population (Hyzy, 1995) and in relation to individual patient care (Rogers and Fuller, 1994).

The utility of prognostic models among patients requiring *prolonged* critical care intervention is particularly problematic, given that the predictive value of illness severity on ICU admission decreases significantly beyond 7 days (Suistomaa et al, 2002). Attempts to modify these tools, in addition, for the *prospective identification* of patients requiring prolonged critical care intervention (and by inference, the more “efficacious distribution” of resource) have met with limited success (Wong et al (1999), Hughes et al (2001), Estenssoro et al (2005)). The utility of these models, in summary, has yet to be determined and cannot be used in isolation in the clinical decision-making processes (Gunning and Rowan, 1999).

#### 1.4.1.1.2 Long-term mortality

Until very recently, short-term survival was widely accepted as an appropriate surrogate of both clinical effect and long-term outcome. It is increasingly recognised, however, that the short-term effects of critical care intervention may result in negligible or even harmful long-term effects (Angus et al, 2003). There is growing consensus within the critical care community regarding the importance of long-term mortality as an important patient-centred measure of worthwhileness (Williams et al (2004), Marshall et al (2005)). In contrast to other patient groups requiring critical care intervention (e.g. following cardiac surgery), however, this data is not routinely collected.

While there is an evolving consensus on the optimum duration of follow up (Angus et al, 2003), research has tended to focus upon specific sub-sets of the population e.g. survivors of sepsis and acute respiratory distress disorder (ARDS), and its generalisability to the wider patient population is therefore uncertain. A recent systematic review of long-term mortality among survivors of critical illness identified discrepancies in the design, methodology and reporting of existing studies, with implications for their interpretation and comparison (Williams et al, 2005). Comparisons of long-term mortality, moreover, are traditionally made with reference to an age and sex-matched general population; an approach which is perhaps inappropriate, given the increased prevalence of pre-existing morbidity among the critically ill (Wehler et al, 2003).

Methodological issues notwithstanding, there is nonetheless evidence to suggest that survivors of *prolonged* critical illness experience higher short-term mortality than the wider patient population (Heyland et al (1998), Wong et al (1999), Friedrich et al (2006), Hartl et al (2007)) and an increased risk of death in comparison with age and sex matched general populations for many years following hospital discharge (Flaaten and Kvale (2001), Wright et al (2003), Williams et al (2008)), raising important questions around the value of intervention among this patient group. The *quality* of survival, however, is as important as its duration, and long-term mortality alone is insufficient as a measure of patient-centred outcome.

#### 1.4.1.2 Economic analyses (cost-effectiveness)

Economic evaluations are commonplace in relation to many aspects of healthcare intervention and are widely regarded as rational basis for the prioritisation, allocation and optimisation of resource, based on the relative “worth” of alternative treatments or interventions. The most widely used index of cost-effectiveness integrates both the quantity and quality of life years gained from healthcare intervention into a single weighted index; the Quality Adjusted Life Year (QALY). This approach facilitates the direct comparison, in economic terms, of interventions that may differ in their effects upon life expectancy, health and HRQoL (Rapley, 2007).

Economic analyses are likely to feature more prominently in estimations of “worthwhileness” among the critically ill, and among the long term patient group in particular given, as previously described, that they accrue the highest costs in terms of bed days utilised. Their widespread use among the North American critical care community is attributed to (i) a predominantly private healthcare system and (ii) the introduction of Diagnosis Related Groups, whereby healthcare institutions are reimbursed on the basis of *diagnosis* as opposed to the nature or amount of resource dedicated to individual patients. The latter resulted in substantial deficits in critical care budgets, particularly in relation to patients with a *prolonged* ICU stay (Seneff et al, 2000).

Economic analyses of critical care intervention are currently rare in the United Kingdom. It is entirely feasible that recent statutory initiatives in England for the reimbursement and commissioning of NHS critical care services (“Payment by Results”, DoH, 2003) may result in greater economic scrutiny, given the explicit recognition that

“Patients with a long length of stay may represent a significant financial risk to the organisation meeting the costs” (DoH, 2003: 3).

Methodologically, however, little consensus currently exists on the most appropriate means of calculating the complex and diverse costs associated with critical care intervention with, presumably, implications for robust derivations of cost-effectiveness (Pines et al, 2002). The central imposition of a cost-effectiveness threshold of £30,000 per QALY gained is also noteworthy, and is perhaps untenable

within the context of critical care; a specialty known to attract the highest health care costs.

“Excellent” cost effectiveness has nonetheless been reported among an *unselected* critically ill patient group (Ridley and Morris, 2007), although wide variation would appear to exist in relation to age, illness severity on admission and prognosis (Hamel et al (2001), Cox et al (2007)). The reported cost effectiveness of critical care intervention among patients requiring *prolonged* mechanical ventilation is, perhaps unsurprisingly, considerably less, but has been reported, in turn, as both “reasonable” (Heyland et al, 1998) and “excessive” (Cox et al, 2007).

While conceptually appealing, in as much as that important patient-centred outcomes (i.e. long term survival and quality of life) are taken into account, the derivation of QALYs has attracted considerable criticism. The “dehumanising” imposition of detached values upon intrinsically ethical questions may result, for example, in the denial of effective (and by implication, prolonged) treatment on the basis of cost (Lupton (1997), Cox et al (2007)). Their rigid application, moreover, may result in the inequitable rationalisation of treatment to patient groups (e.g. the elderly, or those with high short term mortality) who may simply not accrue sufficient life years to warrant expensive healthcare intervention (Ebrahim, 1995).

An inescapable caveat to cost effectiveness, in addition, is its incompatibility with the “Rule of Rescue” previously described. Its application in the face of imminent and avoidable death is considered to be both socially and morally repugnant (Jonsen, 1986) and if intervention within this context is cost effective, it is arguably “per accidens”, not *because* it is cost effective (McKie and Richardson, 2003). The cost-effectiveness agenda, in summary, is both complex and contentious.

#### **1.4.1.3 Guidelines and protocols**

Institutional approaches to the rationing of critical care resource in the United States include the development of consensus statements by leading professional bodies and the development of organisational protocols for the initiation, withdrawal and withholding of treatment (Osborne and Evans, 1994). There is evidence to suggest, however, that these are rarely adhered to in clinical practice (Sinuff et al (2004),

Garrouste-Orgeas et al (2009)). Despite some endorsement of the requirement for clinical guidelines in relation specifically to the *withdrawal* of life-sustaining therapy in the United Kingdom, this approach has all but been rejected (Wunsch et al, 2005) and greater emphasis is currently placed on the judgement of individual clinicians.

#### **1.4.1.4 Advance directives**

Also relevant in the United States, since the passage of the Patient Self Determination Act (1990) is the legal requirement to observe patients' "advance directives". Advance directives are widely cited as a means of promoting patient autonomy and are generally understood to describe an individual's pre-determined preferences for (and right to refuse) life-sustaining intervention in the event of a loss of decision-making capacity. Individuals may also designate an advocate or proxy to make health care decisions on his or her behalf under these circumstances.

Adherence to advance directives may, in the absence of other objections, prevent significant and unnecessary suffering, given that the majority of deaths among the critically ill occur following *active* limitation in life-sustaining therapies (Sprung et al, 2003), often late in the clinical course (Camhi et al, 2009). Advance directives are rarely available in practice, however, (Johnson et al, 1995) and where present appear to exert limited influence in the clinical decision-making processes (Goodman et al, 1998). Attempts to broker legislation with regard to advance directives or "living wills" have been vetoed in the United Kingdom.

Preference-based studies have tended to be anticipatory in nature (as opposed to "real time"), however, or have focused upon end of life (i.e. palliative) care, as opposed to preferences for the initiation, continuation or withdrawal of critical care intervention. There are few such studies among the critically ill, and fewer still among those surviving a prolonged illness. One such study nonetheless reports an overwhelming preference for prolonged mechanical ventilation (of  $\geq 7$  days' duration) among those surveyed (Guentner et al, 2005). While likely to be of limited utility in routine clinical practice, given the extant fiscal, resource and ethical constraints associated with this patient group, preference-based studies among survivors may provide

invaluable insights into the experience of prolonged critical illness and constitute a powerful patient-centred measure of worthwhileness.

This brief review, in summary, reveals both the limited availability and applicability of explicit approaches to decision-making in clinical practice, and their frequent augmentation by “softer” implicit approaches.

### **1.4.2 Implicit approaches**

“Soft” (i.e. highly subjective, judgement-based) notions of worthwhileness are said to offer greater flexibility under conditions of uncertainty, and are more sensitive to both the complexity of medical decision-making and to the perceived needs of patients (Mechanic, 1995). Implicit approaches within the context of the rationalisation of resource include: clinician estimations of survival, perceptions of medical futility (Cook et al, 2003) and perceived prior and projected (health-related) quality of life (HRQoL) (Faber-Langendoen (1994), Cook et al (1995), Vincent et al (1999)). The latter, importantly, is among *the most frequently cited rationale* for withholding, limiting or withdrawing critical care resource (Vincent et al, 1999) and therefore warrants closer inspection.

#### **1.4.2.1 (Health-related) Quality of life (HRQoL)**

Due to the emergency nature of critical illness, information on patients’ pre-admission quality of life is rarely available. While there is some empirical support for the hypothesised relationship between prior HRQoL and *mortality* among the critically ill using standardised questionnaires (Rivera-Fernandez et al (2001), Iribarren-Diarasari et al (2009)), the relationship between prior and subsequent HRQoL is less well understood.

Experience suggests that clinician estimations are generally derived from evidence of pre-existing morbidity and information provided by family members, close friends and general practitioners (“proxies”). Considerable disagreement, as later work will demonstrate, exists between clinicians, lay and patient populations with regard to “what is meant” by quality of life (Mozes et al, 1999), estimations of pre-existing disease severity and its impact upon HRQoL (Kwoh et al, 1999) and the relative

importance of various aspects of experience (including health) to HRQoL overall (Rothwell et al, 1997). Neither clinicians nor proxies, in short, can reliably estimate prior quality of life (Yip et al (2001), Rogers et al (2004)) or predict subsequent quality of life (Rocker et al, 2004).

HRQoL is rendered rather more “explicit”, importantly, by its use as a measure of *outcome* and is widely reported as the “ultimate” measure of worthwhileness among the critical care literatures (Angus et al (2003), Williams et al (2005)). It has been identified as a research priority among the critical care community (Angus et al (2002), Dowdy et al (2005)) and among patient groups, is as *important as survival* (Pearlman et al, 2000).

HRQoL is particularly pertinent given that survival is associated with a significant burden of physical and psychosocial morbidity (Eddleston et al (2000), Herridge (2002)), occurring largely irrespective of the admitting disease, and often super-imposed upon pre-existing conditions. The symptom burden associated with survival is often extraordinary resulting, in extreme cases, in states “worse than death” (Patrick, 1994). An evolving body of literature suggests that recovery may be both protracted and incomplete, with often considerable and prolonged effects upon everyday life and perceived HRQoL.

An impressive body of work has been developed around HRQoL and recovery following critical illness using, almost exclusively, standardised HRQoL questionnaires. Serious concerns have been raised among the wider healthcare literatures, however, about the extent to which these measures reflect the experiences and perspectives of patients. These concerns have received limited attention among the critical care community. This thesis deals with the conceptual, epistemological and methodological issues which currently militate against their use as a truly patient centred measure of worthwhileness among survivors of critical illness.

## **1.5 Discussion**

As this chapter has demonstrated, questions of “worth” cannot be addressed by explicit approaches and/or “technical fixes” alone, irrespective of their alleged transparency or subsequent attempts to improve their methodological rigour. Perhaps

more importantly, explicit approaches have come under increasing scrutiny from lay and patient audiences. The Multiple Sclerosis Society, for example, has expressed serious concern regarding the National Institute of Clinical Excellence's (NICE) unfavourable appraisal of  $\beta$ -interferon, despite empirical evidence of its efficacy in the reduction of relapse.

The concerns raised are potentially applicable to the worthwhileness of many aspects of healthcare (including critical care) intervention and comprise; an overly narrow focus upon costs to the NHS, the inadequacy of the QALY as a measure of health gain, the inappropriateness of the cost-effectiveness threshold, an overly conservative view of long-term benefits and the failure to capture "the patient experience" in relation to illness and treatment (Devlin et al, 2003). Understanding, addressing and reconciling conflicting views is likely to become increasingly important, given NICE's commitment to increase lay and patient involvement in healthcare decision-making through "social judgement" processes (Devlin et al, 2003).

Implicit approaches, while ostensibly sensitive to the needs and perspectives of patients are, in turn, likely to attract similar scrutiny, given that they are generally held to be arbitrary, inequitable and uninformed (Mechanic, 1995). "Prognostic pessimism" (the shortfall in clinician estimations of survival versus actual survival), for example, has recently been described in the management of particular sub-groups of the critically ill patient population, raising concerns around "soft" or conspicuous paternalism (Wildman et al, 2007). The issues, as Mechanic (1997) suggests, are "incredibly difficult".

"Thus, we proceed better by honestly recognizing their complexity...the imperfections of our tools, and the uncertainty of medical knowledge and treatment. This requires continuing engagement, flexibility, and humility. The fitting response is to muddle through, changing course as knowledge and experience guide us. If we are particularly thoughtful and lucky, perhaps we will be able to say that we have "muddled through elegantly." (Mechanic, 1997: 91)

A rather more pragmatic approach, however, is to address the issues by

"...strengthening both the information base to support decisions and the institutional framework in which decisions are taken. The contribution both of experts and of lay people is needed to inform decision-making, and the processes adopted need to allow for this as well as being transparent and accountable." (Ham and Coulter, 2001: 163)

This thesis examines both the “imperfections” of existing HRQoL measures and advocates the engagement of patients in their development, validation and application as a means of informing and strengthening the existing information base for the decision-making processes. The introduction of the “patient’s voice”, as later work will show, has implications not only for HRQoL as an evaluative measure, but also for the development of interventions to ensure that our interventions are “worth the cost”

## Chapter 2: A Lothian-based prevalence study of prolonged critical illness

### 2.1 Introduction

The requirement for robust measures of worthwhileness is ever more pressing, given that the demand for critical care services is rapidly increasing. SICSAG report an almost year-on-year increase in critical care admissions between 1996 and 2006 (appendix 1); a trend which is reflected rather dramatically at local level (appendix 2). The increased demand for critical care provision is largely attributed to the ageing of the “baby boomer” generation and the rise in concomitant morbidity (Angus et al (2000), Needham et al (2005)). The *long-term patient group* is likely to increase in number, given that advanced age (Friedrich et al (2006), Bigatello et al (2007)) and concomitant morbidity (Friedrich et al (2006) have been associated with critical illness and the prolongation of mechanical ventilation .

Data from North American studies suggest that this patient group is already increasingly in number and, importantly, in excess of existing critical care resource (Angus et al (2000), Zilberberg et al (2008)). The implications for critical care provision are likely to be keenly felt both locally and across the United Kingdom, given the historically “ad hoc” (DoH, 2000) and “under-resourced” development of existing services (Edbrooke et al, 1999).

Data are not routinely collected specific to this patient group, however, and very little is subsequently known about their demographic and clinical characteristics or the current and future resource implications. The purpose of this chapter is to provide a descriptive review of demographic, clinical and organisational (i.e. resource-related) data among this patient group, thereby “fleshing out” the notion of worthwhileness as previously described from a local perspective.

### 2.2 Defining “prolonged critical illness”

The requirement for mechanical ventilation is widely held to be the hallmark or defining characteristic of critical illness. There is little consensus among the critical care community, however, regarding the definition of *prolonged* mechanical

ventilation. Among the European literature, definitions range, for example, between  $\geq 48$  hours (Chelluri et al (2004)) and  $\geq 14$  days (Combes et al (2003), Euteneuer et al (2006)). Among the North American literatures, widely adopted definitions comprise tracheostomy and/or mechanical ventilation for at least 4 days (Cox et al, 2007) or, alternatively,  $\geq 21$  day's duration for  $\geq 6$  hours a day (MacIntyre et al, 2005). The latter is based largely upon the mean duration of ventilation among those discharged to dedicated long-term or tertiary care settings (Scheinhorn et al, 2007), few of which exist in the United Kingdom.

A number of papers have nonetheless identified  $\geq 14$  day's ICU *stay* as a marker of prolongation (Fakhry et al (1996), Heyland et al (1998), Wong et al (1999), Teno et al (2000)). Given its clinical relevance as a point at which "family members and clinicians begin to wonder about the "worthwhileness" of continuing care" (Heyland et al, 1998: 193), 14 days' mechanical ventilation was adopted as a marker of prolonged critical illness for the purposes of this study.

### **2.3 Data collection**

Screening and active recruitment began on the 1<sup>st</sup> of June, 2006. In order to recruit survivors at up to six months following ICU discharge (in line with existing professional recommendations), data pertaining to patients requiring  $\geq 14$  days' mechanical ventilation were collected from the 1<sup>st</sup> of January, 2006 from each of the Wardwatcher® databases at RIE, WGH and SJH. The study database was closed upon recruitment of the 20<sup>th</sup> patient (21.11.07), extending the data collection period over approximately 23 months. The following demographic, clinical and resource-related data were collected.

Demographic variables comprised age and gender. Clinical variables comprised: illness severity score on ICU admission (APACHE II); duration of mechanical ventilation; length of ICU stay and ICU outcome (survivor, non-survivor, transfer to other ICU or acute hospital setting). Data was also collected on ICU discharge destination (other ICU, HDU or ward with the acute hospital setting), additional hospital (i.e. ward) length of stay, hospital outcome (survivor, non-survivor, transfer to other acute hospital setting) and hospital discharge destination (home,

rehabilitation, convalescence or other healthcare setting). A summary and description of the data fields and attendant issues are summarised in appendix 3.

In order to determine the “representativeness” of the study cohort, the dataset was replicated among patients requiring  $\geq 14$  days’ mechanical ventilation over a 5 year period (1.1.2003-31.12.2007). Data were collected on a total of 708 patients.

## **2.4 Statistical analyses**

Data were entered into a study database, and descriptive statistical analyses were performed using SPSS® version 14. Given the abnormal distribution of the data, summary statistics are presented as medians (1<sup>st</sup>, 3<sup>rd</sup> interquartile range) as opposed to means. Differences between survivors and non-survivors were tested for using the Mann Whitney U test and a two-tailed independent t-test, where appropriate. Associations between demographic and clinical variables and mortality were tested for using the Chi square test. A p value of  $<0.05$  was considered to be significant.

## **2.5 Findings**

The demographic, clinical and resource-related characteristics of the study cohort (n=20) and the Lothian long-term patient cohort from whom they were recruited (n=222) are summarised in appendix 4. Those of the 5 year cohort are summarised in appendix 5. Given the robustness and comparative wealth of data provided by a larger dataset, the following data are derived from the latter unless otherwise stated. The “representativeness” of the study cohort is subsequently discussed.

### **2.5.1 Number and proportion of patients with a prolonged critical illness**

The number of patients experiencing prolonged critical illness remained relatively static between 2003 and 2007 inclusive; 133, 139, 157, 139 and 140 patients respectively. Based upon the *total number of admissions* to RIE, WGH and SJH in 2007 (n=2122, derived from SICSAG (2008) data), this equates to 7% of patients annually. Based upon the annual number of patients *requiring mechanical ventilation* at any point during their ICU stay at these three centres in 2007 (n=1245, derived

from SICSAG (2008) data), 11% of all ventilated patients require mechanical ventilation of 14 or more day's duration.

## **2.5.2 Demography and clinical characteristics**

### **2.5.2.1 Age, gender and illness severity**

The median age of patients was 62 (47, 72) years of age, 58% of whom were male. The median APACHE II score was 21 (16, 25), indicating high illness severity on ICU admission.

### **2.5.2.2 Duration of ventilation and ICU length of stay**

The median length of ventilation was 21 (17, 29) days and the median length of ICU stay was 25 (19, 34) days. This patient group utilised a mean 3498 ICU bed days annually, equivalent to 9.6 fully occupied ICU beds across Lothian. Patients experiencing prolonged critical illness, in short, utilise an extraordinary and disproportionate amount of scarce ICU resource.

## **2.5.3 ICU mortality**

An ICU mortality rate of 22% has been reported among the Scottish patient population (SICSAG, 2008) and is comparable with the 20% reported in a large UK retrospective audit (Harrison et al, 2004). While the mortality rate among *ventilated* patients has not been reported, it is widely accepted that these patients experience a higher mortality rate, largely attributable to higher illness severity (Antonelli et al, 1998). The existing literature suggests that patients requiring *prolonged* mechanical ventilation experience an additional increased risk of death (Hughes et al (2001) and higher ICU mortality rates (Heyland et al (1998), Wong et al (1999), Friedrich et al (2006), Hartl et al (2007)) than the wider patient population. An ICU mortality rate of 28% among the 5 year cohort supports this observation.

There were important differences between ICU survivors and ICU non-survivors (appendix 6). ICU survivors were significantly younger with a median age of 59 (46, 69) years compared with non-ICU survivors, who had a median age of 67 (57, 75) years. While differences in median illness severity scores were *statistically*

significant; 20 (15, 24) among survivors and 22 (18, 27) among non-survivors, they were not *clinically* significant. There were, however, statistically and clinically significant differences between ICU survivors and ICU non-survivors in terms of ICU length of stay. Survivors utilised a median 27 (20, 36) ICU bed days, whereas ICU non-survivors utilised a median 21 (17, 30) ICU bed days. ICU survivors, in short, were younger and utilised significantly more ICU resource than ICU-non survivors.

#### **2.5.4 ICU discharge destination**

ICU discharge destination is rarely reported in descriptive or epidemiological studies. There are, nonetheless, important implications for the local patient population in terms of rehabilitative provision and long-term outcomes. Unlike other critically ill patient groups in the United Kingdom for whom a dedicated “care pathway” exists (e.g. those following cardiothoracic surgery or neurological intervention), survivors among the “general” ICU patient population are dispersed widely throughout the hospital. Following ICU discharge, parent specialties (those relevant to the admitting disease process) generally assume/resume responsibility for the care of survivors. Approximately 50% of ICU survivors at RIE are discharged to either a General Surgery or Respiratory Medicine ward; the remainder are dispersed to a total of 18 wards throughout the hospital.

Clinical experience in a ward-based follow-up service (and indeed, later work) implicates the widespread dispersion of patients in the provision of fragmented and often specialty (or “organ”) specific care with limited recognisance of the significant physical and psychological morbidity associated with and often specific to critical illness. These are rarely screened for or addressed within the general ward setting. Despite often profound debilitation, survivors currently receive “routine” rehabilitative provision, effectively competing with less severely ill patient groups (e.g. elective surgery patients) for scarce resource with implications for recovery and long-term outcomes.

### **2.5.5 Acute hospital length of stay**

Survivors spent a median 20 (10, 38) additional days in the acute healthcare setting; representing a mean 3037 additional hospital bed days annually and 8 fully occupied hospital beds. Survivors of prolonged critical illness, in short, consume an extraordinary amount of additional hospital resource and exert significant pressure upon the acute health care setting

### **2.5.6 Additional hospital mortality**

SICSAG (2008) report an additional hospital mortality rate of 9% among ICU survivors, which is consistent with the UK-wide retrospective audit previously described (Harrison et al, 2004). Additional hospital mortality among ICU survivors of *prolonged* critical illness is unknown. These data reveal an additional hospital mortality rate of 11%. Combined ICU and hospital mortality (39%) is comparatively high among this patient group. A significant proportion and number of patients, however, survive to hospital discharge.

There were important differences between hospital survivors and hospital non-survivors (appendix 7). Hospital survivors were significantly younger with a median age of 58 (46, 69) years, compared with non-ICU survivors who had a median age of 67 (57, 75) years. While differences in median illness severity scores were *statistically* significant; 20 (16, 25) among survivors and 22 (18, 26) among non-survivors, they were not *clinically* significant. There were, however, statistically and clinically significant differences between hospital survivors and hospital non-survivors in terms of length of additional hospital stay. Hospital survivors utilised a median 21 (12, 38) additional hospital bed days, whereas hospital non-survivors utilised a median 15 (6, 40) additional hospital bed days. Hospital survivors, in summary, were younger, and utilised significantly more acute hospital resource, with implications for rehabilitative provision and return to work.

### **2.5.7 Crude ICU and acute hospital costs**

Crude costs were calculated using published estimates and mean lengths of ICU and hospital stay. Using £1315 as a conservative estimate of the cost of an ICU bed day (NHS Reference Costs, 2006), the annual cost of ICU care among this Lothian

patient population totals approximately £4.6 million. Using £275 as a conservative estimate of the cost of a general ward bed day (NHS Reference Costs, 2006), the annual cost of ward care totals approximately £835,000. This brings the annual cost of care for this patient group alone to over £5.3 million.

### **2.5.8 Hospital discharge destination**

Hospital discharge destination is infrequently reported in epidemiological or interventional studies. There are, nonetheless, implications for recovery and long-term outcomes among this patient group. Only 16% of survivors were discharged to rehabilitative or convalescence settings, while the majority (some 55%) were discharged directly home. This compares somewhat unfavourably with other critically ill patient groups (e.g. those following cardiothoracic surgery or neurological intervention) for whom there are dedicated local rehabilitative facilities. A ward stay of  $\geq 5$  days post cardiac surgery at RIE, for example, “automatically” renders patients eligible for formal rehabilitation. Given, as later work will demonstrate, the significant symptom burden of prolonged critical illness, it is likely that this patient group would derive significant benefit from additional rehabilitative input.

### **2.5.9 “Long-term” survival**

The limited existing literature suggests that survival carries a risk of death in excess of that reported among an age and sex matched general population. Among an *unselected* cohort of patients admitted to an ICU in Glasgow, for example, survivors experienced an increased risk of death of up to 3 times that of an age and sex matched general population for up to 4 years following hospital admission (Wright et al, 2003). This excess mortality has been reported in a number of European studies (Niskaanen et al (1996), Flaaten and Kvale (2001), Kaarlola et al (2006)), although there appears to be an increased risk of death in different patient populations for variable lengths of time (Kaarlola et al (2006), Kvale (2007)). It is not currently known whether survivors of *prolonged* critical illness experience an excess mortality greater than a “normative” population of ICU survivors. It was not possible, however, to determine long term mortality among the study cohort.

## **2.6 The “representativeness” of the study population**

The survivors who participated in “the study proper” were largely representative of the wider long-term patient population in terms of age and illness severity. The median lengths of ventilation and ICU stay among participants were 28 (20, 40) and 35 (24, 47) days respectively, however; significantly longer than the cohort from whom they were recruited, with potential implications for the prevalence and severity of critical illness-related morbidity.

The vast majority of participants were recruited from RIE (n=17), the remainder (n=3) from WGH. There were statistically significant differences in the median age, illness severity, duration of ventilation and length of ICU stay across settings among those admitted (appendix 5), presumably due to differences in case mix.

## **2.7 Discussion**

Survivors of prolonged critical illness consume an extraordinary and disproportionate amount of scarce ICU and hospital resource, yet have an increased mortality rate (both short and probably long-term) raising important questions, as described in the opening chapter, around traditional (i.e. explicit) notions of worthwhileness among this patient group. Given, however, that these notions are increasingly augmented by the prevalence of morbidity and the HRQoL of survivors, the following chapters examine the ability of existing measures to reflect their experiences and concerns.

# Chapter 3: The Literature Review

## Section One

### 3.1 Introduction

Illness narratives, as a means of accessing the “patient’s voice” appear to have declined with the professionalisation of medicine and advances in medical technology (Clark and Mishler, 1992). In his widely acclaimed critique of the clinical encounter, Mishler (1984) pitches “the voice of medicine”, with its technical and scientific assumptions against the “voice of the lifeworld” as expressed by patients. Medicine’s inherent legitimacy is seen to dominate the clinical encounter and structure the nature of the communication by suppressing patients’ unique and highly contextualised accounts of their symptoms and experiences (Barry et al, 2001), resulting, potentially, in ineffective and “inhumane” care (Mishler, 1984).

“What a lot of valuable time would be saved if our patients could be taught that all we want to hear from them is an account of their symptoms, as concise as possible and chronological!” (Cassidy, 1938: 177)

The decontextualising nature of the questionnaire resembles, in many ways, the voice of medicine in Mishler’s (1985) “characteristic” clinical exchange; the structured elicitation of symptoms, response and additional elicitation. Jylha (1994), for example, notes the

“...implicit conflict between the logic of the survey, which requires unambiguous and absolute answers to often very abstract questions and the logic of everyday conversation, which is characterised by contextualisation, comparisons, accounts and narratives” (Jylha, 1994: 988).

Questionnaires are gaining an unprecedented prominence in many aspects of health services research, development and policy, with the corollary that “the patient’s voice” may become increasingly marginalised. The purpose of this chapter, accordingly, is a review of the use of HRQoL measures in health services and critical care outcomes research, and a critique of the extent to which the patient’s voice can and ought to be incorporated in such measures.

The complexity and diversity of the HRQoL literature precludes all but a selective review. This review is divided into two main sections. The first explores and expands upon the research questions alluded to in the opening chapters to include the following:

1. Where did the notion of (health-related) “quality of life” come from?
2. How is HRQoL operationalised in contemporary health services policy, practice and research?
3. How is HRQoL utilised in contemporary health services policy, practice and research?
4. To what extent are lay and patient perspectives incorporated in the development and validation of widely used measures?
5. What are the implications of the inclusion/exclusion of lay and patient perspectives in the development and validation of HRQoL measures?

In the second section, I outline the operationalisation of HRQoL as an outcome measure in critical care research with specific reference to professionally endorsed measures, existing recommendations and contemporary practice. Given the heterogeneity of the patient population, this review subsequently examines the current state of knowledge with reference to a relatively homogeneous and particularly well studied sub group of the patient population (survivors of ARDS), in an attempt to address the following questions:

1. How is HRQoL operationalised in critical care outcomes research?
2. To what extent have professionally endorsed generic measures been validated for use amongst survivors of critical illness?
3. What is known about HRQoL among survivors of (prolonged) critical illness?
4. What can existing approaches tell us about the nature of the relationship between critical illness-related morbidity and HRQoL?

This review is both lengthy and complex, but it provides a critical basis upon which the methodological approach and central themes of this thesis are constructed. Given the breadth of innovation in the development and validation of increasingly “patient-centred” instruments in other areas of HRQoL research, this review demonstrates that critical care research has adopted an overly narrow and restrictive approach to its measurement, yielding clinically relevant, yet somewhat limited, insights into patterns of critical illness related morbidity, its putative contribution to dimensions of experience and HRQoL overall.

I conclude that the absence of a clear conceptual or theoretical basis for HRQoL measurement in health services research is largely responsible for this state of affairs, and that the exclusion of the patient’s voice is increasingly less tenable. Incorporation of the latter, as this thesis will demonstrate, affords significant opportunity for both the patient-centred evaluation of critical care intervention and the development of appropriate and responsive interventional strategies.

## **3.2 The origins of (health-related) quality of life**

### **3.2.1 Quality of life**

The notion of quality of life has its roots in classical Greek philosophy. The Aristotelian notion of “the good life”, for example, was derived largely from “virtuous activity” and associated with pleasure, honour or wealth. Modern conceptualisations of quality of life, however, have undergone considerable permutations and are said to originate from the “social indicators movement” of the United States in the 1960’s, with its explicit focus upon the material wealth of nations (Rapley, 2003). The former US President Lydon Johnson is credited with the *individualisation* of the notion, in his assertion that social progress could not be measured in terms of material wealth, but in terms of the quality of citizens’ lives.

Two prominent and divergent conceptualisations emerged in the 1970’s. The “Scandinavian” model placed considerable emphasis upon “the good society” and welfare policy, while the “American” model emphasised subjective well-being, life satisfaction and happiness (Rapley, 2003). Adoption of the latter in the UK is

attributed to Thatcherite policies in the 1980's, with the inception of the market economy, consumerism and the "quality revolution" (Rapley, 2003). Buoyed by its intuitive and popular appeal (due largely to its positive connotations), quality of life has become firmly entrenched as an individual level construct.

### **3.2.2 Health-related quality of life (HRQoL)**

The inclusion of a simple item assessing the general health status of respondents in questionnaire-based surveys conducted towards the end of World War II is cited as among the earliest attempts to gauge subjective perceptions of health or well-being among the general public (Armstrong et al, 2007). A model for the elicitation of *symptoms* is attributable to psychiatry, however, in the development of personality-based questionnaires and screening tools in the post-war years to identify psychological neuroses. These measures, importantly, mimicked the psychiatric interview and diagnostic process.

The emergence of formal symptom "checklists" for non-psychiatric disorders quickly ensued, facilitating both comparative studies across patient groups and population-based screening. Despite the assertion that early instruments were derived from a pragmatic attempt to capture symptoms with little attention to what quality of life actually meant (Armstrong et al, 2007), their elicitation by questionnaire signalled a radical realignment from more objective measures (such as clinical examination or laboratory tests) to the patient's subjective experience (Sullivan, 2003). Increasing recognition of the insensitivity of existing pathophysiological measures to important treatment effects or salient differences between patients in terms of disease severity, impairment or disability underlined the significance of subjective experience as a useful adjunct to the traditional "clinical gaze" (Armstrong et al, 2007).

An evolving emphasis upon the measurement in of physical function or the ability to perform the activities of daily living (ADLs) provided, in turn, a novel means of illness categorisation; thus, an inability to climb stairs became as much a symptom of arthritis as pain (Armstrong et al, 2007). Roughly coincidental with the World Health Organisation's (1948) definition of health as "a complete state of physical, mental and social well-being" was the emergence of global rating scales to include these ever more "distal symptoms" (McHorney et al, 1997). The subsequent inclusion of

social participation and mental health in multi-dimensional scales formed the classic four-dimensional format of contemporary measures (Armstrong et al, 2007).

The coalescence of an “epidemiological transition” in the late 1950’s saw a shift in emphasis upon chronic and degenerative conditions, and increasing recognition of the insensitivity of mortality to health gains as a consequence of medical intervention, and variation in health status. Sociological enquiry subsequently began to explore lay conceptualisations of health and illness, forcing an epistemological shift in medicine, with an evolving focus upon patients’ *lives* as opposed to patients’ *bodies* (Sullivan, 2003), and simultaneously marking an era in which the “medicalisation” of everyday life began in earnest.

The term “health-related” QOL emerged in the 1960’s in order to distinguish outcomes relevant to health research from earlier sociological research on subjective well-being and life satisfaction in healthy general populations (Smith et al, 1999). This distinction appears to have been drawn without, it has been argued, adequate recognisance of the complex inter-relationship between “health” and the as yet ill defined “quality of life” (Hunt and Leplege, 1997). Nonetheless, the concept first appeared in Elkington’s (1966) editorial in the *Annals of Internal Medicine*, “Medicine and the Quality of Life” (Sullivan, 2003). In his impressively germane acknowledgement of the “social, ethical and philosophical quandaries” thrown up by advances in medical technology, Elkington (1966) skilfully outlines the tensions between (health-related) quality of life as an inherently individualistic notion, the nature of the patient-physician relationship, and the contentious mediatory role of medicine in a “just” society.

The 1970’s saw a proliferation of generic health status measures, funded largely by statutory bodies in the United States. The Quality Adjusted Life Year (QALY) and preference-based measures were developed in the late 1970’s for use in health care planning, priority setting and resource allocation (McHorney, 1999). The psychometric validation of instruments advanced considerably in the 1980’s, in line with widespread interest in the use of HRQoL as both an individual and population level construct, and the following decade marked an exponential growth in the number of publications reporting upon the HRQoL of patient populations (Moons et

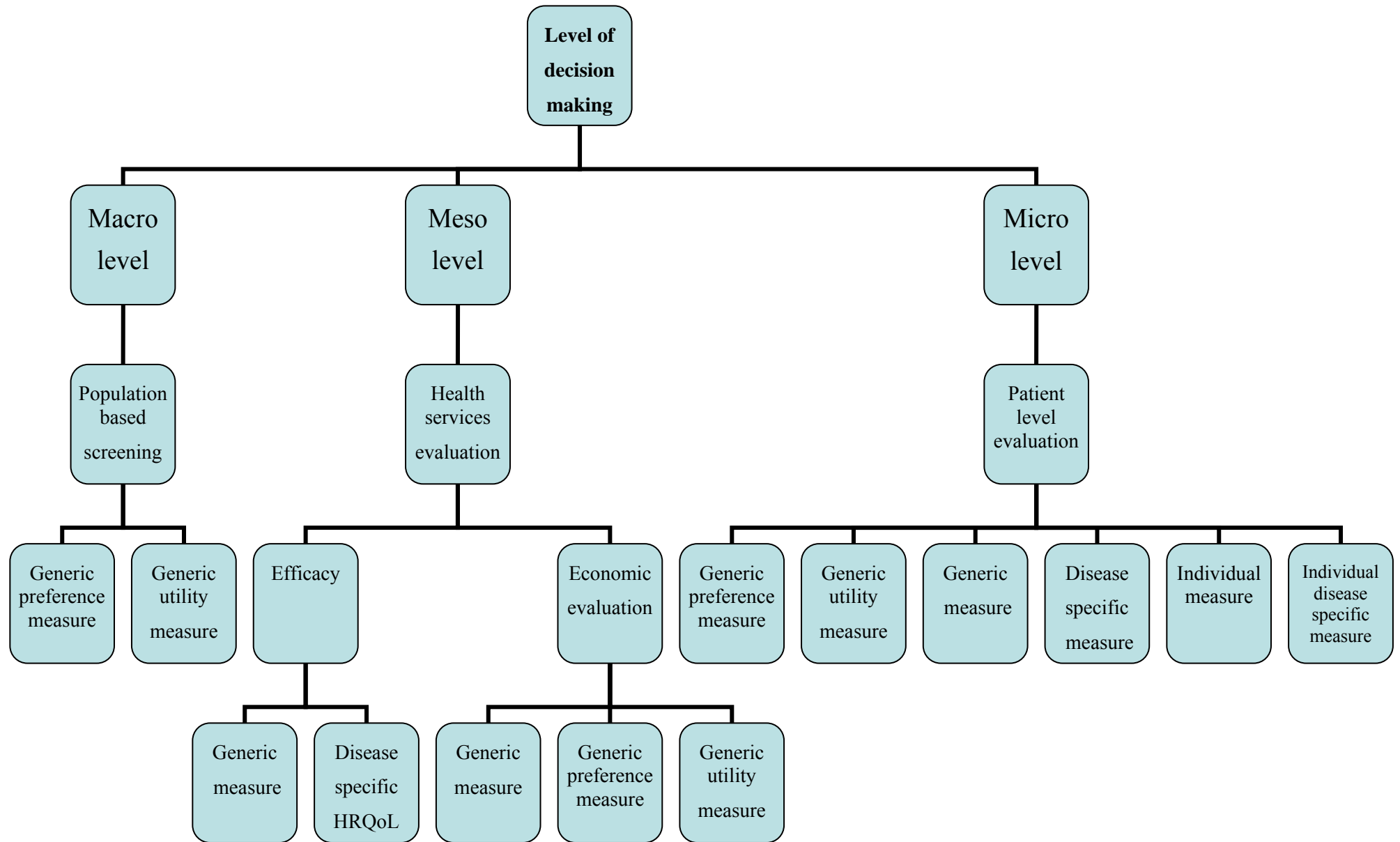
al, 2006) (see appendix 8). The burgeoning “corporatisation” of HRQoL in health and social services policy has rendered HRQoL a very powerful notion indeed (Rapley, 1998).

### **3.3 Why measure HRQoL?**

It is widely acknowledged that change in the patient’s quality of life is among the main determinants of demand for care, compliance with treatment and satisfaction (Leplegé and Hunt, 1997). HRQoL is an outcome of considerable interest in relation to the therapeutic success of health care intervention in (i) chronic illness (ii) conditions with significant disease burden and (iii) conditions in which curative interventions are either limited or uncertain. The wider evaluation, commissioning and rationalisation of health care intervention and service development is increasingly defined in these terms. HRQoL, in short, has relevance and currency across multiple levels of the health care organisation.

A fundamental problem with the outcomes movement, however, has been the underlying assumption that “one size fits all”. Different applications in different populations or settings often require different health concepts, measures and approaches (McHorney, 1999). Taxonomies of use for HRQoL research have therefore been proposed (Till et al (1994), Osoba (2002)), and these have been adopted here for the purposes of illustration (see figure 1).

Figure 1: A taxonomy of uses for HRQoL instruments in health services decision-making



### **3.3.1 Macro level decision-making**

HRQoL data at macro (general population) level have been shown to be predictive of health services utilisation (Dorr et al, 2006), patterns of morbidity (Moller et al, 1996) and mortality (Idler and Benyamini, 1997) and are frequently used in order to characterise, quantify and predict the burden of disease among general and specific subsets of the population (e.g. according to socioeconomic background, age or ethnicity) for the purposes of health care policy and planning. Specific strategies include; (i) population based screening for health conditions (Ventegodt et al, 2003) (ii) assessing the health of general or specific populations at a point in time (Burstrom et al, 2001) and (iii) monitoring the health of general or specific populations over time (Swallen et al, 2005).

### **3.3.2 Meso level decision-making**

The influence of disease processes, healthcare interventions or services upon the perceived HRQoL of patients is inherently meaningful to health services investigators and clinicians (Rapley, 2003) and has increasingly been used in their evaluation within the contemporary culture of cost containment (Fitzpatrick (1992), Joralemon and Fujinaga (1997)). The most prevalent use of HRQoL measures here relates to (i) evaluating the efficacy of health care interventions in observational studies, service evaluation and randomised controlled clinical trials (RCTs) and (ii) the economic evaluation of health care interventions (Till et al, 1994).

HRQoL measures are frequently used to elicit and evaluate the effects of healthcare interventions including, for example, organ transplantation (Philips et al, 2001), cardiac rehabilitation (Kardis et al, 2007) and self management programmes among primary care patients (Lorig et al, 1999). Recent policy initiatives such as High Quality Care for All (DoH, 2008) have underlined the importance of “the patient experience” in the now mandatory administration of patient reported outcome measures following some forms of elective surgery in England (e.g. pain specific, disability and HRQoL measures following unilateral hip replacement). Patient reported “quality metrics” are thus intended to drive the commissioning, development and rationalisation of health care services.

HRQoL has become an increasingly important end-point in randomised controlled trials. Both NICE and the US Food and Drug Administration (FDA) explicitly recognise HRQoL as a basis for the approval of new pharmaceutical agents. Clinical trials in oncology serve as exemplars of the use of such data in as much as that an impressive array of HRQoL measures exists and are increasingly specific to the type and site of cancer, disease progression and the nature of treatment (chemotherapy, radiotherapy, palliative care, etc).

HRQoL data have been advocated within this context as a means, amongst others, of elucidating the effects of treatments (e.g. in terms of toxicity or distressing side-effects), informing clinical decision-making (e.g. in terms of alternative treatments) and facilitating symptom management. There is considerable debate, however, surrounding the use and relevance of HRQoL data among clinicians. A preference for traditional markers of clinical response and mortality is said to persist (Blazeby et al (2006), Joly et al (2007)), ostensibly in response to the diversity of measures used, the poor methodological conduct of trials, the limited interpretability of findings and the poor quality of reporting (Sanders et al (1998), Effiface et al (2003), Fossati et al (2004)).

### **3.3.3 Micro level decision making**

A number of uses for individual level HRQoL data have been advanced and these include: the monitoring of change in disease states or response to medical intervention (Espallargues et al, 2000), the facilitation of doctor-patient communication (Velikova et al (2004), Skevington et al (2005)), the identification and prioritisation of health concerns (Higginson and Carr, 2001) and the identification of treatment preferences in shared decision-making (Guyatt et al, 2007). These are most well studied within the context of primary care consultations, and are therefore described here.

Quality of life-related issues are of inherent relevance to patients and several studies report a preference for their elicitation in clinical practice (Schor et al (1995), Wagner et al (1997), Detmar et al (2000)). Despite its perceived relevance among primary care clinicians (Morris et al (1998), Bezjak et al (2001), Skevington et al (2005)), competing expectations regarding the initiation, nature and content of

HRQoL-related discussion appear to militate against its application in the routine clinical encounter (Detmar et al, 2000). A small number of studies report, in addition, a preference among clinicians for the *informal* elicitation of HRQoL-related information (particularly among “well-known” patients), or for its subjective assessment based upon examination and history (Taylor et al (1996), Morris et al (1997)).

A number of randomised studies using predominantly disease or dimension-specific questionnaires have nonetheless reported an increase in the frequency and extent to which HRQoL related concerns are discussed in this context (Wagner et al (1997), Taenzar et al (2000), Detmar et al (2002), Gutteling et al (2008)). The authors report increased discussion around psychosocial concerns (i.e. psychological distress and social function), “unexpected” health concerns, or concerns of a more diffuse or chronic nature (e.g. fatigue or impaired sleep) which might otherwise have been overlooked.

There is limited evidence, nonetheless, of the impact of HRQoL measurement upon treatment strategies (Wagner et al (1997), Espallargues et al (2000), Greenhalgh et al (2005)). Traditional biomedical concerns are said to prevail and patient reported HRQoL-related concerns may result in the modification or discontinuation of therapy in only a minority of cases (Detmar et al, 2000). There is limited evidence also of the effects of HRQoL measurement upon patient reported outcomes such as well-being or satisfaction (Wagner et al (1997), Greenhalgh et al (1999)). Velikova et al (2004) report a moderate improvement in emotional well-being and overall HRQoL associated, importantly, with the *feedback* of data but not with questionnaire completion.

A prevalent concern in relation to the feedback of HRQoL information relates to the timeliness and interpretability of HRQoL data in routine clinical practice. Existing measures, it has been argued, were developed for use in clinical research where time and budgetary constraints are different from those in clinical practice (Higginson and Carr, 2001). Significant advances appear to have been made in this respect, however, with the development, for example, of “real time” computer assisted analyses and graphical representations for use in clinical consultations (Velikova et al, 2008).

The majority of these studies have, however, focused primarily upon outpatient based oncology consultations and general practice. Their applicability in wider health services practice and research (and particularly the acute setting) has not as yet been studied.

### **3.4 Summary**

The relevance of HRQoL measurement is undeniable and the implications for service development and patient care are compelling. The vast majority of measures, however, were designed for and have been implemented at macro (population, aggregate or policy) level. While potentially the least controversial, the use of HRQoL measures at this level of decision-making demonstrably lacks precision for use at individual patient level (McHorney and Tarlov, 1995), only touching “the tip of the iceberg” with respect to the human burden associated with disease and disability (McHorney, 1999: 315).

In the following sections, a comparison of the intended use and inherent “sensitivities” of the prevailing nomothetic (population level) and idiographic (individualised) approaches to HRQoL measurement are therefore examined. Subsequent sections explore the extent to which lay and patient perspectives are incorporated in their development and psychometric validation, including a commentary on their proximity, as it were, to those aspects of experience which are of most relevance to patients in their estimations of HRQoL.

### **3.5 How is HRQoL operationalised?**

Despite (or perhaps because of) its relevance across multiple levels of health services decision-making, attempts to reach consensus on the conceptual definition of HRQoL have all but been abandoned. Health services research is highly pragmatic and the conceptual definition or “intended meaning” of quality of life is rarely defined and moreover, is “justifiably avoided” due to its abstract nature (Rosenberg (1995), Fitzpatrick (1996)). Whatever the concept of quality of life “means”, it has been argued, is largely dependent upon the purposes to which any given operationalisation of the concept is to be put (Rapley, 2003).

There is broad consensus, nonetheless, within health services research upon the operationalisation of HRQoL as a multi-dimensional construct and upon the aspects of experience or “dimensions” considered essential for its measurement. A quantitative, hypothesis-driven approach is adopted, requiring researchers to predetermine those factors that are relevant or important to the issue or patient population under investigation, and thus to identify in advance the variables or dimensions to be measured and the relationships between them. Precisely which dimensions are selected varies greatly, often for theoretical and/or pragmatic reasons (Rapley, 2003).

Importantly, there is broad agreement within the HRQoL literature that both subjective *and* objective indicators are necessary preconditions of its measurement. A wealth of evidence supports the observation that objective indicators of HRQoL (e.g. measures of physical function or disability) do not consistently correlate with its subjective evaluation (Guyatt et al, 2007). Subjective indicators, in turn, may contradict observed states too grossly to be relied upon. Patients may, for example, report a quality of life which is startlingly inconsistent with their situation; the so called “disability paradox” (Albrecht and Devlieger, 1999) or “response shift” phenomenon (Schwartz and Sprangers, 1999). Subjective or objective indicators alone are sufficient, in short, to capture the effects of healthcare intervention or the totality of experience (Cummins, 2000).

Given these limited preconditions, a number of approaches to HRQoL measurement currently exist, with wide variation in their conceptual bases, developmental strategies and intended use. Two broad conceptual approaches exist. *Nomothetic* (i.e. generic and disease-specific) measures seek to establish abstract general laws, through the use of measures in which the questions asked, the response format provided, and the relative weights applied to the answers have all been predetermined (Waldron et al (1999), Joyce et al (2003)). *Idiographic* (i.e. individualised) measures, in direct contrast, seek to capture the unique and non-recurrent in as much as that quality of life, quite simply, “is what the patient says it is” (Joyce et al, 2003).

### **3.5.1 Nomothetic approaches to HRQoL measurement**

#### **3.5.1.1 Generic profile measures**

Generic measures are designed to provide a global or holistic assessment of health status and are broadly applicable across a wide range of health issues. Generic profile measures (such as the SF-36) are designed to yield scores on multiple aspects or dimensions of HRQoL and are intended to characterise the relative burden of disease therein. They are specifically designed for use at population or aggregate level. Health status “profiles” have thus been elicited among a wide range of patient populations (McHorney and Tarlov, 1995).

#### **3.5.1.2 Generic utility measures**

Preference-based or utility measures (such as the EQ-5D) are designed to yield a single summary score and are intended to evaluate any given health state, be it previous, current or a hypothetical future state (Rapley, 2003). Their primary function, quite distinct from profile measures, is evaluation of the utility or value that either patients or members of society (as potential patients and tax-payers) place on various health states for the purpose of economic evaluation and resource allocation.

By definition, generic measures include a number of items or dimensions that are irrelevant to specific patient populations, and/or exclude other areas of importance (Doward et al, 2004). A cogent and prevalent criticism, consequently, is their lack of sensitivity (or “responsiveness”) to the effects of medical intervention or changes in disease progression (Oga et al (2003), Eurich et al (2006)). They are generally held to be less responsive to clinical changes than their disease-specific counterparts (Jenkinson et al, 1997).

The responsiveness of generic measures to alternative disorders also varies widely. The responsiveness of the SF-36, for example, is relatively high in diabetes mellitus (Ahroni and Boyko, 2000), but relatively low cardiovascular disease (Smith et al, 2000). Measurement of the responsiveness of generic measures to alternative disorders is therefore recommended (Oga et al, 2003) as is their administration in

conjunction with disease-specific measures among patient populations (McColl et al, 2004).

### **3.5.1.3 Disease-specific HRQoL measures**

Disease-specific measures may be population-specific (e.g. the elderly), function-specific (e.g. respiratory function), dimension-specific (e.g. pain) or, most commonly, condition or disease-specific (Guyatt et al, 1993). These measures attempt to explore health issues which are of most relevance to the individuals suffering from particular conditions. Disease-specific measures account for the vast majority of evaluations in the latter part of the decade (Garratt et al, 2002) and a plethora of disease-specific instruments now exist across a broad spectrum of disorders including, for example, Parkinson's disease (Jenkinson et al, 1997), haemophilia (Arranz et al, 2004) and epilepsy (Cramer et al, 1998).

While the responsiveness of disease-specific measures may vary from condition to condition and from instrument to instrument (McColl et al, 2004), they are generally responsive to small changes in condition. Disease-specific measures may, however, focus too narrowly upon specific symptoms to capture important broader aspects of experience, such as social function or depression (Jenkinson et al, 1997). Their use in conjunction with generic measures is therefore intended to reveal clinically relevant insights into the relationship, for example, between symptoms and these broader aspects of experience. Additional comparison of the responsiveness of generic and disease-specific instruments across a range of conditions is nonetheless recommended (McColl et al, 2004).

### **3.5.2 Idiographic approaches to HRQoL measurement**

Individualised instruments emerged in the late 1980's as a direct challenge the traditional biomedical conceptualisation and measurement of quality of life using externally (i.e. professionally) predetermined categories and values in its assessment (Joyce et al, 1999). Individualised instruments, in stark contrast, attempt to capture the *diverse* priorities and concerns of *patients*, including the varying weights or values which they attach to these concerns (Fitzpatrick, 1999). Their use has

deservedly been described as a “paradigm shift” in HRQoL measurement (Moons et al, 2005).

Many of these instruments originated from QOL research outside health care (i.e. from psychology and the social sciences), using alternative conceptual frameworks and developmental strategies (Dijkers, 2003). The Patient Generated Index (PGI, Ruta et al, 1994) and the Schedule for the Evaluation of Individual Quality of Life (SEIQoL, O’Boyle et al, 1994) are the most widely used of the individualised measures, and their application in health services HRQoL research is therefore described here.

### **3.5.2.1 The Patient Generated Index (PGI)**

The Patient Generated Index, unlike the vast majority of measures, is based upon an explicit conceptualisation of quality of life; “the extent to which our hopes and ambitions are matched by experience” (Calman, 1984). The developers’ original intent was to

“...construct a questionnaire that quantifies the effect of a medical condition on patient’s quality of life in a way that has *meaning and relevance in the context of their daily lives.*” (Ruta et al, 1994: 1112) (my emphasis)

The PGI is administered in three stages. In the first, the individual nominates the five most important areas of life affected by their health problem (they may also be provided with a list of the areas most frequently nominated by patients with the same condition). (Later versions incorporate, in addition, “other health related areas” and “other non-health-related areas”). They then evaluate how badly affected they are in each chosen area on a scale of 0 to 100 (where 0 represents the worst imaginable state and 100 represents how they would like to be). In the final stage, respondents are given “points” to “spend” across one or more areas that they would most like to improve. The points allocated are taken to represent the relative importance of potential improvements in that area (Ruta et al, 1999).

The PGI is available for both self and interviewer administration, and has been used among a range of conditions including lower limb amputation (Callaghan et al,

2003), arthritis (MacDuff and Russell (1998), Hawker et al (2008)), cardiac failure (Witham et al, 2007) and cancer (Llewellyn et al, 2007).

Given the potential for change in the salience of patient reported concerns over time, three formats are available for use in longitudinal research; “blind”, “open” and “closed”. In the blind format, the areas previously nominated as important (e.g. at baseline) are not made available to the respondent. In the open format, previously nominated areas of importance are shown to the respondent. Here, respondents may add, remove or substitute previously nominated areas as appropriate. The closed format does not permit their alteration, and previously nominated areas are simply re-rated (Martin et al, 2007).

The cognitive burden associated with the evaluative procedures has, however, been reported as problematic among elderly and disabled respondents (Macduff and Russell, 1998). A modified version of the PGI has since been made available (Tully and Cantrill, 2000), although its cognitive burden among these patient groups has yet to be determined.

### **3.5.2.2 Schedule for the Evaluation of Individual Quality of Life (SEIQoL)**

The SEIQoL is an interviewer administered measure in which respondents are invited to nominate and appraise aspects of their lives of greatest relevance to their overall QoL. Respondents, importantly, are not obliged to consider the impact of “health” related issues upon perceived quality of life. The SEIQoL is administered in three stages. In the first, individuals nominate the five areas of life they consider most important in assessing their QoL (“elicited cues”) or, alternatively, to choose from a list of possibilities. In the second stage, individuals rate their current status for each cue and current overall QoL on a visual analogue scale. In the final “weighting” stage, individuals rate their overall QoL for 30 randomly generated hypothetical states, in order to quantify the relative contribution of each elicited cue to overall QoL (Patel et al, 2003).

The SEIQoL has been administered in a range of patient populations including, for example, gastrointestinal disorders (McGee et al, 1991), mild dementia (Coen et al, 1993) and spinal cord injury (Effing et al, 2006). In common with the PGI, the vast

majority of studies using the SEIQoL have been observational in nature (Patel et al, 2003), although Ribi et al (2008) report upon its recent use in a Phase II clinical trial.

The SEIQoL can take between 30 and 45 minutes to complete and criticisms include; its “cumbersome” nature, cognitive burden among the elderly (Browne et al, 1994) and problems eliciting cues (Westerman et al, 2006). An abbreviated version, the SEIQoL-DW (Hickey et al, 1996) has subsequently been developed and is considerably less cumbersome and time-consuming than its predecessor. Here, the weighting procedure is replaced with a pie chart of five interlocking coloured discs representing the nominated areas of importance. Respondents adjust the discs until the size of each coloured segment corresponds to its relative importance in everyday life.

The SEIQoL-DW has been administered in a range of patient populations including HIV and AIDS (Hickey et al (1996), mental illness (Prince et al, 2001), diabetes (Wagner et al, 2004) and cancer (Westerman et al, 2006). Validity and reliability are reportedly similar to that of the SEIQoL (Hickey et al, 1996). It has recently been validated for use in internet administration (Ring et al, 2006) and health and disease-specific versions are beginning to emerge (Wettergen et al, 2005). Much like its predecessor, the SEIQoL-DW has primarily been used in observational studies. It has rarely been used in clinical trials (Campbell & Whyte, 1999).

### **3.5.2.3 Idiographic disease-specific measures**

The Asthma Quality of Life Questionnaire (AQLQ) (Juniper et al, 1992) is but one example of an individualised disease-specific measure. The AQLQ is a hybrid of fixed and elicited items. 32 items cover 4 dimensions (symptoms, activity limitation, emotional function and environmental stimuli). Recognising the wide variation in activity limitation during the early stages of questionnaire development, this dimension contains 5 individualised questions. Here, patients nominate 5 activities in which they have been most limited in the past 2 weeks (or, alternatively, they may select them from a standardised list) and evaluate the level of impairment on a 7 point scale. Patients select the activities which are of most importance to them, and

these form the basis of subsequent evaluations. The results are expressed in terms of each dimension and QoL overall, and all items are unweighted.

Citing the ease of use of standardised measures in large scale clinical trials, a standardised version of the AQLQ (the AQLQ-S) has also been developed (Juniper et al, 1999). Here, 5 generic activities (strenuous exercise, moderate exercise, work-related activities, social activities, and sleep) are substituted for individualised items. Importantly, the generic activities were selected following review of the original item reduction data and a number of clinical trial databases in which the AQLQ was used (Juniper et al, 1999). An abbreviated (Juniper et al, 1999) and acute version (Juniper et al, 2004) of the AQLQ have subsequently been developed for use in clinical trials.

### **3.6 Summary**

With regard to their relative proximity to the perspectives and concerns of patients, idiographic approaches to HRQoL measurement in particular offer unique insights into the “patient experience”. A major criticism, nonetheless, is their failure to provide a form of standardisation (or psychometric “validity”) required for the comparison of results in clinical trials or population analyses (Patel et al, 2003).

Given the *dynamic* nature of individualised measures, however, the application of conventional psychometric indices are rather less relevant in their validation (Macduff (2000), Carr (2003), Joyce et al (2003)). Diversity and change in the salience or value of respondents’ concerns over time is considered particularly problematic for traditional conceptualisations of construct and criterion validity (Martin et al, 2007), reliability and responsiveness (Stenner et al, 2003). The exclusion of irrelevant items, however, eliminates much of the “noise” associated with the conventional nomothetic approach, facilitating greater responsiveness to change (Tugwell et al, 1990).

The nomothetic approach to HRQoL measurement currently prevails, however, given (presumably) the diversity and divergence of idiographic data from overtly biomedical operationalisations of illness and impairment and their as yet limited use in randomised clinical trials. They have been advocated, nonetheless, in the development of new measures (Patel et al, 2003).

### **3.7 The development of HRQoL instruments**

There is widespread consensus that the validity of a HRQoL instrument is enhanced by the incorporation of lay and patient perspectives in its development (Gill and Feinstein (1994), Lepage and Hunt (1997), Hunt (1997), Fitzpatrick et al (1998)). The consistency with which survey developers do so varies widely, however, as does the significance clinicians and researchers attach to this largely overlooked aspect of HRQoL measurement. In this section, I therefore provide a broad overview of the methods used in the development of nomothetic and idiographic instruments and outline the implications for their “patient-centredness”. A subsequent section outlines the incorporation of patient perspectives in their evaluation, including the implications for existing psychometric theory.

#### **3.7.1 Generic measures**

The vast majority of generic measures are historically based on professional values and belief systems i.e. on extensive literature reviews, revisions of existing scales and clinical expertise (Carr et al, 2003). The extent to which particular patient groups (including the “well” general population) are consulted in relation to the identification and significance of relevant or important dimensions of experience varies considerably (Bowling, 1995). Few of the widely used generic HRQoL instruments have been developed in consultation with the lay public or with patient populations. The Sickness Impact Profile and the Nottingham Health Profile, for example, are among a very small number whose component dimensions have been derived directly from respondents.

Diverse and often incommensurable conceptualisations of “health” exist between lay, patient and professional communities (Bowling (2005), Hendry and McVittie (2004)). The implicit assumption that “health” is the principal determinant of quality of life persists, however, despite a strong body of social science research which suggests that other (e.g. social and interpersonal) aspects of experience are rather more salient in the lives of respondents and in estimations of HRQoL overall (Bowling (1995), Lhussier et al (2005)). This disparity is likely to evolve, moreover, given demographically driven changes in societal, cultural, and life-course expectations for health and functioning (McHorney, 1999).

New instruments, it has been suggested, may very well incorporate a different configuration of “health” than is represented in existing HRQoL measures (McHorney, 1999).

Considerable disparity has also been demonstrated between the professional and lay communities with regard to global conceptualisations of HRQoL (Mozes, 1999), those aspects of everyday experience which are important in peoples’ lives, and their relative importance to one another (Bowling, 1995). In an attempt to derive UK population norms on pertinent dimensions of QoL, HRQoL and their relative importance in everyday life, Bowling (1995), for example, reports that among the dimensions included in the most frequently used measures (including the SF-36), several of those ranked by the general public as important were absent, and that not all of the domains included in widely used measures were considered important among those surveyed.

### **3.7.1.1 Generic utility or preference-based measures**

Utility-based approaches generally elicit preferences for hypothetical health states among general or patient populations using standardised vignettes (short descriptions of hypothetical situations or scenarios). They are useful in understanding how respondents would answer questions about these situations and in showing whether the conceptual boundaries of the questionnaire vary between respondents. One or more of three techniques are generally used: visual analogue/direct rating scales, time trade-off (TTO) and the standard gamble.

#### **3.6.1.1.1 Visual analogue/direct rating scales**

In direct rating scales, respondents are invited to directly rate and/or rank their preference for the standardised vignette on a visual analogue scale using a metric scale between 0 and 1, where 0 represents death and 1 represents full or perfect health (Green et al, 2000). This approach facilitates, as previously described, the integration of health and mortality into a single weighted measure; the “quality-adjusted life year” (QALY) for the purposes of economic analyses (Rapley, 2007). The calculation of QALYS thereby facilitates the prioritisation and allocation of scarce health service resource based upon the relative “worth” of alternative interventions.

#### 3.7.1.1.2 Time trade-off (TTO)

TTO requires respondents to choose between two certain outcomes, and to establish incrementally, the point at which they are indifferent between them (Rapley, 2007). In an exploration of treatment preferences among sufferers of advanced cancer, for example, respondents were invited to report upon the reductions in life expectancy which they would hypothetically trade off their current state of illness in order to achieve good or perfect health (Perez et al, 1997). Incremental standardised trade-offs were provided, and the mean “maybe” response (considered the point of equivalence between a definite “yes” and definite “no” response) was used to derive the utility score.

#### 3.7.1.1.3 The standard gamble

In contrast to the TTO technique, the standard gamble incorporates an element of risk or uncertainty in the decision-making process (McNamee et al, 2004). Respondents are invited to gamble between two alternative states of health relative, typically, to good or perfect health and death. McNamee et al (2004), for example, used this technique in combination with TTO to explore treatment preferences among sufferers of oesophageal cancer. Using standard gamble, respondents were asked to choose between living in the health state described for 12 months with certainty or gambling with the probability of good/perfect health or immediate death. In a similar fashion to the TTO, incremental standardised probabilities were provided, and the point of equivalence was used to derive the utility score.

While the examples provided here concern themselves with the preferences of specific patient groups, as has been advocated elsewhere (Nord (1999), Ubel (2000)), economic evaluations are predominantly based on *societal* (i.e. general population) preferences. It might reasonably be argued that the perspectives of the “well” general population are of limited relevance to patient populations (Bowling, 1995), given the questionable assumption that *hypothetical* preferences are applicable to “real-life” situations (Lupton, 1997) and the consistency with which the general population underestimate the value patients attach to various health states (Nord (1999), Ubel (2000)).

The thorny issue of whose preferences to adopt in economic evaluation is further complicated by argument that patient preferences, in turn, are contingent upon the myriad processes of *adaptation* to illness or impairment (Menzel et al, 2002). Neither alone, in short, may be sufficient to address the moral and ethical tensions thrown up by the elicitation of hypothetical preferences in economic evaluation and the rationalisation of health care resource (Menzel et al, 2002).

### **3.7.2 Disease specific measures**

The breadth of techniques used in the development of disease or dimension specific measures is, in many ways, exemplary of HRQoL survey methodology and therefore warrants close inspection. The development of disease-specific measures, where none previously existed, intuitively requires the elicitation and incorporation of patient experience and perspectives. A combination of the following techniques is generally employed: individual qualitative and focus group interviews, evaluative exercises such as ranking or card sorts (for the purposes of item selection and reduction), expert panels and cognitive interviewing.

#### **3.7.2.1 Individual qualitative interview**

Individual interview with representatives of the patient population of interest is intended to elicit those aspects of experience which are of direct relevance and concern to patients in their everyday lives, and are generally conducted in the early stages of questionnaire development. The rich insights that in-depth interviews provide into the attitudes, values and beliefs of participants are said to be invaluable in the derivation of questionnaire content.

A “meaning-based” or phenomenological approach is adopted in qualitative exploration, privileging subjective experience of and perspectives on health and illness and the meaning or value individuals ascribe to varying aspects of “living with” symptoms impairment and disability, often from a broader social perspective. Importantly, biomedical or pathophysiological models of health and illness implicit in existing HRQoL measures are frequently contested by this wider focus of enquiry.

In a qualitative study of HRQoL among sufferers of MS, for example, maintaining meaningful occupations and roles, establishing mutual relationships, consciously valuing positive life experiences and finding benefit in adversity brought quality into the lives of participants (Reynolds and Prior, 2003). Congruent with much of the qualitative HRQoL literature, participants were seen to assimilate a plethora of both negative *and* positive influences upon their lives in order to *negotiate* an acceptable QoL (Larsson et al, 2003).

Given, as has been suggested, the limited integration of qualitative research within health services research (Popay and Williams, 1998) and notwithstanding the epistemological and ontological objections of its authors, qualitative HRQoL research represents an important and relatively untapped source of idiographic data for potential use in questionnaire development. The meta-synthesis of qualitative data is a recent development in qualitative inquiry that offers a means of enhancing the contribution of qualitative findings to conceptual development. Hammell's (2007) recent meta-synthesis of qualitative HRQoL research among individuals with spinal cord injury, for example, while intended for use in service as opposed to questionnaire development, is promising in this regard.

### **3.7.2.2 Focus group interviews**

Focus group interviews comprise a more general group discussion of the topic under investigation, and are useful both in the early stages of questionnaire development and in their evaluation. They are useful in the exploration of underlying assumptions about the topic at hand, about the ways people understand the terms or concepts used in the questionnaire, or to determine the acceptability of potentially sensitive topics or questions. The Leeds Multiple Sclerosis Quality of Life scale (LMSQoL, Ford et al (2001)), for example, was developed using items selected solely from focus groups comprising sufferers. The items identified included family, social and work life, fatigue, lack of hope and adjustment to illness, in stark contrast to traditionally developed instruments with a biomedical focus upon impairment and disability.

### **3.7.2.3 Ranking exercises and card sorts**

“Ranking” generally involves an evaluation of the frequency and importance of the items identified for potential inclusion. Card sorting is a technique which determines how individuals organise and understand complex concepts and in particular, what they believe a concept *includes* or *excludes*. Respondents are presented with a number of cards containing explicit descriptions of related concepts and are requested to organise them into groups that “go together”. May and Warren (2001), for example, usefully modified this technique with a ranking exercise in order to determine which aspects of experience contributed most to a “good quality of life” among patients with spinal cord injury. They report that the dimensions perceived as important by participants differed somewhat from those of the developers, resulting in significant revision of the original questionnaire.

### **3.7.2.4 Expert panels**

Expert panels are generally implemented in the late stages of questionnaire development. Here, reviewers often appraise a questionnaire for face and content validity or problematic items. “Experts” may include questionnaire design experts, clinicians experienced in the disease process or substantive topic of the questionnaire and patients. The inclusion of patient expertise is particularly pertinent here, given the consistency with which clinicians impose traditional biomedical concerns upon questionnaire content and misrepresent dimensions of importance to patients (Rothwell et al (1997), Hewlett et al (2001)).

### **3.7.2.5 Cognitive interview techniques**

Cognitive interview techniques are designed to examine the processes through which patients understand, interpret and respond to questionnaire items, and have an increasingly important role in the design, development and evaluation of HRQoL questionnaires. Comprising purposively sampled patients, cognitive interviews are intended to explore the “real world” use of the questionnaire and to identify problematic items e.g. ambiguous terminology or irrelevant questions. Murtagh et al (2007), for example, used sequential cognitive interviews to refine and add explanatory detail to a number of items included in a palliative care questionnaire

among patients with end-stage renal failure. These techniques, the authors suggest, provided the researcher with an appreciation of the burden associated with questionnaire completion, and the opportunity to maximise data collection with reference to patients' capabilities.

### **3.7.2.6 Frameworks for developing disease-specific measures**

There is wide variation in the extent to which survey methodologists and clinician-researchers utilise these techniques. Guyatt et al (1986) usefully characterise this variation with reference to a "Volkswagen" and "Rolls Royce" model of disease-specific questionnaire development.

#### **3.7.2.6.1 The "Volkswagen" model**

The 54-item Multiple Sclerosis Quality of Life Scale (MSQoL-54, Vickrey et al (1995)) amply fulfils Guyatt et al's (1986) analogy of the "Volkswagen" model. This measure was derived simply by supplementing the SF-36 (Ware et al, 1992) with 18 additional items perceived by physicians (n=2) to be relevant or important to sufferers. Immediate concerns for "patient-centredness" and respondent burden aside, the MSQoL-54 has been extensively psychometrically validated since development and remains one of the most widely used measures in MS research (Mitchell et al, 2005).

The use of existing items to develop "ad hoc" disease-specific measures is nonetheless problematic, given the detachment of the survey developer from the matter at hand; HRQoL as derived from the patient's perspective (McHorney, 1999) and the general absence of adequate explanation for the dimensions included or excluded (Hunt, 1997). While existing items may provide known measurement properties (e.g. population norms), these are invariably dependent upon the group from which they were originally derived and may no longer be applicable to the population under study (McHorney, 1999). The often inadequate testing of derived measures for validity, reliability and responsiveness, in addition, impinges upon the interpretability of study results (Guyatt et al, 1986).

### 3.7.2.6.2 “Rolls Royce” models

#### 3.7.2.6.2.1 *A standardised approach*

Guyatt et al’s (1986) “Rolls Royce” model, in contrast, requires extensive literature review and detailed semi-structured interviews with between 50 and 100 patients in order to explore the impact of the condition upon salient aspects of everyday life. Purposive sampling is advocated here, in order to determine the effects of the disease in relation to demographic and clinical factors such as age, sex, severity and chronicity of disease. A second sample of approximately 100 patients evaluate the identified items for frequency and importance (using, for example ranking and/or card sorts) before pre-testing (using the cognitive interview techniques previously described) in a smaller sample of approximately 20 patients.

Using this model, Guyatt et al have developed, amongst others, extensively validated disease-specific measures for chronic respiratory disease (Guyatt et al, 1987), inflammatory bowel disease (Wong et al, 1998) and chronic heart failure (Guyatt et al, 1989).

#### 3.7.2.6.2.2 *A modular approach*

Guyatt et al’s model differs somewhat from that employed by the European Organisation for the Research and Treatment of Cancer Group (EORTC). Founded in 1962, the group comprise an international multi-disciplinary collaboration of clinicians, scientists and clinical trial methodologists in the evaluation of anti-cancer drugs. A sub-group is dedicated specifically to their evaluation using HRQoL as an outcome of interest, and another to their translation and cross-cultural adaptation for the purposes of international collaboration and comparison.

The group have developed a standardised or modular approach for questionnaire development among increasingly specific patient groups, based upon a core instrument designed specifically for use in clinical trials. The cancer-specific 30-item EORTC Quality of Life Questionnaire (EORTC QLQ-30) (Aaronson et al, 1993) is intended to be supplemented by additional modules which assess specific disease and treatment-related HRQoL issues among particular sub-groups of the patient population. Modules may be specific, for example, to symptoms associated with the

tumour site (e.g. lung or head and neck), disease progression (e.g. localised or metastatic cancer), side effects associated with treatment (e.g. chemotherapy or radiotherapy) or other HRQoL dimensions such as fatigue, body image and fear of recurrence (Sprangers et al, 1993).

There are established guidelines on the development of modules. The four phases of development comprise: the generation of items; operationalisation into questions, pre-testing and large scale field testing. The generation of items is based upon extensive literature review, and item reduction following sequential evaluation among expert clinicians and purposively sampled patients. Pre-testing consists of questionnaire administration to between 10 and 15 patients from the target population using cognitive interview techniques. (This phase in particular has been described by the developers as “invaluable” in the revision of poorly performing items). Questionnaire content may be further revised on the basis of large scale field testing and rigorous peer review. Using this model, a wide range of extensively validated measures has been developed for use in large scale clinical trials.

#### 3.7.2.6.2.3 *A conceptual model approach*

A number of disease-specific measures have been developed based upon the needs-based model of HRQoL proposed by Hunt and McKenna (1992), whose theoretical basis is that “life gains its quality from the ability and the capacity of the individual to satisfy his or her needs” (Doward and McKenna, 2004: S6). In contrast to function-based measures, it is possible to enquire here about the *needs* that might be affected by a particular function. With reference to the aesthetic effects of psoriasis, for example, expressed needs might include self-image, socialisation and sexuality (McKenna et al, 2004).

The needs-based model derives questionnaire content exclusively from the issues raised by patients during *unstructured* in-depth qualitative interviews. Following item reduction by an expert panel, items are constructed, wherever possible, from respondents’ verbal accounts.. Validation comprises field testing using cognitive interview techniques and large scale postal surveys. Using this model, a range extensively validated measures have been developed for a range of conditions including, for example, rheumatoid arthritis (De Jong et al, 1997), multiple sclerosis

(Doward et al, 2009) and systemic lupus erythematosus (Doward et al, 2009). Importantly, response rates among these measures are impressively and consistently high.

### **3.7.3 Idiographic measures**

Social judgement theory (SJT) (Brunswick, 1956) forms much of the basis of idiographic measures. SJT provides insight into human decision processes, and particularly into the selection and weighing up of alternative information in the formulation of decisions (Smith et al, 2003). SJT, in short, examines the extent to which information is used in *judgement* as opposed to the actual utility of that information in the ‘real world’ (Smith et al, 2003). By using regression-based statistical analyses, SJT can also evaluate whether its importance, weight or the decision made correlates with some criterion value (Smith et al, 2003).

The PGI, for example, was derived from Guyatt et al’s (1986) “Rolls Royce” model of questionnaire development, in conjunction with a “priority evaluation method” (Ruta et al, 1999). Using regression-based analysis its validity has been established across a number of conditions through its correlation with the dimensions of the SF-36 (as a criterion value).

## **3.8 Summary**

The use of instruments developed in collaboration with patient groups has intuitive appeal. They are rather more likely to identify relevant (as opposed to biomedically defined) dimensions of everyday experience for inclusion in questionnaires, and there are implications not only for acceptability, respondent burden and response rates but for the development of meaningful clinical interventions and their appropriate evaluation.

The conceptually-based model of instrument development is particularly noteworthy in this respect. It is widely acknowledged that the identification of theoretically derived aspects of experience increase the likelihood of developing appropriate (and potentially more successful) measures and interventions (Medical Research Council, 2008). Using a theoretical basis may also increase the cost-effectiveness of clinical

intervention, given that the mechanisms by which they succeed or fail are better understood (Medical Research Council, 2008).

### **3.9 The validation of HRQoL instruments**

HRQoL measures vary widely in terms of conceptual basis, content, breadth, and depth of measurement and it is increasingly well recognised that the legitimacy and relative importance of an instrument's measurement or psychometric properties differ dependent upon its intended use (Fitzpatrick (1996), McHorney (1999)).

“Discriminative” instruments, for example, must demonstrate the ability to reproducibly differentiate between patient groups at a given point in time e.g. in terms of disease severity or disability and place greater emphasis upon “reliability” (Guyatt et al, 2002). “Evaluative” instruments must demonstrate the ability to detect changes in HRQoL over time e.g. the effects of medical or other intervention, and place greater emphasis upon “responsiveness” (Guyatt et al, 2002).

A number of guidelines exist concerning the conduct, transparency and reporting of clinical trials using HRQoL measures (Staquet et al, 1996). There are, however, few definitive guidelines detailing the minimal psychometric properties required of HRQoL instruments (Hays et al, 1993) and considerable debate surrounds the interpretation and application of HRQoL data due to the inappropriate application of psychometric indices relative to their intended use (Testa and Nackley, 1994). There is broad consensus, nonetheless, that HRQoL instruments should demonstrate validity, reliability and responsiveness. In the following section, I outline the extent to which lay and patient perspectives can contribute to defining or improving the psychometric properties of HRQoL measures.

#### **3.9.1 Validity**

##### **3.9.1.1 Face validity**

Validity refers to the extent to which an instrument measures what it purports to measure. There are several means of evaluating validity (face, content, construct and criterion) and their application is dependent upon the nature or intended purpose of the instrument (McDowell, 2006). Face validity is a subjective evaluation which describes the extent to which a measure “looks like” it is measuring the intended

construct, and is arguably the weakest form of validation (Trochim, 2001). Evidence of face validity is often provided in *post hoc* expert panel reviews. Given that the evaluators, be they lay or expert, are not provided with the rationale whereby alternative items were included or omitted, only limited evidence of validity can be assured.

### **3.9.1.2 Content validity**

Content validity is particularly important among constructs which are highly abstract in nature (De Von et al, 2007), although it is rarely formally tested (McDowell, 2006). It is indicated if the items included in a questionnaire are relevant to and representative of the range applicable to the construct under scrutiny. A comprehensive pool of items may be generated following, for example, extensive literature review, expert opinion and qualitative fieldwork (De Von et al, 2007).

Content validity is provided through expert (lay and/or professional) review of the potential items for inclusion/exclusion and is enhanced by precise conceptualisation and definition of the construct under exploration, including definition of the individual dimensions which the measure includes. Precise conceptualisation and definitions are, however, rarely provided in many of the most widely used HRQoL instruments (McDowell, 2006).

### **3.9.1.3 Criterion validity**

Criterion validity refers to the extent to which results using one measure are associated with the results from another external criterion, the latter being taken to be the “gold standard” or best available (Jenkinson et al, 1994). Often, however, few such criteria exist, and the *relevance* of external criteria to potential respondents has been a matter of some debate. Breathlessness upon climbing stairs is of obvious salience to respondents with respiratory disease, for example, as opposed to clinical measurements of respiratory flow or volume.

### **3.9.1.4 Construct validity**

Construct validity has been described as the most rigorous approach to demonstrating validity (Guyatt et al, 1993) and was developed to augment the evaluation of complex measures for which no external criterion or “gold standard” exist (McDowell, 2006). Determining construct validity involves testing a measure against operationally or theoretically derived hypotheses concerning the nature of the underlying variable or construct (De Von et al, 2007) and is explored by investigating its relationship with other related (convergent validity) and unrelated (discriminant validity) constructs. Researchers may examine, for example, the (expected) correlation between quality of life and a measure of depression, or explore the performance of an instrument across the target population and healthy controls.

### **3.9.2 Reliability**

#### **3.9.2.1 Internal consistency**

Reliability is the extent to which a measure is free from random error in the population of interest, and is a generic term which refers to its internal consistency as well as its reproducibility. Internal consistency is a function of the number of items within a questionnaire and their correlation in an instrument measuring a particular construct (Hays et al, 1993), or how well they “fit together” (De Von et al, 2007). Cronbach’s alpha is the most commonly used statistic, providing an indication of the average correlation among all of the items that make up an instrument (Pallant, 2002). Guidelines for acceptable correlational coefficients vary, dependent, for example, on the extent to which it has previously been validated or whether the instrument is being used for group or individual level analysis. Many widely used instruments, however, fail to meet accepted standards for reliability (Hays et al (1993), McDowell (2006)).

#### **3.9.2.2 Reproducibility**

The reproducibility of a measure is the degree to which it yields consistent scores over time among respondents whose conditions are assumed not to have changed. Test-retest reliability is estimated by administering the same measure to the same group of respondents at different times. The correlation between the two scores (and

often between individual questions) indicates the stability of the instrument (De Von et al, 2007). There is some debate with regard to the appropriate length of time between administrations, however, and the extent to which intervening factors, such as a change in the nature or severity of symptoms, spuriously affect reliability. Test-retest correlation, in short, may not accurately reflect the reliability of the questionnaire.

### **3.9.3 Responsiveness**

Responsiveness refers to the ability of a HRQoL measure to capture true underlying change in the patients' health status over time (Terwee et al, 2003). It is often conceptualised as the ratio of "signal" to "noise" (i.e. true change over time versus other variability which is not associated with a change in health status) and has been described as an essential measurement property in clinical trials and interventional studies (Guyatt et al, 2003). Little consensus exists, however, on its precise definition or the most appropriate or effective methodology for its measurement.

Responsiveness has been variously defined in terms of: the ability to detect change in general (regardless of its inherent relevance or meaning, but often described in terms of statistical significance); the ability to detect clinically relevant change, or the ability to detect change in the concept being measured (Terwee et al, 2003). Each raises distinct conceptual and methodological issues which are largely overlooked in the prevailing literature including, in the latter definitions, the relative status of the evaluator (clinician or patient), and the extent to which "health" or symptoms, for example, are taken to influence perceived HRQoL. Perhaps unsurprisingly, over 30 measures of responsiveness have been identified in the literature (Terwee et al, 2003).

Distribution and anchor-based approaches are most frequently applied, occasionally in tandem (Cella et al (2002), Yost et al (2005)). Distribution-based approaches are reliant upon the statistical characteristics of a population and the variation therein. Responsiveness is based here upon effect size, the standard deviation from the mean, or the standard error of the mean. Interpretation of change is entirely dependent upon the variability of the data, however, and it is increasingly recognised that a statistically significant change may not necessarily constitute a *clinically* significant

(Terwee et al, 2003) or *minimally important* change (Wyrwich et al, 2005) or vice versa, for that matter. The latter refers, importantly, to the smallest change in scores perceived by patients as beneficial.

Anchor-based approaches assess the extent to which changes on the HRQoL measure correspond with those of a *clinically* relevant external criterion or “anchor” (e.g. respiratory function tests among patients suffering from chronic obstructive airways disease) and are generally preferred by clinicians (de Vet et al, 2006). Multiple anchors are often used to determine clinically meaningful change, and differences can be determined either cross-sectionally (between clinically defined groups at a given time point) or longitudinally (the change in score of one group over time) (Cella et al, 2002). Much like the nature of external comparators in criterion validity, the nature or sensitivity of the anchor used and its relevance to patients may have important effects upon responsiveness (Eurich et al, 2006).

A *clinically* significant change in HRQoL, it has been argued, reveals little about the underlying clinical reason for that change and may, moreover, be of limited relevance to patients (Wyrwich et al, 2005). Clinician’s estimations of “significance” have been found to be higher than those based upon patients’ views (Wyrwich et al, 2005), with the corollary that changes which patients perceive to be important would go unnoticed. A small number of studies have therefore incorporated clinician and/or patient evaluations of change (e.g. global transition assessments) as a clinical anchor (Kosinski et al, 2000), Cella et al (2002)), in an attempt to render the perception of change more meaningful to both patients and clinicians.

### **3.10 Summary**

The validation of HRQoL instruments is a complex, partial and incremental process. Perhaps, as Guyatt et al (1993) suggests, we should never conclude that a questionnaire has been “validated”, but rather that strong evidence for validity has been obtained in a number of different settings and studies. The psychometric properties of HRQoL instruments are, however, enhanced in a number of ways by the formal inclusion of patient perspectives. The extent to which clinicians and trial methodologists do so varies enormously, however, with clear implications for the measurement or psychometric properties of the instruments used, for the extant and

putative uses of HRQoL measures, and for the legitimacy of the data they provide. Perhaps as Gill and Feinstein (1994) suggest,

“...quality of life can be suitably measured *only* by determining the preferences of patients and supplementing (or replacing) the authoritative opinions contained in statistically “approved” instruments. Unless greater emphasis is placed on the distinctive sentiments of patients, quality of life may continue to be measured with a psychometric statistical elegance that is accompanied by unsatisfactory face validity.” (Gill and Feinstein 1994: 626)

### **3.11 Discussion**

This review has demonstrated the relevance of the patient’s voice in the conceptualisation of HRQoL (including its likely determinants) and the development and validation of HRQoL measures. This review has also outlined the range of methods available for its elicitation, and the implications for the legitimacy and application of HRQoL data. Crucially, the identification of patient-elicited and theoretically derived aspects of experience are seen to offer significant potential to develop more appropriate evaluative measures and health care intervention; more so, importantly, than the dominant biomedically informed approach. This potential is often usurped, however, by pragmatic concerns around their use in population-based studies and clinical trials. These observations are revisited in the concluding section of this chapter.

## **Section Two**

### **HRQoL in critical care outcomes research**

#### **3.12 Introduction**

In this section I provide a general overview of the operationalisation and relevance of HRQoL in critical care outcome studies, including the current state of knowledge in relation to the use of professionally endorsed generic HRQoL questionnaires (the SF-36 and the EQ-5D) among various sub-groups of the ICU patient population.

The heterogeneity of the patient populations studied is, for the most part, prohibitive of the meaningful comparison of data. A subsequent exploration of HRQoL studies among a relatively homogeneous and particularly well-studied sub-group of the patient population (survivors of Acute Respiratory Distress Syndrome (ARDS)) is therefore provided, and is intended to exemplify the application and implications of current measures and approaches. This section reflects a marked preoccupation with the methodological conduct of HRQoL research within critical care; an approach which is arguably impoverished by the exclusion of patient perspectives as previously described, and by the inattention to innovative strategies previously described in the development and validation of instruments.

#### **3.13 Why measure HRQoL?**

The measurement of HRQoL is an inherently important outcome of interest in critical care research. Congruent with wider health services research, there is increasing recognition of the insensitivity of (short-term) mortality to important patient-centred outcomes (Angus et al, 2003). Survival, moreover, is associated with a diverse range of physical and psychosocial sequelae (see Appendix 9), occurring largely irrespective of the admitting disease, and often super-imposed upon pre-existing conditions. The symptom burden associated with survival is, in short, often extraordinary.

Prevalent physical sequelae include, but are not restricted to, generalised muscle wasting, weakness, profound fatigue, joint stiffness, impaired mobility and weight loss (Griffiths and Jones (1999), Herridge (2002)). A higher prevalence of anxiety, depression (Jackson et al (2003), Ringdal et al (2009)) and post-traumatic stress disorder (typified by distressing and recurrent recollections of ICU) (Scragg et al (2001), Jones et al (2001)) has been reported, and persecutory dreams, delusional memories and amnesia are common (Jones et al (2001), Rattray et al (2005)). An evolving body of literature suggests that recovery may be protracted and incomplete, with often considerable and prolonged effects upon everyday life and perceived HRQoL.

### **3.14 How is HRQoL operationalised in critical care outcome studies?**

#### **3.14.1 Generic measures**

In keeping with HRQoL research in general, the vast majority of critical care studies are observational or descriptive in nature and are population-based (Dowdy et al, 2005). A particular problem among studies of the critically ill is the heterogeneity of the patient population and studies to date have therefore used, almost exclusively, generic HRQoL measures (Black et al, 2001). The most recent systematic review of outcome measures used in critical care identified a total of nine generic HRQoL measures (Hayes et al, 2000). The authors also identified over 20 measures which have been used on only one occasion, and an additional 18 studies which administered a “non-specific” (presumably ad hoc) measure.

The most widely used measures comprise the Sickness Impact Profile (SIP, Bergner et al (1976)), the Nottingham Health Profile (NHP, Hunt et al (1981)), the SF-36 (Ware et al, 2000) and the Perceived Quality of Life scale (PQoL, Patrick et al (1998)). Only one generic measure has been developed for use among the critically ill (the Fernandez Questionnaire (Fernandez et al, 1996)), but this measure does not appear to have been tested in the UK. Despite the widespread use of these instruments, the authors of the systematic review are critical of their inadequate

psychometric validation among survivors of critical illness and call for their “urgent and rigorous assessment” (Hayes et al, 2000: 81).

Precipitately, in order to increase the comparability of study data, Hayes et al (2000) recommend the adoption of a limited number of generic measures. A subsequent European Roundtable recommends the use of the SF-36 and the EQ-5D (Angus et al, 2003). While the rationale for the choice of measures has not been made explicit, their recommendation would appear to be pragmatic as opposed to methodological in intent. Personal communication with one of the co-authors of the systematic review (Professor Nick Black) suggests that the selected measures were simply “the best of a bad bunch”.

### **3.14.2 Disease-specific measures**

There is a dearth of critical illness-specific measures in critical care outcomes research, and generic measures are invariably administered in conjunction with disease specific HRQoL instruments or screening tools designed for use among other patient populations. The St George’s Respiratory Questionnaire (Jones et al, 1991), for example, has been used as measure of HRQoL in numerous studies among survivors of Acute Respiratory Distress Disorder, despite its development for use among sufferers of *chronic* respiratory disease. The authors of the systematic review are similarly critical of the inadequate validation of adjunctive measures among survivors of critical illness, adding that there is often limited evidence of their measurement properties in *non-ICU* populations upon which to support their use (Black et al, 2001).

### **3.14.3 Screening tools**

The widespread use of screening tools as opposed to more comprehensive diagnostic tools has attracted similar criticism. An inflated prevalence of Post Traumatic Stress Disorder constitutes a particularly cogent illustration of their inappropriate use (Griffiths et al (2007), Jackson et al (2007)). Widely used measures, it has been suggested, may fail to reflect qualitative differences in symptomatology among survivors of critical illness as opposed to “traditional” patient groups such as war veterans and survivors of natural disasters (Jackson et al, 2007). They may also fail to assess the full range of symptoms or result in an inappropriate diagnosis of PTSD,

as opposed to the recognition of associated symptoms (Rattray, 2007). These issues have received surprisingly little attention in the critical care literatures.

#### **3.14.4 Duration of follow-up**

A follow up period of at least six months has been advocated (Angus et al, 2003). Previous recommendations were based upon the increasingly questionable assumption that persistent health problems are attributable to chronic underlying conditions, or to new and unrelated health problems commonly encountered in an elderly population (Konopad et al, 1995). The most recent recommendation is based upon the interval of risk (of mortality) and relates explicitly to clinical trials among survivors of sepsis (Angus et al, 2003) despite, it seems, widespread recognition that survival varies widely across patient populations (Adamson and Eliot, 2005).

It is more generally accepted, however, that patients *ought* to be followed until their survival curve matches that of a control group, where appropriate (Adamson and Eliot, 2005), or that of the general population (Cuthbertson et al (2005), Heyland et al (2005)). Given the difficulties associated with long-term follow-up, few studies currently do so.

#### **3.14.5 Caveats to the use of HRQoL data in critical care outcome studies**

##### **3.14.5.1 Comorbidity**

Comorbidity is increasingly measured in health services research (de Groot et al, 2002) and its recognisance is likely to become more pressing in critical care HRQoL research given current demographic trends. The cumulative effects of co-existing morbidity upon perceived HRQoL in non-ICU populations suggest that synergistic effects exist between prevalent chronic and age-related disorders (e.g. cardiovascular disease, chronic respiratory disease and arthritis) such that patients may experience an increased risk of physical impairment (Rijken et al, 2005) and reduced HRQoL (Wee et al, 2005) than might reasonably be expected from their separate effects.

Despite the reported prevalence of pre-existing morbidity among ICU patient populations (Brooks et al (1997), Ridley et al (1997)), remarkably little is known about its effect on critical illness-related morbidity and/or HRQoL. There is a dearth, moreover, of appropriately validated indexes of comorbidity (de Groot et al, 2002). The most widely used among ICU populations, the Charlson Comorbidity Index (Charlson et al, 1987) comprises 19 disease states, selected and weighted on the strength of their association with *mortality*. A recent comparative review of its association with *HRQoL* suggests that it is inappropriate for use within this context (Fortin et al, 2005).

Studies among the critically ill suggest that poorer quality of life among survivors is more strongly associated with previously poor HRQoL or prior chronic illness than with illness severity scores on admission to ICU (Capuzzo et al, (1996), Orwelius et al (2005), Cuthbertson et al (2005)). The emergency nature of critical illness makes this difficult to quantify, however, and several studies have therefore incorporated proxy (Cuthbertson et al (2005), Hofhuis et al (2007) or recalled measures of HRQoL (Konopad et al, 1995).

While relatives may be able to provide accurate information in regard to observable components of the health status (such as physical function), they are rather less accurate in terms of subjective experience such as emotional status, life satisfaction and well-being (Niskanen et el, 1998). Retrospective assessment of HRQoL among patients, moreover, is heavily influenced by “recall bias”, in as much as that pre-admission HRQoL is often described as falsely high (Flaatten et al (2001), Wehler et al (2003)).

#### **3.14.5.2 Adaptation and response shift**

Response shift is defined as a process of accommodation or adaptation to chronic disease, in which internal standards, values and perceived quality of life are reconceptualised through various stages of the disease process (Sprangers and Schwartz, 1999). It has also been described as a psychological response to illness and impairment such that the individual is enabled to maintain an acceptable QoL in the face of deteriorating health, impairment or disability (Sharpe et al, 2005). Response

shift theory consistently demonstrates that as the individual's health status changes over time so do the means by which they make judgements (beta change), or indeed their entire conceptualisation of the concept under study (gamma change) (Allison et al, 1997). The interpretability of change in perceived health status over time is therefore problematic, given that perceived change might not be "real" (alpha), but forms of beta or gamma change instead.

Function-based measures, it has been suggested, are somewhat insensitive to the processes of adaptation (Doward and McKenna, 2004), and conventional comparisons of mean scores before and after an elapsed period of time do not differentiate between alternative types of change (Ahmed et al, 2004). The vast majority of empirical work on response shift is concerned, in addition, with adaptation to *deterioration* in health status, and comparatively few studies have concerned themselves with the process of *recovery* over time. Local research experience among survivors of critical illness and indeed, later work suggests that response shift may be an important issue in recovery from critical illness, but it is one that is not widely acknowledged in the professional literature, either in conventional psychometric form or in relation to recovery.

### **3.15 A review of professionally endorsed generic HRQoL measures**

In this section, I review the background, development and use of the SF-36 and the EQ-5D in contemporary critical care outcome studies.

#### **3.15.1 The SF-36**

##### **3.15.1.1 Development**

The Rand Corporation's Health Insurance Study (HIS) (1992) was designed to investigate policy-relevant issues on the relationship between health insurance and use of health care services (defined as ambulatory, hospital, dental, and psychological), health status, quality of care and patient satisfaction in the United States. The resultant questionnaire was designed to be a generic indicator of health status for use in population surveys and evaluative studies of health care policy (McDowell, 2006).

A total of 7708 people were enrolled for periods of between three or five years at six sites across the United States. Health status instruments were selected or adapted from measures which had previously been used among the general population during the 1970s and 80s, and data were obtained using a total of six different survey instruments, all but one of which was self-administered. Completion of each of the questionnaires was a condition of enrolment and participants received financial incentives.

Recognising of prevailing multi-dimensional conceptualisations of HRQoL, the developers placed particular emphasis upon physical, mental, and social health. Operational definitions were developed following extensive literature review. Following intense psychometric testing, the 149-item Functioning and Well-Being Profile (FWBP) (Stewart & Ware, 1992) was derived from the multiple measures administered, and 20, 30, 36, 38 and 56-item versions of the existing questionnaire were subsequently developed. The SF-36 was first made available in its standard form in 1990 (Ware & Sherbourne, 1992). Comprising, as the name suggests, 36 questions or “items”, the SF-36 measures 8 dimensions; physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, energy/vitality, pain and general health perception (see appendix 10).

Respondents are asked to describe their health status across these domains within the previous 4 weeks (or within the past year for the general health status item) using a yes/no format or a 3-6 point scale to indicate the degree (not at all, slightly, moderately, etc) and frequency (all of the time, most of the time, a good bit of the time, etc) with which, say, physical health status interferes with social activities.

A standardised scoring algorithm is available, whereby raw scores are transformed into 100 point scales, with higher scores indicating better health status. A score is calculated for each of the eight dimensions and two summary scores, the Physical and Mental Component Summary Scores may also be calculated. Age and sex-matched population norms are available for the purposes of comparison between patient populations and across interventions (Jenkinson et al, 1993). The SF-36 has

been translated for use in more than 22 countries, facilitating international and cross-cultural comparison.

Following extensive psychometric testing by the developers, the “family” of abbreviated and revised versions of the original 36-item questionnaire now includes; SF-36 version 2 (Ware et al, 2000), SF-12 (Ware et al, 1994), SF-12 version 2 (Ware et al, 1998) and the SF-8 (Ware et al, 2001). The SF-6D, a preference or utility-based measure has also been developed (Brazier et al, 2002). The SF-12 and SF-8 are additionally available in acute (1 week) recall versions, and the SF-8 is available in a 24-hour recall version. All are said to yield results which are comparable with previously published age and sex-matched population norms. The SF-8 is hailed by the developers as a major advance in the application of Short Form technology in terms of its brevity and comprehensiveness in population health surveys, and is intended to replace both versions of the SF-36 and SF-12.

#### **3.15.1.2 Use and validation in non-ICU populations**

The SF-36 has been administered among a diverse range of patient populations including, for example, sufferers of rheumatoid arthritis (Birrell et al, 2000), Parkinson’s disease (Schrag et al, 2006), sleep apnoea (Jenkinson et al, 1997) and erectile dysfunction (Guest and Das Gupta, 2002). It is arguably the most widely evaluated of the generic HRQoL measures (Garratt et al, 2002). At UK population level, reliability (Brazier et al, 1992) and validity (Brazier et al (1992), Jenkinson et al (1993)) have been demonstrated.

#### **3.15.1.3 Use and validation among survivors of critical illness**

A total of 66 studies using SF-36 were identified in the literature (see Appendix 11). Reflecting its international use, the identified studies originate from over a dozen countries. The patient populations studied comprise; the general ICU population (n=35) and specific sub-groups comprising; ARDS (n=13), pancreatitis (n=4), renal failure (n=3), sepsis (n=3), trauma (=2), multiple organ dysfunction (n=1), acute lung injury (n=1), pneumonia (n=1), chronic respiratory failure (n=1), multiple organ dysfunction (n=1) and cardiogenic shock (n=1). The majority of studies were observational or descriptive in nature. There were comparatively few case control

studies or randomised trials of pharmaceutical or other medical interventions. One randomised study attempted to evaluate the effects of a rehabilitation package following ICU discharge (Jones et al, 2003). The authors utilised only the Physical Function dimension of the SF-36, however.

There was marked variation in the range of patient populations studied, duration of follow-up (ranging from between one month and 14.5 years) and the use of comparison groups. In the vast majority of identified studies, the SF-36 was administered on only one occasion. There was an overwhelming emphasis on measures of physical function using crude, standardised and clinically derived adjuncts. There was considerable variation, however, in the measures used, with implications for comparison between patient groups.

Comparatively few of the identified studies attempted to discern the psychometric properties of the SF-36 among their respective patient populations. Acceptability (Chrispin et al, 1997), internal consistency (Chrispin et al (1997), Welsh et al (1999), Heyland et al (2000), Clermont et al (2002), Graf et al (2003), Heyland et al (2005)) criterion validity (Broome et al (1996), Heyland et al (2000), Wehler et al (2003)) and test- retest reliability have been reported (Heyland et al (2000), Clermont et al (2002) Khoudri et al (2007)), however, across a range of patient populations. Using a battery of self and interviewer administered tests, Christie et al (2006) report construct validity on the basis of a correlation between cognitive impairment and both the Mental Health and General Health dimensions of the SF-36. Evidence of construct validity is also claimed by Khoudri et al (2007) on the basis of lower HRQoL overall among female respondents, the elderly and those with multiple comorbidities. Responsiveness remains less well measured (Hayes et al, 2000).

#### **3.15.1.4 Criticisms of the SF-36**

##### **3.15.1.4.1 “Floor” and “ceiling” effects**

Significant concerns have been raised regarding the suitability of the SF-36 among patient populations experiencing marked functional and psychosocial morbidity. Pronounced “floor” and “ceiling” effects of the SF-36 have been reported among stroke populations, for example, (Hobart et al (2002), Weimar et al (2002)).

Remarkably few have studies among the critically ill have reported upon these effects, despite their obvious relevance among this patient population. A recent study has, however, reported floor and ceiling effects in the Role Physical, Role Emotional, Social Function and Pain dimensions among a surgical ICU patient population (Khoudri et al, 2007).

Due to the widespread representation of health in terms of the absence of limitations, ceiling effects (the highest scores possible) are more prevalent and problematic than are floor effects (the lowest score possible), and are considered critical when over 15% (McHorney and Tarlov, 1995). At population level, ceiling effects produce type II errors in hypothesis testing. Furthermore, it is impossible to measure improvement in health over time (which is a commonly articulated objective) for those already at the ceiling (McHorney, 1999).

Ceiling effects have been most frequently reported in the role emotional and role physical domains of the SF-36 in UK populations (Brazier et al, 1992) and greater concern for the interpretation and applicability of data is perhaps warranted here. A revised version of the SF-36 (Version II) attempts to redress these effects, and has been validated in UK populations, albeit in adults of working age (Jenkinson et al, 1999). Few studies among the critically ill appear to have adopted its use.

#### 3.15.1.4.2 Use among the elderly

The elderly represent a significant and increasing proportion of the critically ill patient population. The perspectives of the over 65's are rarely addressed in the development and use of HRQoL measures (Walters et al, 2001), and widely used measures are frequently reported to neglect the perspectives and priorities of this patient group (Farquhar (1995), Hendry and McVittie (2004), Grewal et al (2006)). Lower response rates to the SF-36 (and HRQoL measures more generally) have been reported among this patient group (Brazier et al, 1992), with attendant concerns for their representation in population based studies.

### **3.15.2 The EuroQoL (EQ-5D)**

#### **3.15.2.1 Development**

The European Quality of Life (EuroQoL) group, an international network of multidisciplinary researchers was first established in 1987, with the sole purpose of developing a generic health status measure for the purposes of international comparison. Questionnaire content originated from a review of existing instruments and was later tested using a survey of lay concepts of health. The EQ-5D was originally designed to form one component of a battery of instruments, supplemented, for example, by other generic HRQoL instruments (such as the SF-36) or disease-specific measures (McDowell, 2006). It is increasingly used, however, as a stand alone measure in population-based and health services research.

Designed for brevity and ease of administration, the EQ-5D comprises 5 single-item dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression (see appendix 12). Three levels of severity in each of the 5 dimensions (no problems =1, some problems =2 and severe problems =3) generate a total of 243 ( $3^5$ ) possible health states. Two additional health states; “unconscious” and “dead” also exist, but are clearly inapplicable for self-completion. Each composite health state is assigned a 5 digit code; 11111, for example, denotes no problems on any of the dimensions. A visual analogue scale (VAS) is also included, on which participants denote on a scale of 0 to 100 how they rate their health “today”; 0 denotes the worst and 100 denotes the best imaginable health state.

In contrast to the SF-36, the EQ-5D is intended to capture respondents’ health status at the time of completion. The EQ-5D is intended for self-completion, although proxy and telephone versions are also available. It has been translated into over 100 languages, and electronic modes of administration are currently being developed (Ramachandran et al, 2008).

The EQ-5D is widely used in economic evaluations. Here, self-classified health states may be transformed into a single numerical index by applying scores from a standardised set of preference weights derived from the general population for the derivation of QALYs. Index scores are typically applied from a societal perspective

and have been derived for example, for a wide range of chronic conditions in the U.S. (Sullivan and Ghushchyan, 2006). (They may also be derived on an individual basis from the respondent's reported health status on the visual analogue scale.) Similar initiatives have been advocated in the UK by the National Institute for Clinical Excellence.

### **3.15.2.2 Use and validation in non-ICU populations**

The EQ-5D has been administered and validated for use among a diverse range of patient populations including, for example, sufferers of arthritis (Harrison et al, 2010), diabetes (Clarke et al, 2002), chronic fatigue (Myers and Wilks, 1999) and dementia (Ankri et al, 2003). The most frequent criticisms of the EQ-5D are its insensitivity to important differences in patient reported outcomes (Fransen and Edmonds, 1999) and lack of responsiveness to change (Harper et al (1997), Wu et al (2002)). Construct validity (Johnson and Pickard, 2000) test-retest reliability (van Agt et al, 1994) and responsiveness (Luo et al, 2007) have nonetheless been reported.

At population level, support for construct validity has been reported on the basis of expected correlations between age, gender and self-reported health (Johnson et al (2000), Kontodimopoulos et al (2008)). Given its brevity, the EQ-5D is frequently criticised with regard to its incongruence with accepted multidimensional conceptualisations of health and HRQoL (Nordlund et al, 2004) and ceiling effects have frequently been reported among general populations (Hawthorne et al (2001), Brazier et al (2004), Nordlund et al (2005)).

### **3.15.2.3 Use and validation in ICU populations**

This measure has been administered in a comparatively small but increasing number of ICU studies (n=20), and these are summarised in Appendix 13. Much like the studies utilising the SF-36, there is variation in the patient populations studied. The identified studies comprised the general ICU population (n=12) and various sub-groups including sepsis (n=3), trauma (n=2), pancreatitis (n=1), ARDS (n=1) and cardiac arrest (n=1). The duration of follow-up ranged between 3 months and 7 years, and there was wide variation in the use of comparison groups. The EQ-5D has also been used in the derivation of QALYs (Kaarlola et al, 2006) and in economic

evaluations of ICU intervention (Sznajder et al (2001), Alhstrom et al (2005), Edwards et al (2006)).

In each of the identified studies, the EQ-5D was administered on only one occasion. In stark comparison to the studies utilising the SF-36, the EQ-5D was very rarely administered in conjunction with other standardised adjuncts of physical, neurocognitive or psycho-affective impairment. A total of 7 studies adopted return to work or place of residence as crude measures of functional ability, and a singular study utilised a standardised measure (Merlani et al, 2007). The EQ-5D, in summary, would appear to provide rather crude insights into the HRQoL and its recovery among survivors of critical illness (potentially under the guise of economic evaluation). Given that the majority of papers were published in the last 6 years, its increasing use might be described as a worrying trend.

Measurement of the tool's psychometric properties in ICU populations has been limited, moreover, to a small number of studies, and it is generally accepted that the EQ-5D has not been adequately validated for use among survivors of critical illness (Black et al (2001), Dowdy et al (2005)). Weak discriminatory power and ceiling effects in relation to mobility self-care and have also been reported (Kaarlola et al, 2004). Construct validity has been assessed by comparison with the Short Form 36 (Orwelius et al (2005), Kaarlola et al (2004)) and utility in proxy measurement of quality of life have, however, been demonstrated (Cuthbertson et al, 2005).

### **3.16 Summary**

The adequacy with which professionally recommended measures and widely used adjuncts have been validated for use among survivors of critical illness remains unclear, and responsiveness has not been adequately tested. The meta-synthesis of HRQoL data in existing studies is difficult, due the heterogeneity in the patient populations studied, variation in the duration of follow-up, variation in the use of comparison groups, the reporting of data and international differences in healthcare organisation and delivery. Ceiling and response shift effects are potentially problematic among critically ill patient populations, although are rarely acknowledged or reported.

Given the inherent crudity and the (as yet) comparatively limited use of the EQ-5D, enquiry focuses hereafter upon the SF-36. In the following section, I explore the current state of knowledge through the review of critical care outcomes studies among a relatively homogeneous and particularly well studied sub-set of the ICU patient population.

### **3.17 Exemplar; HRQoL among survivors of ARDS**

Survivors of Acute Respiratory Distress Syndrome (ARDS) comprise a relatively homogeneous sub-group of the population, in as much as that there is international consensus on diagnostic criteria, illness severity classification and treatment strategies (American Thoracic Society, 1998). Over a third of the studies identified as using the SF-36 were conducted among this patient group (see appendix 14). Administered with a diverse range of adjuncts, these studies serve as a useful exemplar of the application and interpretation of HRQoL measures in critical care research. A secondary aim, given the frequent use of the SF-36 as a stand alone measure or in association with crude measures of recovery (such as return to work) is an exploration of its sensitivity to prevalent physical and psychological morbidity.

#### **3.17.1 The SF-36 and decrements in HRQoL dimensions**

A summary of the decrements by dimension, and in comparison with age and sex-matched general populations is provided in Appendix 15. Global impairment below that of the general population is demonstrated by decrements in all 8 domains of the SF-36. Only three studies report upon changes in dimensional scores over time (Herridge et al (2003), Hopkins et al (2004) and Heyland (2005)). While interpretation is difficult due to differences in reporting, there appears to be significant improvement across the physical dimensions at 12 months remaining, nonetheless, below population norms.

Dowdy et al's (2006) meta-analysis of HRQoL among this patient group suggests that decrements in the physical dimensions (physical function, role physical, vitality, bodily pain and general health) exceed those in the mental dimensions (social function, role emotion and mental health). These decrements, in addition, appear to

remain relatively stable at 12 months, with minimal improvement in subsequent evaluations. While the demonstration of sustained global impairment and incomplete recovery across dimensions is clearly important, this data alone offers limited clinical information in terms of their underlying rationale or potential interventional strategies.

### **3.17.2 The SF-36 and disease-specific measures of HRQoL**

The simultaneous administration of generic and disease-specific measures, as previously described, is intended to explore the relationship between condition-specific symptomatology and broader aspects of HRQoL. Based on limited evidence of criterion and construct validity among the critically ill, the American Thoracic Society's Respiratory Questionnaire (Ferris et al, 1978) has been recommended for use among ICU patient populations (Black et al, 2001). Three of the identified studies administered the St George's Respiratory Questionnaire (SGRQ, Jones et al (1991)) in conjunction with the SF-36. Weinert et al (1997) administered only selective items from the Chronic Respiratory Questionnaire (GCRQ, Guyatt et al (1987)) and their findings are therefore not examined here.

Heyland et al (2005) report strong correlation between each of the domains of the SF-36 and the SGRQ, while Davidson et al (1999) and Parker et al (2006) report correlation between all but the general health dimension of the SF-36 and the symptom and activity-related dimensions of the SGRQ. Parker et al (2006) additionally report upon the relationship between the mechanisms of lung injury and HRQoL and demonstrate apparent differences in the HRQoL profiles and recovery between direct (e.g. aspiration, pneumonia, near drowning) and indirect insults (e.g. as a result of sepsis or blood transfusion).

### **3.17.3 The SF-36 and functional ability**

The SF-36 has been widely used in conjunction with objective measures of physical function and impairment among survivors of ARDS. Based on some evidence of construct validity, criterion validity and responsiveness among the critically ill, recommended standardised measures of function comprise the questionnaire based

Katz Activities of Daily Living (ADL, Katz et al, 1963) and the Karnofsky Index (Karnofsky et al, 1948).

Three of the identified studies utilised these standardised measures. Weinert et al (1997) report only a weak correlation between the Karnofsky Index and the physical dimensions of the SF-36. Heyland et al (2005), similarly, report only a weak correlation between the Zubrod (Zubrod et al, 1960) scale and the physical dimension. Hopkins et al's (1999) use of Katz's ADL appears to demonstrate a correlation between improvements in the physical function, role physical and vitality in the SF-36 with independence in activities of daily living.

A number of studies included *clinically* derived measures of function or impairment comprising chest X ray, spirometry, pulmonary function tests (PFT) and the 6 minute walk test (6MWT). In the 5 studies using PFTs, Schelling et al (2000) report a correlation between *multiple* pulmonary symptoms and HRQoL overall, while Orme et al (2003) and Heyland et al (2005) report a significant correlation between PFT and the physical dimensions of the SF-36. While Cheung et al (2006) do not report directly upon the relationship between PFT and the SF-36, they do report, however, only *moderate* decrements in PFT at 1 and 2 years following ICU discharge.

Herridge et al (2003) and subsequently Cheung et al (2006) do not explore the relationship between the 6MWT and HRQoL. They do report, however, moderate impairment in as much as that survivors achieved 66% and 68% of predicted values (based on age and sex-matched norms) at 1 and 2 years respectively. Importantly, *patients* attributed exercise limitation to generalised weakness, global muscle wasting, foot drop, immobility of large joints as opposed to limitations in respiratory function (Herridge et al, 2003).

Crude measures of functionality comprise return to work and place of residence, although the latter was not studied among this patient population. Despite limited construct and criterion validity of return to work (RTW) among survivors of critical illness (Hayes et al, 2000), it is widely used. Given wide variation in the duration of follow-up, it is difficult to report upon the proportion of patients returning to work at

specific time points. 49 % of Herridge et al's (2003) patients had returned to work at 1 year follow-up, however, increasing to 65% at 2 years (Cheung et al, 2006).

Schelling et al (2000) report a statistically significant relationship between employment status and higher scores on the Physical Component Scale of the SF-36. Rothenhausler et al (2001) report a significant correlation between cognitive dysfunction and employment status. Herridge et al's (2003) survivors attributed an inability to return to work to persistent weakness, fatigue and poor functional status due to immobility, suggesting that RTW is affected by physical, psychological and neurocognitive morbidity.

### **3.17.4 The SF-36 and psychological morbidity**

#### **3.17.4.1 Anxiety**

The prevalence of anxiety was examined in 5 studies among this patient population, none of which explored the correlation between the measured used and the mental health dimensions of the SF-36 or HRQoL overall. The Beck Anxiety Inventory (BAI; Beck et al (1988)) was utilised in 4 studies and the State-Trait Anxiety Index (Laux et al, 1991) was used in one. The Symptom Checklist 90-R (SC90-R, Derogatis et al (1977)), a multi-dimensional measure of psychological distress was also used in two studies.

Among the studies utilising the BAI, the prevalence of moderate anxiety at one year follow-up was remarkably consistent at between 23% and 24% of patients (Hopkins et al (1999), Orme et al (2003) respectively). At 2 years follow-up among the same cohort, Hopkins et al (2004) the prevalence of moderate anxiety remained unchanged at 23%. Hopkins et al (1999) also report an absence of abnormal symptomatology using the SC90-R, whereas Deja et al (2006) report "significantly more intense symptoms" among patients scoring highly for PTSD.

#### **3.17.4.2 Depression**

The prevalence of was depression examined in 6 studies. The Beck Depression Inventory (BDI; Beck et al (1961)) was used in 3 studies. The Centre for

Epidemiologic Studies Depression Scale (CES-D; Radloff et al (1977)), the Zung Depression scale (ZDS; Zung et al, 1965) and the Montgomery-Asberg Depression Rating Scale (MADRS; Montgomery et al (1979)) were each used once. Few report on the relationship between depression and the mental health dimensions of the SF-36 or HRQoL overall.

Among the studies using the BDI, at one year follow-up, the prevalence of moderate depression ranged between 16% and 23% (Orme et al (2003) and Hopkins et al (1999) respectively). Among the same patient cohort at 2 years follow-up, Hopkins et al (2004) report moderate depression among 23% of patients. Using the CES-D, Weinert et al (1997) report “a strong likelihood of depression” among 43% of survivors, and a strong correlation between the CES-D and the mental health components of the SF-36. Using the ZDS, Mikkelsen et al (1999) report a prevalence of moderate depression in 34%. Using the MADRS, Kapfhammer et al (2004) report minimal evidence of depressive symptomatology at a mean 8 years’ follow up.

#### **3.17.4.3 Post Traumatic Stress Disorder (PTSD)**

The prevalence of PTSD was examined in 3 studies. The Post-Traumatic Stress Syndrome 10-Questions Inventory (PTSS-10; Weisaeth (1999)) was used in all 3. Schelling et al (1998) report a prevalence of PTSD of 27.5% among their study cohort at a median of 48 months follow up. They also report an association between the number of traumatic experiences recalled by survivors, the incidence of PTSD and the mental health dimensions of the SF-36. Kapfhammer et al (2004) report a prevalence of PTSD among 44% of survivors on ICU or hospital discharge, and a prevalence of 24% at a mean of 8 years later. They report a correlation between a diagnosis of PTSD and the general health, social function and mental health dimensions of the SF-36. 29% of Deja et al’s (2006) participants were described as “at high risk” of PTSD, and this designation of was strongly correlated with each of the dimensions of the SF-36.

#### **3.17.4.4 Neurocognitive impairment**

Cognitive function comprises mental activities that involve the acquisition, storage and retrieval of information and includes attributes such as memory, attention,

executive function, mental processing speed, spatial ability and general intelligence. Reflecting the breadth of relevant attributes, a range of measures were utilised. A detailed review is therefore not attempted here.

The prevalence of neurocognitive impairment was examined in 4 studies among survivors of ARDS. Two others are not included in this discussion: one recruited (self-selecting) participants from an internet support site (Mikkelsen et al, 1999) and the other was a feasibility study of a battery of instruments for telephone administration (Christie et al, 2006).

Hopkins (1999) report that 45% of patients with severe ARDS exhibited generalized cognitive decline at 1 year follow-up and 78% of patients exhibited at least one of the following: impaired memory, attention, concentration and/or decreased mental processing speed. The prevalence of neurocognitive dysfunction remained relatively static, at 47% at 2 years follow up among the same cohort (Hopkins et al, 2004). Rothenhausler et al (2001) report mild to moderate cognitive impairment among 24% of survivors at a median of 6 years follow up. Kapfhammer et al (2004), in contrast, report the absence of cognitive impairment among survivors at between 3 and 13 years of follow up.

Hopkins et al (1999) and Rothenhausler et al (2001) report that patients with cognitive impairment exhibited significant reductions in SF-36 scores overall when compared to an age and gender matched normative population. The latter report the most marked decrements in the role physical and social function dimensions. Christie (2006), however, describes a correlation between cognitive impairment and the mental health dimensions, but not with the physical function dimensions of the SF-36.

### **3.18 Summary**

The physical function dimensions of the SF-36 appear to reflect physical and functional morbidity relatively consistently among this patient group. These studies support previous findings that physical function undergoes significant improvement at 1 year follow-up among survivors of ARDS but is relatively static thereafter,

generally remaining below population norms. The majority of survivors are nonetheless able to return to the workplace.

The relationship between respiratory symptomatology, physical function and HRQoL remains uncertain, however. Davidson et al (1999), for example, conclude that decrements in HRQoL are caused “exclusively by ARDS and its sequelae”, whereas Heyland et al (2005) report a rather more modest “causal contribution” of pulmonary symptoms to overall HRQoL. Herridge et al (2003), in contrast, note both moderate impairments in pulmonary function and the prevalence of “extra-pulmonary” symptoms (i.e. more generalised impairment such as weakness and fatigue). They argue that it is *these* that account for the largest decrements in functional ability and possibly HRQoL. Herridge et al’s (2003) conclusions, importantly, are supported by ongoing engagement with the participants in their landmark longitudinal study. Moreover, they suggest that these sequelae may simply represent the typical residua of *any severe critical illness* as opposed to ARDS exclusively.

The ability of the mental health dimensions of the SF-36 to reflect psychological morbidity and neurocognitive impairment among this patient group is less well established, due in part to wide variation in the ancillary measures used. These data appear to support Dowdy et al’s (2005) assertion, nonetheless, that decrements in the mental health dimensions of the SF-36 are less pronounced than in the physical dimensions. The reported prevalence of psycho-affective disorders varies widely, but appears to be somewhat refractory to improvement over time.

These data provide clinically relevant yet limited insights into the prevalence of critical illness-related morbidity and the temporal process of recovery among this patient group. Despite a marked preoccupation with the *prevalence* of physical and functional morbidity associated with ARDS, there remains, as yet, little engagement in the broader interpretation of data, particularly in relation to its putative relationship with HRQoL. There is limited engagement also in the translation of findings into interventional strategies.

### 3.19 Discussion

While reputedly “robust” in terms of their *psychometric* validation (McHorney, 1999), the first section of this review demonstrated that widely used generic HRQoL measures often lack both an explicit theoretical basis for its underlying constructs (Leplege and Hunt, 1997) and a clear methodological focus upon the experiences and perspectives of patients, with the corollary that it is often difficult (if not impossible) to delineate what existing instruments, with their inherent inconsistencies, are *actually* measuring (Hayry (1991), Leplege and Hunt (1997)).

The theoretical ambiguity of such measures is nonetheless of limited relevance to the naturalist, empiricist or pragmatic traditions associated with medicine (Faden and Leplege (1992), (Rosenberg, 1995)), leading presumably, to their largely uncritical use (Gill and Feinstein, 1994). Existing measures vary widely in the extent to which “the voice of the lifeworld” is incorporated in their development and validation, often reflecting little more than the preoccupations and presuppositions of researchers (Fitzpatrick (1996), (Leplege and Hunt, 1997)); an approach said to preserve the supremacy of professional judgments (Leplege and Hunt, 1997) to the detriment of patients’ autonomy in expressing their own health care needs and priorities (Dijkers, 1999).

Implications for the patient-centred evaluation, development and rationalisation of health care intervention are seldom addressed in the prevailing literature, but are nonetheless compelling,

“...the notion of quality of life is employed by theorists to address certain problems on the basis that those actually facing the problems see this as a relevant factor. But if the theorist solves the problem in terms of a distorted theoretical account of the factor, distorted because the theoretical refinements slant the notion in a certain way-if this is the case, then the theorist has not solved the original problem”. (Megone, 1990: 29)

An examination of the patient-centredness of widely used HRQoL measures is therefore critical to the development of appropriate and responsive health services provision, given the accelerating use of HRQoL instruments in the evaluation, commissioning and rationalisation of scarce resource. This thesis therefore “interrogates” a widely used and professionally endorsed HRQoL measure (the SF-

36) through both patient narratives and social science theory in order to examine its fitness for purpose as a patient-centred measure of outcome among survivors of prolonged critical illness. The following chapter outlines the ways in which this was done.

## Chapter 4: Methods

### Section One

#### 4.1 Introduction

The absence of financial investment in *academic* work stands in stark contrast to strong public sector and commercial backing for the operationalisation and application of HRQoL in health services research has arguably contributed to a lack of theoretical advancement (Hunt, 1997). Supported by a burgeoning body of social science theory, qualitative approaches to health services research have helped to explore the patient experience and, to a lesser extent, the tension between the outcomes movement which continues to be driven by professional and organisational concerns and the policy goals of patient-centredness (Lhussier et al, 2005).

Having identified, in the previous chapter, the ways in which qualitative methods are enabled to both access and incorporate the patient experience into HRQoL measures, the following questions are addressed in the remainder of this thesis. (While they are specific in this thesis to the SF-36, they are inherently relevant to HRQoL research more generally.)

- What are survivors' "real world" experiences of and perspectives on completing the SF-36?
- What can the integration of the patient experience lead to the interpretation of the SF-36?
- What can the integration of the patient experience lead to the use of the SF-36 in practice, policy and critical care outcomes research?
- What can the social science literatures bring to theoretical understandings of HRQoL?

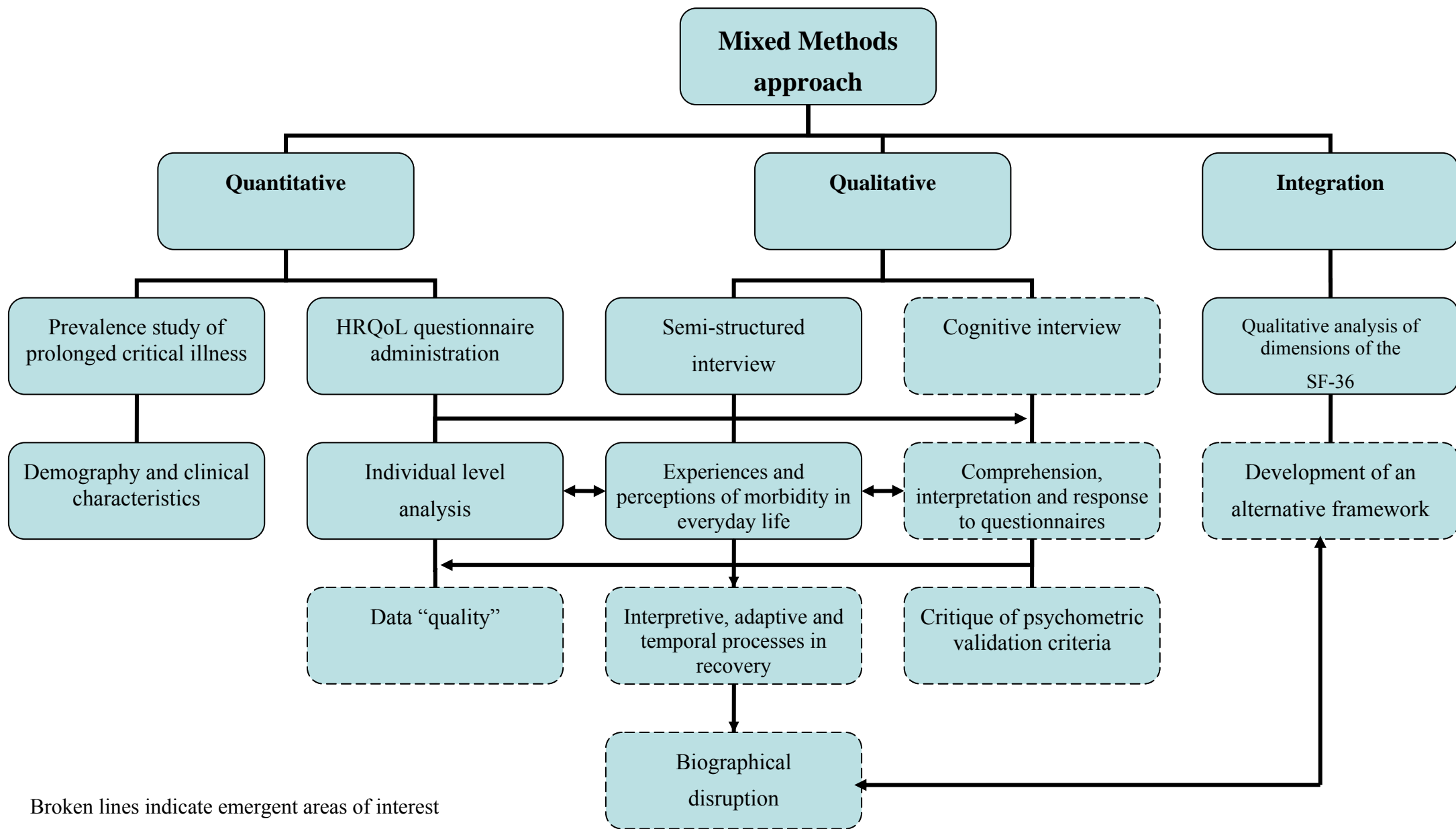
A particular problem, however, in relation to qualitative explorations of HRQoL is the dearth of literature relative to that devoted to experiences of health and illness more generally. Fewer still qualitative data exist which are specific to experiences of

morbidity and HRQoL following critical illness. Given the therefore exploratory nature of enquiry in this thesis, early iterations of the research strategy (which were focussed upon and inevitably constrained by the questionnaire) proved somewhat unsophisticated in terms of addressing the anomalies thrown up by both the richness and complexity of the “lifeworld” and the wealth of social science theory available for its interpretation.

Despite some not insignificant trepidation associated with the adoption of an inductive and responsive approach to the concurrently evolving research question(s), concerns around the appropriateness of alternative methods and the complexity of data analysis in line with existing theory, the research strategy inevitably proved a “messy untidy business” (Pope and Mays, 1995: 3) (see figure 2) such that

“...the whole idea of a method for discovering things is *ex post facto*...you go back, trying to re-create the steps that led you, not quite by accident, not quite by design, to where you wanted to be. You call that re-creation your “method.” (Koller, 1983: 88, cited by Sandelowski, 2008).

Figure 2: The research strategy



Given that different methods of enquiry yield different and often inconsistent kinds of data, dependent upon their sensitivity to “real world nuances”, the research strategy offered significant opportunity for deeper insight into the relationship between method and the phenomena under study (Patton, 1999). An exploration of the divergent philosophical assumptions underpinning quantitative and qualitative HRQoL methodology was therefore conducted, including the extent to which these might be reconciled in the analytic process.

In the following sections, the research methodologies are defined in terms of their philosophical and theoretical principles with particular reference to health services research; a pragmatic or applied discipline which has tended to overlook the extant academic or philosophical debates around their use. The research *process* (defined here in terms of issues related to recruitment, ethical approval, etc) is quite distinct from this discussion and is therefore described separately.

## 4.2 A brief clarification of terms

Following a bewildering “grand tour” of the literature with regard to these philosophical and theoretical considerations, in which imprecise, contradictory (and frankly often incomprehensible) definitions of the relevant terminology abound, a brief overview of the research strategy is provided, using Crotty’s (1998) “four elements” as a basic framework:

- (i) Methods; the techniques or procedures used to gather and analyse data.
- (ii) Methodology; the research design that shapes the choice and use of particular methods and links them to the desired outcomes.
- (iii) Theoretical perspective; the philosophical stance informing the methodology and thus providing a context for the process and an anchor for its logic and criteria
- (iv) Epistemology; the theory of knowledge embedded in the theoretical perspective, and thereby in the methodology (Crotty, 1998)

It is noteworthy that Crotty (1998) does not include or make a clear distinction between epistemology and ontology, arguing that the use of the term should be reserved for those rare occasions when the nature of *existence* is to be examined.

Ontology, he suggests, sits

“alongside epistemology informing the theoretical perspective, for each theoretical perspective embodies a certain way of understanding *what is* (ontology) as well as a certain way of understanding *what it means to know* (epistemology)”. (Crotty, 1998: 10)

The relationship between the researcher’s theoretical perspective (or more generally his/her use of theory), epistemological stance and research method(ology) in particular, has been a source of some considerable debate within the health services literature. Given the reputedly “atheoretical” nature of much quantitative research (Mills, 1956), however, debates around their significance and implications have generally been confined to the qualitative tradition.

#### **4.2.1 Theory and health services research methodology**

Much of qualitative health services research methodology is derived from that of the social sciences including, in particular, sociology and anthropology. Few health services researchers are familiar, however, with its underlying philosophical principles (Pope et al (1998), Brazil et al (2005)), adopting instead a *problem* or *process* oriented approach to data collection and analysis (Harding and Gantley (1998), Katz and Mischler (2003)).

A subsequent emphasis upon *method* without due consideration of the underlying theoretical or philosophical principles has led, it is argued, to a “slavish cook book” “generic” or “pick and mix” approach to the research question (Harding and Gantley (1998), Appleton and King (2002)). Thus, the scope of problem or process oriented research is defined by pragmatic, localised concerns, often resulting in the mere assembly of “empirical” data which is diminished in terms of its analytical or explanatory potential and in terms of its ability to advance knowledge (Harding and Gantley, 1998).

A central assumption of a theoretically informed approach is that the apparent authenticity of the data should not necessarily be taken at face value (Harding and Gantley, 1998). Social science theory, accordingly, provides a set of general, modifiable propositions including basic assumptions that help *explain, predict, and interpret* phenomena of interest (Patton 2002), including an understanding of causal links, confounding variables and the context within which a phenomenon occurs.

Qualitative health services researchers, nonetheless, are often unfamiliar with the corpus of sociological theory, and generally adopt a somewhat unidisciplinary approach to the phenomenon

under study. A common ground is said to have emerged, however, in response to both the decline in funding for theoretically orientated research relative to that available for health services research (Harding and Gantley, 1998), and in recognition of the increased credibility of theory-based research among health services managers and policy makers (Brazil et al, 2005).

#### **4.2.2 Epistemology and health services research methodology**

Epistemology deals with the relationship between the researcher, the researched and the nature of knowledge; put simply, what kinds of knowledge are possible or how we come to know what we know (Crotty 1998).

“Epistemology is concerned with providing a philosophical grounding for deciding what kinds of knowledge are possible, and how we can ensure that they are both *adequate* and *legitimate*.” (Maynard, 1994: 10) (my emphases)

The knowledge or “truth” claims associated with alternative methodologies are, to some extent, based upon the impact of *values* upon the enquiry process (Appleton and King, 2002). Empiricism, for example, remains the dominant discourse in health services research and has become the taken-for-granted norm that is rarely subjected to critique. There are fundamental limits, however, to the extent to which empiricism can be applied to the social world (Devers, 1999). Multiple and sometimes contradictory “knowledges” often exist and are, to some extent, dependent upon the method used to garner them.

The relationship between epistemology and method is rarely articulated in the extant literatures, however, and given the often imperfect relationship between (qualitative) method and epistemology (Devers (1999), Bryman (1984)) the latter has been described as a somewhat “negative” discipline; one which traditionally concerns itself with “oughts” (i.e. is overly prescriptive) and one which settles its questions by reasoning from first principles as opposed to empirical enquiry (Becker, 1996). This approach, it is argued, is of limited relevance among health services research, as a discipline which lends itself to the latter. Epistemology, within this context, is said to have undergone something of a transformation, “giving up preaching about how things should be done and settling for seeing how they are, in fact, done” (Becker, 1996).

#### **4.2.3 Summary**

Crotty’s (1998) definition of “the four elements”, while useful, provides limited insight into the sometimes contentious inter-relationships therein, or their relevance and implications for health

services research and practice. The “classic” features of research within the social science tradition are, to some extent, attenuated by pragmatic and localised concerns in health services research, although a common ground appears to be emerging amidst calls for greater multidisciplinary (Trivedi and Wykes, 2002).

In the following sections, a review of quantitative, qualitative and mixed methods approaches to HRQoL is provided, with reference to these philosophical and practical concerns. Given that *what is done* with evidence on patient experience is as important as the methods used to generate it (Devlin, 2003), attention is directed, in addition, to the evaluation of these alternative approaches.

### **4.3 Quantitative approaches to HRQoL**

Despite the predominance of the quantitative approach in health services research, much of what is known about its fundamental principles and epistemological distinctness from qualitative methodology is derived from writers within the latter tradition (Bryman, 1984). Quantitative HRQoL research generally assumes an “objectivist” epistemology and a “positivistic” theoretical perspective, whose basic premise is that HRQoL can be objectively measured or quantified. There is considerable emphasis upon measurement, operational definitions, objectivity, replicability, causality and the like. A deductive form of logic prevails wherein hypotheses are tested in a cause and effect order (Creswell, 1994) and the researcher views “scientifically” produced data as neutral or value-free and ultimately generalisable to other situations (Rubin and Rubin, 2005).

The HRQoL questionnaire is readily adaptable to positivist concerns (Bryman, 1984) in as much as that: HRQoL can be operationalised (broken down into component “dimensions”); objectivity is maintained by the “distance” between the researcher and the researched (e.g. through postal administration or the use of fixed response categories) and by the application of external checks (e.g. objective measures of physical function); replicability can be demonstrated by the use of the questionnaire in another context or sub group of the patient population; and causal relationships (e.g. between physical and psychosocial morbidity and HRQoL) can be determined through sophisticated statistical techniques.

#### **4.3.1 Evaluating quantitative approaches to HRQoL**

The relative strengths and weaknesses of the quantitative approach to HRQoL measurement are summarised in appendix 16. Prominent criticisms include: the potential for discontinuity or divergence

between the researcher and participants' perspectives; concerns around the generalisability of findings to specific local situations, contexts, and individuals and inattention to emergent phenomena due to an emphasis on the cause and effect testing of hypotheses (Johnson and Onwuegbuzie, 2004).

A plethora of formal evaluative criteria exist in relation to the review and selection of HRQoL instruments (see appendix 17) and to the reporting of HRQoL data in clinical trials (see appendix 18). Often developed and supported by public sector agencies, the former reflect an emphasis upon the psychometric properties of prospective instruments, as previously described.

#### **4.4 Qualitative approaches to HRQoL**

HRQoL is widely conceptualised in the qualitative research tradition as an amorphous and dynamic construct (O'Boyle and Waldron (1997), Allison et al (1997)). Arguing that individuals neither experience nor can represent aspects of QoL as falling into discrete dimensions (Hendry and McVittie, 2004), health-related or otherwise (Leplege and Hunt, 1997), its operationalisation into component dimensions has been described as "reductionist" and "mechanistic" (Felton, 2005). Quantitative approaches, it is suggested, provide only

“...superficial evidence on the social world, winking out the causal relationships between arbitrarily chosen variables which have little or no meaning to those individuals whose social worlds they are meant to represent.” (Bryman, 1984: 78)

Qualitative HRQoL research therefore generally adopts a “constructionist” or “subjectivist” epistemology, examining human experience in terms of the way in which people live and interact within the social world (Popay, 1992). Its “meaning” is said to exist in the form of multiple and intangible social constructions, which are experientially based, local and specific in nature, and dependent for their form and content upon the individual concerned (Guba and Lincoln, 1994).

The constructionist-subjectivist approach assumes an interaction between researcher and the researched, adopting a “naturalistic” set of methodologies, the purpose of which, generally speaking, is to remain “true” to the nature of the phenomena being investigated (Bryman, 1984). The researcher's role, accordingly, is to gain a holistic, highly contextualised or “insider view” of the phenomenon under exploration, through intense and/or prolonged interaction with the participants (Miles and Huberman, 1994), often through observation or in-depth interview.

The researcher adopts an *inductive* and flexible approach to data collection and analysis, with attention to nuance and complexity, sensitivity towards emerging and unanticipated findings and the production of an account “thick” or “rich” in description. Thus, the researcher is often described as both the research instrument and *bricoleur*. The latter refers, importantly, to the pragmatic and strategic adoption of alternative strategies, perspectives or empirical materials, always hoping to get a “better fix” on the subject matter at hand (Denzin and Lincoln, 2005).

#### **4.4.1 Evaluating qualitative approaches to HRQoL**

The relative strengths and weaknesses of a qualitative approach to HRQoL and considerations in its evaluation are summarised in appendices 19 and 20, respectively. Prevalent criticisms of this approach include; its “impressionistic” and “unscientific” nature (Bryman, 1984); the inherently subjective or idiosyncratic nature of the analytic process (Hammell et al, 2005) and the specificity of findings to the individuals or settings involved (i.e. limited “generalisability”).

Much has been made of the inability of qualitative approaches to allow for generalisation in the conventional (i.e. statistical) sense. Alternative conceptualisations of the term include “fittingness”, “comparability” and “translatability”, which broadly speaking, rely on detailed description of the phenomenon, context, theoretical stance and research techniques employed (Schofield, 1993). “Naturalistic” generalisation allows the reader to use both explicit comparisons and tacit knowledge of similar situations to make an informed judgement about the application of the findings to alternative contexts (Schofield, 1993). This approach provides “analytical” or “theoretical” generalisation, through “replication logic” (Yin, 1994) in as much as that the strategic selection of cases may facilitate (a) literal replication (similar results) or (b) theoretical replication (contrasting results, but for predictable reasons) (Yin, 1994).

A significant literature is dedicated to discerning and reporting the quality, rigour or credibility of qualitative research and analysis, resulting in a proliferation of guidelines, checklists and criteria. Little consensus exists, however, on their relevance or use. There is a persistent failure, for example, among the burgeoning literature to distinguish between those concerned with the *transparency* of analysis and reporting, and those concerned with its *quality*, with the corollary that the authors of a study may provide clear details of the rationale and appropriateness of the procedures followed, but only limited insights into the phenomenon at hand (Dixon-Woods et al, 2004).

The vast majority of the literature concerns itself with the latter, and three broad “camps” appear to have emerged: those who favour the adoption of similar evaluative criteria to those used in quantitative research; those who favour the development of distinct, alternative criteria and those who question the appropriateness of *any* predetermined criteria for judging qualitative research (Hope and Waterman (2003), Rolfe (2004)). The latter, predictably, has garnered little support among health services researchers and is therefore not described in detail here. Guba and Lincoln’s (2004) criteria of “trustworthiness” are perhaps the most frequently cited. They comprise;

- credibility; the “believability” of constructed realities
- transferability; related to the richness of description, whereby the reader may make an informed judgement about the application of findings to alternative situations
- dependability and confirmability; broadly defined in terms of the transparency of the research process

These evaluative criteria are said to parallel the notions of internal validity, external validity, reliability and objectivity associated with the quantitative approach. Many authors are critical, however, of attempts to “neutralise” the distinctive features of qualitative research by aligning it with inherently positivist criteria (Katz and Mishler, 2003), arguing that the issues at stake in qualitative research are fundamentally different, and that its emergent and idiosyncratic nature requires the development of alternative evaluative strategies (Koch and Harrington, 1998). A plethora of alternative criteria have been advanced – including, for example, “quality” (Mays and Pope, 2000), “validity” (Rolfe, 2004) and “relevance” (Hammersley, 2000) with, however, often little evidence of common ground (Dixon-Woods et al, 2004).

Those questioning the appropriateness of *any* predetermined criteria for judging qualitative research argue that the imposition of “scientific” criteria or artificial consensus distorts the individuality and “meaningfulness” of the findings (Sandelowski, 2003). Others have argued that, given the plurality of approaches and the absence of a unified paradigm, it makes little sense to establish generic criteria for judging the quality of qualitative research (Rolfe, 2004). A more pragmatic approach, perhaps, is the development of appraisal criteria suited to the different methods of qualitative data collection and to different methodological approaches (Dixon-Woods et al, 2004). Whichever approach is taken, however, aspects relating to quality of insight and interpretation remain difficult to appraise, relying heavily upon subjective judgement (Dixon-Woods et al, 2004).

## 4.5 The over-arching research strategy: mixed methods

In much the same way that the qualitative paradigm evolved as a counter-movement to its quantitative counterpart, mixed methods evolved from an increasing emphasis upon more socially sensitive and applied research (Tashakkori and Teddlie, 2003). The focus of mixed methods approaches is upon the *technical* and *methodological* aspects of the research process, such that the philosophical and theoretical assumptions underpinning their use have not yet been elucidated (Johnson and Onwuegbuzie, 2004). Compelling arguments nonetheless exist for a combined or integrated approach to the research question(s) at hand, and these generally comprise:

- *Triangulation*; seeking convergence and corroboration of results from different methods and designs studying the same phenomenon
- *Complementarity*; seeking elaboration, enhancement, illustration, and clarification of the results from one method with results from the other
- *Initiation*; discovering paradoxes and contradictions that lead to a re-framing of the research question
- *Development*; using the findings from one method to help inform the other
- *Expansion*; seeking to expand the breadth and range of research by using different methods for different components of the enquiry (Greene et al, 1989).

Triangulation is perhaps the most cogent argument for the mixed methods approach, although contemporary conceptualisations have developed beyond this initial goal. Triangulation is additionally defined as a means of producing a more complete picture of the investigated phenomena (i.e. without the need for convergence or corroboration) (Johnson and Onwuegbuzie, 2004), and as a means of attenuating the inherent flaws of either approach (Blaikie, 2000), through the combination of two or more data sources, methodological approaches, theoretical perspectives or analytical methods (Thurmond, 2001).

Mixed methods approaches have nonetheless sparked considerable controversy among the academic community, and three classic stances have been evolved in response: “purists”, “situationalists”, and “pragmatists” (Rossman and Wilson, 1985). Purists argue that methodological approaches are derived from mutually exclusive epistemological assumptions about the nature of knowledge and reality and cannot therefore be combined (Guba, 1994). Situationalists argue from a methodological perspective

that particular methods are more or less appropriate for particular circumstances and that while alternative methods may be complementary, they represent quite distinct entities. Little integration is fostered by the purist or situationalist stance (Rossman and Wilson, 1985).

Methodological pragmatists argue, in contrast, that a common logic for research exists in as much as that the same epistemological arguments underlie and provide warrant for both quantitative and qualitative methodologies (Becker, 1996)

“...research is a method for generating robust evidence in response to a question open to an empirical answer. Therefore, the value of research activity depends upon the ability of the researcher to substantiate a number of claims about the suitability of the research question for a research design, the credibility of the research evidence, and the validity of their interpretation of the evidence in the light of theory” (Avis, 2005: 12).

Health services research is particularly well suited to a mixed methods approach, given its increasingly pragmatic and ecumenical approach to how research should be conducted, and the legitimacy of problems, solutions and proof. Advocated here are

“...research methods suited to exploring...the experiential aspects of health care as well as classic epidemiological data about incidence, morbidity and mortality... Researchers must also consider various types of theoretical and conceptual frameworks to explain their findings. Clinical knowledge must be integrated with social science expertise as well as other disciplines...in order to explore and understand contemporary healthcare.” (Tritter, 2007: 306)

Models of mixed methods are generally defined by;

- The structure of the research project; whether the quantitative and qualitative data collected simultaneously or sequentially
- The foregrounding of the quantitative or qualitative data
- The purpose of the integration of data; e.g. triangulation, explanation, or exploration
- The stage(s) at which multi-method research strategy occurs; whether it be in the formulation of the research question, or at data collection and analysis (Bryman, 2006).

Triangulation may occur simultaneously (addressing both qualitative and quantitative questions simultaneously (without the necessity for convergence or corroboration between findings) or

sequentially (across two phases of the research, with the conduct of the second contingent upon the results of the first) (Morse, 1991).

#### **4.5.1 Evaluating mixed methods approaches to HRQoL**

Despite the inherent relevance of the mixed methods approach in health services research, much work remains to be undertaken regarding, amongst others, its rationale, design, analysis and validation strategies (Johnson and Onwuegbuzie (2004), Bryman, 2007)). The relative strengths and weaknesses of this approach are summarised in appendix 21.

Perhaps the most cogent concern around the use of mixed methods is the extent to which researchers “genuinely integrate” (i.e. analyse, interpret and report) their findings in such a way that the end product is “more than the sum of the individual quantitative and qualitative parts” (Bryman, 2007).

### **4.6 Summary**

There is limited guidance available on the used of a mixed methods approach to HRQoL (Cox, 2003). A primary concern in this research was the integration of highly contextualised narratives with quantitative approaches designed to establish empirical generalisations (Bryman, 2004). The following section outlines the ways in which this was done.

The methods used are presented in the order in which they appear in this thesis (as opposed to their relative importance or temporality in relation to the evolving strategy and analyses). They also demonstrate the increasingly abstract nature of the research questions, and their “answerability” using alternative methods. Their presentation here belies, however, the inherent “messiness” of the process, and the continual “cycling back and forth” between critiques of HRQoL instruments, the qualitative data and relevant theory.

### **4.7 Quantitative methods used in this thesis**

#### **4.7.1 A prevalence study of prolonged critical illness**

Data are rarely collected in relation to the long-term patient group as a specific sub-set of the ICU patient population. Very few data are therefore available in terms of the number or proportion of patients experiencing prolonged critical illness, their clinical or demographic characteristics, short-

term (i.e. ICU and hospital) mortality, their utilisation of acute health services resource and/or associated costs. A detailed retrospective and longitudinal review of demographic, clinical and resource-related data was therefore presented in chapter two, providing some insight into the traditional biomedical and organisational conceptualisations of “worthwhileness” defined in the opening chapter. Importantly, that data is intended to provide a context for the study, as opposed to a basis for the generalisation of the research findings to the wider long-term patient population.

#### **4.7.2 The administration of generic HRQoL questionnaires**

Clinical and research experience suggests that survivors of prolonged critical illness experience the highest prevalence and severest forms of critical illness-related morbidity. Very few studies, however, have sought to measure the prevalence of morbidity among this patient group and fewer still have sought to examine its relationship with quality of life or the temporal processes of recovery. As described previously, the professionally recommended generic HRQoL questionnaires (the SF-36 and EQ-5D) were administered to the study population (n=20) at up to six months following ICU discharge and were analysed in accordance with the developers’ recommendations.

Recognising at the outset that the small sample size would prohibit complex analysis, meaningful comparison between patients, and the generalisation of the results to similar patient populations, the administration of HRQoL questionnaires was intended in this study to provide insights into the relationship between morbidity and perceived HRQoL on an *individual* basis. Given the inherent crudity of the EQ-5D and its limited exploratory or analytical utility, analysis focussed upon the SF-36.

Analysis of the questionnaire data was, in several instances, confounded by; ambiguous and contradictory responses (e.g. feeling “full of life none of the time”, but having “a lot of energy a good bit of the time”); altered responses (e.g. from “limited a lot” to “not at all limited”) and by missing data. This observation prompted a review of the literature in relation to data *quality* (an aspect of questionnaire-based research that is rarely reported upon) and an exploration of the rationale for these confounding factors.

## 4.8 Qualitative methods used in this thesis

### 4.8.1 “Any comments?”

The vast majority of HRQoL questionnaires comprise fixed choice response categories requiring respondents to denote, for example, limitations in their ability to perform “moderately” taxing activities. Congruent with the principles of survey methodology, there are few, if any, opportunities for the elicitation of “extraneous” contextual information or for clarification of terms such as “moderate” or “limitations”. Given the concerns expressed by participants in previous local HRQoL research (among anaemic survivors of critical illness), survivors were invited to note, in the margins of the questionnaire, any issues or problems encountered during their completion. Few were provided, however, leading ultimately to the exploration and use of cognitive interview techniques.

### 4.8.2 Cognitive interview techniques

Cognitive interview techniques were identified following a review of the literature pertaining to data “quality” and in response to the failure of “any comments” to elicit wider insights into the rationale for missing, ambiguous or contradictory responses. Used predominantly in the *developmental* stages of questionnaire design, a small but accumulating literature has directed attention towards the use of these techniques in the *evaluation* of existing measures.

Derived largely from Tourangeau’s (1984) cognitive response model, cognitive interview techniques explore the semantics and logistics of questionnaire completion in terms of the processes through which participants comprehend, interpret and construct their responses to questionnaire items and the fixed choice categories therein. This literature, importantly, facilitated a critique of the “real world” applicability of psychometric principles. The serendipitous discovery of a model of HRQoL appraisal (Rapkin and Schwartz, 2004) provided, in addition, a means of augmenting the processes of questionnaire interpretation and response to include a means of exploring response shift phenomena. An alternative cognitive response model was subsequently derived.

Cognitive interview was identified as a potential avenue for exploration late in the recruitment phase. Its use was therefore restricted to only five participants and to the administration of the SF-36. This data nonetheless elicited “real world” insights into the difficulties experienced by participants in the interpretation of question and response categories, revealing both the multifarious and highly

contextualised factors taken into account in the construction of a response and the rationale for often startling discontinuities between survivors' narrative accounts and questionnaire response.

### **4.8.3 The semi-structured interview**

In order to compare, in a meaningful way, the nature and type of data acquired by the dominant quantitative approach to HRQoL measurement, a primary aim of this thesis was the exploration of survivors' experiences and perceptions of critical illness-related morbidity, their effects and relative importance in everyday life and their impact upon perceived quality of life following discharge home. Using the developers' definitions of the dimensions of the SF-36 as a broad conceptual framework, qualitative interview data were "mapped" onto the relevant dimensions, revealing unforeseen insights into the subjective meaning, relative importance and complex inter-relatedness of these objectively defined dimensions of experience in everyday life.

This strategy revealed both the *temporal processes* of recovery (as opposed to the decontextualised scores or "snapshot" afforded by the quantitative approach) and alternative conceptualisations of health and quality of life which were attenuated by experiences of pre-existing morbidity, expectations of recovery, and the life threatening nature of critical illness.

A more inductive approach to data analysis was also appropriate, necessitating repeated reading and re-reading of the data, ultimately facilitating the "naturalistic" emergence of key aspects of experience from the survivor's perspective. This approach revealed the prominence, within and across survivors' accounts, of the ways in which survivors were enabled to deal with ongoing morbidity in everyday life and the unexpected protraction of the recovery process. This data prompted an exhaustive review of the social science literature on adaptation and the self-management of (chronic) illness, leading ultimately to the use of Bury's (1991) notions of "strategy" (what people do in the face of illness or impairment) and "coping" (the attitudes people develop) as a guide for the analysis of data. The integration of the dimensions of the SF-36 with these data resulted in the development of an alternative framework of "quality of life" following prolonged critical illness.

Examining the temporal processes of adaptation and recovery failed to take into account, however, of (re)conceptualisations of morbidity and recovery within the wider context of survivor's *lives* or the ways in which survivors "told their stories". Bury's (1982) "biographical disruption" was identified as an appropriate theoretical framework within which to organise and explain the ways in which survivors augmented "strategy" and "coping" by drawing upon their own stock of life experience and

self-knowledge. The unexpectedly phlegmatic and sometimes positive nature of survivors' accounts prompted, in addition, a review of the literature on illness narratives.

In an attempt, finally, to complete the “biographical narrative” of recovery following prolonged critical illness, the influence of ward-based care and rehabilitation upon biographical disruption was examined. “System-induced setbacks” (Hart, 2001) i.e. inadequacies in its organisation and delivery were seen, in many instances, to contribute to much of the biographical disruption associated with critical illness. This approach, importantly, revealed useful insights into potential future interventions to expedite the recovery process in ways which are most meaningful to survivors.

#### **4.9 Summary**

The research strategy, while somewhat tortuous in its evolution and explication, addresses a number of the concerns previously outlined as they relate to health services research, namely: adherence to the philosophical and epistemological basis of the methods used, their appropriate use in relation to the research questions at hand, the integration of theory and its in the reinterpretation of existing sociological constructs, such that they are developed and enriched. The research strategy also addresses the pragmatic concerns of health services research in as much as that the implications for the use and interpretation of HRQoL measures among survivors of critical illness are comprehensively examined, and there is potential for future service development.

## **Methods: Section Two**

### **4.10 Introduction**

In this section, I outline the *practicalities* of the research process, the purpose of which, broadly speaking, is to ensure transparency and, where appropriate, to facilitate replication, given that many of the issues encountered during this study are more generally applicable to the conduct of research among survivors of critical illness.

### **4.11 The setting(s)**

The prevalence study utilised data from each of the three general ICUs across Lothian; the Royal Infirmary of Edinburgh (RIE), the Western General Hospital (WGH) and St John's Hospital (SJH) at Howden. The ICU at RIE is the largest in Scotland, comprising an 18 bed mixed ICU and High Dependency Unit (HDU). The Unit receives approximately 1,000 patients per year, including those referred for specialist services from across Scotland (e.g. for liver and pancreatic transplant) and is the major general trauma unit for Edinburgh. The ICU at WGH comprises a 12 bed mixed ICU/HDU. A significant proportion of its ~700 annual admissions comprise patients requiring specialist neurological intervention. The ICU at SJH comprises an 8 bed mixed ICU/HDU, admitting some 450 patients per year.

### **4.12 The research ethics**

#### **4.12.1 Ethical approval**

Despite several years' clinical experience as a Research Co-ordinator in ICU, I had very limited experience of the complex and often protracted processes of acquiring ethical approval. Initial difficulties centred on the interpretation and negotiation of the extensive and detailed forms. These were generally resolved, however, following consultation with the ICU Research Lead and colleagues in the R&D Department of the RIE respectively.

The vast majority of critical care studies involve patients recruited during the acute phase of critical illness, many of whom are "incapacitated" i.e. are unable to provide informed consent as a consequence of illness acuity, sedation and ICU delirium (a highly prevalent and often refractory acute confusional state). The ethical review process for these types of studies is conducted by a dedicated

Research Ethics Committee (REC) based in Lothian. Given, however, that potential participants would be contacted following discharge into the community and would, in the vast majority of cases, be considered legally “capacitated” to provide informed consent, ethical approval was sought from the “standard” Lothian REC. Advice was also sought from the Head of Primary Care Research, with respect to the requirement to ascertain survival status and inform/request permission from potential participants’ General Practitioners.

Following advice from the ICU Research Lead (and not without some trepidation), I accepted the customary invitation to attend the REC meeting. Here, I was afforded the opportunity to clarify, in person, the uncertainties and concerns raised by its members. These centred, primarily, on the storage of patient identifiable data and were quickly addressed, effectively “speeding up” the approvals process.

#### **4.12.2 Ethical conduct**

A number of “generic” issues relate to the ethical conduct or “good practice” of research including, primarily, the acquisition of informed consent, access to potential participants, the research burden and patient confidentiality. Issues relevant in critical care research and this study specifically (given the significant symptom burden) include sensitivity to ongoing morbidity and the highly emotive nature of the critical illness experience. These are addressed throughout the following sections.

### **4.13 The recruitment strategy**

#### **4.13.1 Access to patient data**

Both the prevalence study and access to potential participants was facilitated by the use of the Scottish Intensive Care Society Audit Group’s (SICSAG) national database; “Wardwatcher®”. The Wardwatcher® database collects a core data set from each of the 23 ICUs across Scotland, including demography (age, gender), diagnosis, critical care interventions (e.g. the duration of mechanical ventilation), severity of illness (using Acute Physiology and Chronic Health Evaluation system (“APACHE”, Knaus et al (1985)), length of ICU and hospital stay and outcomes (survival, ICU and hospital mortality) using a case-mix adjusted method. Access to this data for the purpose of the epidemiological review was granted by virtue of my employment as a Research Co-ordinator in ICU at RIE and following discussion with the SICSAG’s Clinical Co-ordinator and the Clinical Leads in each of the three general ICUs across Lothian.

Wardwatcher® also holds highly sensitive patient identifiable data, including contact details for patients, next of kin and general practitioners. Permission to use this information for the identification of potential participants (as opposed to its intended audit purpose) was formally sought from and granted by: SICSAG’s Project Lead, the Caldicott Guardian for Lothian, and the Lead Clinicians at each of the participating ICUs. The Data Protection Managers and the Research and Development (R&D) Departments at each of the participating hospitals also sanctioned this use of the data.

#### **4.13.2 Eligibility**

Data collection and the screening of potential participants were conducted on a monthly basis. With reference to the prevalence study, routine demographic, clinical and outcomes data was collected on *all* patients requiring prolonged mechanical ventilation (of  $\geq 14$  day’s duration) from each of the three Lothian ICUs throughout the recruitment period. In order to examine the representativeness of the study cohort, data was collected on the corresponding patient cohorts from the 1<sup>st</sup> of January, 2003 to the 31<sup>st</sup> of December, 2007.

With reference to “the study proper”, survivors were screened with reference to a number of simple inclusion and exclusion criteria. Inclusion criteria, in the first instance, comprised survival to hospital discharge. In keeping with previous local research, exclusions comprised survivors with a primary neurological diagnosis or documented psychiatric disorder. Patients transferred to other acute settings out with Lothian (in whom ultimate hospital outcome was therefore unknown) were also excluded. For pragmatic reasons (i.e. the feasibility of funding travel to and from interview), patients out with a feasible geographical radius were also excluded.

#### **4.13.3 Sampling**

It was my intention at the outset to sample widely and purposively from the patient population in terms of age, social circumstances (e.g. marital and employment status) and comorbidity. In relation to the limited information available on the Wardwatcher® database and to the low response rate, this was not always feasible. Sampling was therefore largely convenience based.

#### **4.13.4 Recruitment**

Previous local research experience had identified a number of difficulties associated with recruitment to critical care follow-up studies. These include loss to follow-up due to death, change of address (often for the purposes of convalescence) or re-admission to hospital. A poor response rate among

survivors with a history of drug and/or alcohol dependence has also been noted. Previous local research had also identified the potential for ongoing ill health among survivors following hospital discharge, and a reluctance among some to be “reminded” of the critical illness episode. A consort diagram summarising the eligibility of the patient group is provided in appendix 22.

Survivors’ general practitioners (GPs) were contacted in the first instance, in order to ascertain survival, the appropriateness of requesting patient participation and to minimise the potential for distressing the relatives of those who had subsequently died. GPs were contacted by letter and were provided with a broad overview of the study aims (appendix 23) and a copy of the Patient Information Sheet (appendix 24). GPs were also provided with a stamped addressed proforma upon which they were invited to document survival status and permission to contact the participant or the rationale for refusal (appendix 25). A stamped addressed letter containing an invitation to participate and Patient Information Sheet was also provided, and GPs were requested to forward this to potential participants, where appropriate. Those interested in taking part were invited to contact me directly for further information and/or to arrange for interview.

Despite the intention to minimise the burden upon busy GPs, their response rate was unexpectedly poor. Reminders were frequently required. Permission to contact the patient was denied on a number of occasions, often on the grounds of ill health or chronic alcoholism. The response rate among potential participants was also poor despite the reluctant use, on several occasions, of a third reminder. One survivor’s daughter wrote to explain that her elderly mother had been deeply traumatised by her experiences and “would really rather forget what had happened to her”, underlying the need for extreme sensitivity among this patient population. In this and several other instances, I provided contact details for the ICU specialist follow-up service at RIE.

#### **4.13.4.1 Alternative strategies for recruitment**

In an attempt to improve the response rate and increase the potential for purposive sampling, a Substantial Amendment was made to the local REC, requesting permission to approach potential participants during the *ward* phase of recovery. This was requested on the premise that potential participants would be deemed “competent” to provide informed consent (i.e. free from delirium) following assessment by the lead clinician in our ward-based follow-up service. Before contacting these individuals following discharge home, GPs were contacted in order to ascertain survival and the appropriateness of the request for participation. Five participants were recruited using this strategy,

one of whom sadly died shortly after hospital discharge. A “potted history” of the research participants is provided in appendix 26.

#### **4.14 The research venue**

Following verbal consent to participation by phone, participants were invited to select a date, time and venue for the research interview which was most convenient to them. In anticipation of the potential for ongoing physical impairment, and in order to minimise any inconvenience to participants, return transport was offered to and from the research venue by wheelchair accessible taxi. With respect to ongoing frailty and the potentially emotive nature of the interview, participants were also invited, should they have wished, to be accompanied by a family member or friend. I met each participant at the entrance to RIE and accompanied them to and from the interview room. Access to wheelchairs was available and was required on several occasions.

Permission to use the facilities at the Wellcome Trust Clinical Research Facility (RIE) for the purposes of interview had been granted by its Research Manager, and I was subsequently granted permission to use a Consultation Room adjacent to RIE’s ICU. Despite the occasional interruption by clinical staff, the proximity of the latter for the purposes of an optional ICU visit quickly made this the venue of choice. With deference to individual preferences and the ability to travel, a total of five interviews were conducted in participants’ own homes. In these instances, professional guidelines for lone healthcare workers (e.g. community nurses and GPs) were adhered to, a colleague was fully informed of my whereabouts and travel arrangements and I was contactable via mobile phone.

#### **4.15 Conducting the interviews**

The interviews were surprisingly informal in nature and were, for the most part, both fascinating and extremely enjoyable. In several instances, rapport had already been established with participants through interaction during the course of a ward-based follow-up service, the ward-based visit to acquire consent, and/or the confirmation of interview and travel arrangements by telephone.

The interviews were semi-structured and were intended at the outset to capture experiences and perceptions of ongoing and/or critical illness related morbidity throughout the recovery process and their impact upon perceived quality of life. The interview schedule (see appendix 27) was adhered to relatively loosely, in as much as that issues not addressed throughout the natural course of discussion were later returned to or explored within the context of expressed concerns.

Participants were afforded significant freedom to discuss in greater depth those aspects of experience which were of most importance or relevance to them, often challenging my naïve assumptions and revealing highly contextualised or unanticipated aspects of experience. They were also free, however, to omit distressing or highly sensitive topic areas, to “take a break”, or to terminate the interview at any time. The interviews varied widely in length (between 45 minutes and 2 hours), and were often dependent upon participants’ ability or willingness to discuss the issues at hand. The interview schedule and questions were iteratively restructured and/or refined on the basis of successive survivors’ responses.

With participants’ consent, the interviews were recorded. Only one participant expressed some initial objections, but subsequently acquiesced. The initial interviews were tape recorded. The quality of those recordings was poor, however, in as much as that tape “hiss” was often compounded by the voice changes associated with prolonged endotracheal intubation and/or tracheostomy (notably the pitch and volume of speech). The remainder were therefore conducted using a digital voice recorder, which afforded greater clarity and ease of transcription.

Brief notes served as an aide memoir during the interview process, largely in relation to its loose structure. My transcription of the initial interviews and the use of brief field notes made immediately following each interview proved invaluable in “getting to know” the data and in developing tentative associations between and across successive survivors’ accounts.

#### **4.16 Conducting the post-interview ICU visits**

ICU visits are a long-standing feature of the ICU Clinical Nurse Specialist’s service at RIE, although their therapeutic value has only recently been reported in the professional literature (Engstrom et al, 2008). Her advice was invaluable in alerting me to the sensitivities associated with this approach. These included, in the main, the recollection of “weird” or distressing “dreams”, “strange experiences” and “jumbled” or fragmented memories of the ICU stay.

Despite some understandable trepidation, each of the survivors interviewed at RIE took the opportunity to visit the ICU. The vast majority of participants found the experience “really helpful”, in allowing them to; “get a handle on what had happened”, “make sense of weird dreams” or “put things into perspective” (often in terms of the severity of illness). Many enjoyed the opportunity to meet the clinicians involved in their care, ask questions about the nature of their illness and the course of events, and express their gratitude in person. Sadly, one participant found the experience distressing, citing the

realisation of how very ill she had been and of what her family had “been through”. In this and several other instances, a “debriefing” session ensued, in which participants were able to explore unanticipated emotional responses.

Three of the five participants interviewed in their own homes subsequently visited the ICU at their own convenience, and this was facilitated by the provision of return transport by wheelchair accessible taxi.

## **4.17 Confidentiality**

### **4.17.1 The prevalence study**

All patients admitted to ICU are assigned a 5-7 digit “key” number; a unique identifier generated centrally by the Wardwatcher® database. For the purposes of audit, these are accessible centrally, through on-site ICU-based computer terminals and locally across sites. Due to the highly sensitive nature of this information, data were entered directly into an SPSS database on a password protected laptop. In accordance with Data Protection requirements, the data were later transferred onto an NHS encrypted USB stick, and secured in a locked drawer on NHS premises only accessible by me.

### **4.17.2 The semi-structured interview**

In order to facilitate the linkage of centralised clinical data (illness severity scores, etc) with individual participants, key numbers were used. Once the requisite data had been collected, participants were assigned a pseudonym which replaced the key number on data forms (e.g. accounts of the ICU trajectory, contact details, field notes, etc). Paper-based screening logs were destroyed following entry into the SPSS database.

An NHS medical secretary was employed to transcribe of the majority of interviews and she was fully aware, through the nature of her employment, of the requirement to maintain participant confidentiality. Out with the transcription process, voice recordings and transcripts were secured in a locked cabinet on NHS premises, and were accessible only by me.

### **4.17.3 Ongoing engagement with participants**

Contact was maintained with two of the participants in this research, through my invitation to speak at subsequent multidisciplinary critical care conferences. Despite never having publicly spoken, both kindly agreed to do so, providing unique and invaluable insights into the processes of care and recovery for those present. Both kindly agreed to review the final chapters of this thesis, and also to act as patient advisors on subsequent research applications. In an extension of my thanks, both allowed their identification in the acknowledgement section of this thesis. Their confidentiality is maintained throughout, however, through the use of pseudonyms.

### **4.18 Funding**

The funding for this research was generously provided by the Centre for Integrated Healthcare Research (CIHR) and the Research and Development Department (R&D) of the Royal Infirmary of Edinburgh through successful application for a PhD studentship and a Small Project Research Grant, respectively. The CIHR met PhD fees, provided a small stipend and £1000 annually for conference attendance and research training out with the University of Edinburgh. Support costs (i.e. transport and transcription fees) were met by a combination of CIHR and R&D funding.

# Chapter 5: A “quasi-qualitative” exploration of the SF-36

## 5.1 Introduction

This chapter explores the data generated by administration of the SF-36 among study participants. Data analysis was confounded, however, by missing, ambiguous and contradictory responses, prompting an exploration of HRQoL data “quality”; an aspect of survey methodology which is rarely acknowledged or reported on. There are implications, nonetheless, for the interpretability of HRQoL data, and its validity, reliability and applicability in large scale critical care outcome studies. The incidence of missing, ambiguous and contradictory responses would seem, in addition, to suggest that survivors experienced uncertainty with regard to the everyday logistics, as it were, of questionnaire completion. Ascertaining the “representativeness” of survivors’ experience in questionnaire form is a critical feature of this research, and this notion is therefore examined in greater detail in subsequent chapters through the use of cognitive and qualitative interview.

## 5.2 Data Collection

In order to reflect current practice (i.e. self-completion at home), the SF-36 was administered by post, approximately one week prior to qualitative interview. Respondents were invited to bring the completed questionnaire to interview, although several simply forgot to do so. (The majority were subsequently returned by post.) Given, as described elsewhere, the unanticipated difficulties experienced by participants in previous local HRQoL research (among anaemic survivors of critical illness), survivors were also invited to note, in the margins of the questionnaire, any issues or problems encountered during its completion, in addition to any other general comments or queries.

## 5.3 Data analysis

Data were analysed in accordance with the UK analysis and interpretation manual (Jenkinson et al, 1996) and with reference to published UK population norms (Jenkinson et al, 1993). Given, as previously described, that the small sample size (n=20) prohibited complex analysis, meaningful comparison between patients, and the generalisation of the results to similar patient populations, the data are provided here on an *individual* level. Group level analyses were not attempted due to wide variation in the timing of questionnaire administration (at *up to* 6 months following ICU discharge).

Analysis was confounded in several instances by the dearth of age and sex matched population norms for those aged 65 years and over (of whom there were 5). Analysis was also confounded by missing data (both entire questionnaires (n=4, equivalent to 20% of all possible data)) and missing items (n=49, equivalent to an additional 9% of all possible data) and by altered (n=8), ambiguous and contradictory responses (n=8). The following section explores their effect upon data quality. The subsequent section explores the likely rationale for missing, ambiguous and contradictory responses within the relevant dimensions.

## **5.4 Data quality and implications**

### **5.4.1 Missing data**

Incomplete questionnaires are commonplace among patient populations with significant ongoing morbidity and high short term mortality. Missing data, broadly speaking, can be classified as missing at random (i.e. by chance), non-random or systematic (due, for example, to the selective under-reporting of problems or age and gender-related effects). The primary effects of missing data in large scale critical care outcome studies include (i) loss of statistical power with regard to the detection of clinically meaningful differences in HRQoL and (ii) the introduction of bias due to non-random missing data. With regard to the latter, data from oncology trials, for example, suggests that those most severely affected by ongoing morbidity are least likely to complete the questionnaires, resulting in an overestimation of HRQoL which is not truly representative of the population under study (Fairclough et al, 1998).

Despite the importance of these effects, few critical care outcome studies report upon the incidence of missing data. While the effects and management of *randomly* missing data is potentially less problematic, given that they might reasonably be expected to occur equally across respondents, the assumption that *all* missing data are missing at random has been described as “usually unjustified” (Fairclough et al, 1998: 667), given the implications for its effects and management. Analysis often reveals that, if participants omit to answer one question, they are more likely to omit others. There is often, in addition, a pattern of non-response to consecutive questions, even if they are unrelated in terms of content (Fayers et al, 1998).

Two main strategies are adopted in the management of missing data: simply treating the data as randomly missing (which may lead to biased results) or statistically “imputing” a score. The primary objective of imputation is to replace the missing data with estimations which reflect, as far as possible, the most likely “true” value (Fayers et al, 1998). The most commonly used strategies include the imputation of mean scores based on (i) existing respondent-specific information (usually when at least half of the items on a dimension have been completed) or (ii) mean scores and between item correlations derived from all other participants.

Imputational strategies, however, are highly complex and are generally dependent upon the amount of missing data, its statistical variability (e.g. the standard error or deviation from the mean) and the psychometric reliability of the questionnaire. They may still, importantly, yield biased or unreliable results. The identification and prevention of (non-random or systematically) missing data, in short, is preferable to attempted cure (Bernhard et al (1998), Simes et al (1998)).

#### **5.4.2 Ambiguous or contradictory data**

HRQoL questionnaires (including the SF-36) generally comprise standardised questions in order to ensure comparability of response. In the interests of brevity, there are limited opportunities for clarification of the developers’ intended meaning with regard to problematic terms and questions. Despite often rigorous pre-testing and extensive psychometric validation, many widely used instruments contain ambiguous terminology (including, as this and the following chapter will demonstrate, the SF-36). There are implications, nonetheless, for data quality. Systematic ambiguity may lead respondents to consistently misinterpret the developers’ intended meaning, introducing, by definition, biased estimations of HRQoL (Fowler, 1992). Unsystematic ambiguity (i.e. wide variation in interpretation) often introduces greater measurement error and uncertainty about the validity of the data (Fowler, 1992).

#### **5.4.3 Respondent comments**

The SF-36 comprises closed choice questions and fixed choice response categories in order to maximise the efficiency of data collection and analysis. There are limited opportunities for the collection of “extraneous” information, the utility of which has been described as “small and miscellaneous” (McColl et al, 2001). Survey developers occasionally incorporate open questions,

however, or invite respondents to provide additional information “in their own words”. These may be used for the purposes of extension or expansion in relation to specific questionnaire items or as a means of more general enquiry

- Extension; ‘Other, please specify’ is used at the end of a list of response options to ensure that all options are covered. Responses are framed by the context provided by the explicit options. The use of this open option is considered good practice in survey methodology.
- Expansion; A closed question is followed by an open question in which respondents are asked to elaborate on the answer given within the closed question. These open questions may be used to address ‘why’ and ‘how’ questions and have clear roles in that responses will help to explain, illuminate or expand upon a specific quantitative question.
- General enquiry; Respondents are asked to elaborate on their general experience in relation to the overall topic of the survey. This includes the general “any other comments” which researchers often place at the end of a questionnaire (O’Cathain and Thomas, 2004).

An advantage to the use of such questions is increased validity, through the identification of unanticipated responses and taking account of explanatory remarks (McColl, Jacoby et al, 2001). A rather more aesthetic advantage is the qualitative illustration of key issues. Their primary disadvantage, however, is the resource intensity of analysing complex and diverse data, and the use of qualitative techniques which are often unfamiliar to survey researchers (O’Cathain and Thomas, 2004).

The provision of *unsolicited* comments (often in the margins of a questionnaire or in letter form) would seem to suggest that (some) respondents wish to share their experiences of living with a particular condition through more than the pre-determined questions and response categories provided. In other HRQoL research, a number of respondents provided personal experiences of living and coping with chronic pain in letter form, in an attempt to educate the researchers of the “real” issues (Warms et al, 2005). Despite completing a raft of both generic and disease specific questionnaires, Clayton et al’s (1999) respondents expressed a range of concerns around employment, balancing rest and activity, and the maintenance of social and familial relationships, all within the context of profound fatigue and *in addition* to that measured by questionnaire.

Respondent comments would also seem to elucidate ambiguous terminology and uncertainty with regard to the inclusion of otherwise “irrelevant” aspects of experience (i.e. out with the disease process being investigated). Ong et al’s (2006) respondents, for example, supplied rich contextual information in the margins of the questionnaire, often in order to justify the inclusion of pre-existing illnesses or “exceptional circumstances” (such as a recent illness or distressing event) in their evaluation of HRQoL. Respondent comments, in short, have implications for the validity of both individual questionnaire items and for the conceptualisation and evaluation of HRQoL more generally i.e. from the respondent’s perspective.

## **5.5 Findings**

### **5.5.1 HRQoL scores (individual level analyses)**

Scores were derived, as previously described with reference to UK population norms (Jenkinson et al, 1993). Population norms for survivors aged  $\geq 65$  years were derived from a study among the community dwelling elderly (Walters et al, 2001). These data are provided in appendix 28. It is difficult, however, to draw any conclusions, given the prevalence of missing data. The following sections therefore examine the prevalence and patterns of missing data and their likely rationale among the survivors in this study. Data were missing for a total of 49 items and were most prevalent within the following dimensions.

### **5.5.2 Physical Function**

The Physical Function dimension comprises a total of ten questions related to the respondent’s ability to perform “vigorous” activities (defined as running, lifting heavy objects or participating in strenuous sports), “moderate” activities (defined as moving a table, pushing a vacuum cleaner, bowling or playing golf) and eight other ostensibly routine activities such as carrying groceries, climbing stairs, bending/kneeling/stooping, walking defined distances and self-care, all within the past four weeks. Responses comprise limited a lot, a little or not at all.

There were 10 instances of missing data in relation to the physical function dimension. HRQoL research among elderly and disabled patient populations suggests that the “vigorous” and to a lesser extent “moderate” activities are often out with respondents’ capabilities and may therefore be omitted due to their perceived irrelevance (Parker et al (1998), Mallinson et al (2002)). The often profoundly

debilitative effects of critical illness have the potential to evoke a similar response among the wider patient population. In an attempt to improve response rates within this dimension, the reversed order of the provided activities i.e. from least to most vigorous has been recommended (Walters et al, 2001).

Despite the avoidance of double questions as a basic recommendation of questionnaire design, the physical function dimension contains several e.g. limitations in “bending, kneeling *or* stooping”; both evoking uncertainty and forcing respondents to choose between two often functionally distinct alternatives (Mallinson, 2002). The response format, in addition, has been described as cognitively burdensome (Mallinson, 2002). There were three instances of altered responses here. Robert had altered his response from “limited a little” to “limited a lot”, while Andy had altered his response in two instances from the extremes of “not at all limited” to “limited a lot”. An alternative explanation for altered responses is the desire to appear consistent across questionnaire items. There is evidence to suggest that respondents strive to do so, and will therefore select logically consistent responses even if they do not reflect their experiences (Clarke and Schober, 1992).

There were also, however, two instances of ambiguous or contradictory responses. Roy was “limited a *little*” in walking one hundred yards, half a mile *and* more than one mile. Robert had responded twice to the same question, and was seemingly both “limited a little” and “limited a lot” in climbing several flights of stairs. Either or a combination of the given rationales is possible.

### **5.5.3 Role Physical**

The Role Physical dimension asks respondents to denote their limitations in the ability to perform “*work or other activities*”. The perceived irrelevance of work among those retired (and their subsequent omission) has been noted in other HRQoL studies (Hayes et al (1995), Fowler (2000), Mallinson (2002)). Given that Sandra, Ken and Robert were in fact retired, this seems a feasible rationale for their omission. Dave (aged 32 years) also omitted these items, explaining in the margins that he was “not back at work yet”. This comment, importantly, extends the perceived irrelevance of “work” beyond retirement to include the forced exclusion from work due to functional impairment. Both the demography of the wider patient population and the often protracted recovery process suggest that the use of the term “work” (in terms of its interpretation as paid employment) may be problematic for a significant proportion of survivors. One study reports upon its removal for use among the elderly, although it is unknown whether this approach garnered a higher response rate (Walters et al, 2001).

#### 5.5.4 Energy/vitality

The energy/vitality dimension comprises four questions. Here, respondents are asked to denote how much of the time over the past four weeks they have felt “full of life”, “worn out”, “tired” or “had a lot of energy”. There were no missing responses, although close inspection of the data revealed a number of seemingly ambiguous or contradictory responses. Elizabeth, for example, felt “full of life *all* of the time”, although she both had a “lot of energy” and felt “worn out” *some* of the time. Similarly, Sandra felt “full of life none of the time”, but “had a lot of energy” a good bit of the time, and felt “worn out” and “tired” only some of the time. These observations would seem to indicate ambiguous terminology.

#### 5.5.5 Mental Health and Role Emotion

The mental health dimension requires respondents to denote how they have “been feeling” over the last four weeks across a total of five questions i.e. “nervous”, “so down in the dumps that nothing could cheer you up”, “calm and peaceful”, “downhearted and low” or “happy”. Responses comprise all/most/a good bit/some/a little or none of the time.

There were 4 instances of missing data and two instances of altered response. Robert had altered his response from being “downhearted and low” from some to none of the time, while Pat had altered her response from being “down in the dumps” a little of the time to a good bit of the time. The inherent sensitivity of these questions and the negative connotations of the terms “nervous”, “down in the dumps”, “downhearted and low” is one possible explanation for missing and altered data (King and Bruner, 2000). The cognitively burdensome response format of this dimension is another (Mallinson et al (2007), Fowler (2000)).

Much like its Physical counterpart, the Role Emotion dimension asks respondents to denote their limitations in the ability to perform “*work* or other activities”. There were four instances of missing response in this dimension; the perceived irrelevance of work, as previously described, is one possible rationale. Despite, however, omitting these items in the Role Physical dimension, Ken (who was retired) had answered here, suggesting that respondents may alter their evaluative strategies for unexplained reasons.

### **5.5.6 General Health Perception**

This dimension comprises a total of five questions. Respondents are requested to evaluate their health “in general” (excellent, very good, good, fair or poor) and to indicate whether they “seem to get ill easier than other people”, are “as healthy as anybody they know” or “expect their health to get worse”. Respondents are asked to denote “how true or false” the given statements are; definitely true, mostly true, don’t know, mostly false, definitely false. An additional question asks respondents to rate their current health in comparison with one year ago; much better, somewhat better, much the same, somewhat worse or much worse than one year ago.

There were five instances of missing data in this dimension and one of an altered response. There were also three instances of the “don’t know” response, suggesting that survivors experienced difficulty in formulating a response to these items. HRQoL research among other patient populations suggest that aspects of “health” considered important by respondents are not included in many widely used instruments, and that the ways in which “health” is defined is often perceived as inadequate (Devlin et al, 2004). Respondents may also experience difficulty in evaluating “health” within the given time frames, opting alternative frames of reference instead e.g. a younger, “healthier” self or in comparison with others worse off (Ong et al, 2006).

### **5.5.7 Others**

Elizabeth had scored out “in the last 4 weeks” in the instructions for questionnaire completion and in response to questions regarding her general health status, role emotion and bodily pain, but *not* in response to questions regarding physical function, role physical, energy/vitality, social function or mental health. In the absence of any qualifying statement, it is difficult to second guess her intentions. Research among other patient populations suggests, however, that respondents may reinterpret the relevance of the time frame in the light of their own experiences (Ong et al, 2006).

## **5.6 Discussion**

It is difficult in this study to draw any conclusions about the scores generated by the administration of the SF-36. The conclusions drawn from large scale critical care outcomes studies, similarly, may be somewhat tenuous, given that numerical scores may indicate a particular trend or reveal problematic aspects of experience, but may not be specific or comprehensive enough to provide information about

the impact of intervention upon an individual's life or about which aspects require improvement. There are 8350 different ways to achieve a score of 50 on the Physical Function scale of the SF-36, for example (McHorney, 1999). This observation alone would seem to suggest that additional descriptive information is required in order to interpret the data (Cox, 2003).

These data would seem to suggest that survivors experience some not insignificant uncertainty (and, on occasion, frustration) when formulating a response to ostensibly straightforward questionnaire items. Lynne, for example, described questionnaire completion in a subsequent letter as “so frustrating that they impacted on her emotional state of health!” These data would also seem to raise questions around the *interpretation* of ambiguous terminology and the *relevance* of various aspects of experience in the everyday lives of survivors (including, for example, the use of the term “work”): issues (including, in particular ambiguous and altered responses) which are inevitably lost in the process of data analysis and rarely taken into account by health services researchers.

Important questions remain, however, regarding the “*representativeness*” of survivors' experiences. The rationale provided here for altered, ambiguous and contradictory responses are somewhat speculative, given that they are, for the most part, derived from the existing literature as opposed to first hand accounts of questionnaire completion. The following chapter therefore utilises cognitive interview techniques in order to examine the ways in which survivors interpret questionnaire items and formulate their response with reference to their everyday lives. Subsequent chapters utilise in-depth qualitative interview, allowing for some interesting comparisons of the data when survivors are afforded significantly greater freedom to articulate their experiences.

## Chapter 6: Cognitive Interview Techniques

“All this he knows but will not tell  
To those who cannot question well”

Percy Bysshe Shelley

### 6.1 Introduction

Cognitive interview techniques have an established and increasingly important role in the design, development and pre-testing of questionnaires in HRQoL survey methodology. Many organisations (such as the National Centre for Social Research in the United Kingdom) routinely subject their large scale and national surveys to formal cognitive testing prior to widespread administration. For the most part, the focus of researchers has been upon the establishment and reporting of the psychometric properties (validity, reliability, responsiveness to change, etc) of new and existing measures (McColl et al, 2003). Increasingly, widely used and often extensively psychometrically validated HRQoL questionnaires have come under scrutiny using these techniques.

### 6.2 The evolution of cognitive interview techniques

A broad range of pre-testing techniques have been used in the development of HRQoL measures (e.g. card sorts, vignettes, focus groups), many of which have been described in previous chapters. Techniques generally described as more evaluative in nature (i.e. applied among larger, more representative samples of the population than other methods of pre-testing generally allow), and upon which contemporary cognitive interview techniques are largely based, comprise “respondent debriefing” and “respondent observation” or “behaviour coding”.

Respondent debriefing, widely attributed to Schuman (1966), incorporates follow-up questions at the end of a standardised interview, in an attempt to explore the respondent’s interpretation of key terms and concepts. Respondent observation or behaviour coding, developed by Cannell et al (1971), is a technique whereby the interaction between (i) the respondent and questionnaire (e.g. hesitation or expressions of uncertainty) and (ii) exchanges between interviewer and interviewee (e.g. requests for clarification) are systematically observed and quantified.

A key feature of early survey methodology was analysis of interviewer behaviour (asking leading questions, for example) and interpersonal effects (e.g. gender, ethnicity, social class) upon survey data. Latterly, comprehensive meta-analyses of these “response effects” indicated that the nature of the *cognitive processes* involved in responding to questionnaire items far outweighed the influence of interviewer and respondent characteristics.

Since the early 1980’s, the term ‘Cognitive Aspects of Survey Methodology’ (CASM) has been used to describe the resultant collaboration between survey methodologists and cognitive psychologists. More recently, the term has come to describe an expansive interdisciplinary effort which now includes anthropologists, socio-linguists and statisticians, with a heightened emphasis upon the respondent and upon the cognitive processes through which they comprehend, interpret and formulate answers to questionnaire items (McColl et al, 2003). Tourangeau’s (1984) Cognitive Response model is the foundation upon which much of CASM research is based (Willis, 2005).

- *Comprehension* is concerned with question intent (what the respondent believes the question to be asking) and meaning (what specific words and phrases in the question mean to the respondent).
- *Retrieval* concerns the recallability of information (the types of information needed to answer the question) and strategy of recall (recounting individual events or adopting an estimation strategy, for example).
- *Judgement* is concerned with motivation (the devotion of sufficient mental effort to answer the question accurately) and social desirability (truthfulness in the face of a potentially undesirable response).
- *Response* relates to the accuracy with which the respondent can match his/her internally generated answer to the response categories provided in the questionnaire. (Tourangeau, 1984)

Using this model, cognitive interviewing has developed as a method for the identification and localisation of errors in the response process and latterly, an evaluation of their cause and effect upon data quality (Hak et al, 2004).

### **6.3 The cognitive interview process**

Cognitive interviewing relies heavily upon the respondent’s *verbalisation* of normally “hidden” cognitive processes, facilitated by interviewers trained in the techniques described below, and often

using formal standardised interview protocols. A critical feature of the highly formalised interview is the observation and/or standardisation of interaction between respondent and interviewer. Respondent requests for clarification, for example, may be met with repetition of the question (which may or may not comprise minor scripted or unscripted revisions), repetition of the response categories or the traditional “whatever it means to you” (“WIMTY”) response.

Cognitive interviews are designed to provide *information* about the nature of problematic items in a questionnaire as opposed to their formal validation in any statistical or psychometric sense (Willis, 2005). In keeping with the qualitative tradition, sample sizes are generally small, comprising 12-15 respondents representative of specific sub-groups of the population of interest.

### **6.3.1 Think aloud**

Think aloud techniques were originally developed in order to explore the process of retrieval. Here, subjects are asked to vocalise their thought processes as they respond to questionnaire items. Implicit in the use of this technique is the notion that respondents’ concurrent verbal reports reflect *actual* cognitive processes (although this has been a matter for some debate). Advantages of this technique include; freedom from interviewer-imposed bias, minimal interviewer training requirements and the potential for unanticipated responses. Disadvantages include; the need for respondent “training”, respondent burden (particularly among those whose first language is not English), and the potential for irrelevant information (Willis, 2005).

### **6.3.2 Verbal probing**

Here, respondents are invited to provide additional information related to their response either immediately a question is answered (concurrent probing) or upon completion of the entire questionnaire (retrospective probing). Concurrent probing is the preferred technique, although retrospective probing is useful in testing self-administered questionnaires. Examples of the types of probes frequently used are provided below;

- *Comprehension or interpretation probe*: What does the term “health” mean to you?
- *Paraphrasing*: Can you repeat the question I just asked in your own words?
- *Confidence judgment*: How sure are you about..?
- *Recall probe*: How do you remember that..?
- *Specific probe*: Why do you think..?
- *General probes*: How did you arrive at that answer? (Willis, 2005)

Probes may be structured prior to interview and administered in a standardised fashion (see Appendix 29), spontaneous (arising from unanticipated responses) or a combination of both. A major advantage of verbal probing techniques is the maintenance of focus and control over the interview. A disadvantage, however, is the potential for interviewer-imposed bias. In practice, cognitive interviewing is characterised by a combination of probing and think aloud techniques (Willis, 2005)

### **6.3.3 The Three Step Test Interview (TSTI)**

The methodological differences between these techniques in interviewer-administered questionnaires and the cognitive response process in *self-completion* questionnaires have, however, been largely neglected (Hak et al, 2004). The TSTI (Hak et al, 2004) has been designed exclusively for the cognitive pre-testing of the latter. In contrast to the cognitive testing of interviewer-administered questionnaires, the principal approaches comprise concurrent think aloud and *retrospective* probing. The TSTI, as the name suggests, comprises three consecutive stages:

1. *Concurrent think aloud*; aimed at collecting strictly observational data (e.g. correction of the chosen response category, hesitation, uncertainty, etc).
2. *Focused interview*; aimed at remedying gaps and clarifying the observational data (e.g. the rationale for correction, hesitation, etc)
3. *Semi-structured interview*; aimed at eliciting experiences and opinions in relation to questionnaire completion.

While Willis (2005) describes the TSTI as “logical in principle” and “promising”, there is little empirical evidence to support its use beyond that provided by the developers (Jansen and Hak, 2004). Given the overwhelming preference for self-completion questionnaires within health services and HRQoL research, this is undoubtedly a strategy which demands robust empirical investigation.

## **6.4 Analysis of cognitive interview data**

Cognitive interview techniques do not provide precise direction in question design, and their analysis involves a significant degree of judgement and interpretation (Willis, 2005). The analytical processes are highly dependent upon the observations, annotations and judgement of highly trained and experienced interviewers (Willis, 2005). An objective, theoretical approach to the analysis of data generated during cognitive interviewing has therefore been advocated. While existing analytical

models are largely based upon Tourangeau's (1984) model, there is wide variation in their content and complexity.

Conrad and Blair's (1996) 15 item "Respondent Problem Matrix", for example, cross references comprehension, "task performance" (a composite of the retrieval and judgement stages of Tourangeau's model) and response with 5 problem classes identified by the authors. The problem classes comprise;

- *lexical*; uncertainty around the literal or "central" meaning of the question
- *temporal*; uncertainty around the time period to which the question applies
- *logical*; the use of "and" and "or" in questionnaire items or false presuppositions
- *computational*; residual issues not captured by the other categories e.g. problems of memory and mental arithmetic
- *omission and/or inclusion*; uncertainty around which aspects to consider within the scope of the question.

The extent to which existing analytical models have been empirically tested, however, remains unclear.

## **6.5 CASM and HRQoL research**

The principles of CASM are clearly applicable to HRQoL research in as much as that;

"Quality of life assessments typically require respondents to: understand complex questions, deal with abstract concepts; effectively retrieve information from long-term memory; aggregate that information; apply frequency judgements, magnitude estimation and decision heuristics in selecting which response category to endorse." (McColl et al, 2003: 217)

Given the proliferation of survey methodology in the measurement of HRQoL, surprisingly few studies have utilised cognitive interview techniques in the development or evaluation of new and/or existing questionnaires. Those which have evaluated often extensively validated measures call into question the "real world" applicability of the prevailing psychometric paradigm.

### **6.5.1 Adaptation of the "generic" cognitive model**

While demonstrably valuable, "generic" cognitive approaches may fail, however, to take account of psychometric anomalies and complex phenomena inherent in HRQoL measurement. These include, for

example, responsiveness to change (as a measure of efficacy in health care interventions), adaptation and response shift. The augmentation of generic cognitive approaches with strategies useful in the identification of these anomalies is one possible solution. In an important departure from Tourangeau's (1984) model of survey response, Schwartz and Rapkin (2004) operationalise four cognitive processes (or appraisal parameters) in correspondence with the processes of coping and adaptation inherent in HRQoL appraisal. These comprise;

- *establishing a frame of reference*; comprising categories of experiences or events that the individual considers relevant to the HRQoL item at that time (e.g. periods of relative "wellness"). An individual's response is necessarily shaped and constrained by this frame of reference.
- *sampling strategy*; the identification and sampling of specific experiences or events (e.g. good or bad days) within the frame of reference. The sampling strategy is determined or constrained by some way of thinking that leads them to consider specific experiences or events over others.
- *standards of comparison*; each experience is compared with some optimal situation or desired outcome. Standards for optimal situations or desired outcomes are derived relative to specific reference groups (e.g. "sicker" or more unfortunate patients or patient groups), reference points (e.g. previous abilities or experiences of illness) or other external criteria (e.g. medical opinion), each of which may be subject to change.
- a *subjective combinatorial algorithm* for summarising one's experiences; a composite of the specific experiences of HRQoL at that time.

Schwartz and Rapkin's (2004) model of HRQoL appraisal would appear to add important technical detail to the "retrieval" and "judgement" stages of Tourangeau's (1984) model. Their amalgamation therefore offers significant potential to examine and incorporate adaptation, responsiveness and response shift into both existing and future instruments. An (admittedly crude) amalgamated model is presented in figure 3 (page 128).

Building upon both theoretical work and empirical studies of response shift, Schwartz and Rapkin (2004) argue that, contrary to existing psychometric theory which views these individual differences in HRQoL response as sources of *error*, individualised differences in the cognitive processes of HRQoL appraisal are *intrinsic* to its measurement and appropriate interpretation;

“It follows that any QoL score is ambiguous without attention to this process. By explicitly addressing differences in QoL appraisal, it is possible to more accurately interpret and compare QoL ratings and gain a more clinically relevant understanding of the impact of illness and treatment.” (Schwartz and Rapkin; 2004: 2)

Following a complex theoretical interrogation of existing psychometric theory using the proposed appraisal process, Schwartz and Rapkin (2004) argue that existing psychometric models of HRQoL should be *expanded* to take these individual and adaptive cognitive differences into account. Schwartz and Rapkin’s (2004) theoretical model of HRQoL appraisal constitutes a significant advance upon Tourangeau’s (1984) model in terms of opportunities for empirical investigation and methodological development. The implications for clinical significance, they suggest, are substantial with regard to how existing measures should be used.

Its application, nonetheless, is as yet limited to the measurement of responsiveness to change among the chronically ill (Wyrwich and Tardino, 2006) and response shift among palliative care patients (Westerman et al, 2007). A review of the literature as it pertains to the interrogation of psychometric theory using cognitive methods necessarily includes these. Other cognitive and qualitative approaches have, however, been used to interrogate the validity, sensitivity and specificity of existing measures, and the effect of social desirability bias upon survey data, and these are subsequently described.

#### **6.5.1.1 Responsiveness to change**

Using the Rapkin and Schwartz (2004) model as an analytic framework for qualitative and think aloud data, Wyrwich and Tardino (2006) demonstrate salient (and often disease-specific) differences in the processes through which respondents with chronic disease appraise and report perceived change in HRQoL over time. In relation to levels of activity, respondents with respiratory disease, for example, adopted “breathing difficulties” as a frame of reference, and recalled the frequency of wheezing, use of oxygen and their limitations upon the performance of everyday activities as sampling strategy. Respondents with cardiovascular disease, in contrast, adopted “walking” as a frame of reference, and recalled the ability to perform activities such as walking or climbing a flight of stairs as sampling strategy.

Standards of comparison for both groups were largely based upon previous abilities in terms of; reduced function or involvement in activities, an increase in symptoms, an increase in the use of medication, or observations made by doctors or significant others.

The authors add that concerns central to the appraisal of change (at least in terms of functional ability) are often incommensurate with the range of activities routinely presented in existing measures (e.g. climbing stairs) and are therefore likely to be overlooked or misrepresented. Their data also confirms previous work which suggests that (i) respondents construct their estimation of change based upon current or recent health status as opposed to that provided in baseline or previous assessments (Guyatt et al, 2002) and that (ii) in the absence of intervention, any perceived change is likely to be small (Fischer et al (1999), Ong et al (2006)). The authors conclude that in the absence of patient-reported insights into the process of change appraisal, existing interpretations are likely to remain “psychometrically shaky”.

Exploration of the framework through which patients assess and report changes in HRQoL is clearly useful in eliciting meaningful markers of change at both individual and group level. Future work may include the recalibration of HRQoL measures such that the measurement of change (or effect size) is determined through the statistical adjustment of these appraisal parameters. This in turn may lead to the increased sensitivity of measures to change over time, leading to smaller changes than the prescribed 0.5 standard deviation being considered clinically meaningful (Schwartz and Rapkin, 2004).

### **6.5.1.2 Response shift**

Existing measures are based upon the (increasingly questionable) assumption that individuals evaluative strategies consistently, and that HRQoL scores are directly comparable over time (Schwartz and Rapkin, 2004). Supporting instead the conceptualisation of quality of life as a *dynamic* construct (Allison et al, 1997), response shift theory attempts to capture the nature and extent of those changes over time, and is conceptualised as a change in the *meaning* of one’s self-evaluation as a result of (i) a change in one’s internal standards of measurement (recalibration) (ii) a change in values (i.e. the relative importance of the domains which constitute HRQoL) and/or (iii) a re-definition of HRQoL (reconceptualisation) (Sprangers and Schwartz, 1999).

Westerman et al (2007) report, for example, intrapersonal change in; (i) “what matters” to palliative care patients and (ii) its reconceptualisation throughout the illness trajectory. “Health”, for example, became more important for one respondent when, in a state of relative wellness, he reflected upon its previous impact upon his life. His conceptualisation of health in relation to cancer also shifted from “being cured” to “feeling well”.

In other work, using the *then* test in combination with questionnaire and qualitative interview, Westerman et al (2007) describe “recalibration” among chemotherapy patients in terms of the under-reporting of fatigue through a number of processes including; the mediation of expectations (in terms of treatment toxicity), the moderation of previous estimations based on current experience (and vice versa), and social comparison (with other “sicker” patients).

Response shift effects include the under-reporting of morbidity (Breetvelt and Van Dam, 1991) and/or paradoxical reports of a good or relatively static HRQoL, most notably in the face of significant impairment or life-threatening disease (Ahmed et al (2004), Sharpe et al (2005)). In longitudinal studies, a change in the process through which the individual appraises values or conceptualises HRQoL may render subsequent assessments incomparable, posing a significant threat to the internal validity and reliability of the measures used and the results acquired (Visser et al, 2000). With reference specifically to healthcare interventions, response shift phenomena are increasingly recognised as confounding the efficacy (and by association, cost effectiveness) of healthcare interventions both within and across patient groups; effects which, in turn, have important policy implications (Sprangers and Schwartz (1999), Visser et al (2000), Ahmed et al (2005)).

Developing measures which interrogate the relationship between objectively measured outcomes and changes in respondents’ values, priorities and conceptualisations is essential for the measurement of HRQoL in outcomes research (Ahmed et al, 2005). It is currently unclear, however, whether these changes occur independently or simultaneously, whether or when different patient groups are more likely to express these changes (e.g. patients with acute or chronic illness), whether different methodological approaches uncover different aspects of response shift, and how or whether response shift can be elicited at group level (Ahmed et al, 2005).

While recognisant of the requirement for substantial empirical work, Schwartz and Rapkin (2004) argue that assessment of the appraisal process has a robust theoretical basis. They add that the elicitation, through cognitive techniques, of individual and temporal variance in QoL appraisal will help determine the ways in which these processes affect existing measures. Understanding variant effects, they suggest, may inform the development of new measures (based, for example, upon known appraisal parameters), the selection of existing measures (stratified, for example, by appraisal processes), the comparison of patient groups (e.g. patients with acute and chronic illness), and the interpretation of study findings.

### 6.5.1.3 Validity

The validity of survey data, Mallinson (2002) argues, depends upon shared understandings or the “equivalence of meaning” across questions and response options. The *standardisation* of questions does not, as the previous chapter demonstrated, ensure equivalence of meaning across patient groups or populations, and an increasing body of literature suggests that respondents interpret and respond to questionnaire items in unanticipated and highly context-dependent ways (Clark and Schober (1992), McColl et al (2003)). The issue of meaning in HRQoL research is

“...absolutely central to understanding subjective views and without more assessment of peoples’ understandings of survey questions it is difficult to see how one can establish their validity as subjective health measures.” (Mallinson; 2002: 20)

In an important examination of the face validity of the SF-36, Mallinson (2002) presents us with respondents’ “in the field” interpretations of question and response options. “Elementary flaws” included questions which presented respondents with unfamiliar terms (which often required clarification); terms with both literal and intended meanings (e.g. “bathing” as the act of maintaining personal hygiene) and diverse conceptualisations of key terms (e.g. “health”). Several questions were also found by respondents to be “vague”; a scenario in which response is consequently constructed upon highly individualised and contextually relevant information (Shwarz, 2007).

Variations in interpretation and response are invariably lost in routine data processing, however, and the measurement error they elicit may ultimately go undetected. Given empirical evidence that comprehension constitutes the most frequent response error (Willis, 2005), establishing the validity of specific HRQoL measures through alternative methods is likely to be an increasingly important consideration in questionnaire development and evaluation.

Alternative approaches comprise the development of qualitative testing protocols (Mallinson, 2002), and a substantive review of the highly standardised cognitive interview process. The prohibition of interaction between respondent and interviewer, it is argued, suppresses crucial elements of ordinary conversation through which the intended meaning of questionnaire items might be clarified and appropriately responded to (Suchman and Jordan, 1990).

Empirical studies demonstrate that comprehension and accuracy of response (i.e. one more closely aligned with the developer’s intended meaning) are poorest in standardised cognitive interview formats (Conrad and Schober (2000), Schober et al (2004)). The authors demonstrate improved comprehension

and accuracy of response in “conversational” interviews in relation to clarification of meaning i.e. upon request or at the interviewer’s discretion and in a scripted or unscripted manner. A more collaborative approach is advocated; one in which respondents and interviewers work together towards the mutual understanding of questionnaire items (Suchman and Jordan, 1990) and/or in which interviewers exercise discretion in response to individual contexts (Mallinson, 2002).

#### **6.5.1.4 Social desirability bias**

Social desirability bias (the tendency to present oneself in the most favourable light, relative to prevailing social norms) is one of the most pervasive yet most consistently neglected sources of bias affecting the validity of survey research in the social sciences (King and Bruner, 2000). The provision of socially desirable responses may obscure measurement of the primary variables under investigation and lead to spurious correlations between dependent and independent variables, ultimately compromising the validity of the instrument used (King and Bruner, 2000).

Using the Three Step Test Interview, Westerman et al (2007) implicate “self presentation” in the under-reporting of fatigue among lung cancer patients receiving chemotherapy. The authors concluded that response shift did not adequately account for the observed discrepancies between questionnaire and subsequent think aloud data. Their qualitative analyses suggest that verbal reports were mediated by, among others, expressions of optimism with regard to the prognostic effects of treatment; acceptance of the severe side-effects of chemotherapy as an inevitable consequence of treatment, social comparison (with other “sicker” cancer patients) and, importantly, attempts to distance oneself from the stigma of cancer.

Social desirability bias may also be evoked by the nature of the setting in which questionnaire administration or cognitive interview takes place, the respondent’s motives (e.g. achievement or approval), and/or the respondent’s expectations regarding the evaluative consequences of their behaviour (e.g. the expedited treatment) (King and Bruner, 2000). They present a number of strategies for the identification and moderation of social desirability bias in survey research including; the simultaneous administration of measures of social desirability in both newly constructed and established measures, and across situational demands that may evoke this response (with regard, for example, to anonymity or interviewer characteristics).

### **6.5.1.5 Sensitivity and specificity**

Using think-aloud and retrospective probes, Hak et al (2004) argue that the cognitive burden associated with the completion of a disease-specific questionnaire challenges respondents' ability to provide the information typically required by the researchers i.e. (i) whether impairments in health status were caused by the disease process under investigation (ii) whether they prevented individuals from living as they would prefer to and (iii) within the specified time frame. Respondents tend, in contrast, to construct their responses based upon (i) the absence or presence of symptoms irrespective of perceived aetiology (ii) the absence or presence of symptoms as opposed to their interference with preferred activities and (iii) with reference to a range of symptom-specific time frames (e.g. taking variation in symptoms over time into account).

They conclude that the identified response processes contribute to an inflated internal consistency and construct validity of the measure used, as ratings of symptoms or impairments were more closely related to one another and to clinical measures than to perceived quality of life (at least in terms of their interference with preferred activities).

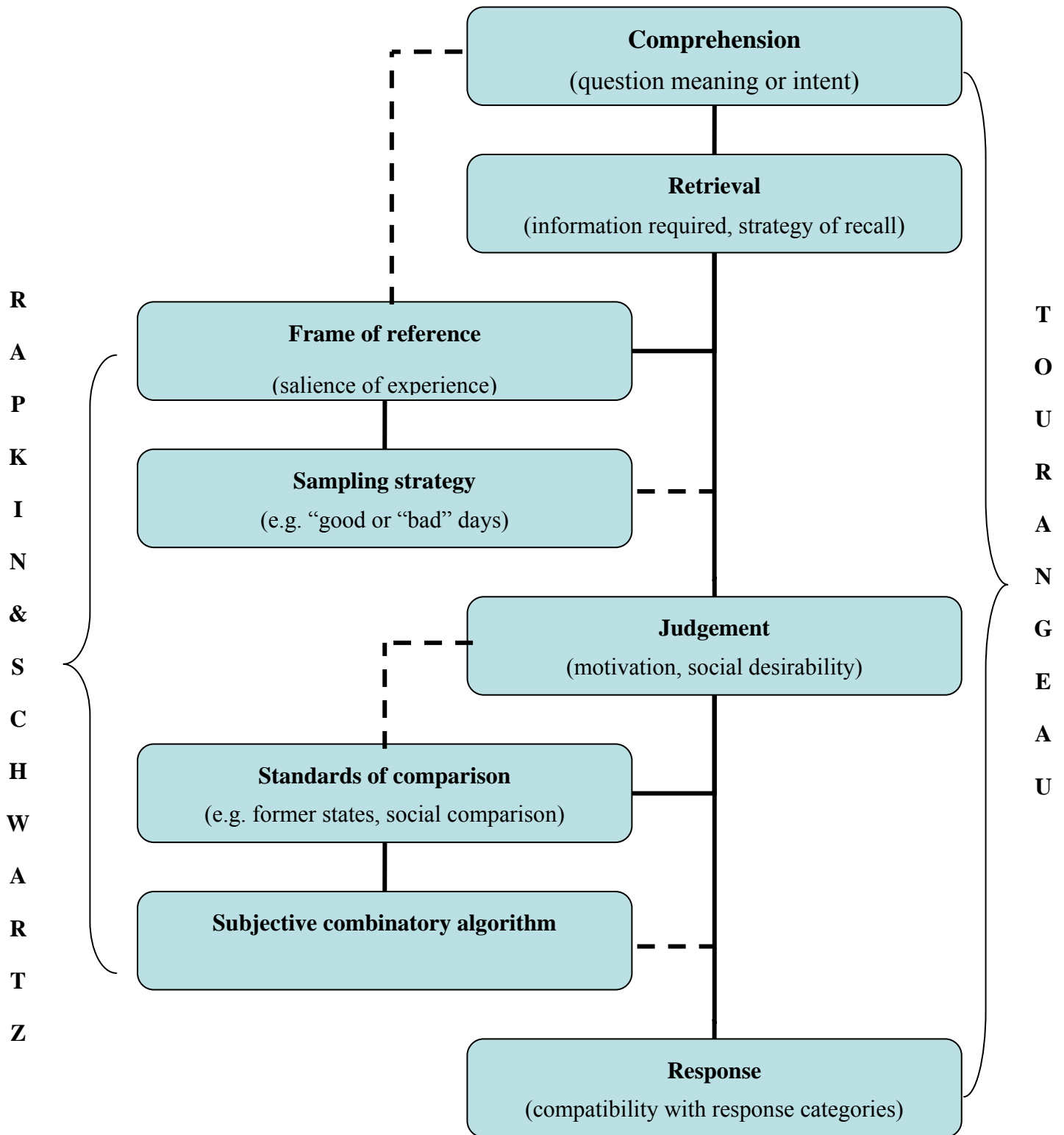
They advocate a heightened emphasis upon (i) the temporal frameworks within which respondents are directed to consider their responses and (ii) consideration of the targeted condition only. Given their recognisance of the cognitive complex tasks required of respondents, however, the authors' recommendations seem overly simplistic and mechanistic. Given also the frequency with which non-targeted conditions confound the appraisal of HRQoL (disease-specific or otherwise) in other studies, alternative approaches are undoubtedly required. While the Rapkin-Schwartz (2004) model previously alluded to has not been applied within this context, the elicitation of HRQoL appraisal strategies within specific disease processes and across disease severities are potential avenues for exploration.

## **6.6 Summary**

The CASM approach, while comparatively limited in its impact upon HRQoL methodology, affords intuitive insights into the "real world" application and interpretation of HRQoL research findings. "Basic" cognitive models may, however, be insensitive to psychometric anomalies of existing HRQoL measures and HRQoL measurement in general (Bjorner et al, 2003). The use of Schwartz and Rapkin's (2004) model of HRQoL appraisal, either in singular or amalgamated forms adds important explanatory and analytical detail for the development of existing psychometric theory in relation to adaptation, responsiveness and response shift. While there is limited data in the current study with

which to apply these models, they provide a useful framework within which to analyse respondents' accounts.

Figure 3: An augmented cognitive response model



## **6.7 The use of cognitive interview techniques in this study**

Cognitive interview was identified as a potential avenue for exploration only late in the recruitment phase. The selection of respondents for cognitive interview was therefore largely convenience-based. The following sections describe the use of these techniques in this study.

### **6.7.1 Questionnaire administration**

An important consideration was the reflection of current practice (i.e. self-completion at home). As described elsewhere, the SF-36 was administered by post, approximately one week prior to interview. Survivors were invited to bring the completed questionnaires to interview. Three survivors simply forgot to do so (although the questionnaires were subsequently returned by post), limiting the use of cognitive interview techniques to only five participants. In view of time constraints (with regard to the often lengthy preceding qualitative interview), respondent burden (in relation to the often emotive qualitative interview), the use of cognitive interview techniques were restricted to *problematic* questions (and, to a lesser extent, the response categories) of the SF-36.

### **6.7.2 Methods**

Given that the SF-36 was completed several days prior to interview, and as recommended in the TSTI, retrospective probing was used to elicit the cognitive processes through which survivors had responded to problematic questions. Think aloud and spontaneous probing techniques were employed at time of interview in order to elicit these processes in relation to missing, ambiguous or altered responses. While “thinking aloud” evoked a certain sense of artificiality, sufficient rapport had been built throughout the preceding qualitative interview that this was markedly reduced. Spontaneous probing was particularly useful in exploring new insights into the interpretive and evaluative processes of questionnaire response.

### **6.7.3 Analysis**

Interviews were recorded and transcribed verbatim, and brief field notes were made immediately after each interview. Drawing upon respondent observation techniques, these included non-verbal cues such as hesitation and uncertainty. Using NVIVO2® software, data were coded with reference to the question and the domain of the SF-36 from which they originated and in relation to both Tourangeau’s (1984) cognitive response model and Schwartz and Rapkin’s (2004) HRQoL model.

## 6.7.4 Findings

Reflecting to a large extent, the concerns expressed by survivors during qualitative interview, there was a proliferation of issues around particular dimensions, namely; Physical Function, Mental Health and General Health Perception and these are described in detail here. While the experience of pain was neither a prominent nor prevalent feature of survivors' accounts, its exploration during cognitive interview highlighted some interesting phenomena. First, the following short sections outline some rather more general observations.

### 6.7.4.1 Motivation and social desirability bias

Survivors, in general, appeared sufficiently motivated to complete the questionnaires. When asked, several described their participation in terms of their desire to "help other patients" and/or as a mark of gratitude for the care they had received in Intensive Care. It was difficult to gauge in general terms, however, the extent to which (i) the opportunity to express individual concerns during qualitative interview affected the devotion of sufficient time and care to questionnaire completion and (ii) the resultant suspension of anonymity affected survivors' willingness to respond truthfully or consistently across data collection methods.

Albert, a seasoned research participant, had taken time and care to answer to answer the questions "properly" and was initially reluctant to offer criticism;

"I didn't want to say anything, actually...because I thought they were questionnaires that *you* had put together! (laughs)" (Albert, his emphasis)

Albert's remarks are perhaps indicative of both "interviewer effects" and "ordering effects". Significant rapport had been established during the preceding qualitative interview had the questionnaires been administered prior to interview, Albert might not have felt sufficiently comfortable to offer criticism, and the opportunity to do so might have been lost.

Galesic and Tourangeau (2007) also describe "framing effects"; whereby significant differences in the response process were demonstrated following experimental manipulation of questionnaire sponsorship, leading the authors to conclude that "it depends who's asking". Cox's (2003) cancer sufferers, for example, described the HRQoL questionnaires they completed during clinical trial as "a useful guide for the doctor" despite expressing concerns to researchers that they gave "no real

indication” of the magnitude of associated side effects (such as nausea, vomiting and fatigue), the psychosocial or emotional burden of trial participation or their impact upon perceived quality of life.

#### **6.7.4.2 Cognitive burden**

Albert’s subsequent remarks suggested that significant cognitive effort was required in order to interpret and respond accurately to the questionnaire items and response options. He expressed irritation with regard to variation in the indication of his chosen response, and in the grouping of seemingly disparate question types;

“They were a bit annoying, actually. I didn’t think they were very scientific...some you had to tick, some you had to circle...and some were in reverse order. And then they were jumping about from physical things to emotional things...” (Arthur)

Christine’s remarks, similarly, support the requirement for close attention to the formatting of the questionnaire response categories;

*“Some of them you had to read more than once, but that’s only because they were on a different level. They were in reverse order or something like that...”* And later, *“...the rest of the questions were ok... provided you read them all properly and ticked the right boxes.”* (Christine, my emphases)

Cognitive burden has important effects upon the ability to self-complete questionnaires, the time taken to complete them and the proportion and types of missing data (Hayes et al (1995), Parker et al (2006)). Mallinson’s (1998) elderly respondents, for example, expressed difficulty with the complex response format of the physical function and mental health/energy-fatigue domains of the SF-36.

Age-related cognitive decline is likely to be important in relation to survivors of critical illness, given both the proportion of patients aged 65 or over, burgeoning demographic shifts and the reported prevalence of cognitive dysfunction (including, for example, impaired concentration and executive functions such as decision-making) among this patient group (Jackson et al, 2003). Many well-established HRQoL measures (including the SF-36), it has been suggested, are likely to benefit from the application of cognitive design principles and empirically substantiated formatting techniques (Mullin et al, 2007).

### 6.7.4.3 Physical Function

Ten questions in the SF-36 relate to physical function dimension, examining respondents' ability to participate in "vigorous" (defined as running, lifting heavy objects or participating in strenuous sports) "moderate" (defined as moving a table, pushing a vacuum cleaner, bowling or playing golf) and a range of ostensibly routine activities such as walking and climbing stairs.

Contrary to the significant limitations described throughout qualitative interview (e.g. his self-enforced retirement from a physically demanding job due to the cumulative morbidity of pre-existing Parkinson's disease and the generalised weakness associated with prolonged critical illness), Frank described himself during cognitive interview as "limited a little" in terms of his ability to perform "vigorous" activities;

"In those questions, I probably could've ticked two of the boxes. I can lift a heavy box, say, but there's no way I could run or play football." (Frank)

In this instance, Frank adopts "lifting heavy objects" as his frame of reference, having recently helped a friend move house. Respondents generally, however, are obliged to (i) ignore one or more of the illustrative activities and respond in relation to the other or (ii) adopt an estimation strategy, neither of which may accurately reflect their abilities (Adamson et al, 2004). An alternative strategy is to select the "normal" mid category in cases of uncertainty (Adamson et al, 2004).

Questions 5 (lifting *or* carrying groceries), 8 (bending, kneeling *or* stooping) and 12 (bathing *or* dressing yourself) were similarly problematic in that the given alternatives assume a degree of functional equivalence which may not be reflected in survivors' everyday experience. Roy, for example, was able to lift but not carry (light) groceries, "at least, not for any distance", and while "possibly" able to kneel (he had neither tried nor had cause to following his hip replacement) "would never be able to get back up again". On both occasions, however, he opted for the middle response, "limited a little". Data from other studies confirms that respondents may rate their limitations according to either their actual *or* perceived ability to perform the prescribed tasks and moreover, may inconsistently apply these sampling strategies across the questionnaire (Paterson, 2004).

Roy also experienced uncertainty with regard to rating his ability to climb stairs (one flight or an ill defined "several") or to walk the prescribed distances (100 yards, half a mile or "more than a mile") without additional contextual information; an observation noted in other studies (Mallinson (2002),

Adamson et al (2004)). While “probably” able to walk a mile, he later described being considerably constrained by cardiovascular disease, steep inclines and prevailing weather conditions.

“Well, how many stairs are we talking? I can do the stairs to my son’s flat alright...they’re not too bad...there’s a rail...but I sometimes need to stop and take a wee breather halfway up.” (Roy)

Others, similarly, described their ability to describe the prescribed tasks, but outlined a number of constraints which were not reflected in the given response; typically, experiencing difficulty or being “slowed down” in their efforts. Survivors frequently contextualised their response during cognitive interview, presumably in order to render the items more relevant within their individual frames of reference and their responses, therefore, more “accurate”. On the whole, the physical function dimension presented survivors with a normative level of function which was either incongruent with their frames of reference (in terms of their everyday experiences) and/or exceeded their current abilities. The latter, importantly, has been described by respondents in other studies as “demoralising” (Mallinson, 2002).

#### **6.7.4.4 Mental Health and Role Emotion**

As described in the previous chapter, the Mental Health dimension requires participants to denote how they have “been feeling” over the last four weeks across a total of five questions i.e. “nervous”, “so down in the dumps that nothing could cheer you up”, “calm and peaceful”, “downhearted and low” or “happy”. The Role Emotion dimension requires participants to denote the extent to which “emotional problems” interfere with work/other and social activities.

“Emotional problems” are defined in item 5 as “feeling depressed or anxious” and given that there is no additional guidance to its interpretation in question 10 (the interference of physical health or emotional problems upon social activities), it is feasible that survivors understood and constructed their responses to these items using the prescribed definition. While Albert had made a range of emotionally charged disclosures during qualitative interview, he expressed concern regarding the propriety of requesting patently sensitive information in questionnaire form. While he had initially responded to these items, he subsequently obliterated his responses.

“I didn’t like the ones on your emotional state. I thought that was a bit...personal, you know? You might not want to say how you were feeling inside, especially if you were feeling a bit low.” (Albert)

Frank and Roy also expressed some reluctance to respond to items regarding emotional problems. While there is limited data here to support gender differences in the self-reporting of psychosocial distress, this phenomenon is widely reported in the literature (Curtis and Lawson, 2000).

Here, Frank makes an important moral distinction between being an “emotional person” and allowing emotions to infringe upon his phlegmatic approach to the recovery process and to life in general.

“I found the emotions questions really hard to answer...because I’m not really an emotional person, if you know what I mean? I *get* emotional, don’t get me wrong... but I’m not the kind of person to let things get me down. I just get on with it, really.” (Frank, his emphasis)

In the following extract, Christine alludes to normative assumptions regarding both the intended meaning of “depression” (which respondents in other studies have described as off-putting (Paterson, 2004)) and the socially desired response to illness. Using powerful imagery, she distances herself from the negative connotations of a less than positive outlook;

“That sort of suggested to me that that was your mental wellbeing...that you haven’t *fallen into a chasm of pitch blackness* or anything. All those questions were about...how you’re going to fight back. I mean, I’m quite positive about that anyway, my mental wellbeing.” (Christine, my emphasis)

Roy appeared to base his response upon internal standards of comparison i.e. his former self. He spoke at length during qualitative interview of the ways in which he felt like “a different person” in the wake of the critical illness experience. He described the loss of his trademark sense of humour, “embarrassing” and inexplicable displays of emotion, flashes of “sickening fear” and the short-lived use of anxiolytics (Diazepam) as prescribed by his GP. Here, however, he uses humour to lighten his account.

“I think I can keep my emotions quite well under control but I have never had that before, that something would bring me to tears... why it happens I don’t know. I mean this is Mr Invincible, you know? The tears come to my eyes and why, I don’t know. I just presume that I’ve got weak tear ducts (laughs)” (Roy)

He subsequently described himself in the Mental Health dimension as “a nervous person” only “a little of the time”. It is feasible that the discrepancy between Roy’s verbal account and questionnaire response is attributable to his desire to reflect his “normal” sanguine response to emotional distress i.e. discounting his current experience as out of the ordinary. His concession that he is “a nervous person” at least a little of the time reflects the desire to take *some* account of his current “temporary” status;

providing some insight, simultaneously, into the “subjective combinatorial algorithm” through which he seems to have constructed his response.

These data suggest that survivors may under report “emotional” problems. Taken together, the items pertaining to role emotion and emotional well-being appear to elicit a range of self presentation strategies and are therefore somewhat prone to social desirability bias. While face-to-face interview is reported to elicit more social desirability bias than the “anonymised” self-completion questionnaire, a trusting relationship with the interviewer is likely to enhance respondents’ willingness to respond openly and honestly (Holbrook, Green et al, 2003).

#### **6.7.4.5 General health perception**

The SF-36 asks a total of 5 questions pertaining to perceptions of general health. The items are designed to tap a range of health beliefs comprising; general health perceptions; resistance to sickness; current health and health outlook (Ware & Sherbourne, 1992). Interpretations and expressions of “health” varied. As in several other studies, survivors seemed unsure whether to compose their response in terms of their general health, or in terms of morbidity relative to the critical illness episode (Adamson et al (2004), Paterson (2004), Ong et al (2006)). Here, Christine takes account of her impaired mobility (due to critical illness polyneuropathy) in her estimation of general health, and in her comparative estimation of “health” one year ago.

“I think the only one that I had any difficulty with was the one where you assess how good your health is... Other than my legs, I consider my health to be quite good. If I had to put an X down as “not so good”, in that respect and that’s why I marked it as a three (good), really, and not a two (very good)...”

She subsequently rated her health as “somewhat worse than one year ago” in a desire to reflect the effects of physical impairment on her health. Had she, however, excluded her impaired mobility from her estimation of health (as others might), it is likely that she would have rated her health much more positively.

Frank rated his health as “fair”, taking into account a current chest infection. (He seemed not to take account, however, of a range of long-standing conditions including Parkinson’s disease, hepatitis and chronic back pain). He subsequently reported difficulty in arriving at a representative response, and did so only following a lengthy discussion with his wife.

“I had a good long chat with my wife about this one. I’d say I’m about 70%, but I’ve got a chest infection just now. I wouldn’t be as bold as to say I’m 80% because I’m not as good as I used to be...”

He also expressed some difficulty in relating to his general health one year ago, and despite his assertion that he was “not as good as he used to be”, opted for the middle response “about the same as one year ago”. It is noteworthy that Frank appeared to omit long-standing conditions from his frame of reference as it relates to “general health”. A literal interpretation of the instruction to rate his health “within the last 4 weeks” (i.e. implicitly excluding longer term conditions) is one possible scenario.

Conceptualisations of “health” are, however, inherently broad, multi-dimensional and complex (Jyhla, 1994) and there are, moreover, contradictory reports of the contribution that long-standing conditions make to estimations of health (Jordan et al, 2000). Conceptualisations and self-reports of health become ever more complex in the wake of life-threatening illness; these issues are explored in greater detail in the following chapter. Taken together, the items pertaining to general health perception seem to elicit significant comprehension issues, and in the absence of additional information regarding question meaning or intent, respondents appeared to construct their own conceptualisations, based upon their individual circumstances.

#### **6.7.4.6 Bodily pain**

Bodily pain is defined as the degree to which pain has interfered with everyday activities (including employment and housework). In response to these items, Frank rated his pain as “moderate”, and interfering “moderately” with everyday activities. During cognitive interview, however, he described the severity and chronicity of his *back* pain, and despite taking powerful analgesia, seemed to discount it as an ordinary and expected consequence of prolonged, heavy manual work. Despite the apparent severity of his *hip* pain, he appeared to minimise its effect, describing it as relieved by activity as opposed to analgesia.

“Well, I’ve got this back pain.... occupational hazard, I suppose. I’ve been taking Co-Proxamol for it for about 20 years...it’s the only thing that seems to hit the spot. And *my hip is shot to pieces*...but I find that that tends to ease off once I’m moving about.” (Frank, my emphasis)

Christine rated her pain as “moderate”, but interfering “slightly” with everyday activities. She described variation in symptoms, and implicated her use of mild analgesia as a salient factor in distinguishing “good” days from “bad”. More importantly, she contradicted normative assumptions

regarding the nature of pain, describing her experience as a *positive* one, one that signified improvement in her condition (critical illness polyneuropathy).

“I still get pain from my legs but that’s it. I take painkillers, and that’s the only thing that I take. It’s just...the neuropathy. *The nerve endings are all, what I assume is working their way back to normal.* Not...I mean, it’s always there, but they’re a wee bit sorer than others at times. *It feels as though they’re coming back to life again, hopefully.*” (Christine, my emphases)

#### **6.7.4.7 Energy/vitality**

Here, respondents are asked to denote how much of the time over the past four weeks they have felt “full of life”, “worn out”, “tired” or “had a lot of energy”. Perhaps surprisingly, given the prominence of fatigue in survivors’ broader accounts, only Frank identified the questions presented by the energy/fatigue domain as a source of uncertainty.

“Well, I would normally feel full of life, but I’ve got this chest infection just now.” (Frank)

His response suggests that information related to *temporary* and unrelated sub-optimal health states may also confound attempts to distinguish the effects of critical illness-related morbidity upon perceived quality of life.

### **6.8 Discussion**

There are significant limitations to the use of cognitive interviewing techniques in this study. Data is available only for items which survivors reported as problematic, and the number of respondents participating in this aspect of data collection was small. Detailed retrospective enquiry into the requisite techniques also revealed the initial preparation to be inadequate, particularly in relation to the range of probes available. The Rapkin and Schwartz (2004) HRQoL appraisal model, similarly, was identified retrospectively and would undoubtedly have proved useful in eliciting more precise forms of data. The data, nonetheless, provided useful insights into the normally hidden cognitive processes of questionnaire response.

Existing psychometric approaches to the measurement of HRQoL, it has been argued, “exalt the method” without genuinely appraising their ability to produce the requisite information (Mallinson, 2002). The extant literature, and to a lesser extent, these data suggest that cognitive interview techniques provide significant potential to enhance our current understanding of psychometric theory. The incorporation of respondent perspectives provides a means through which to examine and

incorporate inherently complex phenomena in HRQoL measurement (i.e. adaptation and response shift) into new and existing instruments.

Also relevant within the context of this research (and examined in subsequent chapters) is the existence and effects of *social* phenomena such as self presentation/social desirability bias and social comparison in the response process. Perhaps most importantly, however, these data reveal the importance of *highly individualised* and *context-dependent* aspects of experience; the complexity of which respondents actively attempt to translate into the response process (Ong et al 2006). More broadly speaking, these observations are reflective of the previously described and historical conflict between “the voice of medicine” and the “voice of the lifeworld” (Mishler, 1984), the latter reflecting the respondent’s contextually grounded experiences of events and concerns and expressed in familiar terms.

A broader exploration of “contextually grounded experience” is therefore critical to understanding what it is that HRQoL instruments are “actually” measuring (Leplege and Hunt, 1997), and to understanding the convergence and divergence between everyday experience and questionnaire response. In a move away from the processes of questionnaire completion, the following chapter therefore examines the relevance and meaning of various aspects of experience “expressed in familiar terms” as they relate to the dimensions of the SF-36.

# Chapter 7: A qualitative exploration of the dimensions of the SF-36

## 7.1 Introduction

The purpose of this chapter is twofold. The first is to “interrogate” the dimensions of the SF-36 using qualitative interview data in an attempt to open up “the black box” of what is ostensibly captured within; an exploration of its validity in effect, among this patient group. The second is to position, in a meaningful way, the breadth and diversity of survivors’ accounts of the recovery process within the multidimensional framework of the SF-36. A synthesis of the dimensions and qualitative data is therefore proposed, and is intended to integrate “everyday” experiences of recovery with the prescribed dimensions of experience.

As described elsewhere, the SF-36 measures 8 dimensions of HRQoL comprising; Physical function, Social function, Role limitations due to physical problems, Role limitations due to emotional problems, Mental health, Energy/vitality, Pain and General Health Perception. I propose an alternative framework within which to consider dimensions of experience among the patient group (see figure 4, page 174). The principle dimensions comprise Physical, Mental and Social dimensions. Conceptualisations of (General) Health are demonstrably altered both by the experience of life-threatening illness and the process of recovery, and as a critical component of *health-related* quality of life, receives particular attention.

## 7.2 Data collection

As previously described, the SF-36 was completed within the week prior to interview. Relevant aspects of the qualitative interview included an exploration of life before the critical illness episode, the recovery process following discharge home, expectations of recovery and hopes for the future. In an attempt to explore whether and how survivors’ experiences and perceptions were captured by the measure, qualitative themes relative to the dimensions of the SF-36 were developed and explored, using the process described below.

## 7.3 The complexities of the analytical process

In the very early stages of analysis, a very literal interpretation of the questionnaire items faced by respondents (e.g. the operationalisation of physical function in terms of the ability to walk prescribed distances, climb stairs, etc.) guided the selection of qualitative data. As anticipated, this approach was felt to be overly restrictive and limited in analytical scope. The developers' broader operational definitions of the eight domains were subsequently referred to (e.g. the operationalisation of physical function in terms of those considered "normal" for an individual "in good health"), and their liberal interpretation provided a rather more useful basis for the selection and NVIVO® coding of data.

### 7.3.1 The inter-relatedness of data and dimensions of experience

The existing (and predominantly quantitative) critical care literature tends to report upon the significance of dimensions either in terms of their aggregate or discrete component scales or in terms of their contribution to overall HRQoL, effectively "glossing over" their complex inter-relatedness. While the dimensions of the SF-36 were generally relevant across different aspects of experience, the fragmentation of qualitative data into discrete dimensions failed to capture the complexity and diversity of survivors' accounts, and the interdependence of various dimensions.

A review of the literature among other patient populations provided both empirical support and qualitative insights into unanticipated relationships between seemingly disparate dimensions; e.g. between social support and functional outcome, and these were heavily drawn upon in the analysis. The amalgamation of closely related dimensions e.g. Physical Function and Role Physical, and similarly, Mental Health and Role Emotion went only some way, however, to resolving these issues.

### 7.3.2 The development of qualitative themes

The dimensions of the SF-36 are operationalised by the developers in terms of the interference in or limitations imposed by illness or impairment upon the ability to participate in "normal" activities. Survivors' accounts, in contrast, were suggestive of an active and evolving process of *adaptation* in relation to the accommodation of ongoing morbidity into everyday life. They spoke with surprising consistency, for example, of severe physical impairment in terms of the *pragmatic strategies* they instigated in its management, and impairment as a source of loss was, to some extent, subsumed within this broader communal account.

In order to capture these alternative conceptualisations, and the nuances of survivors' experiences, qualitative themes and sub-themes were derived, where possible, using direct quotes from survivors' accounts. Where appropriate, these also drew upon the prevailing literature. "Pacing", "finding new ways of doing doings" and "setting goals", for example, are well described among the qualitative literatures on adaptation to chronic illness and impairment. Using constant comparative techniques, sub themes were derived in order to describe alternative aspects of experience within each of the dimensions.

### **7.3.3 Unraveling aspects of experience; "strategy" and "coping"**

The terms "strategy" and "coping" are used synonymously or in combined form within the extant literature on adaptation to (predominantly chronic) illness or impairment. The analytical distinction between these terms is advocated, however, for the purpose of directing attention to different aspects of experience (Bury, 1991). Bury's (1991) analytic distinction guided the selection of qualitative data, although an "inevitable" degree of overlap was seen to exist (Bury, 1991).

The term "strategy" directs attention to "what people do" in the face of illness or impairment, as opposed to the attitudes they develop (Bury, 1991). Strategy within this context refers to the actions people take in order to mobilise resources and maximise favourable outcomes, including the setting of realistic goals in order to maintain everyday life. The use of this term underlines a dynamic view of choice and constraint as individuals attempt to weigh up alternative forms of action in the face of illness or impairment (Bury, 1991), wherein everyday life "becomes a burden of conscious and deliberate action" (Bury, 1982: 176). Within the context of recovery following critical illness, strategy refers to survivors' pragmatic, experiential and often innovative attempts to negotiate both everyday life and the emergence of alternative "normalities".

The term "coping", Bury (1991) suggests, refers to the cognitive processes through which the individual learns *how* to tolerate or *put up with* the effects of illness or impairment- that is, the maintenance of a sense of value and meaning in life, often *in spite of* its symptoms and effects. Bury (1991) usefully draws attention, in addition, to the explicitly *social* nature of the response to illness or impairment by adding that the values held by the individuals and the responses of others help determine what it is that people must "cope" with. Within this context, coping refers also to the emotional responses and interpretive processes through which survivors were enabled to come to terms with the interference of ongoing morbidity in everyday life, the unexpected protraction of the recovery process and the spectre of a life-threatening illness.

The chapter following this one also directs attention towards these cognitive processes and there was, in effect, significant overlap within and across these analytical “lenses”. The following chapter, however, examines these processes within the context of the “biographical disruption” associated with critical illness, thereby providing a useful (albeit imperfect) strategy for the selection and positioning of the findings.

### **7.3.4 Capturing temporality**

The SF-36 invites respondents to consider their responses within the context of “the past four weeks” or, in the case of the General Health dimension, “compared to one year ago”. The temporal processes of adaptation in response to illness or impairment are well documented elsewhere (Bury (1982), Carricaburu and Pierret (1995), Faircloth et al (2004)). Temporality was reflected in survivors’ accounts of an evolving and dynamic recovery process; one in which strategy and coping styles were negotiated and revisited throughout. Differential aspects of experience took precedence at different points in the recovery process. “Strategy” was privileged, for example, in the early stages of physical impairment and later, in the recovery of social function, while “coping” appeared to take precedence in the later stages of recovery, particularly within the mental/emotional health, social and general health dimensions.

Temporality was also reflected not least in relation to the desire to return to previous ways of living and the unexpected protraction of the recovery process, but also in terms of survivors’ concerns for the future. In order to capture the temporality of the recovery process, data were selected and organised, where appropriate, into roughly sequential themes. The Physical, Mental Health and Social Function dimensions, accordingly, comprise a number of sub-themes which broadly relate to their occurrence through time. The alternative framework is summarised in Figure 4 (page 174).

## **7.4 The Physical function, Role Physical and Energy/Vitality dimensions**

### **7.4.1 Physical function**

Physical health has been operationally defined by the developers in terms of functional status i.e. the performance of or capacity to perform a variety of activities that are “normal” for an individual in “good health” (Ware et al, 1980). The developers define categories of activities considered to reflect a person’s physical health, and these comprise; self-care activities, mobility (e.g. walking and climbing stairs) and physical activities (described as “moderate” or “vigorous”). As previously described, the

Physical Function and Role Physical dimensions were amalgamated. Given that fatigue was a prominent and indistinguishable feature of the general debilitation and impairment experienced by survivors, the Energy/vitality dimension was later incorporated into the Physical Function-Role Physical dimension. Henceforth, this dimension will be referred to as the Physical dimension.

Critical illness is associated with a broad spectrum of physical and functional sequelae. The most widely reported include; neuromuscular disorders (characterised by muscle wasting, global weakness, fatigue and sensory impairment (e.g. numbness in the extremities)); marked weight loss; joint stiffness and breathlessness on exertion (Griffiths and Jones (2002), Broomhead and Brett (2002)).

Neuromuscular disorders, in particular, are associated with prolonged critical illness (de Jonghe et al (1998), Fletcher et al (2003), Amaya-Villar et al (2009)), and survivors report significant impairment in mobility and the performance of everyday activities for many months (and sometimes years) following hospital discharge ((Weinert et al (1997), Chaboyer and Grace (2003), Griffiths and Jones (2007)).

#### **7.4.2 Role physical**

Role activity is defined in terms of those activities considered typical for an individual of a specified age and social role, and includes work, household and leisure activities. Limitations are described in terms of spending less time on the defined activities, accomplishing less than one would like, limitations in the types of activities engaged in and experiencing difficulty in their accomplishment. The developers' definitions are congruent, to some extent, with the existing professional literature on adaptation to stroke, in as much as that recovery is conceptualised in terms of the recovery of physical function and/or functional ability (Hafsteinsdottir and Grypdonck (1997), Pound et al (1998)).

Lay and patient conceptualisations of recovery challenge this narrow (and arguably professionally mediated) view and include, in addition, a return to previous ways of living and to valued activities including social participation and work (Doolittle (1991), Bendz (2000)). There are few, if any, empirical studies outlining the conceptualisation of recovery among survivors of critical illness. The data from this study suggests that survivors subscribe to the latter. The *process* of recovery requires, in addition, a renegotiation of previous ways of living and the evolution of alternative, if not temporary, "normalities".

### **7.4.3 Energy/vitality**

The energy/vitality dimension is defined by the amount of time felt “full of life”, “having a lot of energy”, “worn out” or “tired”. Among other patient populations, fatigue has been reported as one of the most prevalent and *disabling* features of illness (Fisk et al, 1994), affecting every aspect of everyday life (Stuifbergen and Rogers, 1997) including social participation (Flensner et al, 2003). Among stroke populations, fatigue has been associated with the protraction of the recovery process, functional impairment (Ingles, 1999), decrements in QoL and an increased incidence of depression (Bakshi et al (2000), Janardhan and Bakshi (2002)).

Weakness and fatigue have generally been reported among the critical care literatures as somewhat incidental findings (see Herridge et al, 2003). Weakness and particularly fatigue are increasingly reported, however, among studies associated with ward and community-based follow up services (Hall-Smith et al (1997), Pattison et al (2005)). The data from this research confirm their status as a significant confounder of the recovery process. There are to date, however, no empirical studies of weakness and/or fatigue among the critical illness literatures.

## **7.5 An alternative Physical Dimension**

The most prevalent physical concerns (notwithstanding those related to pre-existing disease) which restricted survivors’ engagement in seemingly “normal” or “routine” activities comprised profound generalised weakness, muscle wasting, unprecedented levels of fatigue and impaired mobility. Their cumulative impact was pervasive and keenly felt across almost every aspect of everyday life. Two broad themes, related to the temporal processes of recovery were identified.

“Getting by” outlines the pragmatic strategies survivors employed in the challenging transition to “life at home” and comprises the sub-themes “organising resources”, “organising (informal) support” and “finding new ways of doing things”. “Moving on” outlines the strategies through which survivors subsequently attempted to manage impairment and recover physical function within the broader context of negotiating a return to normality, comprising the sub themes; “pacing” (managing weakness and fatigue), “pushing through” and “making progress and setting goals”. Importantly, these strategies were revisited in later attempts to resume social, leisure and work-related activities.

## **7.5.1 “Getting by”**

### **7.5.1.1 Organising material resources**

In the early stages of life at home, most were restricted both to and within the home. Many experienced difficulty getting out of chairs, navigating household furniture and mobilising between rooms, for example, and environmental factors such as upstairs bathrooms and bedrooms proved unexpectedly challenging. At the time of interview, several were reliant upon the mobility aids provided at hospital discharge. Ken, in particular, described his reliance upon additional home adaptation (in this case, hand rails) following a fall shortly after hospital discharge. Betty had remained “stranded” in an upstairs bedroom for several weeks following hospital discharge, while awaiting the installation of a stair lift while Anne, unable to get upstairs “even on her bum” had little option but to sleep in a makeshift bed downstairs.

While Andy was unperturbed by the private purchase of a “grabber” and jar openers, for others, informal attempts to acquire more substantial aids and adaptations were met with little success. Having effectively foregone OT assessment as a consequence of convalescence with relatives, the return home presented Jane with fresh challenges, including an unforeseen inability to get in and out of a bath. Her attempts to acquire the requisite aids from Social Services were unsuccessful.

“I think she thought I was just somebody ringing up that had a whim for a seat (laughs). So I’m still waiting, and I don’t know whether to ring back or persevere. Maybe somebody’s need is greater than mine. But initially, it would’ve been a big help to me.” (Jane)

Among those for whom an established programme of OT assessment and home adaptation already existed (i.e. Roy and Sandra, following hip replacement), provision was, in contrast, both extensive and timely.

“I filled forms in to see what height certain things were and they sent somebody up with the toilet seat and to raise the bed. These things were all done before I was in the house. They gave me the chair, my walking sticks, the gripper, shoe horn, the long handled shoe horn and I’ve got a thing to put my socks on with.” (Roy)

### **7.5.1.2 Organising (informal) support**

Survivors were variably dependent upon (often elderly) spouses, family members or friends for assistance or surveillance in a range of previously taken-for-granted activities. Anne, a sufferer of

chronic and frequently incapacitating rheumatoid arthritis, described an all-encompassing and unparalleled dependence upon her husband and latterly, her adult daughter.

“Oh, I was glad to be home but very, very tired and very weak ...frustrated by the fact that my life was gone as I knew it. I couldn't do this, I couldn't do that. I had to rely on someone to be in the house to help me get up, dress me, that sort of thing. *That was the most disabling thing...the fact that you've got to be reliant on someone else for everyday life.*” (Anne, my emphasis)

Assistance with self-care notwithstanding, survivors were variably reliant upon others for a range of activities including; the purchase and preparation of food, household chores, laundry, the payment of bills, etc. Only Pat and Andy were in receipt (albeit reluctantly) of formal personal and domestic assistance which, despite a significant burden of care, Albert's wife steadfastly declined. Having already outlined the desire to relieve his elderly mother of household chores, Andy felt compelled to justify his reliance upon a Home Help.

“I'm no' swingin' the lead here. I said that to the lassie. I *do* need help just now, I'm just not *able*...but it's just temporary, just until I get back on my feet, like...” (Andy)

### **7.5.1.3 Finding new ways of doing things**

In the early stages of life at home, survivors invested significant effort in “mapping out” the nature and extent of their physical and functional impairment (Charmaz (1983), Olofsson et al (2005)), devoting careful attention to the contingencies upon which “getting by” depended. Jane, for example, felt “unsafe” getting in and out of the bath, and would do so only when her housemate returned from work in the evening. Unable to stand for long periods of time for the purposes of cooking, Pat relied upon microwave meals, while Lynne positioned a stool by the cooker, and relied intermittently on take-away meals.

Andy's account serves to demonstrate the ways in which previously simple activities (in this instance, getting out of the bath) took on new and surprising levels of complexity.

“I would never have got back out again. I would've had to let the water out and try and climb over...and I would've been lying on the carpet, trying to get myself up. I've just got no strength in my arms. My shower's in the bath and I have to get in the bath to have my shower, so I couldnae (couldn't) have a shower. So I had to...just wash with a sponge.” (Andy)

The contingencies upon which getting by depended were, moreover, *evolving* in relation to the ongoing recovery process. Here, Andy describes his somewhat tentative attempts to get in and out of the bath,

“When I got a bit more strength, *then* I could get in and out the bath... I took my time, mind. I didnae (didn't) jump in.” (Andy, his emphasis)

For some, the negotiation of everyday life revolved not only around weakness, fatigue and functional impairment, but also around the additional restrictions imposed by treatment-related concerns. Unarguably the most severely constrained in this regard, Albert described the “nuisance” of washing, with his elderly wife's assistance, while mindful of a urinary catheter, a stoma and a conduit for the purposes of nutrition. Here, he outlines the nightly ritual of getting into bed, a now complex activity structured by attention to his impaired swallow, his artificial feeding regimen, a urinary catheter and pressure relieving boots.

“I lie in bed in a semi recumbent position so I don't swallow anything... I've got a sore heel and the District Nurse made me bootees. Jean puts these on for me. I'm already attached to my (feeding) pump. I swing my leg up and she puts the bootees on, so that's the bootees. She assists with the leg bag and she fits it down here (indicates calf) and I open it...” (Albert)

The nightly “ritual” is indicative of the elaborate strategies which Albert and his wife constructed around routine aspects of everyday life. While affording the everyday a sense of manageability and predictability, the stringency with which the couple executed these strategies brought its own constraints, leading Albert to reflect that his life was “not his own”.

While many were well placed in terms of tangible support, those who lived alone or with non-significant others (in which case, assistance with various aspects of everyday life was considered inappropriate) faced rather different challenges. Pat's strategy for “getting by”, for example, included the transfer of her fridge, microwave and kettle into her living room, all within easy reach of her chair.

“I have what I call my “messy corner”...my newspaper, the remote for the telly, my pills, the phone, my grabber and what have you. I just have everything where I can reach it. I get by (laughs). I can make myself a cup of tea, microwave my meals...” (Pat)

#### **7.5.1.4 Summary**

These data outline both a degree of variability in relation to the ease of access to material resources, and their impact upon survivors' ability to “manage” at home. They support previous work in outlining the infrequent uptake of formal support services and a strong preference for more *informal* means of

support among patient groups (Bugge et al, 1999). These data also support the observation that individuals develop pragmatic and innovative strategies in the management of everyday life. These strategies, it is suggested, are ever more innovative in the absence of formal or social support (Grimmer et al, 2004).

## **7.5.2 “Moving on”**

Moving on from this period of marked impairment was experienced in terms of being “(more) able to do things for myself” or “the things I did before”. Survivors adopted a range of strategies in the recovery of mobility (i.e. walking) and physical function in general, many of which appeared to be intuitive or experiential in nature. Sub themes comprise; “pacing” (managing weakness and fatigue); “resistance” and “marking progress and setting goals”.

### **7.5.2.1 Pacing (managing weakness and fatigue)**

Pacing constitutes a rather complex strategy including; the planning of tasks, the introduction of frequent rest, slowing down and the strategic use of energy and time (Pound et al, 1998). It is a strategy which was of particular relevance among survivors in relation to the management of weakness, fatigue and functional impairment.

“I could do the stairs, turn the corner to the set of lights and I used to stop at the set of lights and gather my energy...and then cross the road to get to the supermarket. And the same on the way back. I’d need to stop at the stairs and just...mentally get myself together for getting up the stairs.”  
(John)

Despite a heightened awareness of their functional limitations, many struggled to manage the circuitous relationship between physical activity and fatigue. Each described significant limitations upon physical activity as a consequence of fatigue, and physical activity, in turn, elicited significant fatigue. Survivors utilised alternative strategies (e.g. “giving in” to or “fighting” fatigue), with varying degrees of success, and with attendant concerns about whether they were doing “the right thing”. Many described being “caught out by” or “paying for” their efforts.

“...it was alright me saying, “Oh, I’d like to do such and such”, but with my body being so low, if I do a lot, it’s counter-acting, you know? If I have my strength coming back to me, it’s gonna go, because I’m doing too much. So it’s a no win situation, and I surmise that that’s why it takes so long to get better.” (Jane)

There was increasing recognition during this time that the recovery process was likely to be both difficult and prolonged. In the following excerpt, Ken alludes to the reduction in activity as a

management strategy; one intended, it has been suggested, to render impairment “manageable” and “invisible” to the sufferer (Charmaz, 1999). As the following excerpt suggests, this strategy simultaneously introduces the risk of consolidating any existing impairment.

“...one afternoon, I walked right over there (gestures out of the window). *But I was so knackered later that day that I daren’t get out the next day at all.* At first I thought, “Oh, I’ll perhaps do this every day” when I was out there, but *I’ve not been out since* (laughs).” (Ken, my emphases)

The “invisibility” of weakness and fatigue often extended to others. Only close friends and family members were witness, for example, to excessive fatigue following social events, and several alluded to a lack of understanding among their wider social circle in the later stages of recovery. Jane, tanned from a recent holiday, was at pains to point out the persistence of fatigue long after more obvious signs of recovery (such as weight gain) had occurred.

“You appear to do things, but it can be an effort, at different times of the day... And I mean, I look healthy, I look...well...but you can look what you’re not...” (Jane)

Fatigue, moreover, was often slow to resolve.

“I have just generally felt tired, all the way through. Every time I’ve sat down I feel as if I’ve just run a mile... and that’s just started to ease a little bit, just in the last few days, actually” (Dave, at 6 months post-ICU discharge)

### **7.5.2.2 Resistance**

Many described an adversarial relationship with the intrusion of symptoms and impairment into everyday life, and with the recovery process in general. The intrinsic value and positive benefits of a “fighting spirit” were frequently espoused. Anne related her “fighting spirit” to her struggle with chronic and intermittently disabling rheumatoid arthritis, for example, while others alluded to a “determined” personality. Still others suggested that resistance was not a matter of choice. Its maintenance, however, was often far from easy.

“You’ve *got* to have the will...and say, “Yes, I *am* going to get better. I’m going to try and get my life back”. Really having the determination...it’s not easy.” (James, his emphases)

The following accounts serve to demonstrate the multiple and often unexpected “pathways to resistance” (Bonnano, 2004). Alternative aspects include the associated risks, unanticipated benefits and its adoption as a rather more social strategy. Roy, for example, having had “no real heart problems” since cardiac surgery some 15 years previously, experienced shortness of breath and chest

pain on exertion. His frustration with regard to the unexpected protraction of the recovery process led him, worryingly, to “push on” through his symptoms.

“I was getting breathless and I felt the pain I get from the angina, so I had to use the spray and calm myself. Maybe doing too much too soon, I dunno. If I’m going to the shop...especially if it’s windy...it catches my breath and I feel the pain in my chest. I just put my back to the wind and have two puffs of the spray.” (Roy)

In the following excerpt, the “pathway to resistance” is rather less deliberative. Here, Sandra alludes to a somewhat accidental (and seemingly counter-intuitive, although professionally recognised) strategy for the management of breathlessness.

“I still get a bit breathless. It could be the first wee while...Sometimes I find if I’m walking more, it’s not as bad, funnily enough. You’d think it’d be the other way round.” (Sandra)

The following excerpt outlines the social stigma associated with the visibility of suffering and its effects upon “sociability” (Charmaz, 1983). Jane’s account of impaired mobility associated with painful joints outlines, in addition, the additional “effort” required to maintain the requisite show of public stoicism.

“...if your face is tripping you, nobody wants to be around someone that’s...So I try to walk, and even if it does hurt, I try not to show it. So that’s a bit of an effort” (Jane)

### **7.5.2.3 Marking progress and setting goals**

Many survivors described a heightened and evolving awareness of their functional limitations and abilities throughout the recovery process. In the following excerpt, John describes a tacit process through which he and others recognised “improvement”.

“...there were all these mechanisms going on at the time about getting better...one of them being ticking off things that you couldn’t do before, but could now do...*I didn’t have a big kind of programme written out, but it helped to just kind of acknowledge what I could and couldn’t do.* So that helped...marking progress.” (John, my emphasis)

Survivors described some aspects of recovery as “naturally occurring” in as much as that its recognition seemed rather more incidental. Here, Don describes his increasing ability to participate in childcare activities with his young grandson.

“I have a grandson who keeps you busy at times ...and that was another way I was able to measure how I was doing. At the start, there was no way I could lift him, but gradually I found I was able to lift him a wee bit further and now I can do it with no trouble at all.” (Don)

Others described the active and incremental “testing” of their abilities against variously well defined goals, often in terms of mobility or the ability to participate in other light physical activity.

“I used to walk into the village every morning to get my paper. It’s only about a mile there and back, but I had to build up to it. Having said that, I’m still feeling it...by the time I’m heading back, I start to feel tired.” (James)

#### **7.5.2.4 Summary**

These data provide clinically relevant insights into the largely experiential or intuitive strategies survivors adopted in the management and evaluation of the recovery process. Despite their often tentative inception, given the confounding effects of fatigue, many had made significant functional gains at the time of interview. Most, however, suffered from residual weakness, impaired mobility and the majority described being significantly “slowed down”. Surprisingly few questioned the origin, severity or longevity of weakness and fatigue, and implicit among survivors was the notion that these symptoms were “to be expected” or “not out of the ordinary”, having survived a prolonged life-threatening illness. Implicit also was the notion that there was little option but to simply “get on with it” as best they could.

## **7.6 The Mental Health and Role Emotion dimensions**

### **7.6.1 Mental Health**

Mental health is defined by the developers in terms of affective (mood) disorders and upon positive well-being and self-control (Ware et al, 1980) i.e. as the amount of time respondents felt “nervous”, “calm and peaceful”, “so down in the dumps that nothing could cheer you up”, “down-hearted” or “happy”.

The unique psychological sequelae of critical illness are well described in the professional literatures, largely within the context of amnesia, delirium (an acute confusional state) and dreams of an often persecutory nature (Jones et al (2001), Roberts and Chaboyer (2004), Roberts et al (2006)). The latter have been described as more vivid and emotive than the recall of factual events (e.g. care or treatment-related activities) or bodily sensations (e.g. thirst, discomfort), and have consistently associated with significant short-term distress (Lof et al (2005), Magarey and McCutcheon (2005)) and in the longer-term, the development of anxiety, depression and post-traumatic stress disorder (characterized by distressing and intrusive “flashbacks”) (Jones et al (2001), Griffiths and Jones (2007)).

Anxiety and depression have been widely reported in the critical care literatures with a firm emphasis on *prevalence* (Rattray and Hull, 2008) and the “direction” of the relationship between psychological distress and the recovery process is, at best, poorly understood. Implicit in the existing literature, nonetheless, is the notion that psychological distress is largely attributable to the subjective interpretation of the acute phase of critical illness (Rattray et al, 2005). Both the previous and the following data, however, challenge that assumption as over simplistic and direct attention, in addition, to the recovery process (Compton, 1991).

“...everybody has told me, “Oh what a massive thing you’ve been through”, but for the whole ICU thing, I was completely out of it...so forget all that, what most people consider being the worst stage, forget it, because I didn’t know *what* was going on.” (Dave, his emphasis)

The following excerpt suggests, in addition, that for some, psychological distress may emerge late in the recovery process i.e. once a certain “distance” from the acute event, or a semblance of “normality” is reached.

“It is only now I am a little more removed from what happened to me last year that I am dealing with everything. I think at the time *I was so focussed on getting better that there weren’t really the emotional repercussions of what had happened.*” (Lynne in email correspondence, almost a year post-interview) (my emphasis)

### **7.6.2 Role emotion**

Role Emotion is defined by the developers as the extent to which “emotional problems” (defined as “feeling depressed or anxious”) interfere with work, daily or social activities. Limitations are described in terms of spending less time on the defined activities, accomplishing less than one would like or carrying out those activities less carefully than usual.

Among other patient populations, psychological distress has been associated with poorer functional outcomes (De Beurs et al (1999), Brenes et al, 2005)), reduced social participation (Eslinger et al, 2002) and decrements in overall HRQoL (Kim et al, 1999). Among survivors of critical illness, psychological distress (in particular, post-traumatic stress symptomatology) is increasingly associated with the protraction of the recovery process and delayed return to work (Rothenhausler et al (2001), Ringdal et al (2006)). Neurocognitive deficits in memory, attention, concentration and executive function (e.g. decision-making) have also been reported (Jackson et al (2003), Hopkins and Brett (2005)), with important effects upon the ability to perform activities of daily living, including money management, driving and the return to work (Hopkins et al (2005), Rothenhausler et al (2001)).

Survivors were, by and large, disarmingly pragmatic and cautiously optimistic in their approach to both the recovery process and an anticipated return to “normality”. The intrinsic value of “the right attitude” was a prominent feature of survivors’ accounts.

“The physical rehab - speaking, walking, weight gain, stairs etc. is just training...it’s the head (head) that matters...” (John)

## **7.7 An alternative Mental Health Dimension**

Importantly, “mental health” was conceptualised by survivors not only in terms of the critical care experience or (lay conceptualisations of) the pathological processes inherent in the critical care literatures, but also as Bury (1991) suggests, in terms of the interpretive and adaptive processes through which they were able to “put up with” the effects of symptoms and ongoing impairment in everyday life. Two broad themes were derived from survivors’ accounts. “Making sense of the ICU experience” explores the interpretive processes through which survivors were able to rationalise the experiences and effects of the “memory gap” and delusional “memories”. “Putting things in perspective”, in contrast, explores the ways in which survivors were able to negotiate an acceptable place for ongoing morbidity in their everyday lives, comprising the sub-themes “It’s better than being six feet under” and “There’s always somebody else worse off”.

### **7.7.1 “Making sense of the ICU experience”**

#### **7.7.1.1 “Filling in the memory gap”**

The vast majority of survivors experienced a “memory gap” in relation to the critical illness episode. The gap frequently preceded critical illness by several days and most described only a “jumbled” or limited recall of their ICU stay, punctuated by obscure “memories” and “experiences”. A very small number remembered “absolutely nothing” of their ICU stay. Amnesia was variously attributed to the sedative drugs received in ICU, the severity of illness or “the subconscious”.

Here, Elizabeth describes her response to a complete lack of recall in the face of numerous invasive procedures and radical and repeated surgical intervention for a ruptured oesophagus.

“The last thing I remember was...the ambulance. I don’t remember anything else until I woke up six weeks later. It’s amazing what that does to you...it’s hard to explain...you’re out for the count and you’ve got...no say in what they’re doing to you.” (Elizabeth)

Alluding later to the significant trust she placed in the clinicians who had ultimately saved her life, she remarked that she had little option but to accept her situation. Reflecting, in the wider literature, the notion of amnesia as an avoidance mechanism or protective mechanism against what must have been an unpleasant reality (Richman (2000), (Stoddard and Todres (2001))), several ascribed to the view that “it wouldn’t have been a bad way to end life, really. You don’t know a thing about it”. (Ken)

“They say your mind has a room it’ll go to... if you’re in trauma or something major happens, your mind will go to a little room, and that’s exactly where I went.” (Jane)

Importantly, despite providing full and open accounts of their experiences, both Sandra and Pat expressed a strong preference *not* to know what had happened to them. For others, however, “not knowing what happened” was associated with a distinct sense of disquiet.

“I feel as if I’ve been on some great journey but I don’t have any postcards, don’t have any photographs. And...that’s a loss.” (John)

Survivors had little (if any) access to the clinicians involved in their care following ICU discharge and were therefore heavily reliant upon relatives’ often reluctant and highly sanitised accounts of the cause, chronology and veracity of recalled “events”. Christine’s husband, for example, had restricted his disclosure, at the time of interview, to only those with humorous undertones. Her adult children and elderly mother had simply “never spoken about it”.

“He told me one time, how he’d battled through the traffic for 45 minutes to visit me, and had sat down...and 5 minutes later I told him to fuck off, apparently (laughs). He tells me things like that! (laughs)...” (Christine)

The majority of survivors were satisfied with relatives’ accounts (a number of which included brief diaries), although several requested (with often limited success) additional information from their General Practitioners or from acute sector clinicians during the course of out-patient appointments. It became apparent during the course of the study that many perceived both the research interview and the invitation to visit the ICU as an opportunity to “get some answers”. The latter, in the vast majority of cases, was perceived as helpful in “jogging the memory” and several took the opportunity to request additional information from the clinicians whom they subsequently recognised as being involved in their care. A small number, thereafter, resolved to request formal access to their medical notes.

### 7.7.1.2 “Making sense of bizarre dreams and experiences”

Each of the survivors, without exception, reported bizarre dreams and “experiences” associated with the acute phase of critical illness and these were a prominent feature of survivors’ accounts. In keeping with existing literature, prevalent features included their unnerving reality and the preservation of often intricate detail several months after ICU discharge (Misak (2004), Roberts and Chaboyer (2004), Lof et al (2005)). These, similarly, were variously attributed to the sedative drugs received in ICU, the severity of illness or “the subconscious”.

A number of survivors described variously benign “misinterpretations of reality”, often incorporating members of staff or routine aspects of care. Nursed, presumably on a pressure relieving mattress, Ian, for example, perceived himself to have been on a boat. The busy ICU environment was variously perceived as a fairground, a train station, a French village and a gaming hall. Contrary to the prevailing literature, several described entirely pleasant and “enjoyable” dreams, which were often recalled with great humour and affection. Sandra, for example, enjoyed “a lovely trip around the world”, while Pat participated in an elaborate Japanese opera.

“I do still miss the surreal dreams. I miss the jazz studio in my flat upstairs...and I miss the raw excitement of running my Chinese textiles/vinyl records franchise on the New York Subway (Line 38), especially with the noodle bar so handy in the next carriage. So many people I hadn’t seen for ages turned up there...” (John, in email correspondence, several months after hospital discharge)

The vast majority, however, described terrifying dreams, “experiences” and hallucinations. Andy, for example, described attempts to cut off his Mother’s tongue with a sharpened spoon, while others described “utterly convincing” conversations with long-dead relatives. Having “witnessed” the murder of two ICU nurses, Anne imagined herself the next intended victim of Jack the Ripper. Here, her distress is compounded by the inability (due to endotracheal intubation) to communicate her fears to the clinicians involved in her care, or to visiting relatives.

“I was convinced...that he was trying to kill me, you know? But I couldn’t get through the dream to tell them that he was trying to kill me. And that was frightening...really frightening.” (Anne)

Many “came to” only during the ward phase of recovery, while others described a “twilight zone” between reality and delusional memories. John, for example, described ongoing “paranoia” in relation his perceived incarceration as a prisoner of war. Anne described, with some embarrassment, entirely “out of character” behaviours including acts of verbal and physical aggression towards ward staff, while Jane experienced visual and auditory hallucinations. Both Anne and Jane were formally reviewed by psychiatrists, eliciting for Jane, significant embarrassment and concern for her sanity.

(Case note review later revealed that neither psychiatrist had identified the possibility of ICU delirium.)

Given their unnerving reality and complexity, many described only a “gradual realisation” that recalled events could not, in fact, have taken place. The ability to “check” with close relatives was often mediated, however, by the nature of the dreams and experiences. Andy in particular described an inability or reluctance to discuss his experiences for fear of appearing “crazy”.

“I’ve never even told my family this, so you’re the first. If I said to somebody, if I told them...they’d say, “You’re off your head. You’re a crazy man, you’re away wi’ it”. (Andy)

Congruent with the existing literature, several described an associated “search for meaning” (Papathanassoglou and Patiraki (2003), Roberts and Chaboyer (2004)). John drew upon his Father’s accounts of strange dreams and experiences during a recent serious illness in order to account for his own. Frank was able to draw upon his experiences of a “bad trip” in relation to LSD usage in his youth, while Roy sought meaning in a book of dreams. The desire to make sense of *distressing* dreams or “experiences”, however, seemed rather more pressing.

In the following excerpt, for example, Andy alludes to the “hidden meaning” of his dreams.

“...if I’ve got a dark side that was it coming out in me. Evil to the extent I wasnae (wasn’t) a murderer or a rapist or anything, but I was daein’ (doing) bad things...in ma head. But I was *actually believing* I’d *done* that. My birthday’s the 6<sup>th</sup> of June. And I worked out that, June, well...it was 666, right? Which is the devil’s number.” (Andy, his emphases)

Despite the retention of often horrifying detail several months later, few associated their experiences with distress in their everyday lives. Ken, for example, had dreamt that he had achieved 12/13ths of his life expectancy and, having calculated his date of death, cheerfully described his recent decision to make a will. James alluded to occasional unpleasant “flashbacks” which he was increasingly able to dismiss. Roy, however, described inexplicable and intrusive flashes of “sickening fear”, for which he reluctantly accepted a short course of anxiolytics (Diazepam) from his GP.

“...you suddenly get this sickening fear and you don’t know why you’ve got it. You can be lying in bed and then suddenly you feel afraid, not climbing the walls, but you are afraid of something. I don’t know why that is, I’d never felt that way before.” (Roy)

### 7.7.1.3 Summary

The amnesia and delusional “memories” associated with the ICU stay often militate against survivors’ ability to “piece together” the events surrounding ICU admission, the nature or chronicity of clinical events therein, or indeed to develop a realistic appreciation of the severity of illness. They drew, nonetheless, upon a wide range of strategies in order to ameliorate or make sense of their experiences. As previously described, many perceived the research interview and the subsequent ICU visit as therapeutic in terms of the opportunity to normalise and reconceptualise their “weird dreams” (Jones et al (2003), Pattison et al (2005), Engstrom et al (2008)) and to “get some answers”

“Without the trigger of your invitation...I am sure that my memory and rationalisation of the whole bizarre business would have been much more retarded and random than it is now. I truly regard that interview as having been the single most therapeutic event since my illness.” (John in email correspondence, several months post-interview)

### 7.7.2 “Putting things in perspective”

The rapid onset and overwhelming nature of critical illness elicited significant concern among survivors. The amnesia that frequently preceded critical illness, for example, led many to believe (sometimes erroneously and despite the accounts of significant others) that they had succumbed to critical illness “completely without warning”, often eliciting a fear of recurrence.

“Sometimes I get a wee bit anxious about it happening again. I think that’s one of the scary things...I know it can happen like that (snaps fingers). You don’t know a thing about it, you know?” (Sandra)

In the following excerpt, Jane describes a heightened sense of awareness and an inability to sleep for fear that “something else” might happen.

“And still I couldn’t sleep, because my mind...it’s still like that now...it’s like it’s on alert, there’s something else going to happen.” (Jane)

Here, Jane alludes to both the temporality of her (somewhat passive) psychological adjustment and to the notion of ongoing morbidity as a palpable and inescapable reminder of the critical illness experience.

“...it’s like...it’s all been a big, bad dream, and yet I know it’s real. And I think, even now, when it’s several months later that I haven’t come to terms with it, not fully, not properly. I think the time...perhaps 12 months, 18 maybe, but *I know it’s gonna take time, because I’ve got the knock on effect.*” (Jane, my emphasis).

A very small number of survivors provided accounts of “depression”; typically, in response to the interference of morbidity upon everyday life and the unexpected protraction of the recovery process.

“I get a wee bit down at night. I’ve tried to fathom that out, but I don’t know. It’s not like me to be like that. Maybe... it’s just that there’s another day past and I’ve done nothing that I would’ve normally done...” (Andy)

With few exceptions, survivors provided compelling rationale for experiences of anxiety or distress. These included the fear of recurrence, uncertainty regarding the prognostic effects of critical illness, the interference of residual symptoms on everyday life, and uncertainty regarding the limits of recovery. To some extent, the elicitation of these very pertinent concerns normalises (rather than pathologises) the experience of anxiety and depression among survivors of critical illness. The vast majority of survivors, however, ascribed to the view that they were “still here” and that their concerns would simply fade with the passage of time.

#### **7.7.2.1 “It’s better than being six feet under”**

The existential gravitas, as it were, of life-threatening illness contributed significantly to the ways in which survivors made sense of and accommodated ongoing morbidity. In keeping with research amongst other patient populations, accounts of profound debilitation and seemingly intolerable morbidity were often perceived as “a lucky escape” (Pattison et al, 2007). Despite significant physical impairment (including, as previously described, a urinary catheter, a stoma and a conduit for the purposes of nutrition) and the orchestration of everyday life around fatigue and treatment-related concerns, Albert considered himself “a very lucky guy”.

Here, James’ wife describes her tacit acceptance of the restrictions placed upon their everyday lives by virtue of his inability to swallow. These included, amongst others, “being tied” to a strict enteral feeding regime, the embarrassment associated with spitting out a constant stream of saliva and the inability to enjoy previous enjoyed social activities such as eating out, theatre visits and holidays abroad.

“It is restrictive but I’m just glad that *I’ve still got you*. So it doesn’t matter. It doesn’t matter ... (pause) (Sally, James’ wife) (my emphasis)

“Saddled with” a highly active stoma and effectively housebound by profound debilitation, Ken suggested light-heartedly that

“Some people will say, “I don’t want to live on and sit stuck at home all day” and I don’t suppose I do, really...but one has to compromise...it’s better than being six foot under, I suppose. (laughs)” (Ken)

Prevalent among those less severely impaired was the notion that they had “got off lightly”. Here, Sandra advocates “acceptance” of one’s lot, while demonstrating hope and expectations of the future.

“Well, it’s just something you’ve got to put up with, you know? If you’re gonna take these illnesses, you just have to accept that...you’re not going to be the same person as you were...but I was really lucky, I suppose that I came through it. I think other folk probably don’t.” (Sandra)

#### **7.7.2.2 “There’s always somebody else worse off”**

Congruent with other literatures on adaptation to illness and impairment, several survivors related their situations favourably to others “worse off” (Pound et al (1998), Sanders et al (2002)). Several drew upon their proximity, during the acute hospital phase, with the “poor souls” they encountered there.

“There was one chap who was dumb...and one of his arms had been amputated... Other than his feed...somebody would come round once very two or three hours to give him a drink. What happens if he was thirsty before that? I just felt terribly sorry for him.” (Dave)

Don drew upon his encounters with fellow sufferers of Guillan-Barre in a specialist rehabilitation unit, one of whose “legs had just gone completely”. Ken, similarly, recalled his experiences of rehabilitation within a specialist stroke ward.

“...they’d a harder job of it because...they’d had a stroke and something had been taken away from them that they couldn’t get back. Whereas I didn’t see myself like that...and I thought how lucky I’ve been, really.” (Ken)

Others drew upon their own and others’ experiences of impairment. Christine, for example, expressed heartfelt “gratitude” for her ongoing recovery, having seen “life from the disabled side” as a consequence of temporary wheelchair dependence. Importantly, the consideration of one’s own situation within the context of others “worse off” was seen, in several instances, to act as a moral impetus to “just get on with it”.

“I don’t know how bad I’m gonnae get, but I don’t think that way, I just get on with it. What’s to be will be. *I’ve seen people a lot worse than me...they get on with it.*” (Frank, on his attendance at a support group with fellow sufferers of Parkinson’s disease) (my emphasis)

### 7.7.2.3 Summary

These data outline prominent cognitive processes through which survivors were enabled to negotiate an acceptable place for even significant ongoing morbidity in their everyday lives. We return to these processes in the following chapter, wherein themes relevant in a wider biographical context comprise “well, what else can you do?” and “everything happens for a reason”.

## 7.8 The Social Function dimension

Social function is defined by the developers of the SF-36 in terms of interpersonal interactions and other activities indicating social participation, and the extent (not at all, slightly, moderately, quite a bit and extremely) and frequency (all of the time, most of the time, some of the time, a little of the time and none of the time) with which “physical health or emotional problems” have interfered with “normal social activities” (Ware et al, 1980).

Among other patient populations, social support has been related to functional ability, decrements in overall quality of life and depressive symptoms (Newsom and Schulz (1996), Kim et al (1999), Kwakkel et al (1996)). The reciprocal effects of patient and caregiver coping strategies upon partners’ HRQoL (Myaskovsky et al, 2005) are receiving increasing attention given the reported significance of social support in the recovery of physical function and the long-term well-being of patients (Glass and Maddox, 1992).

In the early stages of recovery at home, social interaction was generally restricted to that with family members, close friends (and in a small number of cases, health care professionals), largely as a consequence of enforced dependency and restriction to the home. Survivors frequently emphasised the importance of social support during this time, and many expressed both gratitude and concern for their loved ones in relation to the significant emotional and physical strain imposed both by ongoing impairment.

“If you have an illness like this...it’s not just you, it’s everybody else that suffers.” (Don)

Research among other patient populations suggests that caregivers are frequently obliged to make significant lifestyle changes e.g. balancing family, employment and leisure activities for which many are unprepared (Backstrom and Sundin, 2009). Enforced dependence and the requisite lifestyle changes, Bury (1982) suggests, often bring into sharp relief the proximity, reciprocity and resilience of relationships. The impact of critical illness upon caregivers is increasingly well-recognised in the

professional literature. An increased prevalence of anxiety, depression and Post Traumatic Stress symptomatology, for example, have been reported among family members (Jones et al (2004)).

The physical impact of care-giving, although less well recognised, is likely to be substantial, given current policy initiatives towards early hospital discharge and incomplete functional recovery among survivors. Three broad themes were derived from survivors' accounts in relation to social support and social interaction (including the return to leisure and work activities) and they comprise "Leaning on family and friends", "Getting back to normal" and "Being treated differently".

## **7.9 An alternative Social Function dimension**

### **7.9.1 Leaning on family and friends**

The nature and significance of the practical and emotional support provided by family and friends was frequently emphasised during interview, and this theme explores the ways in which these alternative forms of support were negotiated and perceived. Dave, for example, expressed both significant admiration and guilt with regard to his wife's "incredible" stoicism and her ability to manage his care needs and that of their young son within the context of a "high pressure" job. Here, Sandra recounts her husband's assumption of "all the cooking, cleaning...everything, really", within the context of a critical illness of which she remembered very little.

"He's been wonderful, I must admit. I've been really lucky there. I don't know how I would've coped if I'd been on my own, you know? All my friends have told me, "Oh, when you were bad, Sandra, he was really worried" and...*who knows what's he's really been through.*" (Sandra, my emphasis)

Many survivors, as previously described, were well placed in terms of social support. The relative "health" of often elderly caregivers, however, was often a source of concern. Albert, for example, outlined his elderly wife's variable ability to meet his extensive care needs within the context of her own frailty (and consequently, an undoubtedly difficult transition from recipient to the provider of informal care), remarking latterly that she was "just exhausted". Here, Anne is compelled to ask her adult daughter to return from life in Liverpool in order to ease the burden of her husband's care giving and work-related activities.

"I asked her to come back home because her Dad was doing everything. He was trying to look after me, run the house, go to work...and he's got a bad heart, so I wanted the stress lifting off him" (Anne)

Only a small number of survivors described any inherent “tension” in the negotiation of informal care out with those already described. Jane, however, accepted only grudgingly accepted the hospitality of her previously estranged family during a period of recuperation.

“I just would’ve told them in the nicest possible way that I was better with strangers. I mean, they bent over backwards...but it makes you feel beholden, you know what I mean?” (Jane)

Albert, while mindful of his wife’s good intentions, expressed frustration regarding his wife’s “over-attentiveness”, alluding to the circuitous nature of the strain associated with care giving activities.

“I have been bad tempered. I blow up...it’s not that I’m particularly angry, it’s just a lack of understanding (on her part)...and then she gets anxious” (Albert)

The significance of *emotional* support has been most widely reported during the acute phase of critical illness. The presence of close family members has been associated, for example, with a sense of identity and security among the critically ill (Bergbom and Askwall (2000), Engstrom and Soderberg (2007)). Survivors frequently report a sense of “guilt”, however, in recognisance of the considerable psychological distress imposed upon loved ones during the acute phase (Bergbom and Askwall (2000)).

“I felt terrible guilt...for what they had to go through. I remember what it was like when my Dad was ill...the amount of hand wringing, pain and suffering we all went through. By the time I was able to understand...it was all over. So the darkest time for them, I wasn’t aware of...I can only imagine.” (John)

The “guilt” expressed by survivors was to some extent offset by an appreciation of often unprecedented levels of emotional support from family and friends. Several described a “bringing together” of often disparate family and friends and the renewed importance of these relationships.

“When I realised how poorly I had been, in that I had almost died on more than one occasion, I got very upset...which is not me at all... but I became aware of how much people cared, how good our family and friends had been...” (Dave)

Emotional support during the *recovery process* took many forms including; health “surveillance”, advocacy and support in decision-making processes, and the sensitive re-organisation of daily life and prior responsibilities. Betty’s husband, for example, assumed responsibility for visiting her elderly aunt in order to assuage her sense of guilt, while Sandra’s close-knit family provided some light relief when she was “down in the dumps.”

“We just kind of laugh about things, you know? Everybody’s been really, really good...it really helps ...” (Sandra)

In the later stages of recovery, however, negotiating emotional *independence* was problematic for some. Lynne, for example, suggested that her Mother found it difficult to “let go”, perceiving her still to be “ill”.

### **7.9.2 Getting back to normal**

“Normality” was consistently defined by survivors in terms of the social and work-related activities that brought meaning and quality to their lives prior to critical illness. There are few data on the effects of illness on social function in the mainstream literature, however, due in part to the perspective that social participation is beyond the remit of medical intervention (Eslinger et al, 2002). Social and community integration are central features of the stroke and rehabilitative literatures, nonetheless, and these literatures underline the importance of social networks, employment and leisure activities to the individual (Pound et al (1998), Secrest and Thomas (1999), Dowswell et al (2000)). This theme explores the strategies adopted by survivors in negotiating the resumption of valued activities. The theme “Being treated differently” explores the visibility of suffering and impairment and draws upon perceptions of social stigma.

In the early stages of life at home, many, as previously described, were confined to the home. Several described significant periods of boredom and social isolation.

“I spend a lot of the day just sat here. Day time telly is rubbish...and there are only so many magazines you can read...so feeling a bit lonely has been one of the things, because there’s nobody here...” (Dave)

Enforced withdrawal from social and work activities limits opportunities for the maintenance or restoration of a positive self-concept in the face of impairment (Charmaz, 1983), and several described social isolation as a source of “depression”. “Keeping busy” and social contact were often described as a useful distraction from “what might have been”.

“It’s started to get me down...being on my own all the time...you start thinking about things...I just want to get out of that and start doing stuff again, going out and seeing people. It will be good to get back to work as well.” (Dave)

Attempts to “get out and about” were, for many, both tentative and incremental, and drawing upon the strategies adopted in the negotiation of physical function, often required careful attention to the contingencies imposed by ongoing or residual impairment. Betty, for example, took an alternative bus route which accommodated disabled passengers, while Roy, anticipating a return to a previously enjoyed activity had identified an alternative swimming pool into which one might walk (as opposed

to climb stairs into). Here, Andy describes the contingencies associated with a short trip into town “just to get out the house”.

“*You’ve got to have a plan. Like getting the bus. It could work against me, because if I get on the bus and it’s full, I’d have to stand. I’d be in people’s way getting off, they might bump me, I might fall*” (Andy, my emphasis)

Engaging in valued activities is also said to facilitate the maintenance of identity and self esteem by focusing efforts upon activities that are both valued and feasible within the limits of one’s ability (Weitzenkamp et al, 2000), and several described “small triumphs” in their attempts to get back to normal.

“I got on a bus last week, right? Doesn’t sound like much, but it was the first time I’d been out for *months*...actually, the first time I’d been out on my own. All I did was get on the bus, get a newspaper, and get on the bus back home again. It must’ve took all of half an hour, but I was *so* pleased with myself.” (Pat, her emphasis)

Many participated in previous activities in a reduced or alternative capacity; a strategy which, it has been suggested, is intended to render everyday life less restrictive (Charmaz, 1983). Having foregone a much anticipated holiday abroad as a result of her illness, and given her “desperation” for “a change of scenery”, Elizabeth opted for short weekend breaks in the Scottish Borders, suggesting that “everything’s laid on” and “you don’t have to do anything”. Having enjoyed hill walking and fishing as a regular feature of retired life, James, similarly, opted for accessible local venues as opposed to those of the Scottish Highlands. Here, Sandra describes a rather more psychological rationale for her strategy.

“I love going to car boot sales....but the last time...I got claustrophobic...I was getting a bit...panicked...and I thought “God, I’m getting out of here”. I used to enjoy that but...*the open air ones*, I’m fine.” (Sandra, my emphasis)

Many were mindful, however, of the social restrictions placed upon close family members by virtue of their ongoing impairment. Sandra, for example, “nagged” her husband to resume his “nights out with the boys”, perceiving them to be of heightened importance, given the burden of care and “doing everything around the house”.

Restricted by his inability to swallow, the time constraints of his enteral feeding regime and the embarrassment associated with spitting out a constant stream of saliva, James recounts his concerns for his wife.

“...she doesn’t cook now, because it’s only for her. And I’ve got to badger to make her eat properly.... We used to go out once a week dining, and we can’t do that now. So when we get the opportunity, some friends...take her out. So I feel very restricted, not for myself, but for her as well. Although she says she doesn’t mind, she must do. *You can’t help but not.*” (James, my emphasis)

### **7.9.3 Being treated differently**

Several gave accounts of the social stigma associated with overt changes in physical appearance, typically in relation to marked weight loss, impaired mobility, hair loss or having “visibly aged”. Here, Christine recounts her apparent “invisibility” in relation to temporary wheelchair dependence as a consequence of severe neuromuscular dysfunction.

“...when you’re out in public, and you have a wheelchair or you have sticks or something like that, some people can treat you differently. They either don’t see you, or pretend you’re...I’ve certainly seen life from the disabled side, as well as an able bodied person” (Christine)

Others described the perceived stigma of prolonged absence from work or from regular social activities. Ken’s light-hearted suggestion that his elderly friends would think him dead contrasted with others who anticipated “a certain awkwardness” in relation to the spectre of a life-threatening illness.

“...maybe when I go to the Christmas night out, I might find it... They won’t know what to say...will they be scared to ask me about my illness? People can be strange about that sort of thing...same with death. A serious illness can make you a bit...uneasy...about asking someone how they are.” (Christine)

Pat, however, described a “renewed faith in humanity” in relation to her obvious infirmity and the “kindness of strangers” in their accommodation of her significantly impaired mobility in busy thoroughfares and on public transport. John, similarly, was “deeply touched” by enquiries for his health among the “vaguely familiar” faces in his immediate neighbourhood. He went on, however, to add that he would consider himself well when his “illness ceased to be his defining characteristic in the eyes of other people”.

### **7.9.4 Summary**

At the time of interview, only John had returned to his previous employment, albeit in a phased and part-time capacity. Despite chronic ill health and his proximity to retirement age, Roy expressed a determination to return to work, while others, as a consequence of ongoing morbidity, retired early.

Among those retired, many relinquished, temporarily or otherwise, previous activities such as child care and voluntary work.

These data demonstrate the explicitly *social* nature of the response to illness or impairment; that the values held by the individual and the responses of others help determine what it is that people must “cope” with (Bury, 1991). They also support the observation that the ability to make sense of impairment is not found in the de-contextualised progression or deterioration of functional ability, but in its “lived experience” and in the (in)ability to participate in activities that one sees as important (Ironside et al, 2003). The associated internal costs (e.g. the sense of restriction, burden upon significant others and perceptions of social stigma) are, however, significant.

## **7.10 Bodily pain**

Bodily pain is defined by the developers in terms of its severity (none, very mild, mild, moderate, severe, very severe) and the extent to which it has interfered with “normal work” (defined as including both work outside and housework). Responses comprise “not at all”, “slightly”, “moderately” “quite a bit” and “extremely”.

Much like the global effects associated with fatigue, pain has been reported among other patient populations as interfering with every aspect of everyday life including functional ability, emotional well-being and social participation (Whalley et al (1997), Galer et al (2000), Doward et al (2003) and with the protraction of the recovery process (Salmon et al, 2001).

Pain has rarely been explored within the context of critical illness and was not a prominent feature across survivors’ accounts. While an exploration of bodily pain is provided here, it is not included in the alternative explanatory framework proposed. A number of survivors suffered from chronic pain; Anne as a consequence of rheumatoid arthritis, Ian as a consequence of osteoporosis and a spinal deformity (scoliosis) and Frank in relation to his employment as a pipe fitter. Christine continued to suffer mild “aches and pains” related to critical illness neuropathy, while Jane suffered severe idiopathic joint pain subsequent to critical illness. Dave experienced severe post-operative pain following repeated surgical intervention for pancreatitis.

Anne alluded to the development of a high “pain threshold” over the years, reliance upon her husband during her intermittent “bad spells” and simply “taking to her bed”. Ian simply tried to “keep active”, although alluded to having to give up a number of previously enjoyed activities such as bowling and

snooker. Frank dismissed his back pain as “wear and tear” and “part and parcel” of heavy manual labour. (Case note review later revealed, however, a previous addiction to powerful codeine based analgesia.)

Among those experiencing pain as a consequence of critical illness, the adoption of a suitable “strategy” was mediated by a number of concerns. Christine appeared unconcerned by her “aches and pains”, given their amelioration with simple analgesia and her perception that pain constituted a sign that her legs were “coming back to life”. Jane’s ability to “cope” was mediated, however, by a number of concerns including; the inability of both ward and community-based clinicians to provide a satisfactory “medical” explanation for her condition; the unpredictable nature of her symptoms; its interference with everyday life; the apparent inadequacy and side effects of powerful analgesia, and the attendant fear of addiction. Here, here concerns are somewhat assuaged by attendance at a specialist ICU follow-up service.

“...your mind runs rampant. I thought, “Well, is this something that it’s left me with?” It feels like really, really bad rheumatism. It’s alright now, I’ve asked the nurse and it’s put my mind at rest, so I’m not thinking, “Oh, I’m left like this permanently”. (Jane)

Dave’s expectations of post operative pain were derived, to some extent, from the experiences of a close family member.

“My mother (also) had her gall bladder removed... a good many years ago, and she said she was 12 weeks post-op before she was pain free. I’m about 10 weeks now, so it’s starting just now to lift. I have been able to reduce the amount of painkillers I am on considerably. I’m on a lot less than I was.” (Dave)

He went on, however, to describe the interference of pain both in everyday life, and in his subsequent inability to participate in community-based physiotherapy. Additional concerns included the side-effects of opiate-based analgesia regime (including poor concentration, drowsiness and exclusion from driving), and the “depressing” nature of breakthrough pain.

“I’ve had my morning painkiller and I’m feeling absolutely fine, because I’m perfectly comfortable lying in bed...thinking I could climb Everest right now. And I want to get cracking and do stuff, and then I come downstairs and realise that I am still poorly and my stomach is still hurting me and I am cut dead really.” (Dave)

### **7.10.1 Summary**

These data, in short, outline wide variation in the nature, severity, chronicity and aetiology of survivors’ pain and their effects upon the strategies adopted in its management.

## 7.11 General health perception

General health perception is defined by the developers in terms of health beliefs (“I am as healthy as anybody I know”); resistance to sickness (“I seem to get sick a little easier than other people”), current health (My health is excellent”) and health outlook (“I expect my health to get worse”) (Ware & Sherbourne, 1992).

Epidemiological studies reveal the association between general health perception or “self-reported health” and age (Idler, 1993), gender (Deeg and Kriegsman, 2003), functional ability (Bond et al, 2006), socioeconomic status (Borg and Kristensen, 2000) and the use of health services resource (Miilunpalo et al, 2007), amongst others. The correlation between self-reported health and mortality is also well established (Idler and Benyami (1997).

Current understanding of the processes *underlying* subjective evaluation of general health is somewhat limited, however (Kaplan and Baron-Epel, 2003). Qualitative studies among lay and patient groups reveal “health” to be understood as a complex, multi-dimensional and dynamic construct (Mackenbach et al (1994), Robertson (2006)), incorporating a broad spectrum of concepts including health beliefs, health behaviour and expectations (often in relation to the aging process) (Baron-Epel and Kaplan, 2001). The extant literature, moreover, consistently reports that perceptions of general health are closely related to *psychosocial* factors such as positive affect, social support and social function, as opposed to the absence or presence of disease or impairment (Bosworth et al (1999), Carel (2007).

## 7.12 An alternative General Health Perception

This dimension, accordingly, explores the *evolving* conceptualisation and evaluation of general health among the study group and comprises the sub-themes “I was fine, really” and “Since I’ve been ill”. A third theme “I’m probably healthier now” explores the adoption, among several survivors, of a “healthier lifestyle” in response to the spectre of life-threatening illness.

### 7.12.1 “I was fine, really”

During interview, survivors were asked directly about perceptions of relative health prior to the critical illness episode. Health was broadly conceptualised in terms of freedom from “illness” (i.e. run-of-the-mill coughs, colds, and ‘flu), the use of prescribed medication, the requirement for hospitalisation or time off work. Health was also conceptualised in terms of general fitness, being “active” and freedom

from restrictions upon valued home, work or social activities. Being “fit and active” is seen here as contributing to survival.

“I’ve always been fit. Very little illness. I’ve always been active. So, yeah, I was fit. Maybe it’s because I was fit...it helped me get through this little... I’m sure it helped anyway...” (James)

The majority of survivors considered themselves to have been in “good health” prior to the critical illness. Importantly, questions pertaining to the nature of survivors’ previous health evoked some rather counter-intuitive responses. In the following exchange, for example, Sandra recounts her recurrence of breast cancer (for which she required a double mastectomy and an intensive course of chemo and radiotherapy) and a succession of serious and potentially life-threatening sequelae;

**Sandra;** I was fine, really. I got about fine, enjoyed myself, going on holidays...just a normal life, you know. Never really ill or apart from this. Well, I had the mastectomy, a double mastectomy...

**Interviewer;** So did you...had your health deteriorated...before all of this?

**Sandra;** Not really, no. Well, with the mastectomy, I suppose...the cancer affected the left breast first, then it came back in my right breast, so I had to have a double mastectomy. Then I took the clot and that’s what really...the first clot I got over quickly...it was the second one that did the damage. It affected my heart. But I still felt, you know, *I didn’t feel really ill or anything*. (my emphases)

In the following extract, Betty recounts a range of chronic medical conditions which she described as variously intrusive in everyday life, inter-related or attributable to medical intervention.

**Betty;** “I’ve got a lot of things wrong with me. I’ve got lupus, Schrogens, that’s two auto-immune diseases...lupus has given me a large spleen... the Schrogens has given me an enlarged liver, like as if you were an alcoholic. I’ve got familial cholesterol...that was caused by the liver. I’ve got...osteoporosis from the time when I had steroids for the lupus... Meniere’s for about 15 years...*there is other things but I can’t always remember them*. And I was told in the Infirmary I’ve got small gallstones. I’ve also been told by a specialist that came about the cholesterol that I’ve got mild angina, *but I don’t need anything for it. That’s not on my list at the doctors*. (my emphases)

**Interviewer;** Right, I see. And how was your general health before *this* illness?

**Betty;** *Well, I just thought I was fairly normal because I didn’t know any better* (laughs)” (my emphases)

In many instances, information pertaining to previous or “long standing” health conditions was only provided following additional questioning or prompts.

“Yes, well, when I said my health was fine ...many years ago I found out I had a tumour in my bladder which was removed. I was coming back once a year to see that it hadn’t re-occurred...touch wood it hasn’t...so apart from that...” (James)

The under-reporting of health concerns occurs most frequently in relation to conditions which are trivial or unobtrusive; in which treatment is unobtrusive and provides symptomatic relief, or in conditions considered part of the aging process (Manderbacka (1998). Case note review, accordingly, revealed sometimes serious illnesses which survivors omitted to disclose at interview. Survivors frequently discounted “silent” disease processes (such as hypertension or controlled angina); serious illnesses which were no longer of concern (e.g. James’ bladder cancer) and illnesses in which treatment regimes had rendered them asymptomatic. It is also feasible that survivors perceived these illnesses to be somewhat “trivial” in the wake of critical illness.

“The only thing I had...I wasn’t bothered about it, mind...was a hiatus hernia. It’s just one wee tablet in the morning. Everything’s under control.” (Jack)

### **7.12.2 “Since all this...”**

Research among other patient populations suggests that individuals may fail to take some experiences of morbidity into account when evaluating perceptions of general health (Jylha (1994), Manderbacka (1998), Ong et al (2006)). Among patients being treated for prostate cancer, for example, urinary, bowel and sexual dysfunction were not regarded as matters of “health”, were frequently reconceptualised within the context of life threatening illness (and on occasion, the aging process) and did not consistently feature in respondents’ estimations of general health (Korfage et al, 2006).

There is some support for these observations amongst survivors, given previously described perceptions of physical and functional impairment as “to be expected” and “a small price to pay” for survival. Also implicit across several accounts was the reconceptualisation of current “health” on the basis that survivors were simply “grateful” to have survived. Despite some ongoing uncertainty regarding secondary carcinoma and the requirement for chemotherapy, Christine, for example, considered herself “relatively healthy”.

“I feel I’ve been very fortunate to have come out of this with quite a good medical response, a positive future and all of that. You’ve got to be positive about these things. You could’ve gone

down with it all. I could probably be sitting in my house unable to move or...worse”  
(Christine)

A number of survivors, however, described a heightened awareness of their general health following critical illness. Ian, for example, described being “frightened to death” by what had happened to him, while Andy Here, Jane describes to a sense of vulnerability, heightened in part by her family’s insistence that her immune system was “shot to pieces”.

“You know, now, if I’m near somebody, and they say, “Oh, I’ve got flu”, I’ll keep my distance. I’ll try not to breathe the same air (laughs). Obviously *in time, I won’t be as conscious*, but out of choice, I won’t be near anybody that’s ill...because I think I’ve definitely got that vulnerability.”  
(Jane, my emphasis)

### **7.12.3 “I’m probably healthier now”**

Perhaps counter-intuitively, given a significant burden of ongoing debilitation and morbidity, a number of survivors described themselves as “healthier” than they were before critical illness, largely due to the adoption of “lifestyle” changes. A number of survivors had “passively” given up smoking as a consequence of a prolonged ICU and hospital admission.

“Well, with the length of time that I was in Intensive Care...it was basically easy to give up because I didn’t have the cravings. That’s one positive thing that’s come out of it.” (Christine)

A small number of survivors (erroneously) attributed improvements in their health to bronchoscopy (an invasive procedure generally used in the microbiological investigation of pneumonia and the clearance of respiratory secretions) during the acute phase of critical illness.

“...jokingly, my friends say I’m probably healthier now than I was 6 months ago, because I think years of smoking...cleaning out my lungs...and all of a sudden it’s like “Zing!” (John)

Previously heavily dependent upon alcohol, Pat remarked that her critical illness had constituted a “serious wake up call” and that she would “probably be dead if she’d carried on the way she was going”, adding that she “hadn’t touched a drop” since hospital discharge. Having recognised “the usual suspects” (in this case, smoking, alcohol dependence and poor nutrition) as contributing to the development of a severe pneumonia, Ian resolved to take “better care” of himself.

“...so, every morning...instead of opening a can of beer, I’m having my cornflakes. And at night, I have my rice and fruit, which I never had before. But I learned it was good for me while I was in the hospital, so I thought, well why not keep it up when you’re out (out)?” (Ian)

Contingent upon expectations of recovery, a number of respondents resolved, in addition, to “exercise more”. Implicit across a number of accounts was the notion that “taking better care of yourself” constituted a moral or social obligation, given the significant distress and burden of care experienced by close friends and family members. Here, Andy alludes, in addition, to the good work of clinicians in “saving his life”

“You’ve *got* to do it, because at the end of the day, there’s nae point in going into hospital and they’re being that good to you, and...they’ve let you out...to go and spoil it all, by letting yourself go.” (Andy, his emphasis)

In the vast majority of cases, the adoption of a healthier lifestyle was associated with the notions of “learning a lesson” and “taking control”. Jane’s response, however, was rather more reluctant and based, for the most part, upon her relatives’ insistence.

“I haven’t to drink, I haven’t to smoke, and it’s a totally different lifestyle, really. Well, that’s the way I’d been living. It’s taken some of the fun out of life as far as I’m concerned.” (Jane)

#### **7.12.4 Summary**

These data lend support to the notion of “health” as a complex, multidimensional and dynamic construct. They also provide evidence of its reconceptualisation in the wake of critical illness as a cognitive response through survivors were enabled to maintain a sense of relative “health”. Given the prevalence of ongoing morbidity, they also challenge biomedical conceptualisations of health, in as much as “having” health and *feeling* “healthy” are not the same thing (Litva and Eyles, 1994).

#### **7.13 Discussion**

In this chapter, an attempt was made to “interrogate” the dimensions of the SF-36 by using survivors’ accounts of ongoing morbidity and the process of recovery and by drawing upon the critical care and wider social science literatures. This approach was necessarily pragmatic, given the widespread and professionally recommended use of the SF-36 in critical care outcome studies. In so doing, an explicit (and therefore replicable) method for deriving the patient experience (with specific reference to its component dimensions) was developed and a novel “patient-centred” framework for the exploration of HRQoL more broadly was elicited (see figure 4, page 173).

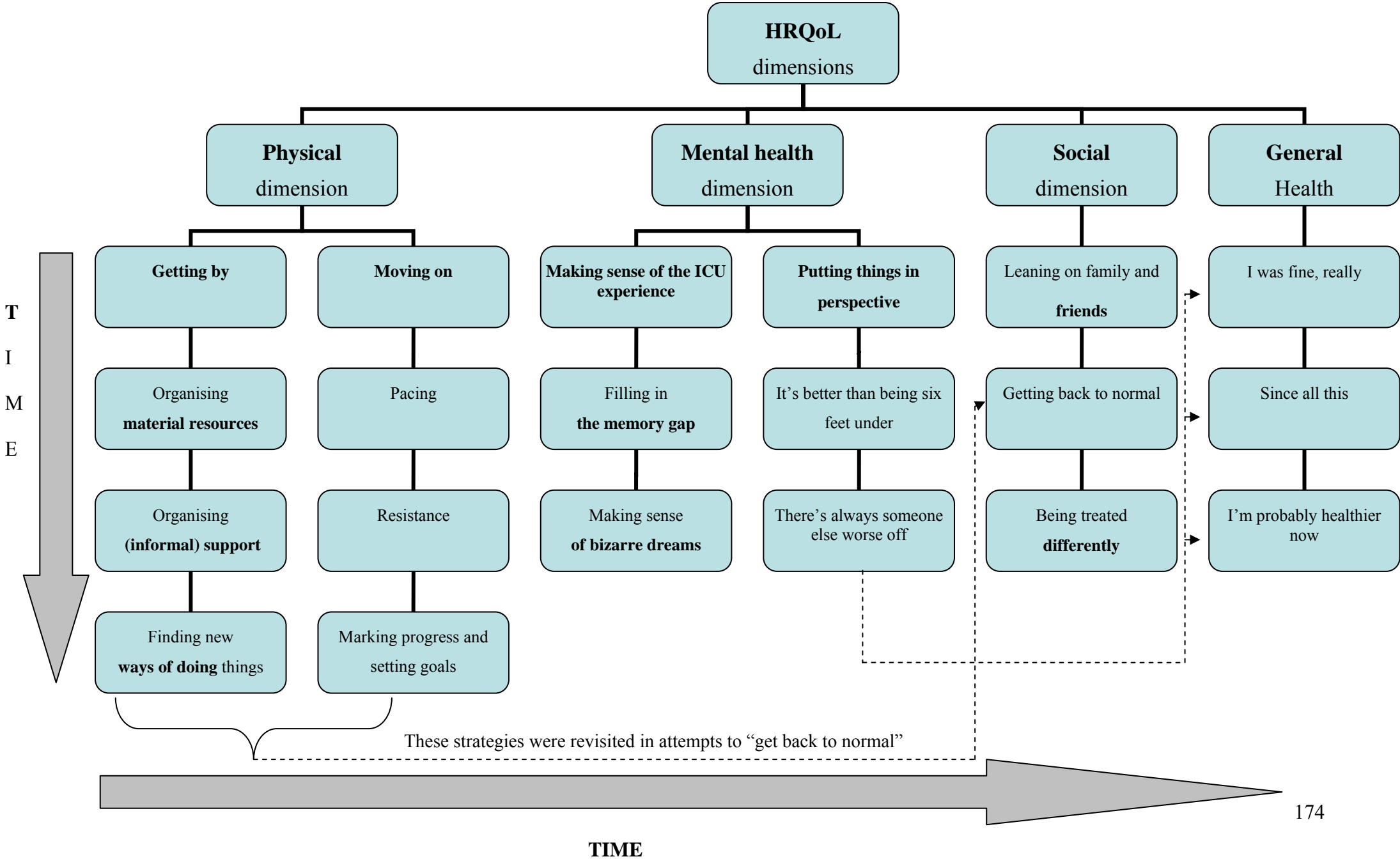
These data reveal wide variation in the patient experience within and across ostensibly discrete dimensions of experience. More importantly, analysis revealed the prominence of the interpretive and

adaptive strategies through which survivors were enabled to negotiate an acceptable HRQoL and the processes of recovery more generally, which are invariably overlooked by existing approaches to HRQoL measurement. Perhaps most importantly, analysis would seem to suggest that *adaptation* constitutes a more relevant and appropriate measure of “recovery” than “HRQoL” in its current conceptualisation (as predominantly function-based measure of outcome).

There are a number of implications of this approach. Although not an intended outcome of this research, the wealth of data affords significant potential, undoubtedly, for the subsequent development of a new and rather more “patient-centred” measure of HRQoL. Issues remain, nonetheless, in terms of capturing the *temporality* of the recovery process, the *response shift* inherent in survivors’ accounts (e.g. in relation to evolving conceptualisations of “health”) and the complex *inter-relatedness* of dimensions of experience. Further research is undoubtedly warranted if these issues are to be incorporated in any such measure.

An important secondary aim of this research was the development of potential interventions to expedite the recovery process in ways which are most meaningful to survivors. The largely *intuitive* or *experiential* nature of the adaptive processes employed by survivors, in particular, affords significant potential for their support, expedition and/or augmentation, through educational and self-management strategies which are likely to be generalisable to the wider patient population. The conclusions from this chapter are nonetheless preliminary, given their limitation to the post hospital discharge phase of recovery as but one discrete aspect of the patient journey. They are also somewhat tentative, given the unexpectedly “upbeat” nature of survivors’ accounts, often in the face of significant and ongoing impairment. The following chapter therefore attempts to explore and expand these findings.

Figure 4: An alternative explanatory model of HRQoL



## Chapter 8: Biographical disruption following critical illness

### 8.1 Introduction

The previous chapter, at the outset, was intended to pragmatically examine alternative aspects of experience as they might relate to the dimensions of the SF-36. Whilst usefully drawing attention to Bury's (1991) notions of "strategy" and "coping" as the deliberative actions taken by survivors in the negotiation of everyday life, the fragmentation of data into component dimensions proved somewhat restrictive in terms of exploring the strikingly phlegmatic nature of the *narrative* processes through which survivors were enabled to account for critical illness within a wider *biographical* context. The requisite focus upon the post-hospital phase of the recovery process (due to the timing of questionnaire administration) was also seen to overlook important aspects of the critical illness journey.

Given, as previously described, the profound alterations in survivors' lives in the wake of critical illness, survivors' accounts are examined in this chapter within the context of Bury's (1982) widely acclaimed work on "biographical disruption". Illness, Bury (1982) contends, is a particular type of event in which "the structures of everyday life and the forms of knowledge which underpin them are disrupted" (Bury, 1982: 169), thereby forcing an uncomfortable biographical shift; from a previously "predictable" life course to one which is fundamentally abnormal, uncertain and chaotic. The data from this (and to some extent, the previous chapter) are also analysed with attention to the narrative form, as a means through which survivors are enabled to account for and repair the disruption that critical illness and its sequelae evoke in everyday life (Williams, 1984).

### 8.2 Illness narratives

Illness narratives usefully provide a biographical context within which to encompass the illness experience, the adaptive processes and surrounding life events, thus recreating a sense of inter-relatedness and continuity (Hyden, 1997).

“...a major illness not only interrupts and transforms one's biography, it also magnifies certain themes of the biography, forces one to actively take control of the biographical process by reflective decision-making, and...alludes to the end of the biography by drawing attention to one's death. (Kaufman, 1998: 217)

Illness narratives constitute a powerful forms of expression, giving voice to the often hidden experience of illness, suffering and loss (Hyden, 1997), and to the processes of reflection or biographical "work" it evokes. There are often therapeutic implications for the individual concerned,

in as much as that he or she is enabled to actively negotiate new meanings and values associated with everyday life (Ezzy et al (2000) and, potentially, to “transcend their losses, resolve their feelings about them, and emerge with a stronger, more valued self” (Charmaz 1999: 72). Despite, however, their often revelatory, emancipatory or therapeutic nature, the “vulgar realism, which assumes illness narratives to be transparent” (Atkinson, 1995: 327) is widely held to be untenable (or at least problematic) among contemporary critiques of the narrative form. We return to these critiques in the final section of this chapter.

Nonetheless, these reparatory processes move beyond the traditional biomedical model of illness and impairment, by restoring a sense of personal agency within the structural and interpersonal context of everyday life (Ville, 2005), and by demonstrating that the processes of adaptation and recovery require much more than “institutional medicine” can offer (Frank 1997). As this chapter will, however, demonstrate, the structure and processes of “institutional medicine” has serious and far-reaching implications for the individual concerned in terms of the nature and temporality of the disruption associated with critical illness and the efficacy of one’s “personal agency”. The individual’s response, in short, involves

“...far more than simply a response to their condition, however creative and active, but also involves a response to the way health...services are organised and delivered. As such, the actions people do, or do not take...need to be explored in relation to their experiences of the system itself” (Hart, 2001: 102)

The acute healthcare system therefore provides an alternative context within which to explore the notions of “strategy” and “coping” described in the previous chapter, through an examination of survivors’ experiences of acute hospital care and rehabilitation. Shortfalls and failures in its processes and delivery, it is argued, often undermine even the best efforts of individuals to manage their lives following discharge home, forcing them to invest more energy into its “strategic management” than might otherwise be the case (Hart, 2001). Patient narratives provide a means through which to explore these inadequacies by making visible

“...patterns of interaction and social process in the delivery of health...services which are...screened out by “professional vision” and obscured by routinised and medicalised ways of seeing.” (Hart, 2001: 103)

Narrative expression, in summary, has implications for lay, patient and professional audiences alike (Sakalys (2003), Greenhalgh and Hurwitz (1999), Wilcock et al (2003)). This chapter therefore attempts to draw out the “biographical narrative” of adaptation to ongoing morbidity, with due

attention to the potential for improvement in the processes and delivery of care and rehabilitation in the acute setting.

### **8.3 Defining biographical disruption**

Derived from a series of interviews with newly diagnosed sufferers of rheumatoid arthritis, Bury (1982) elucidates, in their *emergent* form, three implicitly sequential aspects of disruption.

- The disruption of taken-for granted assumptions and behaviours, the breaching of common sense boundaries.
- Profound disruptions in the explanatory systems normally used by people, such that a fundamental re-thinking of the person's biography and self-concept is involved.
- The response to disruption involving the mobilisation of cognitive and material resource.

#### **8.3.1 The disruption of taken-for-granted assumptions**

Drawing upon a corpus of sociological literature in relation to the embodiment of chronic illness, Bury (1982) defines the disruption of taken-for-granted assumptions and behaviours in terms of a “what is going on here” stage, or “attention to bodily states not normally brought into consciousness and decisions around seeking help” (Bury, 1982: 169). The emergence of (chronic) illness, in short, elicits both a raised awareness of one's previously “invisible” and normally functioning body and disrupts the sense of unity between body, self and one's identity (Charmaz (1983), Charmaz (1995)).

In an interpretation reminiscent of Leventhal et al's (1980) “Common Sense Model”, Bury (1982) alludes to uncertainty surrounding the significance of “observed bodily states”, their attribution as *symptoms* and decisions around the seeking of lay and professional advice. A number of Bury's respondents, for example, provided a range of alternative commonsense explanations for the often insidious onset of symptoms (e.g. a minor injury, “stress” or “overdoing it”) and often delayed medical consultation until symptoms were overtly visible, persistent or debilitating.

#### **8.3.2 Disruption in explanatory systems**

Disruptions in normal explanatory systems result, Bury (1982) suggests, in a re-thinking of the individual's life history and self concept; raising questions of a “why me, why now?” nature in relation to causality. Importantly, while biomedical conceptualisations of causality often constitute a powerful

cultural resource, providing “an objective fixed point on a terrain of uncertainty” (Bury, 1982: 179), Bury’s respondents were ultimately confronted by the limitations of a “scientific” explanation and medical intervention, most notably in terms of *how to live with* debilitating illness. Under these circumstances, biomedical explanations may become less relevant in the individual’s attempt to manage their illness (Becker and Kaufman, 1995).

At pains to liberate himself from the “semantic straightjacket” imposed by biomedical connotations of causality, Williams (1984) urges a wider interpretive approach to the ways in which people account for and make sense of the disruption that illness and impairment brings into their lives—put simply; “why in the sense of from what cause?” and “why meaning to what end or purpose?” (Williams, 2000: 138). The former, he suggests, demands some form of “scientific” answer, while the latter invites a rather more “philosophical” response.

Here, questions centre around the integration of often divergent lay and professional notions of causality in terms of their relevance and explanatory credence. Among Bury’s younger respondents, for example, uncertainty in relation to the aetiology and legitimacy of symptoms was often compounded by the protracted diagnostic process and by the common cultural paradigm of arthritis as a disease associated with the ageing process. Others (invariably older respondents) attributed the disease process to “normal wear and tear”, while yet others implicated genetic predisposition or “shocks to the system” (e.g. emotional distress) as causative factors.

### **8.3.3 The response to disruption**

The search for the cause of illness, Bury (1982) suggests, also constitutes a search for its *meaning*, which he describes in later work in terms of its “consequence” (the effects of symptoms or impairment on everyday life) and “significance” (the imagery or symbolic significance associated with a particular condition) (Bury, 1991). The response to disruption, accordingly, comprises the mobilisation of material and cognitive resources, and it is arguably the latter to which most empirical studies have directed attention. Bury’s (1982) work is nonetheless largely descriptive here and somewhat limited in scope. A burgeoning literature including, for example, Leventhal’s (1984) Illness Representation Model, suggests that cognitive processes have important effects upon coping and adaptation (Heijmans (1999), Vaughan et al (2003), Groarke et al (2005)). Given their prominence across survivors’ accounts, these processes receive particular attention.

Biographical disruption, in summary, constitutes

“...a useful concept, shedding important sociological light on the nature of chronic disabling illness and the *coping processes*, practical strategies and *symbolic styles of adjustment* it calls forth.” (Williams 2000: 49) (my emphases)

## 8.4 Critiques of biographical disruption

Studying only particular illnesses (notably chronic illness among the sociological literature) overlooks the diversity and emergent commonality of experience and meaning across other conditions (Thorne and Paterson, 1998). In an expansive literature on biographical disruption among a range of patient populations, a number of authors have posited “biographical reinforcement” (Carricaburu and Pierret, 1995), “biographical flow” (Faircloth et al, 2004) and “biographical continuity” (Pound et al (1998), Levealahti et al (2007), Wilson (2007)) as alternative, albeit ostensibly comparable conceptualisations. Importantly, biographical disruption may also *co-exist* with these alternative conceptualisations within and across individuals’ accounts (Sanders et al, 2002).

Pound et al’s (1998) elderly participants (from a predominantly lower socioeconomic background), for example, experienced stroke as a “normal crisis” *in a life of hardship and misfortune*. Sanders et al’s (2002) elderly respondents, in contrast, perceived the highly disruptive effects of osteoarthritis on their daily lives as a “normal” or biographically anticipated aspect of the *ageing* process. Wilson’s (2007) respondents (HIV positive women), similarly, perceived the threat of incapacitating and potentially life-threatening illness as comprising both biographical disruption and biographical reinforcement (or continuity) in as much as that “When you have children, you’re obliged to live”.

The disruptive effects of illness, in essence, may be mediated by the timing, context and (ab)normality of various illnesses or events in the lives of affected individuals (Williams, 2000). In arguably the most authoritative critique of Bury’s construct, Williams (2000) underlines its analytical utility, while simultaneously deconstructing its explanatory potential as an empirical datum.

“Biographical disruption cannot simply be assumed or “read off” as a standard response, with similar effects, to a similar event, illness-related or otherwise” (Williams; 2000: 54)

The following analyses explore the nature of the biographical disruption associated with survival and recovery following prolonged critical illness.

## 8.5 Biographical disruption following critical illness

### 8.5.1 Data analysis

Data were initially coded and analysed in accordance with Bury's (1982) original construct, using a literal interpretation of its component parts as they account for the emergence and lay interpretation of chronic illness. Given that the original construct focused upon the *emergence of chronic* illness, its review among alternative patient populations was useful in terms of revealing insights into nature of the disruption associated with *acute* and *life-threatening* illness. Context and meaning, Bury (1991) suggests, cannot easily be separated, and conceptualisations of its component parts in the latter were seen to be quite distinct from those suggested by Bury's original construct.

#### 8.5.1.1 The development of qualitative themes

In order to capture these alternative conceptualisations and both the diversity and commonality of survivors' experiences, qualitative themes and sub-themes were derived using, where possible, direct quotes from survivors' accounts and those derived from the extant literature. Bury's (1982) notion of taken-for-granted assumptions, for example, was conceptualised here not in terms of the subtle emergence of symptoms but in terms of survivors' expectations of everyday functional ability and recovery which were startlingly inconsistent with their situations. Disruption in explanatory systems, similarly, was conceptualised by survivors not only in terms of the limitations of biomedical notions of causality, but in terms of the "lost events" of the critical illness episode and its existential gravitas. Themes here, for example, comprise "I still don't know what happened to me" and "How on *Earth* did I become so ill?"

#### 8.5.1.2 Capturing complex temporal processes

Inherent in Bury's (1982) construct are the implicitly sequential aspects of disruption. Among survivors, these aspects of disruption were not experienced as chronological or discrete categories, nor were they afforded equal significance. As evidenced in the previous chapter, the prevalence of a pragmatic "here and now" approach in relation to startlingly incongruous expectations of functional ability and recovery seemed to privilege attention to disruptions in taken-for-granted assumptions over the associated explanatory systems, although a degree of overlap was seen to exist.

Inherent in Bury's (1982) construct also, given its development among sufferers of rheumatoid arthritis, are the temporal processes of *deteriorating* health. Survivors, in direct contrast, experienced *improvements* in health and functional ability, whereby various assumptions and responsive strategies were progressively relinquished. The extant literature, moreover, posits alternative notions of biographical disruption, in terms of the *timing* or abnormality of illness in the lives of the individuals concerned and in terms of the *co-existence* of biographical disruption and continuity.

Survivors' accounts were analysed, in short, with reference to both the critical illness journey and their wider "biographies" or life stories, and these were seen to be interwoven in complex and unexpected ways. An alternative representation of biographical disruption is provided in Figure 5 (page 201)

As evidenced in the previous chapter, the biographical disruption associated with critical illness is most pronounced following discharge home. In an attempt to complete the "biographical narrative", a retrospective review of survivors' accounts was conducted. Drawing upon clinical experience within a ward-based ICU follow-up service and Hart's (2001) notion of "system-induced setbacks", the constructs of "taken-for-granted assumptions" and "disruptions in explanatory systems", were seen to originate, to some extent, from experiences and perceptions of ward-based care and rehabilitation, and the process of hospital discharge.

## **8.6 Disruptions in taken-for-granted assumptions**

Here, Bury (1982) defines a "what is going on here?" stage in terms of "attention to bodily states not usually brought into consciousness". A review of survivors' accounts in the period immediately following discharge home suggested a rather more complex interpretation; not a "bringing into consciousness" per se, but a heightened awareness and a reinterpretation of bodily states or of one's "situation" within a more naturalistic setting; within one's own home and within the context of a previously routine existence. The character of this reinterpretation, moreover, was both powerful and confrontational, and unlike that associated with the chronic illness literatures was neither "emergent", "uncertain" or "easily explained away" (Bury 1982).

Sources of loss, Charmaz (1983) suggests, are most keenly felt at points when individuals define former actions, lives and selves as now (or at least "temporarily") precluded by impairment. Getting home in the wake of critical illness, as the previous chapter demonstrates, evoked a powerful sense of salience among survivors, challenging both the symbolic significance of the home as familiar and central to everyday experience (Williams, 2004) and bringing into sharp relief the nature and breadth

of survivors' physical and functional impairment. In the following excerpt, for example, John associates his survival with a sense of invincibility and euphoria; an emotive state harshly tempered by a reappraisal of his situation.

“I remember thinking, “See when I get out of here, I can do anything! I’ve survived all that! Nothing’s going to stop me. I’m going to do this, that and the other”...But when I came out, I was actually very frail.” (John)

Having previously described ward life in terms of “Groundhog Day” (a film of the same name in which the protagonist finds himself living the same day repeatedly), Andy describes his return home as a welcome relief from the monotony of hospital life.

“I knew I’d be ok here. Got my comforts and do what I wanted to do when I wanted to do it, not a set routine, like. I want to do things my own way and I don’t want anybody to bother me.” (Andy)

He subsequently described, however, (as did many others) significant and unanticipated concern regarding his ability to perform even rudimentary domestic tasks upon return home.

“It was that bad when I came home...I put water in the kettle, but I couldn’t lift it. It took two hands to put it back on...That’s when I thought to myself, “Oh, man! That’s scary.” That’s when you say to yourself, “You *are* bad”. (Andy, his emphasis)

Qualitative data on post discharge experience among other patient groups (notably the elderly and stroke populations) suggests that individuals are often ill-prepared for the rigours of life at home (Pound et al (1994), Wottrich et al (2004)). A review of the literature implicates, amongst others, a professional emphasis upon functional aspects of recovery (Grimmer et al (2004), Olofsson et al (2004), Corser (2006)), an implicit trust in the clinicians responsible for care and rehabilitation (and relatedly, decisions around hospital discharge), and additionally, contemporary health care reform as a mechanism through which patients are discharged into the community “sicker and quicker”.

The following sections therefore explore the temporal processes of acute hospital care and rehabilitation and their influence upon post discharge experience. Themes here comprise: “You have to be well to be ill” (experiences of debilitation and dependency in the early stages of ward care), “What were they doing for me, really?” (perceptions of nursing care in relation to recovery), “I was a bit disappointed with physio” (experiences of rehabilitation) and “Nobody really spoke to me about getting home” (experiences of and participation in discharge planning).

### 8.6.1 “You have to be well to be ill”

For many survivors, transfer to the general ward was hailed as a significant milestone in the recovery process (Odell (2000), Strahan and Brown (2005)). In keeping with much of the literature on “relocation stress”, however, many were ill-prepared for the reduced intensity and immediacy of nursing care (Odell (2000), McKinney and Deeny (2002), Beard (2005)). Adapted from Strandberg et al’s (2003) phenomenological study of dependence upon nursing care in the acute setting, this theme explores the emotional labour associated with functional dependence in the early stages of ward-based care.

The debilitation associated with survival has been described as “inexplicable and worrying” (Jones and O’Donnell, 1994) and a “critical defining characteristic” of the psychological distress survivors experience following transfer to a general ward (McKinney and Deeney, 2002). Typical morbidity, at this stage, included generalized weakness and fatigue, muscle wasting and severe weight loss.

“I couldn’t walk. I was very, very weak. It took me all my time to get out of bed. When I started...my legs...because I’d lost 2 and a half stone. And all my muscle was gone.” (Andy)

Survivors were often heavily dependent upon nursing staff for assistance with a range of basic self-care activities including using the bathroom, attending to personal hygiene and getting dressed. Here, Christine recounts the sense of indignity associated with her predicament and a distressing incident which she hesitantly rationalised in terms of resource.

“It’s quite upsetting for somebody, well relatively young, still in their right mind, having to be washed, toileted and all the rest of it. And to be left on the commode was (sounds emotional)...I mean, I couldn’t blame the staff because they just didn’t have the time.” (Christine)

While survivors were broadly appreciative of the care they received, given the observed constraints, many were critical of the depersonalising nature of ward life. Congruent with Field et al’s (2007) recent qualitative study among survivors of critical illness, several provided emotive accounts of a perceived indifference or insensitivity among busy ward staff to their ostensibly “basic” needs.

“I remember one of the nurses *insisting* that I sit out on a chair very early on. I had no strength to sit and... she had no understanding as to my plight in that sense. I had to get some assistance having a seated shower. I couldn’t stand because I was so weak...and they maybe showed a little bit of impatience there with me” (Dave, his emphasis)

Among the less heavily dependent, this perceived indifference extended also to the nature and severity of critical illness.

“I just felt they were a bit blasé about the whole thing. I don’t think they realised how very ill James had been...that he still wasn’t well. They should’ve been more aware of that. Especially having been in Intensive Care six and a half weeks...that’s a long time to be in Intensive Care” (Sally, James’ wife)

Here, Lynne describes her response to the untenable expectations of ward staff and their “disappointment” in her “lack of progress” towards functional independence.

“One of the nurses actually got really upset and started to cry when I explained how I felt about the situation. She was really taken aback. I think...when you’re stuck in a room, there every day, really small things become really big things...if that’s all you’ve got, they are really exaggerated...” (sounds emotional) (Lynne)

Very few, however, voiced their concerns to the clinicians involved. Having been “left in a chair all day” in considerable discomfort, Pat describes her rationale for dissuading her relatives from complaining on her behalf.

“I said, “Don’t rock the boat because I’m still here...what are they going to do if you start complaining?” You know, you are actually scared to complain because the power is with them. And I think that happens a lot in hospitals.” (Pat)

The early stages of ward-based care, in summary, were characterised by profound debilitation and functional dependence. Mediated, to some extent, by the perceived indifference or inability of busy ward staff to meet their basic needs and the attendant reluctance to voice their concerns (Strandberg et al (2003), several alluded to a sense of abandonment and despondency. In keeping with Field et al’s (2007) work, survivors were compelled, however, to simply “put up with it” as best they could.

### **8.6.2 “What were they doing for me, really?”**

This theme explores subsequent perceptions of recovery once a degree of functional independence had been reached, often within the context of invasive, technical or specialty-specific aspects of care. Perhaps unrealistically, some associated the removal of invasive treatment devices (in this instance, a mini tracheostomy and a nasogastric tube) with the absence of care needs.

“Well, once that tube was out of my throat...and the one out my nose, I just thought, “Well, what are they doing for me, *really*? I could be at home”. (Frank, his emphasis)

James expressed significant frustration regarding the technical competence and diligence of nursing staff in the management of a complex surgical wound and an enteral feeding regime; both of which, despite a degree of apprehension, he would ultimately assume responsibility for following hospital discharge. Discharged to a respiratory ward (in view of a severe pneumonia following hip replacement), Pat expressed significant concern regarding the perceived inability and reluctance of nursing staff to manage a “basic” surgical wound.

“...they kept saying “You shouldn’t be here, you should be in Orthopaedics...we don’t know what to do with this”. They just didn’t want the hassle. It got to the stage where I was apologising every time I had to bleep them because my wound was bleeding.” (Pat)

Latterly, despite sometimes significant ongoing morbidity, survivors often associated improved mobility with readiness for discharge.

“So apart from this inability to swallow, or eat or drink...I was on the mend. I mean, I was becoming mobile and there was no real reason for me being there....” (James)

Survivors also described prolonged periods of boredom associated with “just sitting around” and several subscribed to the view that there were others “worse off” or more deserving of nursing care; a notion seemingly endorsed in the following excerpt by the clinicians involved in John’s care.

“I was on the ward with...three old men (laughs)...that’s terrible...three people who were clearly in a worse state than I was. And that was proved because I was on that ward for 2 or 3 days, then they (the nurses) said, “We’re moving you to a bed which is further away because somebody else needs to be nearer the door than you””. (John)

### **8.6.3 “I was a bit disappointed with physio”**

This theme examines experiences and perceptions of ward-based rehabilitation in relation, specifically, to the delivery and perceived efficacy of physiotherapy. A widely held view among the rehabilitative literatures is that the individual’s beliefs and expectations of recovery shape the rehabilitative process (Secrest and Thomas (1999), Wade et al (2000), Ostir et al (2008)) and, consequently, its outcomes (Grahm et al (2000), Maclean et al (2002)). Congruent with the stroke literatures, physiotherapy was widely perceived among survivors as the most effective means of recovery (Wottrich, 2004) and, moreover, given a widely professed “desperation” to get home, as a means of expediting hospital discharge (Maclean and Pound, 2000).

Each of the survivors, without exception, expressed a strong desire to adopt an active role in the rehabilitation process, and many spoke emotively of the importance of “determination”. Many expressed “disappointment”, however, with regards to the intensity of rehabilitative provision; a phenomenon widely reported among the stroke literatures (Wiles et al, 2004). Several were frustrated by its late inception, its brevity, relative infrequency and the general absence of clear rehabilitative goals. Supported by clinical experience in a ward-based follow-up service, the following data suggest that resource constraints, environmental factors and, importantly, *organisational* aspects of rehabilitative provision often militated against survivors’ attempts to engage more fully in the rehabilitative process.

Empirical studies among stroke populations suggest that benefits of rehabilitative input may be most pronounced when applied early and *intensively* (Kwakkel et al, 2004). Survivors, however, were often “too unwell”, “too weak” or “too tired” to participate in physiotherapy during the early stages of ward transfer. Among the more severely debilitated, rehabilitative input was perceived to be incommensurate with survivors’ needs. Effectively bed bound by critical illness-related neuromuscular impairment, Christine wondered how she was “*ever* supposed to get better”.

“I’d get maybe 10 minutes of physiotherapy every day. *Eventually*. It wasn’t particularly aggressive physiotherapy...being hoisted up in a stand aid, and sitting down again. Apart from that...I had splints to keep my legs straight...but in terms of getting you back on your feet, it was minimal.” (Christine, her emphasis)

Data from the stroke rehabilitative literatures consistently demonstrate that patients derive significant and sustained benefit from organised, multidisciplinary rehabilitation in the acute setting (Langhorne and Duncan (2000), van Peppen et al (2004)). Unlike other critically ill patient groups (following cardiothoracic surgery, for example), however, there is no specialist or augmented rehabilitative provision for the general ICU patient population. Survivors, in effect, “compete” with other (often less severely ill) patient groups for rehabilitative resource. Its scarcity was frequently remarked upon and implicated in a perceived lack of progress towards functional independence.

“I know it’s a small Department, but I felt, on hindsight, that...they kept me on that Zimmer frame too long. They should’ve been...but they hadnae time.” (Ian)

The following excerpts demonstrate, in addition, the often “uni-disciplinary” nature of rehabilitative input on the general wards and, subsequently, the perceived efficacy of a shared ethos.

“...they (the nurses) were quite happy to let me use the urine bottles rather than say to me “You can go on the Zimmer and go to the toilet”. I did what I was told. I wasn’t allowed to get up on my own. And I think if they had let me, maybe I would’ve been up and about faster. Nothing gets you up like needing the toilet, you know!” (Ian)

Ian’s experience contrasted sharply with Don’s, as the only survivor to be discharged to a specialist rehabilitative ward following a neurological illness.

“I was on...using a Zimmer frame, and just walking up and down the corridor. I was able to get out with the physio along the corridor *and the nurse was available for the same thing. So that was starting to move along.*” (Don, my emphasis)

Survivors discharged to *surgical* wards in RIE currently receive ongoing support from ICU-based physiotherapists, with attendant implications for continuity of care, the recognition of critical illness-related morbidity (including, in particular, neuromuscular impairment) and the negotiation of rehabilitative goals among survivors discharged to other parent specialties. “Goal setting” in particular has been identified as a key feature of rehabilitative programmes across a range of patient populations (Bloom et al, 2006), and active collaboration and participation has been associated with increased goal attainment (Duff et al, 2004) and greater functional gains (Arnetz et al, 2004). Lynne, for example, cited the therapeutic implications of working with trusted ICU clinicians who knew what she had “been through” and what she “was and wasn’t capable of”. Her (professionally mediated) expectations of physiotherapy were, however, immediately compromised upon transfer to a (medical respiratory) ward.

“I was *told* I’d get very intensive physiotherapy...and then I had no physio for five days straight. It was only when I made a fuss that I got physio. But then I got, just a list of things to do on my own...that were way beyond my capabilities. And it was very de-motivating, because...I couldn’t achieve them.” (Lynne, her emphasis)

Several survivors cited a perceived inability to actively participate in the rehabilitative process (Roding et al (2003), Wottrich et al (2004). Lynne, for example (aged 25 years), alluded to the implicit perception among her physiotherapists that she would simply “bounce back”, given her relative youth. Anne (a sufferer of chronic and frequently disabling rheumatoid arthritis) “struggled” with the physiotherapists charged with her recovery; alluding here to the dismissal of her own significant expertise in the management of her situation.

...you know how far you can go and how far you can push yourself...I said to them “I *will* walk and I *will* do this, but you’ve got to let me do it...if you’re pushing me, it’s not going to work.”” (Anne, her emphases)

The following account suggests that there is limited understanding of the profundity and effects of muscle wasting, weakness and fatigue among rehabilitative and other clinician groups. Among the many survivors to associate “being in bed for a long time” with severe muscle wasting, Jane’s apparent sense of neglect is compounded by the “dismissive” attitude of her attending Consultant.

“I said, “I never should’ve been left the way I was. I should’ve done exercises so that I wasn’t in this state.” Dr Jones said to me, “Well, that can’t be helped” and I said, “Yes, it *can!* It *can* be helped! My muscles shouldn’t be like this”. (Jane, her emphases)

While few questioned the origins of the debilitation associated, ostensibly, with *any* serious illness, “not knowing what to expect” was seen to foster significant concern regarding the efficacy of the rehabilitative process. Among the very few to have attended an specialist ICU follow consultation, Jane, for example, expressed considerable frustration on learning the aetiology of neuromuscular impairment, some 3 months following hospital discharge.

“...when I was in Intensive Care... I don’t know if it’s something that happens if you’ve only been in three days, maybe varying degrees, but your body feeds off your muscles. I didn’t know any of this. And I just thought, “I’m not doing enough, I’m not trying hard enough”. Had I have had this knowledge, it would’ve been a lot, well a bit, easier for me to accept.” (Jane)

Reflecting the wider rehabilitative literature, survivors’ informational needs were rarely met in terms of self-management strategies and realistic expectations of recovery (Wiles et al (2002), Roding et al (2003)). Here, Jane describes the belated receipt of an exercise guide (prior to hospital discharge) in terms of a missed opportunity for self-directed rehabilitation and progression towards functional independence.

“I could’ve done more...to help myself...because my brother asked for a sheet of exercises for me to do when I got out. I realise now...I could’ve been doing a lot of that. Seems obvious now, but it wasn’t then...and I think I could’ve progressed quicker.” (Jane)

Many were critical, in addition, of environmental constraints. Elizabeth, for example, remarked that mobilising within the ward area was “not like real life”, given the absence of “inclines, cobbles, potholes and the like”. For most, opportunities for independent mobilisation were restricted to the immediate ward area, were patently uninspiring, and were perceived to be of questionable benefit (Maclean and Pound, 2000)

“...the physiotherapists said to take wee walks, you know. But how often do you go for a walk? I mean where are you gonna walk to? I didn’t know the hospital, so I stayed in the ward area. I mean to say, what good was that supposed to do me?” (Roy)

These data summarise the impact of resource constraints, organisational processes and environmental factors upon the delivery and perceived efficacy of rehabilitative input within the acute setting. These findings are supported, in addition, by data from the small number of survivors who received formal rehabilitative input within a dedicated setting. Additional resource and individualised care are attributed here to rapid improvements in Ian's mobility and functional independence.

“The length of time for all that progression...I think they (the acute hospital) really need more physio or more personal care instead of lumping everybody as one.” (Ian)

Christine attributed, in addition, a “can do” ethos amongst her rehabilitative team and, latterly, a sense of community among her fellow patients (“we were all in the same boat”) to marked improvements in her progress.

“I think it was the intense physiotherapy, really. I found myself moving. They were so good...they really made you feel like you could do it. They were so cheerful, they weren't stressed out like they were at St Elsewhere. They had time for you. Like a different world, really.” (Christine)

#### **8.6.4 “Nobody really spoke to me about getting home”**

This theme relates to experiences and perceptions of the hospital discharge process; a process in which very few survivors described an active involvement. Reflecting, undoubtedly, recent policy initiatives in the NHS, the existing literature has tended to emphasise organisational outcomes such as hospital length of stay, use of primary care resource and re-admission (Connolly, 2009) and the role of clinicians in the expedition of hospital discharge (Bull and Roberts, 2001). Time and resource constraints, however, are frequently implicated in the failure to develop comprehensive discharge plans (Maramba et al (2004), Connolly et al (2008)) or to discuss discharge and informational needs with patients and their carers (Pethybridge (2004), McKenna et al (2000)).

The complexity of patients' needs (Victor et al, 2000) and, as previous data has shown, the inability of individual patients to anticipate and/or articulate their own post-discharge needs have also been implicated in sub-optimal post discharge outcomes (Corser,2006). Poor communication has also been reported between health care professionals within the acute setting (Bull and Roberts (2001), Shepperd et al (2004)) and between the acute and primary care settings (Werrett et al (2001), Prinjha et al (2009)). Individuals and their carers, moreover, often receive inadequate information regarding the availability of and access to community services (Grimmer et al (2004)).

Comparatively few studies, however, have sought to explore the experiences and perspectives of patients and their significant others in terms of their participation in the discharge planning processes (Corser (2006), Almborg et al (2008)), the transitional period between the acute setting and home (Chaboyer et al (2005), or its incipient and long term outcomes (Maddox et al (2001), Paterson et al (2001)). Despite a lack of empirical evidence (Chaboyer et al, 2005), there is increasing recognition, nonetheless, that expedition of hospital discharge may, in effect, “disempower individuals and undermine their potential for improvement and rehabilitation (sic)” (Commission for Social Care Inspection, 2005: 50). The following data support several of the previously described observations

Survivors often received little or no warning of their impending hospital discharge. Despite, in this instance, a diagnosis with a well defined “care pathway” (following hip replacement), which initiated the timely provision of aids, home assessment and pre-discharge adaptation, Roy described a rather hurried an unsatisfactory departure from hospital and “a complete lack of information”.

“I think I knew the day before. They give you your discharge papers but I had to go to my doctor to get...told what was wrong. They tell you are going home, fine, but were they seeing you again? There was a complete lack of information. Nobody told me anything. They told me the taxi was coming for me, so that’s it, cheerio sort of thing.” (Roy)

Despite an unfortunate fall on the day of hospital discharge (for which he required treatment at Accident and Emergency), Ken alludes in the following excerpt to an implicit trust in the auspices of a seemingly “remote” clinician and in professional decision-making processes.

“...obviously he (the doctor) must have okayed it, must’ve thought I was ok. They don’t discharge people that are not capable and they let me out.” (Ken)

The following data resonate with Connolly et al’s (2009) notion of the “systematisation” of patients, whereby fitness for discharge is broadly understood in terms of the resolution of “acute” or “medical” problems, accompanied by the view that “nothing more could be done” within the acute hospital setting (Hart, 2001). Here, a professional emphasis upon functional aspects of recovery (i.e. mobility) is apparent, to the detriment of other important social considerations associated with life at home.

“One young doctor very early on wanted me to go home and I said no (laughs), and it was left at that. Subsequently, I took the view they didn’t understand...at home, how complicated it is...” (Albert)

While, in this instance, premature discharge planning might reasonably be attributed to the over zealousness of a seemingly inexperienced clinician, he goes on to disclose significant concern for his

elderly wife (intermittently disabled by rheumatic disease) and her ability to care for him. He later describes a sense of foreclosure with regard to his obvious functional abilities, and an uncomfortable exchange with his attending Consultant in which he felt compelled to “stand his ground”.

“I could walk about the ward with a stick... I could see they were trying to get shut of me (laughs). I had the big talk, and I said, “I’m not ready to go home, my wife can’t look after me” and eventually I was taken out to convalescence.” (Albert, my emphasis)

As described in the previous chapter, there was often limited professional recognition of the everyday “logistics” of physical impairment. Lynne, for example, was discharged to a fourth floor flat with a chronically unreliable elevator. Here, she describes a lack of discourse with the relevant clinicians, attributed here to her Mother’s planned assistance in the first few weeks of hospital discharge.

“...there wasn’t a family meeting, there wasn’t any meeting with the doctor as such, *because I was really reliant on her when I got home*. Things like that had never been discussed, how I was going to cope when I went home. There was a lot of interest, yes, in getting me home, but not any concrete discussion on ways to make it easier for me.” (Lynne, my emphasis)

Andy, in particular, was critical of a professional emphasis upon the physical and functional aspects of recovery, and a perceived inattention to his expressed psychological and informational needs.

“...nobody asks you how you’re feeling in here (points to his head). “How are you feeling brain-wise, what are you thinking? Are you adapting, are you thinking straight, are you ready for this, do you know what’s happened to you?” Nobody asks you these questions. They just think, “Aye, he’s ok, she’s ok, let them out.” (Andy)

Given the breadth of these concerns, it is perhaps surprising that individuals rarely consciously or explicitly associate the processes of care, rehabilitation and discharge planning with post-discharge outcomes (Paterson et al (2001), Corser (2006)). The following data, however, provide some insights into this phenomenon. Survivors were seen, in many instances, to assume a sense of responsibility for their predicament, by concealing the severity of ongoing impairment, actively negotiating for hospital discharge and declining formal rehabilitation at a dedicated local facility. For some, the difficulties faced in everyday life were offset by the simple “relief” of being at home.

Several alluded to “playing the game” in order to expedite hospital discharge.

“I remember the day I got up the three flights of stairs. I headed up in front of the physiotherapist, so that he didn’t see my face...because it took every ounce of strength...to get up there. But once I came home, I couldn’t walk up the stairs in a oner. I had to take three goes at it. But I did it well enough to get out of hospital...” (John)

Elizabeth, one of the few to receive a “weekend pass” (the purpose of which, generally speaking, is to inform clinicians and patients alike of the manageability of life at home) described the concealment of her “struggle” from clinicians.

“In hospital, it’s a different story. You’re just lying in bed or walking up the ward or up the corridor and back down...but when I got home, I struggled. I’m not saying any more actually, because they might not have let me home if they’d known how much I struggled.” (Elizabeth)

Others were seen to actively negotiate hospital discharge. Elizabeth’s “struggle”, for example, appears to be discounted against the psychosocial impact of a prolonged hospital stay. She alludes here to its coercive use as a means of effecting hospital discharge.

“I just wanted to go home and that was it. You’ve got no idea what it’s like being in hospital that length of time. It’s just absolutely awful. I broke half the nurses’ hearts, “*Please* let me home? *When* can I get home? *Please* let me home?”” (Elizabeth, her emphases)

Andy, in contrast, described an adversarial relationship with his attending clinicians in relation to the discharge decision making processes, ultimately conceding a degree of personal responsibility for his predicament following discharge home.

“When I got home, I got the shock of my life. But I said, “*You’re the mouth, you said you could do it.*” And I suppose if it’d been maybe two months after, it’d be the same scenario, but you’ve just got to learn to do it yourself again.” (Andy, my emphasis)

For others, the “shock” of hospital discharge was offset against the desire for privacy and “a bit of dignity”.

“...when I came home first, the effort of opening the wardrobe door...made me soil myself. That’s how weak I was. I was glad I was here, though. I’d rather soil myself at home than in hospital.” (Betty)

### **8.6.5 Summary**

Taken together, these data suggest that, given (i) the perceived indifference of nursing staff to both basic and “technical” aspects of care (ii) the relative absence of care needs and (iii) limitations in rehabilitative provision, many felt that they would be “better off at home” (see Oloffson et al, 2005). With regard to the process of discharge planning, a marked professional preoccupation with functional aspects of recovery is apparent, often to the detriment of other important social or psychological concerns. Survivors were, however, often complicit in the adoption of dominant professional (i.e. largely functional) conceptualisations of recovery in order to expedite hospital discharge and, importantly, were often seen to adopt a sense of responsibility for their predicament.

## 8.7 Disruptions in explanatory systems

Disruptions in normal explanatory systems result, as previously described, in a re-thinking of the individual's life history and self-concept, raising questions of a "why me, why now?" and "why meaning to what end or purpose?" nature, often in relation to causality (Bury (1982), Williams (1984)). Attempts to repair these disruptions, as the existing literature suggests, are inevitably shaped by the *nature* of the precipitant illness, its temporality and effects upon everyday life.

The nature of the disruption evoked by critical illness is arguably unique, given the diverse and cumulative effects of its often opportunistic and inexplicable onset, the biographical discontinuity associated with amnesia and delusional "memories", the spectrum of (often ill-explained) morbidity, uncertainty in relation to the likelihood and limits of recovery and the *existential gravitas*, as it were, of a life-threatening illness. This section explores the processes through which survivors attempted to renegotiate and repair the multiple disruptions in explanatory systems.

Two broad themes were derived from survivors' accounts. The first ("I still don't know what happened to me") explores the variable importance, assimilation and perceived utility of disparate forms of information in relation to the "lost" events of the critical illness episode. The second ("How on *Earth* did I become so ill?") explores the attribution of causality to both the critical illness episode and "survival against all the odds", evoking a range of biomedically-oriented and "philosophical" explanatory processes.

### 8.7.1 "I still don't know what happened to me"

The seeking of information constitutes a key coping mechanism in adjustment to illness (van der Molem (1999), with implications for adaptation (Grimmer et al (2004), Almborg et al (2007)) and psychological morbidity (Jones et al, 2009). Given the prevalence of amnesia and delusional "memories", survivors seemed rather more concerned, in the first instance, with establishing the chain of events around the critical illness episode than notions of causality. This theme outlines the various processes which militated against survivors' attempts to acquire and assimilate the requisite information.

Many "came to" during the ward phase of recovery, but often remained "not with it enough" "too unwell" or "too tired" to consider or appreciate the nature or severity of their illness. Some were seen to actively forestall the receipt of such information. Despite the best intentions of her concerned relatives, Pat alludes here to its perception as an impediment to recovery and the ability to "cope".

“I said, “Tell me once I’m better. Don’t tell me just now, because every day is a battle”. Obviously I knew about the collapsed lung, and I knew about the...tracheostomy...but I didn’t want to hear how ill I’ve been, I really didn’t want to hear...how close to death I’d been” (Pat)

Others were seen to have “no interest” at that time, in the critical illness episode, preferring instead to focus upon the rehabilitative process.

“I was anxious to get on with my rehab. What’d happened had passed was my view at that time. I knew that I’d had an operation, fairly major...but I wasn’t, at that time, interested in what had happened.” (Christine)

Betty revealed a long-standing inability to “speak to doctors” or to “ask questions”. While some described the surreptitious receipt of information intended for junior clinicians during Consultant ward-rounds, others described their attending clinicians as somewhat aloof and unapproachable. Several recounted instances in which the impassive biomedical nature of the discussion effectively excluded participation.

“There were four of them standing at the bottom of my bed looking at my charts. Excuse me! Speak to me! *I’m* the patient here, it’s *me* you’re discussing. I didn’t like being made to feel like some *thing* in the bed, someone who’s got x, y and z wrong with them and they’re going to do a, b and c to sort it.” (Pat, her emphasis)

Here, John describes, in addition, perceived inefficiencies in communication between successive clinicians involved in his care.

“Maybe they told me...and I don’t remember...I am aware of the possibility that each of the nurses/doctors might have imagined that somebody before had told me. *Even in my fuzzed head*, I was aware on a number of occasions that whoever was momentarily in charge of me had scant knowledge of who I was and how I got there.” (John, in email correspondence) (my emphasis)

In the vast majority of cases, the desire to know “what happened” emerged only following hospital discharge, and often once survivors were beginning to “feel a bit better”. Many felt, however, that the opportunity to discuss the critical illness episode with the clinicians involved in their care had passed. Importantly, the acquisition of information was, on occasion, perceived as a matter of personal responsibility.

“It would have been nice to have somebody to run through exactly what happened to me...maybe six weeks after. Sadly that didn’t happen... but I haven’t asked for it either so, you know, *if I’d wanted to know that badly I should have asked.*” (Dave, my emphasis)

As described in the previous chapter, survivors were heavily reliant upon the witness accounts of close family members (a small number of which included abridged diaries), with attendant concerns, in

several cases, for their adequacy, veracity and partiality. Attempts to garner additional information from general practitioners and acute sector clinicians (during the course of specialist out-patient appointments) were invariably met with limited success. Both the research interview and the subsequent ICU visit were widely perceived as therapeutic in terms of an opportunity for often unprecedented disclosure, and in terms of “jogging the memory”.

Analysis thus far has explored the putative *origins* of the disruption in explanatory systems following critical illness. The following arguably “extreme cases” in which a number of survivors had, or were in the process of, seeking formal access to their case notes elicits important insights into the perceived *utility* of the information therein.

Jane, for example, expressed significant frustration in relation to the fragmented and contradictory information she had received from a succession of clinicians regarding both the origin of a lung lesion and the extent of its surgical excision during her ICU admission. She was grudgingly reliant upon the (seemingly spurious) information provided by previously estranged family members and, perhaps understandably, portrayed herself as the victim of an elaborate conspiracy.

“And then my doctor (GP) told me, “No, it was the lobe”, and I said, “No, it was a part of it”. I need to ask (at an upcoming out-patient appointment), if I’ve to come to terms with what I can do, and what I can’t do. And in the long-term, I don’t know how it’s going to affect me...” (Jane)

The desire for information is seen here as central to the everyday management of her condition and an appreciation of its prognostic effects. Having previously acknowledged the contributory effects of a chaotic lifestyle (by virtue of her own alcohol dependence and that of her physically abusive partner), and her responsibility in the management of the recovery process, her resolve to acquire the requisite information may be seen here as “symbolic attempt to repair ruptures between body, self and society” (Williams, 2000: 43). The lack of information, it might be argued, is symbolic of her sense of marginalisation, and its acquisition represents an opportunity both to regain control of her situation and to repair the associated biographical disruption.

John’s request for case note review (and subsequently, a transcription of the research interview) is seen, in contrast, as an attempt to simply account for the lost events of the critical illness episode.

“...this is the thing about wanting to see my notes...I feel as if I’ve been on some great journey but I don’t have any postcards, don’t have any photographs. And...that’s a loss.” (John)

“Vicarious” access to his medical notes (i.e. in the presence of a seemingly guarded clinician) presented him, however, with a sense of biographical *discontinuity* in relation to a cardiac arrest and the requirement for defibrillation, of which he had known nothing.

“Apart from all the other nonsense, I got to die and get kick-started. And nobody told me. Somebody should have told me that I got to die and come back. *That fact more than any other informs the rest of my life....*” (John, via email correspondence) (my emphasis)

In subsequent email correspondence, he nonetheless attributes (albeit tongue in cheek) the passage of time to the apparent reconceptualisation of his near death experience as “nothing”.

These data, in summary, describe the multiple sources and utility of “information” including their evolving significance in relation to the temporal processes of recovery. Information seeking is seen here, importantly, as an attempt to provide a sense of biographical *continuity* as opposed to a mechanism without which survivors could neither make sense of nor move on from their experiences.

### **8.7.2 “How on *Earth* did I become so ill?”**

Unlike illnesses with “a common cultural paradigm” (Bury, 1982) and/or a more insidious onset, the emergency and often overwhelming nature of critical illness often denies survivors a meaningful basis upon which to attribute causality. Reflecting Bury’s observation that the “search for a more comprehensive level of explanation...is often a long and profound one” (Bury, 1982: 174), survivors sought to augment biomedical notions of causality with alternative explanations derived from past experiences and life events (health-related and otherwise) in order to make sense of the critical illness episode. The otherwise inexplicable nature of the critical illness episode and survival “against all the odds” often precipitated a somewhat “fatalistic” or “philosophical” response.

For some, the aetiology of the admitting illness appeared relatively straightforward.

“I had a fall...which resulted in an injury to my rib cage, which resulted in punctured lungs...which resulted in pneumonia, things like that. So there was a kind of domino effect through what initially seemed like a small dunt (laughs).” (John)

Don described, in overtly biomedical terms, a recurrence of Guillan-Barre syndrome (an autoimmune disease resulting in acute neuromuscular impairment) some 40 years previously, while others acknowledged the contributory effects of having “always been ill”. Numerous and complex co-morbidities notwithstanding, however, Betty alluded to the contributory effects of “stress” and her perceived vulnerability to infection.

“I didn’t realise (I was so ill)...because I’ve got so many things wrong with me. It was pneumonia...on the bus I had sat beside a woman who was coughing something terrible. I think that must have been it. I’ve never heard a cough like it!” (Betty)

“Biomedically plausible” attributions were, in several instances, augmented or usurped by rather more fatalist or philosophical explanatory responses. Dave, for example, remarked, “At first I thought, why me? But then I thought why not me?” Having previously recounted the events surrounding his illness in a somewhat mechanistic manner (“this happened, then that happened”), John subsequently drew upon his involvement in an altercation several years previously, in his demonstration of “just how fickle life can be.”

“.. you can literally turn a corner into the path of a bus or...in my case, into a street fight, which is what happened last time..That happened in the blink of an eye and there was nothing I could’ve done to prevent it. And equally, if I’d been in that same spot 5 minutes before or 5 minutes after, nothing would’ve happened.It just seems like random chance...Do you know what I mean? (John)

Attributing causality and meaning to survival “against all the odds” evoked similar types of responses. While several attributed survival to “medical technology” and to the auspices of highly skilled clinicians, others described rather more *intrinsic* mechanisms such as “the will to live” and “fighting spirit”. Here, Ken describes his wife’s inherent faith in his ability to “pull through”.

“...they weren’t telling her to expect the worst, but they were sort of leaning towards it. My wife said, “I know what you’re trying to tell me. He won’t die. He’s too strong” (laughs). So she had faith in me...” (Ken)

Albert, a deeply religious man (who attributed his beliefs to a long and tortuous battle with alcoholism), defined his survival in terms of a test of faith.

“Everything that gets flung at me I accept it. I say, “Well, God will help me. No matter what happens to me, I’m gonna get help and, you know, He does...” (Albert)

Several described extraordinary “coincidences” without which they would surely have succumbed. Andy’s mother, for example, arrived at his home in the vague belief that “something was wrong”, only to find him collapsed and in extremis. James’ ambulance was involved in a minor road traffic accident en route to hospital, and its replacement with one carrying a doctor lead to the timely administration of a “life saving” injection. Several attributed their survival, quite simply, to chance.

“...it’s luck whether you live or die. If it’s your time or it’s not your time...and I really don’t worry about that any more.” (Anne)

These data, in summary, outline both the diversity and explanatory credence of biomedical and lay conceptualisations of causality, and their integration into the wider biographical narrative of recovery following critical illness.

## **8.8 The cognitive response to disruption**

The search for the *cause* of illness, as previously described, also constitutes a search for its *meaning*, which Bury (1991) describes in later work in terms of its “consequence” (the effects of symptoms or impairment on everyday life) and “significance” (the imagery or symbolic significance associated with a particular condition). Survivors frequently emphasised the importance of a “positive attitude” and many experienced what has been described elsewhere as “finding benefit” (Tallman et al, 2007), “illness gains” (Asbring, 2000) and “existential” (Sodergren et al, 2004) or “post-traumatic growth” (Calhoun and Tedeschi, 2006) despite significant ongoing impairment. The themes “Well, what else can you do?” and “Everything happens for a reason” explore these phenomena.

### **8.8.1 “Well, what else can you do?”**

In an expansive literature on adaptation to illness and impairment, theories such as resilience (Rutter, 1987), hardiness (Kobasa, 1979) and self-efficacy (Bandura, 1977) have sought to explore and explain the cognitive response to a radically altered and adverse situation. The cognitive response has been described more broadly throughout this and the previous chapter, however, in terms of Bury’s (1991) notion of “legitimation”.

Legitimation is defined and summarised here in terms of the ways in which survivors sought to establish an acceptable place for ongoing morbidity in their everyday lives and, in the wider sociological sense, as the process through which authority is made credible. The latter refers, importantly, to the limits of biomedical intervention and its explanatory credence, and to the ways in which survivors were ultimately reliant upon their *own* stock of self knowledge and biographical experience in the negotiation of everyday life (Bury, 1991).

In the vast majority of cases, accounts of loss and impairment were defined in terms of their pragmatic management and their integration in everyday life; a strategy of “active denial” (Kelleher (1988), Radley (1989)) or, more likely, one intended to minimise their inherent abnormality (Pound et al, 1998). Morbidity was also framed within the context of life-threatening illness as “not out of the ordinary”, “to be expected” and “a small price to pay” for survival. Also apparent, at least among

elderly survivors, was the tendency to “normalise” or attribute even recent morbidity to the aging process.

Implicit within and across accounts was the notion that the negotiation of the recovery process presented survivors with a “goal” or sense of purpose as opposed, ostensibly, to an insurmountable task.

“...it was like a chore...it was a drag, but it wasn’t depressing. I thought, I can’t really be bothered with this, but there’s nothing I can do to stop it. When I wake up tomorrow, I’ll feel better.” (John)

While a small number of survivors were simply acceptant of their situations, the vast majority of were hopeful or expectant of a return to (near) normality; an approach intended to cognitively buffer, as it were, the limits of one’s current situation. The re-prioritisation of social activity and participation in a reduced or altered capacity, similarly, resonates with the cognitive process of “bracketing off” the restrictions of everyday life (Bury, 1991: 460) such that the individual’s identity is maintained (Charmaz (1983). An alternative explanation is the moral imperative to be in good health or good spirits having been “saved” from impending death (Pound et al, 1998)

### **8.8.2 “Everything happens for a reason”**

This theme draws upon questions of a “Why meaning to what end or purpose” nature (Williams, 2000: 138). Contrary to much of the prevailing critical care literature, few survivors reported a fear of imminent death during the critical illness episode (Stein-Parbury and McKinley (2000), Almerud et al (2007), Lof et al (2008). A number of survivors, moreover, described deeply meaningful or spiritual experiences during the acute phase of critical illness. Arthur, a deeply religious man, described a “heavenly vision” in the form of his long-dead sister, resolutely attributing her message (that “it was not his time”) to a renewed faith in “the Lord’s work”, adding that

“...there is more to this (life) than people think... It’s not just me, but other people, *a lot of people* have different visions, and that’s how the Lord helps them.” (Arthur, his emphasis)

Andy, a self-confessed “non-believer” haltingly alluded to an extraordinary “out of body experience”, leading him to believe that he had “died and come back”. He subsequently alluded to the impunity of death with reference to a new and strongly held belief that he would be “looked after” when it was his “time” (Papathanassoglou and Patiraki (2003), (Magarey and McCutcheon, 2005)).

“...you know where your soul leaves your body. Well... (sounds tearful) I wasnae here, on this planet...I wasnae *here*...I was out my body and...I’m no’ gonnae tell you what happened but I know it *did* happen. I was away, definitely, but I came back.” (Andy, his emphases)

For some, coming to terms with one’s own mortality elicited a powerful sense of vulnerability, and these concerns seemed either patently indescribable or intensely private.

“We all now have a hidden badge or tattoo which we will wear for as long as we are aware of ourselves and we will wear that forever, even if it is concealed. We each had our own little private war that nobody will ever really know about.” (John, in email correspondence, several months following ICU discharge)

As described in the previous chapter, several attributed critical illness to a “serious wake up call”, actively resolving to take better care of themselves through the adoption of healthier lifestyles.

“...everybody gives their body a lot of wear and tear without (realising)...it’s so resilient, isn’t it? I mean, looking back, I wish I’d treated it with a bit more respect (laughs)” (Jane)

Others resolved to “pay more attention to the important things in life”

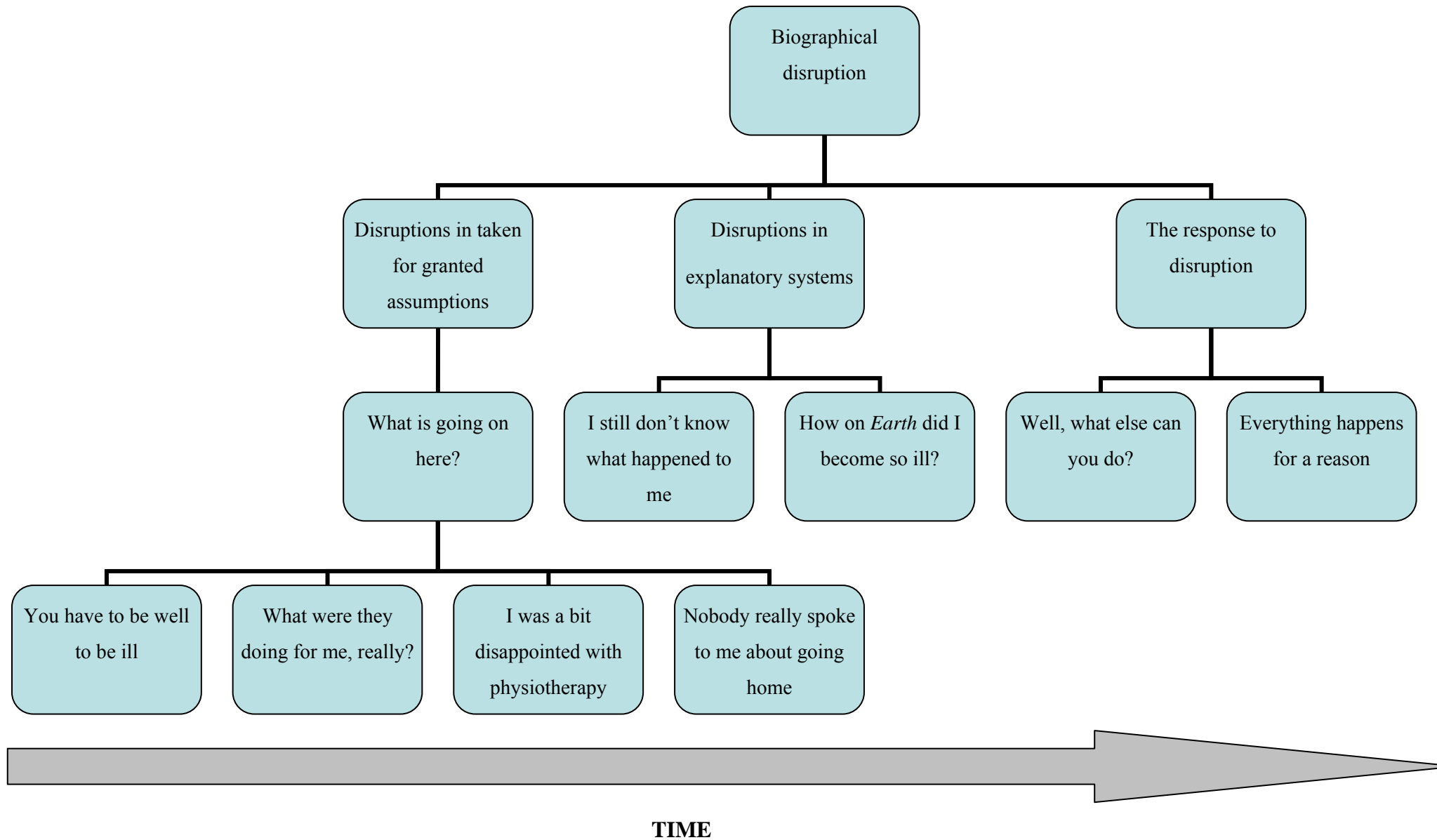
“My family and friends...are much more important to me now. I enjoy life more. I don’t get too worked up about work and things like that. Not manyana or anything like that, but I don’t let trivial things upset me.” (Christine)

Reminiscent of Broyard’s (1992) depiction of serious illness as “a great permission”, John sought voluntary redundancy from his previous employers in order to finance a change in career (in this instance, undertaking training as a mental health nurse)

“I have hugged myself and been near to girly tears at the reality that a once-dead man can walk and learn and be renewed and may be of use. I am revelling in my new life and my new beginning, and am convinced that I am doing the right thing. It’s the best decision I have ever made.” (John, in email correspondence)

These data, in summary, outline the complementarity of lay and professional conceptualisations of causality, their relative utility in terms of explanatory credence and, additionally, their temporality in the reparatory processes.

Figure 5: Biographical disruption following critical illness



## 8.9 Discussion

This chapter reveals the complex nature of the biographical disruption associated with survival and recovery following critical illness. The notion of “system-induced setbacks” provides a novel framework within which to explore the temporality and putative origins of much of that disruption. Professional practices and organisational processes during the ward phase of recovery and rehabilitation were seen to feature in much of the disruption in “taken-for-granted assumptions and behaviours” in relation to ongoing morbidity in the early post-discharge phase. Failure to meet the diverse informational needs of survivors in relation to both the critical illness experience and the aetiology and management of ongoing (and ostensibly “acceptable”) morbidity were seen, similarly, to contribute to much of the disruption in explanatory systems.

Survivors were seen to exercise varying degrees of agency in response to “system failures” in the acute setting; concealing the severity of ongoing impairment, actively negotiating for hospital discharge and forestalling the receipt of “information” in its variant forms, for example. Those alluded to by survivors were rarely explicitly associated with the disruption experienced following discharge home or the protraction of the recovery process. Survivors were seen, instead, to adopt a sense of personal responsibility for its management, actively negotiating the recovery process in often innovative ways.

Accounts of the cognitive response to disruption, importantly, were seen to transcend the otherwise “mundane and ordinary features” of sometimes significant impairment (Thorne and Paterson, 1998), prompting a review of their narrative form. Critiques of the illness narrative have tended to focus upon its inherently *representational* and *metaphorical* nature (Mathieson and Stam, 1995) in as much as that they

“...do more than report events which the person has suffered...by bearing witness to their illness...these authors are *fabricating* “a world of illness”. As part of this world, *they too are re-figured* in relation to both disease and health. The question arises as to how this is achieved, and what form of *symbolisation* might be involved.” (Bradbury, 1999: 779) (my emphases)

“Fabrication” and “symbolisation” relate not only to representational or potentially subversive connotations (Ewick, 1995), but also, and importantly, within the context of critical illness, to the limits of recall and the processes through which repeated recounting, or indeed the integration of others’ accounts (i.e. close family and friends) *become* “fabrications” (Charmaz, 1999). These “fabrications”, it is suggested, are ideological and dilemmatic (Radley and Billig, 1996) in as much as that survivorship “against all the odds” evokes powerful imagery which, while reflecting shared

cultural beliefs and expectations (Radley and Billig, 1996), may well be incongruent with survivors' everyday experiences or "private" accounts of morbidity and impairment.

Drawing upon the situational or co-constructed nature of the research interview and relatedly, Goffman's (1959) notion of "impression management", Reissman (1990) suggests that

"A particular "self" is constituted or projected through narratives, occasioned through the presence of a listener, her questions and comments. *Typically, the moral character of the protagonist is maintained.*" (Reissman, 1990: 1195) (my emphasis)

A prevalent feature of survivors' "public" (i.e. given) accounts was their representation of cheerful stoicism, "determination" and the will and/or ability to overcome adversity which, to some extent, contradicted their content. The "gaps" between them however,

"are best subject to tests of sincerity, not proofs of *truth* and *falsity*. The task for the interviewer is to "see into" them, not to try to peer behind or through them" (Radley and Billig, 1996: 236) (my emphases)

While "public" accounts in short cannot simply be taken at face value, given their alignment with and/or representation of the cognitive response to ongoing morbidity, "peering behind" survivors' accounts seems ethically, if not morally reprehensible. Suffice it to say that "seeing into" the inherently representational nature of survivors' accounts has rather more important implications for the evaluation of HRQoL as a patient-centred measure of health services intervention and for the development of therapeutic interventions than might be gained by their deconstruction.

# Chapter 9: Summary, discussion and implications

## 9.1 Introduction

In this concluding chapter, an overview of the main findings from the various research strategies is provided, including the implications for HRQoL measurement within critical care research and service development. A brief outline of their contribution to existing knowledge and to two recently funded related research studies is also discussed. First, an overview of the background and impetus for this research is outlined.

## 9.2 Background to this research

Patient reported outcome measures have become increasingly prevalent across multiple levels of healthcare policy, practice and development under the rubric of patient-centred healthcare. “Quality metrics” such as HRQoL are increasingly used in the evaluation, commissioning and rationalisation of scarce health services resource. Health services research is inherently pragmatic, and a fundamental problem with current approaches to HRQoL is that existing measures have been adopted almost unquestioningly, with often little or no recognisance of the theoretical ambiguity of its underlying concepts (i.e. “health” and “quality of life”).

Reflecting the predominantly quantitative, population-level (and arguably “atheoretical”) approach prevalent within much of health services policy and research, HRQoL has been operationalised as a quantifiable construct, with a firm emphasis upon the measurement or psychometric properties of its instruments. A deductive form of logic also prevails, whereby those aspects of experience to be examined are determined by the researchers a priori, with an explicit focus upon determining the causal relationships therein. This approach, it is suggested, reveals

“...superficial evidence on the social world, winking out the causal relationships between arbitrarily chosen variables which have little or no meaning to those individuals whose social worlds they are meant to represent.” (Bryman, 1984: 78)

Traditional (predominantly generic) HRQoL measures have tended, however, to lack an explicit methodological focus upon the patient’s perspective, reflecting a purely *biomedical* perspective of disease burden, irrespective of the *meaning* and *values* individuals ascribe to particular symptoms or limitations (Leplege and Hunt, 1997) or the social context in which they are experienced (Koch, 2000).

It is difficult, in short, to explicate what existing measures, with all their inconsistencies are *actually* measuring (Leplege and Hunt, 1997), and to determine whether they are indeed “fit for purpose” as a patient-centred measure of healthcare evaluation.

Limited theoretical or empirical work has examined, however, the extent to which these measures capture the perspectives of patients, with the corollary that service provision and development may potentially fail to meet the needs, concerns and priorities of its recipients.

“...the notion of quality of life is employed by theorists to address certain problems on the basis that those actually facing the problems see this as a relevant factor. But if the theorist solves the problem in terms of a distorted theoretical account of the factor, distorted because the theoretical refinements slant the notion in a certain way-if this is the case, then the theorist has not solved the original problem”. (Megone, 1990: 29)

This approach has come under increasing scrutiny, and it is increasingly argued that

“...quality of life can be suitably measured *only* by determining the preferences of patients and supplementing (or replacing) the authoritative opinions contained in statistically “approved” instruments. Unless greater emphasis is placed on the distinctive sentiments of patients, quality of life may continue to be measured with a psychometric statistical elegance that is accompanied by unsatisfactory face validity.” (Gill and Feinstein 1994: 626)

As a clinician first and foremost, the impetus for this research was a desire to examine experiences of critical illness-related morbidity in the everyday lives of survivors and the extent to which they are reflected in professionally endorsed generic HRQoL measures. Given the rich and unique insights afforded by the qualitative data and, reflecting a pragmatic health services approach, an important secondary aim was the exploration of potential healthcare interventions to expedite the recovery process in ways which are most meaningful to survivors.

### **9.3 The “unfolding story” of this research**

The early chapters of this thesis “set the scene” for later work, comprising an examination of the notion of quality of life within the context of critical care decision-making (specifically, the initiation, withdrawal and withholding of ICU resource), and as a measure of both outcome and “worthwhileness”. A prevalence study of prolonged critical illness across Lothian provided a useful local context for this research. The literature review examined the variable extent to which patient perspectives are incorporated in the development and validation of questionnaires in the wider HRQoL

literature. A subsequent selective review of the literature among a relatively homogeneous and particularly well studied sub group of the critically ill patient population (survivors of ARDS) served to demonstrate contemporary research practice and the current state of knowledge within critical care outcomes research, including the relationship between critical illness-related morbidity and HRQoL. Reflecting contemporary practice, the SF-36 was administered (by post) to survivors and data were analysed with reference to age and sex-matched population norms.

An explicit methodological focus upon the patient's perspective was adopted thereafter, beginning with the survivors' "real life" experiences of and perspectives on completing the questionnaire, moving strategically on to explore wider experiences of critical illness-related morbidity and its "meaning" (i.e. consequences and significance) in everyday life. Drawing heavily upon the critical care and wider social science literatures, a qualitative exploration of the SF-36 was conducted in order to discern whether and how the questionnaire was able to capture those aspects of experience which were of relevance and significance to survivors in their everyday lives.

This broader approach identified the temporal and adaptive processes of recovery following discharge home. The penultimate chapter explored survivors' experiences within the contexts of acute care and rehabilitation, and within the broader context of survivors' life stories or "biographies". Finally, attention focused on the unexpectedly phlegmatic nature of survivors' accounts, in an attempt to examine the implications of qualitative research in HRQoL research and health service development.

## **9.4 Summary of the main findings**

Given the multiple approaches to data collection and an inductive approach to its analysis, there was an inevitable degree of discontinuity or overlap in the findings. The findings from one approach often contradicted or augmented those from another. They are summarised here in order to reflect the evolution of the research strategy, and the "answerability" of the emerging research questions using alternative methods.

### **9.4.1 The current state of knowledge in critical care research**

This chapter critiqued the use of the SF-36 and the EQ-5D in critical care outcome studies. Given the inherent crudity of the latter and its limitations in analytical and explanatory scope, attention focused thereafter upon the SF-36. A review of its use among a particularly well studied sub group of the

critically ill patient population (survivors of ARDS) demonstrated the inherent limitations of existing approaches in terms of explicating (i) the prevalence of critical illness-related morbidity (ii) its putative relationship with HRQoL (iii) the temporal process of recovery among survivors and (iv) potential strategies for healthcare intervention.

#### **9.4.2 The prevalence of prolonged critical illness**

This chapter provided a useful context for the study in terms of describing the local long-term patient population (in terms of their number, demography and clinical characteristics), examining traditional estimations of “worthwhileness” (in terms of short-term mortality and the utilisation of acute hospital resource) and also mapping the patient journey throughout the acute hospital setting.

Approximately 140 patients per year experience prolonged critical illness across Lothian, of whom some 60% survive to hospital discharge. This patient group utilise an extraordinary and disproportionate amount of scarce ICU and hospital resource, equivalent to 6 fully occupied ICU beds and 8 acute hospital beds annually across Lothian. Survivors were comparatively young (with a median age of 62 (49, 72) years). Some 80% of survivors were discharged directly home.

#### **9.4.3 A “quasi-qualitative” exploration of the SF-36**

In this chapter, data from the SF-36 were analysed according to the developers’ recommendations and published UK population norms. Given that the small sample size prohibited complex analysis, meaningful comparison between patients and the generalisation of findings to similar patient populations, the data were intended to provide insights in this thesis into the relationship between morbidity and perceived HRQoL on an *individual* basis.

Analysis was confounded, however, by missing, altered, ambiguous and contradictory responses, the prevalence and management of which are rarely reported on in large scale critical care outcome studies. The incidence of missing, altered, ambiguous and contradictory responses was most pronounced within the Physical Function, Role Physical, Mental Health, Role Emotion and General Health Perception dimensions of the SF-36. Ambiguous terminology, the use of double questions, the decontextualised nature of the questions and response options and the cognitively burdensome response format were identified (from the existing literature) as explanatory factors. The perceived irrelevance of “*work and other activities*” in the Role Physical and Role Emotion dimensions was also

noteworthy, given both the proportion of retirees among the critically ill patient population and the often prolonged exclusion from employment due to ongoing morbidity.

These findings prompted a broader review of the literature, identifying the implications for the validity and applicability of HRQoL data in the evaluation, development and rationalisation of health services intervention.

#### **9.4.4 Cognitive interview and the SF-36**

Cognitive interview techniques are heavily reliant upon participants' *verbalisation* of the normally "hidden" cognitive processes through which they interpret, comprehend and respond to standardised questionnaire items.. They have an established role in the design, development and pre-testing of questionnaires in survey methodology, with a firm emphasis upon eliciting or evaluating the psychometric properties of new and latterly, widely used measures. Surprisingly few HRQoL measures, however, have been developed or evaluated using these techniques.

The data in this chapter supported much of that provided in the previous one, in as much as that there was a proliferation of issues around the Physical Function, Role Physical, Mental Health, Role Emotion and General Health Perception dimensions of the SF-36. Taken together, these chapters illuminate the significant constraints placed upon survivors' ability to represent their everyday experiences of ongoing morbidity. The data acquired here also usefully explored the nature of and rationale for the discontinuities between verbal reports and questionnaire response among this patient group. The main findings are summarised here.

##### **9.4.4.1 The Physical Function and Role Physical dimensions**

Given the prevalence and severity of physical impairment, a number of items in this dimension were either beyond survivors' capabilities or out with their frames of reference e.g. "moderate activities" "such as bowling or playing golf" and may therefore have been perceived as irrelevant. Survivors varied in their response to ostensibly "routine" activities such as climbing stairs or walking prescribed distances, rating their limitations according to either their *actual* or *perceived* ability to perform these activities. Several items were seen to assume a degree of functional equivalence (e.g. bending,

kneeling *or* stooping) which were not reflected in survivors' everyday experience, forcing them to choose between the given alternatives or to adopt the middle response ("limited a little").

Several expressed difficulty composing a response without additional contextual information and often outlined a number of constraints which were not reflected in the given response; typically, experiencing difficulty or being "slowed down" in their efforts. The questionnaire also failed to capture variation in the *nature* or *origins* of these limitations (e.g. weakness, fatigue, painful joints, breathlessness, etc) or the extent to which survivors included pre-existing morbidity and unrelated current illnesses in their estimations. Data garnered from broader qualitative interview suggested, in addition, that ongoing impairment was widely perceived as "to be expected" within the context of a prolonged serious illness, and was generally under-reported in questionnaire form.

#### **9.4.4.2 Mental Health and Role Emotion**

In support of the existing literature, there was some reluctance among several survivors to respond to items of the Mental Health and Role Emotion dimensions, perceiving the questions in general to be somewhat intrusive. The developers' definition of "emotional problems" (e.g. feeling "anxious or depressed") was perceived to be somewhat distasteful, eliciting a degree of social desirability bias. Data from the broader qualitative interview suggested that these terms, moreover, were generally not reflective of survivors' ostensibly stoical response to the process of recovery.

#### **9.4.4.3 General Health Perception**

Data from the broader qualitative interview elicited alternative and often counter-intuitive conceptualisations of "health". A number of survivors, for example, reported comparatively good health in the face of sometimes significant pre-existing morbidity. Reflecting findings from the wider literature, several survivors expressed uncertainty in terms of whether to compose their response in terms of their general health (including the extent to which long-standing or current unrelated conditions were included), or in terms of morbidity relative to the critical illness episode. Survivors also varied in the extent to which ongoing morbidity was considered a matter of "health" and incorporated into the response process. Several, moreover, perceived themselves to be "healthier" in the wake of critical illness, having resolved to "take better care" of themselves.

#### 9.4.4.4 An alternative cognitive response model

Tourangeau's (1984) Cognitive Response Model forms the basis of much of the Cognitive Aspects of Survey Methodology (CASM) approach. This model, however, may fail to take account of complex phenomena inherent in HRQoL measurement including, in particular, adaptation and response shift phenomena. The latter are increasingly recognised as confounding the efficacy (and by association, cost effectiveness) of healthcare interventions, with implications for policy, practice and research. Rapkin and Schartz's (2004) HRQoL Appraisal Model provided theoretical insights into these phenomena and work using this model was also seen, importantly, to challenge the "real life" legitimacy of existing psychometric approaches to the measurement of responsiveness, sensitivity and specificity. A new (albeit tentative) analytical model was proposed, based on the amalgamation of these two models. There was limited cognitive interview data, however, with which to test it.

#### 9.4.5 A qualitative exploration of the dimensions of the SF-36

In an attempt to discern the meaning, everyday relevance and importance of alternative dimensions of experience, the qualitative themes derived from survivors' accounts were broadly "mapped" onto the dimensions of the SF-36. The data were also analysed with reference to the existing critical care literature in order to develop the findings in line with current evidence. An alternative explanatory framework for HRQoL among this patient group was subsequently derived.

Perhaps the most important finding in this chapter was that survivors defined ongoing morbidity and impairment not in terms of *loss*, but in terms of *adaptation*. Survivors were seen to adopt pragmatic, experientially based and often innovative strategies in its everyday management and in response to the recovery process more generally. These were conceptualised using Bury's (1982) "strategy" ("what people do" in the face of illness and impairment) and "coping" (the cognitive processes through which the individual learns *how* to tolerate or *put up with* the effects of illness or impairment).

Inextricably linked with the processes of adaptation was the notion of *temporality*. Qualitative themes relevant to the Physical Function dimension, for example, comprised "Getting by" and "Moving on". The former relates to the early stages of life at home and comprises the sub-themes "Organising resources", "Organising support" and "Finding new ways of doing things". "Moving on relates to survivors' management of the recovery process, comprising the sub-themes "Pacing" (managing

weakness and fatigue), “Resistance” and “Marking progress and Setting goals”. These strategies were revisited in later attempts to resume social participation and employment. Ostensibly discrete dimensions of experience were therefore seen to be inter-related in complex and temporally dependent ways.

A striking feature of survivors’ accounts (and particularly relevant in terms of the Mental Health dimension) was their unexpectedly phlegmatic approach to ongoing impairment and the protraction of the recovery process. Even seemingly intolerable morbidity was perceived as “a lucky escape” or “better than being six feet under”. Despite entirely understandable concerns around the protraction and the limits of the recovery process (which in turn, challenge the implicit assumption among the critical care literatures that the psychological sequelae of critical illness are largely attributable to the ICU experience), survivors were remarkably upbeat in their anticipated return to “normality”. These data also suggest, however, that the emotional response to critical illness experience emerges late in the recovery process, often once a degree of functional improvement or “normality” had been reached.

Due in part to the perspective that social function and participation is considered beyond the remit of medical intervention, this aspect of experience has been somewhat overlooked in the critical care literatures. There is empirical evidence, however, to suggest that individuals place greater emphasis upon physical function in evaluations of health status and greater emphasis upon *psychosocial* aspects of experience in evaluating (HR)QoL (Smith et al, 1999). Here, survivors outlined the significance and renewed importance of friends and family throughout the critical illness episode and the process of recovery. Challenging biomedical conceptualisations of recovery (i.e. of physical function), “getting back to normal” was consistently defined in terms of the social, leisure and work-related activities that brought meaning and quality to survivors’ lives prior to critical illness.

Despite sometimes significant ongoing impairment, survivors attempted to participate in these activities, often in a reduced or alternative capacity; a strategy intended to maintain identity and self esteem and to render everyday life less restrictive. The visibility of impairment (typically, marked weight loss, impaired mobility or having “visibly aged”) and the perceived social stigma of life-threatening illness, however, were seen to serve as a reminder of critical illness and to forestall the perception of normality.

Supported by the wider social science and rehabilitative literatures, this chapter posits alternative conceptualisations of HRQoL, dimensions of experience and recovery. Perhaps most importantly, this chapter foregrounds the interpretive, adaptive and temporal processes through which survivors respond to and manage ongoing morbidity in their everyday lives. *Adaptation* is advanced as a more appropriate measure of recovery than HRQoL in its current conceptualisation (i.e. as a predominantly function-based measure of outcome).

#### **9.4.6 Biographical disruption following critical illness**

Given the profound alterations in survivors' lives in the wake of critical illness, survivors' accounts were examined in this chapter within the context of Bury's (1982) widely acclaimed work on "biographical disruption". The nature of the disruption evoked by critical illness is arguably unique, given the diverse and cumulative effects of its often opportunistic and inexplicable onset, the discontinuity associated with amnesia and delusional "memories", the spectrum of (often ill-explained) morbidity, uncertainty in relation to the likelihood and limits of recovery and the *existential gravitas*, as it were, of a life-threatening illness. Bury's (1982) construct provided an alternative analytical and temporal framework through which to examine the relationship between these aspects of experience and the interpretive and adaptive strategies identified in the previous chapter.

The biographical disruption associated with critical illness was most pronounced in the early stages of life at home, constituting "precisely that kind of experience" whereby "the structures of everyday life and the forms of knowledge which underpin them are disrupted" (Bury, 1982: 169). This observation prompted a retrospective review of the critical illness journey to include experiences of care and rehabilitation within the acute hospital setting. "System-induced setbacks" (Hart, 2001) including fragmented and specialty-specific care, inadequate rehabilitative input and discharge planning were seen to effect much of the disruption associated with the return home, forcing survivors to invest more energy into the "strategic management" of everyday life and the processes of recovery than might otherwise have been the case.

The failure to meet survivors' *informational* needs in relation to the aetiology of critical illness and the "lost" events associated with ICU care was seen to evoke a particular kind of biographical disruption. Survivors were heavily reliant upon the (often highly sanitised) witness accounts of significant others, assimilating disparate forms of information (including participation in this research and the ICU visit)

in order to repair this disruption. Survivors also drew upon their own stock of life experience and self-knowledge (health related and otherwise), resulting, in many cases, in a somewhat “philosophical” or fatalistic explanatory response.

Given the unexpectedly phlegmatic nature of survivors’ accounts, the data were also analysed with attention to the narrative form. Despite entirely understandable concerns around the intrusion of sometimes significant ongoing impairment in their everyday lives, concerns around the likelihood and limits of recovery, and the spectre of a life-threatening illness, a prevalent feature of survivors’ accounts was their representation of cheerful stoicism, “determination” and the will to overcome adversity. Life, for many, was seen to take on renewed meaning, in as much as that survivors resolved to pay more attention to “the important things in life”, identified new priorities, and often took “better care” of their health.

## **9.5 What this research contributes to existing knowledge**

This research introduces an explicit and therefore replicable methodological focus upon “the patient experience” in relation to the exploration of HRQoL among survivors of critical illness. It extends an increasingly used aspect of survey methodology (CASM) into critical care outcomes research, and the augmentation of its core components with a model used in the exploration of known “confounders” of HRQoL research has resulted in a novel (albeit tentative) model for potential use in future research.

Qualitative research is rare in critical care outcomes research. The “mapping” of aspects of patient experience onto the dimensions of the SF-36 therefore adds unique and important explanatory detail to existing approaches to the measurement of morbidity and, perhaps most importantly, foregrounds the interpretive, adaptive and temporal processes through which survivors were enabled to negotiate both an acceptable quality of life and the recovery process more generally, despite its sometimes significant intrusion in their everyday lives. This constitutes an important shift in emphasis, away from survivors’ *bodies* and into survivors’ *lives*, with implications for the augmentation of self-management strategies shown to be effective among other patient populations.

This research also introduces Bury’s (1982) biographical disruption into the field and demonstrates its utility as theoretical construct with which to explore and extend the critical illness “journey”. Its novel use in conjunction with Hart’s (2001) notion of system-induced setbacks implicates not only ongoing

morbidity, but shortfalls in the processes of acute care and rehabilitation in much of the disruption associated with survival following critical illness. The following sections outline the implications for service development and the measurement of HRQoL within the context of recovery following critical illness. First, however, a word about the method(ology) adopted in this thesis.

## **9.6 A word about method(ology)**

The critical care research community has adopted a pragmatic, quantitative and somewhat hermetic approach to the measurement of HRQoL. The exclusion of the patient's voice in the development, validation, interpretation and application of HRQoL measures and data, the prevailing inattention to the wider rehabilitative literature and, crucially, the dearth of qualitative and mixed methods research within this context imposes significant limitations upon its utility as a truly patient-centred measure of critical care intervention and in the development of interventional strategies in accordance with the needs and concerns of survivors.

An explicit methodological focus upon the survivor's perspective, and the "answerability" of the emergent research questions therefore dictated the methods used in this thesis. The epistemological assumptions underpinning the prevailing quantitative methodological approach to HRQoL measurement and the alternative qualitative methods utilised in this study were nonetheless dilemmatic, in as much as that they were seen to yield often inconsistent representations of "reality". Given that mixed methods approaches have tended to eschew the extant philosophical debates around their relative value, the nature of reality and the "truth claims" associated with the qualitative and qualitative research paradigms, attempts at their reconciliation are likely to be tenuous at best.

A particular strength of the methodological approach adopted, nonetheless, is the explication of a rather more comprehensive and temporally-located view of the phenomenon at hand, revealing perhaps most importantly the meaning and significance of critical illness-related morbidity within and across the prescribed dimensions of HRQoL and more broadly in terms of survivors' everyday experience and "biographies". This approach also revealed the influence of shortfalls in the delivery and organisation of care and rehabilitation upon the interpretive and adaptive processes identified, indicating, in turn, implications for patient-centred intervention and the use of HRQoL as a measure of outcome in critical care research.

Despite the relative breadth and utility of the findings, there are a number of limitations of this research, most notably around unanticipated practical and methodological constraints and the validity and generalisability of findings. Purposive or theoretical sampling was not always possible due to the limited available information on the local Wardwatcher® database with regard to pre-defined criteria (predominantly pre-existing comorbidity and social circumstance) and recruitment to the study was difficult, due in part to the significant symptom burden associated with prolonged critical illness, geographical constraints and the low response rate amongst potential participants' General Practitioners. The number of participants was therefore small and sampling was, for the most part, convenience-based, raising important issues around the validity and generalisability of findings to the wider patient population.

Participants were, in effect, self-selecting and given the unexpectedly “upbeat” nature of their accounts, it is feasible that this research unintentionally privileged those who were adapting most successfully to the sequelae of critical illness. It is somewhat difficult to counter questions here around the validity or “truthfulness” of survivors’ accounts. Attention to the narrative form in the penultimate sections of the previous chapter, however, draws attention to its reparatory, metaphorical, and representational purpose and the ethical tension surrounding attempts to “peer behind or through them” (Radley and Billig, 1996).

With regard to more traditional (i.e. quantitative) notions of generalisability, the issue is perhaps best addressed by Schofield’s (1993) alternative conceptualisations of the term; “fittingness”, “comparability” and “translatability”, which broadly speaking, rely on detailed description of the phenomenon, context, theoretical stance and the research techniques employed. The reader is therefore invited to make “naturalistic” generalisations (or an informed judgement) regarding the application of findings to alternative contexts or patient populations through the use of both explicit comparisons and tacit knowledge, although these are inevitably highly subjective.

Other limitations centre around unanticipated methodological issues. Given, for example, the emergence of *temporality* as a central theme of survivors’ experience, a standardised and longitudinal approach might have added important and contemporaneous detail to the processes of adaptation. Future local research (see section 9.8) attempts to address this issue.

## 9.7 Implications for practice

Patient narratives are increasingly prominent in the evaluation and quality improvement of healthcare intervention (Schmidt (2003), Eriksson and Svedlund (2005)). The implications for practice from this research are significant, given the multiple “system-induced setbacks” which contributed to the biographical disruption associated with critical illness. Supported by the wider literature on “the patient experience” in relation to acute hospital care, survivors’ accounts highlighted a number of “generic” shortfalls in its processes and delivery, including the perceived indifference of busy ward staff to their basic care needs, the scarcity of rehabilitative resource, failure to meet their informational needs, and inadequacies in the processes of discharge planning. Patient narratives, however, cannot simply be taken at face value, given that survivors did not consciously or explicitly associate these shortfalls with the difficulties they faced following discharge home, adopting instead a sense of personal responsibility for the recovery process.

Clinical experience in a ward-based ICU follow up service would seem to suggest that the widespread dispersal of survivors throughout the acute setting, in many ways, renders “invisible” the multiple morbidities associated with critical illness and the rehabilitative needs of survivors. There is a wealth of evidence among other critically ill patient populations (e.g. following neurological injury and cardiothoracic surgery) to suggest that patients derive significant and sustained benefit from multidisciplinary rehabilitative input in the acute setting. The development of a dedicated “care pathway” (including access to rehabilitative provision in dedicated settings) is one possible solution to addressing shortfalls in current provision. The adaptation of established rehabilitative models (among the respiratory, cardiac and stroke patient populations has recently been recommended (Herridge, 2007), although the existing evidence base upon which to do so is somewhat limited (NICE, 2009). Future local research attempts to address a number of the identified issues, and these are described in subsequent sections.

Notwithstanding the implications of discharging patients into the community “sicker and quicker”, there is evidence from other patient populations (notably stroke patients and the elderly) that patients derive benefit from early supported discharge i.e. home-based rehabilitative provision (Mayo et al (2000), Cunliffe et al (2004)). Few such strategies, however, have been adopted into routine clinical practice. Perhaps more importantly, little is currently known about the ways in which patients manage the recovery process following discharge home, even among extensively studied patient groups such as

those surviving stroke (Rittman et al, 2004). Data from this research provide unique insights into these processes, offering significant potential to expedite the recovery process in ways which are most meaningful to patients.

## **9.8 Contribution to future research**

Drawing largely upon the data outlining survivors' experiences of ward-based care and rehabilitation, this research has made a significant contribution to the development of a physical rehabilitative complex intervention among patients following ICU discharge; the "RECOVER" study. This study is intended to characterise the nature and prevalence of critical illness related morbidity among survivors during the ward phase of recovery (through the use of professionally recommended screening tools) and to augment existing rehabilitative input, expedite specialist referral processes (e.g. to Occupational Therapy) and co-ordinate the discharge process through the use of a specially trained generic assistant. The "control" group will receive routine care only.

Relevant inclusions drawn from this research in relation, for example, to biographical disruption, include a structured discussion between survivors, family members and an ICU clinician regarding the aetiology of the admitting illness, its course in relation to ICU care and common physical and psychological sequelae. Participants will also receive a written lay summary and will be offered the opportunity to visit the ICU. Unusually for critical care research, this study also incorporates a qualitative component which will include focus groups comprising (i) survivors and their carers (ii) ward-based clinicians. The former will explore experiences and perceptions of ward-based care and rehabilitation among survivors and their carers in both control and intervention groups, and its contribution to the recovery process. The latter will extend our current understanding of the organisation, delivery and perceived barriers to patient-centred care and rehabilitation by drawing on the experiences and perceptions of relevant clinicians (including, in particular, physiotherapists).

Drawing largely upon data outlining the temporal processes of recovery following discharge home, this research has, in addition, led to the development of a longitudinal qualitative study of perceived healthcare and support needs (including access to, preferences for and evolving patterns of (in)formal support and service use) at up to one year following hospital discharge, in which I am the Principal Investigator. Originally developed for use among stroke patients, the "Timing it Right" framework (Cameron et al, 2008) will be used to explore the evolving support and healthcare needs of survivors throughout the recovery process following discharge home. Analysis will also incorporate qualitative

Health Needs Assessment, a technique widely used in health service development. This study, in short, is intended to explore gaps in current service provision and facilitate the development of timely and responsive interventions at critical points in the recovery process, preferences for which will be examined in a subsequent large scale survey.

## **9.9 Implications for HRQoL measurement in critical care outcomes research**

Despite its widely held perception as the “ultimate measure of worthwhileness” in critical care outcomes research, HRQoL has attracted little theoretical or empirical scrutiny within this context. Reflecting a pragmatic health services approach, HRQoL has been measured using, almost exclusively, generic measures, often in conjunction with screening tools or disease specific measures developed for use amongst other patient populations. Neither, however, has been convincingly validated for use among survivors of critical illness. The data from this research demonstrates that existing approaches offer limited insight into critical illness-related morbidity, those aspects of experience which are of most concern to patients and the temporal processes of recovery.

Reflecting the breadth and complexity of the findings, a number of alternative approaches are suggested. “Quick fixes” intended to improve the transparency, interpretability and comparability of study results include (i) standardisation in the use of the SF-36 and adjuncts (ii) greater transparency regarding their utility and limitations through improved validation (preferably in collaboration with survivors) (iii) standardisation in the reporting of data, including the incidence and management of missing data. Review of the literature and data from this research also highlights the need for additional *longitudinal* research beyond existing professional recommendations (i.e. up to 6 months) in order to more adequately capture the temporal processes of recovery.

Given extant concerns around the extent to which existing measures capture the perspectives of the elderly (as a significant proportion of the critically ill patient population) and the reported prevalence of cognitive dysfunction among this patient group, “quick fixes” intended to improve the relevance, acceptability, response burden and, potentially, response rates to the SF-36 are required. These might include (i) the addition and validation of dimension-specific measures which capture the concerns of patients e.g. weakness and fatigue (ii) the clarification of ambiguous terminology (iii) amendment and/or clarification of the term “work” and other activities in the Role Physical and Role Emotion

dimensions (iv) amendment and/or re-ordering of the response categories in problematic dimensions in line with previously described cognitive principles.

Although not an intended outcome of this research, the alternative model explicated through the “mapping” of patient experience onto the dimensions of the SF-36 offers significant potential for the development of a new model of HRQoL among survivors of critical illness. Alternative strategies include the development of new models of HRQoL based on the techniques used in the “Rolls Royce” disease-specific and idiographic models of questionnaire development.

“Rolls Royce” models are enabled to more adequately capture both the nature of the relationship between morbidity and HRQoL and its relative meaning by virtue of their development and validation in collaboration with patient groups. This model incorporates a range of methods including semi-structured, unstructured and cognitive interview, often incorporating purposive sampling to determine the relevance, acceptability and respondent burden of the measures developed among specific sub-groups of the patient population. Idiographic models also offer significant insights into patient conceptualisations of “health”, its likely determinants and its relationship with QoL, given that they allow respondents to nominate and appraise those aspects of their lives (health-related and otherwise) which are of greatest relevance in their overall QoL. Importantly, such measures are often derived from a clear conceptual basis, affording greater analytical and explanatory insights into the evaluative processes, the relative effects of healthcare intervention and the processes through which they succeed or fail.

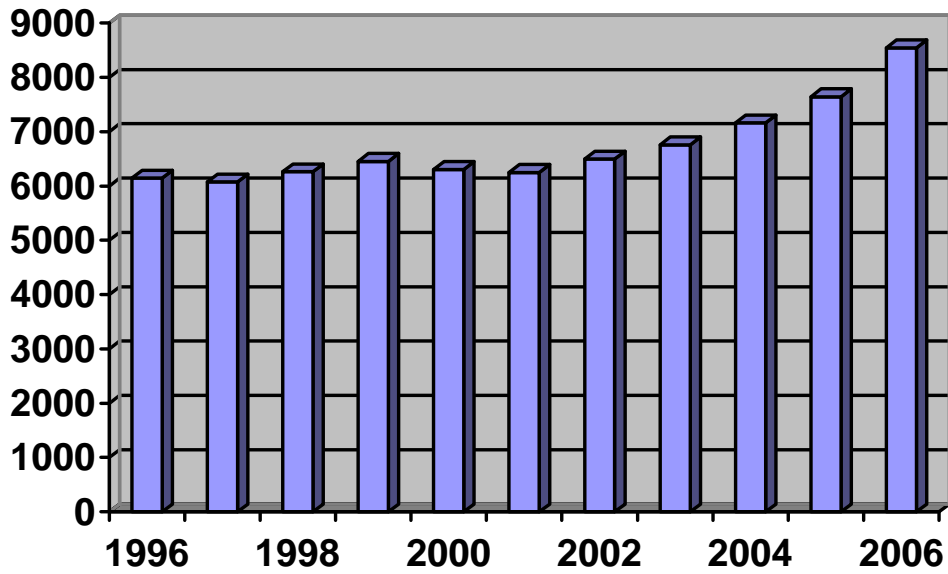
Given the prominence of response shift effects within and across survivors’ qualitative accounts, its incorporation into new or existing measures is also warranted. There was limited cognitive interview data in this research, however, with which to test either Rapkin and Schwartz’s (2004) HRQoL appraisal model, or indeed the augmented model proposed in this thesis. Further empirical research is required.

Getting “a better fix” on the notion of HRQoL and its “measurability” would undoubtedly require significant and sustained collaboration between clinicians, social scientists, survey and trial methodologists, statisticians and patients in order to ensure that outcome data are psychometrically

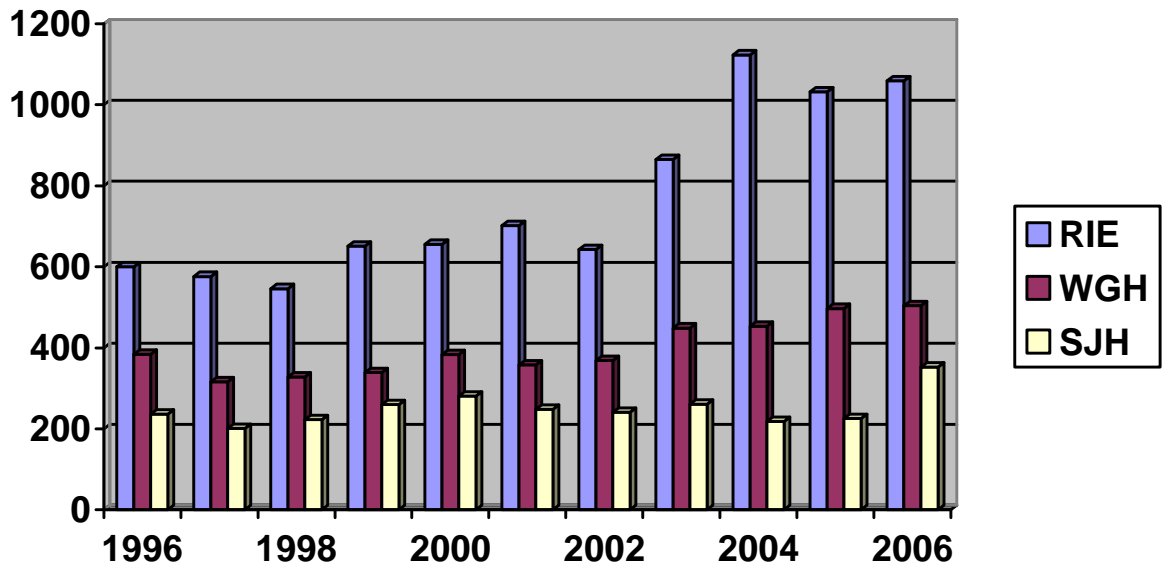
robust, clinically meaningful and applicable, and responsive to the needs and concerns of patients. Challenging times lie ahead if HRQoL instruments are to achieve their full potential as truly patient-centred measures of health services evaluation.

## Appendices

### Appendix 1: Admissions to a Scottish ICU (1996 to 2006)



### Appendix 2: Admissions to a Lothian ICU (1996 to 2006)



Data derived from the Scottish Intensive Care Society Audit Group: Audit of Critical Care In Scotland 2005/2006. NHS Scotland. Crown Copyright 2007.

### Appendix 3: Data fields and attendant issues

Variable	Description	Comments/issues
Key	Unique patient identifier, allocated centrally by SICSAG.	
Age	Age on admission to ICU	Grouped by quartile for chi square test
Sex	Gender of patient; male, female	
APACHE II score	An illness severity scoring system based upon chronic health states and physiological derangement within the first 24 hours of admission to ICU. Scores range from 0 to 71, with higher scores indicating higher illness severity.	Patients re-admitted to ICU within their hospital admission are assigned a value of 0, which is clearly not reflective of their illness severity on re-admission. A score of '0' was recorded as 'missing' for the purposes of data analysis.  Grouped by quartile for chi square test
Length of ventilation	Duration of mechanical ventilation, measured in 'whole' days.	Grouped by quartile for chi square test
Length of ICU stay	Length of ICU stay, measured in <i>proportions</i> of days	By default, length of ventilation may 'exceed' length of ICU stay
ICU outcome	Outcome on discharge from ICU; alive, dead, transfer to other acute setting	Ultimate ICU outcome is unknown among patients discharged directly from ICU to other ICUs out with Lothian.
Ward length of stay	Length of time spent on a general ward in the acute healthcare setting	Data on ward length of stay was missing at SJH in 44% of cases. These data were recorded as 'missing' for the purposes of analysis.
Hospital outcome	Outcome on hospital discharge; alive, dead, transfer to other healthcare setting	Ultimate hospital outcome is unknown among patients discharged to other healthcare settings out with Lothian
Discharge destination	Ultimate hospital discharge destination; home, rehabilitation, convalescence or other healthcare setting	Ultimate hospital discharge destination is unknown among patients discharged to other healthcare settings out with Lothian

**Appendix 4: Demography and clinical characteristics of the study cohort and patient population from whom they were recruited (1.1.2006-21.11.07)**

	<b>Study cohort</b> (n=20)	<b>Long term patient cohort</b> (n=279)	<b><i>p</i> value</b>
<b>Age (years)<sup>1</sup></b>	61(49,71)	60(48,70)	0.934
<b>Gender (%)</b>	57	58	0.927
<b>APACHE score<sup>1</sup></b>	24(21,29)	21(17,26)	0.090
<b>Ventilation days<sup>1</sup></b>	28(20,40)	21(17,29)	0.031*
<b>ICU length of stay (days)<sup>1</sup></b>	35(24,47)	25(19,34)	0.014*
<b>ICU mortality (%)</b>	-	28	-
<b>Ward length of stay (days)<sup>1</sup></b>	24(15,52)	18(5,33)	0.062
<b>Hospital mortality* (%)</b>	-	11	-
<b>Hospital discharge destination**</b>			
Home (%)	70	65	-
Rehabilitation (%)	20	16	-
Convalescence (%)	10	6	-

### Appendix 5: Demography, clinical and resource-related characteristics of the 5 year Lothian cohort, by site

	All (n=708)	RIE	WGH	SJH	<i>p</i> value
<b>Age (years)<sup>1</sup></b>	62 (49,72)	64 (53,72)	58 (41,69)	59 (52,71)	0.000*
<b>Gender (male, %)</b>	58	59	62	49	0.040*
<b>APACHE score<sup>1</sup></b>	21 (16,25)	22 (18,26)	18 (12,22)	21 (16,26)	0.000*
<b>Ventilation days<sup>1</sup></b>	21 (17,29)	22 (17,32)	20 (16,26)	19 (16, 25)	0.000*
<b>ICU length of stay (days)<sup>1</sup></b>	25 (19,34)	27 (20, 37)	21 (17,30)	25 (19, 34)	0.000*
<b>ICU mortality (%)</b>	28	37	24	21	0.000*
<b>Ward length of stay (days)<sup>1</sup></b>	20 (10,38)	20 (11, 37)	21 (10,30)	13 (3, 42)	0000*
<b>Hospital** mortality (%)</b>	8	-	-	-	-
<b>Hospital discharge destination***</b>					
Home (%)	80	-	-	-	-
Rehab. (%)	17	-	-	-	-
Convalescence (%)	4	-	-	-	-

<sup>1</sup>Data presented as medians and interquartile ranges (1<sup>st</sup> and 3<sup>rd</sup>)

\*Statistically significant

\*\*Additional hospital mortality i.e. following ICU discharge

\*\*\* Among those in whom ultimate discharge destination is known i.e. excluding those transferred to other ICUs or acute hospital settings.

### Appendix 6: Differences between ICU survivors and non-ICU survivors

	<b>ICU survivors</b> (n=455)	<b>ICU non-survivors</b> (n=195)	<i>p</i> <b>value</b>
<b>Age (years)<sup>1</sup></b>	59 (46, 69)	67 (57, 75)	0.000*
<b>Gender (male) (%)</b>	58	62	0.349
<b>APACHE score<sup>1</sup></b>	20 (15, 24)	22 (18, 27)	0.000*
<b>Ventilation days<sup>1</sup></b>	22 (17, 30)	21 (17, 29)	0.792
<b>ICU length of stay(days)<sup>1</sup></b>	27 (20, 36)	21 (17, 30)	0.000*

<sup>1</sup>Data presented as medians and interquartile ranges (1<sup>st</sup> and 3<sup>rd</sup>)

\*Statistically significant

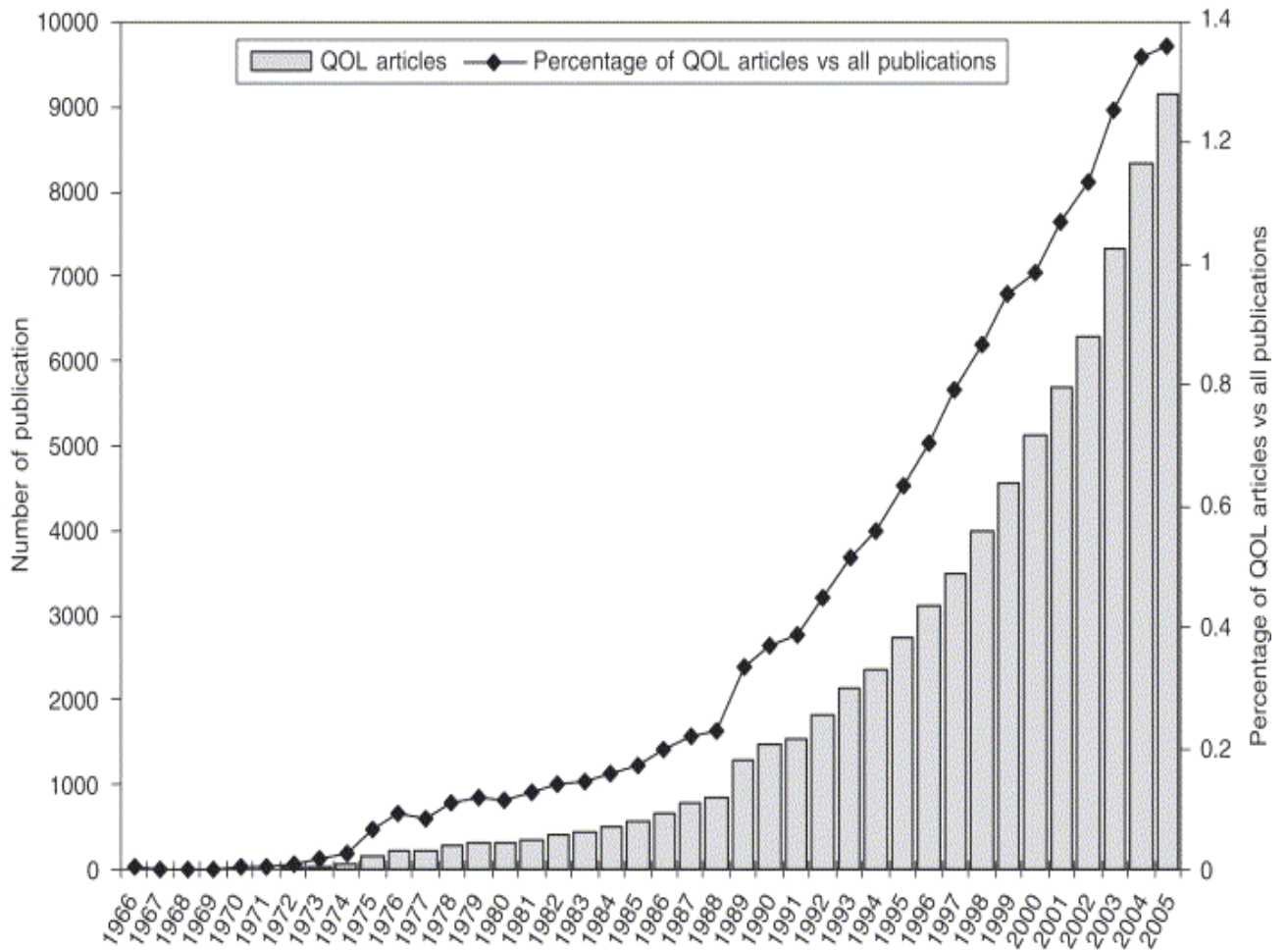
### Appendix 7: Differences between hospital survivors and non-hospital survivors

	<b>Hospital survivors</b> (n=309)	<b>Hospital non-survivors</b> (n=253)	<i>p</i> <b>value</b>
<b>Age (years)<sup>1</sup></b>	58 (46, 69)	67 (57, 75)	0.000*
<b>Gender (male) (%)</b>	56	63	0.072
<b>APACHE score<sup>1</sup></b>	20 (16, 25)	22 (18, 26)	0.014*
<b>Ventilation days<sup>1</sup></b>	22 (17, 30)	21 (17, 30)	0.569
<b>ICU length of stay(days)<sup>1</sup></b>	27 (21, 37)	23 (18, 34)	0.000*
<b>Ward length of stay (days)<sup>1</sup></b>	21 (12, 38)	15 (6, 40)	0.000*

<sup>1</sup>Data presented as medians and interquartile ranges (1<sup>st</sup> and 3<sup>rd</sup>)

\*Statistically significant

## Appendix 8: The number of publications reporting upon HRQoL (1996-2005)



Moons P, Budts W and de Geest S (2006) Critique on the conceptualisation of quality of life: A review and evaluation of different conceptual approaches. *International Journal of Nursing Studies*; 43: 891-901

## Appendix 9: Morbidity associated with survival following critical illness

<b>Physical morbidity</b>	<p>Recovering organ impairment</p> <p>Reduced cardiovascular and pulmonary reserve</p> <p>Severe weight loss</p> <p>Profound weakness</p> <p>Fatigue</p> <p>Joint stiffness</p> <p>Peripheral neuropathy (e.g. numbness)</p> <p>Loss of appetite (including taste changes in food)</p> <p>Alopecia</p> <p>Dry skin</p> <p>Pruritis (itchy skin)</p> <p>Scarring from invasive treatment/monitoring devices</p> <p>Brittle nails</p> <p>Difficulty swallowing</p> <p>Voice changes</p>
<b>Psychosocial morbidity</b>	<p>Anxiety</p> <p>Depression</p> <p>Neurocognitive dysfunction (e.g. impaired memory, concentration and decision-making)</p> <p>Emotional lability</p> <p>Disturbed sleep</p> <p>Recurrent persecutory nightmares</p> <p>Panic attacks</p> <p>Fear of dying</p> <p>Guilt</p> <p>Social isolation</p> <p>Altered family relationships</p>

## Appendix 10: The SF-36

**INSTRUCTIONS:** This survey asks for your views about your health. This information will help keep track of how you felt and how well you were able to do your usual activities.

*There are no right or wrong answers, we are just trying to build up a picture of your health, life-style and activities now.*

These questions relate to your health in the **last 4 weeks**. Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can (*or discuss with the researcher at interview*).

1. In general would you say your health is: (circle one)

Excellent.....  
Very good.....  
Good.....  
Fair.....  
Poor.....

2. **Compared to one year ago**, how would rate your health in general in the last 4 weeks? (circle one)

Much better than one year ago.....  
Somewhat better than one year ago.....  
About the same as one year ago.....  
Somewhat worse than one year ago.....  
Much worse than one year ago.....

3. The following questions are about activities you might do during a typical day in the last 4 weeks. **Did your health limit you in these activities?** If so, how much?

<b>Activities</b>	<b>Yes, limited a lot</b>	<b>Yes, limited a little</b>	<b>No, not limited at all</b>
<b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports			
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
Lifting or carrying groceries			
Climbing several flights of stairs			
Climbing one flight of stairs			
Bending, kneeling or stooping			
Walking <b>more than a mile</b>			
Walking <b>Half a mile</b>			
Walking <b>one hundred yards</b>			
Bathing or dressing yourself			

4. In the last 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	<b>Yes</b>	<b>No</b>
a. Cut down on the <b>amount of time</b> you spent on work or other activities		
b. <b>Accomplished less</b> than you would like		
c. Were limited in the <b>kind</b> of work or other activities		
d. Had <b>difficulty</b> performing the work or other activities (for example it took extra effort)		

5. In the last 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of emotional problems** (such as feeling depressed or anxious)?

	Yes	No
Cut down on the <b>amount of time</b> you spent on work or other activities		
<b>Accomplished less</b> than you would like		
Didn't do work or other activities as <b>carefully</b> as usual		

6. In the last four weeks to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups? (circle one)

Not at all.....

Slightly.....

Moderately.....

Quite a bit.....

Extremely.....

7. How much **bodily** pain have you had during the last 4 weeks? (circle one)

None.....

Very mild.....

Mild.....

Moderate.....

Severe.....

Very Severe.....

8. In the last 4 weeks how much did pain interfere with your normal work (including both work outside and housework)? (circle one)

Not at all.....

Slightly.....

Moderately.....

Quite a bit.....

Extremely.....

9. These questions are about how you feel and how things have been with you in the last 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the last 4 weeks

	<b>All of the time</b>	<b>Most of the time</b>	<b>A good bit of the time</b>	<b>Some of the time</b>	<b>A little of the time</b>	<b>None of the time</b>
Did you feel full of life?						
Have you been a nervous person?						
Have you felt so down in the dumps that nothing could cheer you up?						
Have you felt calm and peaceful?						
Did you have a lot of energy?						
Have you felt downhearted and low?						
Did you feel worn out?						
Have you been a happy person?						
Did you feel tired?						

10. In the last 4 weeks how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives etc)? (circle one)

All of the time.....

Most of the time.....

Some of the time.....

A little of the time.....

None of the time.....

11. How **TRUE** or **FALSE** is each of the following statements for you?

	<b>Definitely true</b>	<b>Mostly true</b>	<b>Don't know</b>	<b>Mostly false</b>	<b>Definitely false</b>
I seem to get ill a little easier than other people					
I am as healthy as anybody I know					
I expect my health to get worse					
My health is excellent					

### Appendix 11: The SF-36 in critical care outcome studies

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Smith 1995(UK)	General ICU	Median 13	-	Place of residence	-	General population
Broome 1996(USA)	Pancreatitis	Mean 51	-	Return to work	Hospital costs	Across treatment groups
Brenneman 1997(Canada)	Trauma	12	-	Return to work	-	Across groups
Chrispin 1997(UK)	General ICU	Pre-ICU discharge	-	-	-	General population
Ridley 1997(UK)	General ICU	Pre-ICU discharge,6	-	-	-	Across groups and general population
Weinert 1997(Germany)	Acute lung injury	6-41	Author-derived disease-specific battery	Karnofsky Index	Focus group	General population
Kriwanek 1998(Austria)	Abdominal sepsis	24	-	-	Hospital costs	Across treatment groups and general population
Schelling 1998(Germany)	ARDS	Median 48	-	Return to work	PTSD Inventory	Critically ill controls and general population

	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Davidson 1999(USA)	ARDS	Median 23	St George's Respiratory Questionnaire	-	-	Critically ill matched controls
Hopkins 1999(USA)	ARDS	12	-	-	Battery of neurological and psychological tests	General population
Welsh 1999(USA)	General ICU	1.5, 6	-	Zubrod functional status	-	ICU baseline and general population
Eddleston 2000(UK)	General ICU	3, 6, 12	-	-	HADS. Interview and clinical examination.	General population
Heyland 2000(Canada)	Sepsis	17±11	Patrick's Perceived Quality of Life Scale	Return to work, place of residence	-	Across groups and general population
Lipsett 2000(USA)	Surgical ICU	1,3,6,12	-	Sickness Impact Profile	-	Proxy, across groups, general population
Miller 2000(USA)	Trauma	84	-	Place of residence, functional independence	-	Across groups and general population
Pettila 2000(Finland)	General ICU	12	-	Return to work, ADL	-	General population

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Schelling 2000(USA)	ARDS	62.5	-	Pulmonary function tests, return to work	-	General population
Soran 2000(USA)	Pancreatitis	12	-	-	Hospital costs	Across groups and general population
Flaatten 2001(Finland)	General ICU	60	-	-	-	General population and ICU controls
Rothenhausler 2001(Germany)	ARDS	Mean 77±38	-	Cognitive performance, return to work	-	General population
Quality of Life After MV in the Aged 2001(USA)	General ICU (elderly)		-	-	-	General population
Clermont 2002(USA)	Pneumonia, organ dysfunction	3	-	Katz ADL, return to work	-	Across groups and general population
Fok 2003(China)	General ICU	1	-	-	Sense of Coherence, Coping scales	General population
Graf 2003(Germany)	Medical ICU	1, 9	-	-	-	Pre-ICU and general population

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Halonen 2003(Finland)	Pancreatitis	12	-	Return to work	Author derived questionnaire	Across groups and general population
Herridge 2003(Canada)	ARDS	3, 6,12	-	Pulmonary function, CXR, 6 minute walk test, return to work	-	General population
Jones 2003(UK)	General ICU	2,6	-	-	HADS, Impact of Events scale, Fear Index	Across intervention groups and general population
Kaarlola 2003(Finland)	General ICU	72	-	Return to work, place of residence, ADL	-	12 months post-ICU and general population
Kress 2003(USA)	General ICU	6	-	-	Impact of Events scale, battery of psychological tests, interview	Across intervention groups
Kvale 2003(Norway)	General ICU	6	-	Karnofsky Index, return to work	Semi-structured interview, memories	General population
Maynard 2003(USA)	Acute renal failure	6	-	ADL	Willingness to undergo dialysis	General population

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Orme 2003(USA)	ARDS	12	Sickness Impact Profile	Pulmonary function tests	Beck Depression/ Anxiety Scale	Across groups and general population
Wehler 2003(Germany)	Multiple organ dysfunction	6	-	Return to work, place of residence	-	Across groups and general population
Boyle 2004(Australia)	General ICU	1,6	-	-	Pain scale, battery of psychiatric tests	Across groups and general population
Chelluri 2004(USA)	General ICU	12	-	ADL	-	Across groups and general population
Hopkins 2004(USA)	ARDS	12, 24	-	Neurocognitive tests	Beck Depression/ Anxiety Scale	General population
Kaarlola 2004(Finland)	General ICU	60	EQ-5D	-	-	Across groups and general population
Kapfhammer 2004 (Germany)	General ICU	Median 96	-	-	Interview, battery of psychiatric and neurocognitive tests	Across groups and general population
Cuthbertson 2005(UK)	General ICU	3, 6,12	EQ-5D	Return to work		Pre-ICU (proxy) and general population

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Euteneuer 2005(Germany)	Chronic respiratory failure	6	St George's Respiratory Questionnaire	-	-	Across groups and general population
Graf 2005(Germany)	Medical ICU	60	-	Authors' Health Status Index	Cost-utility	General population
Heyland 2005(Canada)	ARDS	3, 6,12	St George's Respiratory Questionnaire	Pulmonary function, Zubrod scale	Hospital costs	General population
Hopkins 2005(Canada)	ARDS	24	-	Battery of neurocognitive and psychological tests	-	General population
Kaarlola 2005(Finland)	General ICU	36	EQ-5D	-	-	Critically ill controls
Orwelius 2005(Sweden)	General ICU	6	EQ-5D	Return to work	Author-derived questionnaire	Local general population
Stricker 2005 (Switzerland)	Surgical ICU	12	-	-	-	Across groups and general population

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Boyle 2006(Australia)	General ICU	1, 6	-	-	Pain scale, Pain Self-Efficacy, Depression Scale	General population
Cheung 2006 (Canada)	ARDS	3, 6, 12, 18,24	-	Lung function, 6MWT,return to work	Health care use, costs	Across groups and general population
Deja 2006(Germany)	ARDS	57±32	-	-	PTSD inventory	Across groups and general population
Kaarlola 2006(Finland)	General ICU	36	EQ-5D	-	-	Critically ill controls
Noble 2006(UK)	Renal failure	12	-	-	-	Across treatment groups and general population
Parker 2006(Canada)	ARDS	12	St George's Respiratory Questionnaire	-	Spirometry	Across groups
Scales 2006(Canada)	ARDS	Proxy,3	-	-	-	Comparison with proxy estimations

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Sukantarat 2006(UK)	General ICU	3,9	-	-	Neurocognitive tests	Across groups and general population
Abelha 2007(Portugal)	Surgical ICU	6	-	ASA physical status, ADL, return to work	-	Across groups
Hofhuis 2007 (Netherlands)	General ICU	Admission (proxy), 6	-	-	-	Across groups
Khoudri 2007(Morocco)	Medical ICU	3	-	-	-	Across groups
Longo 2007(Canada)	Sepsis	1,3,5,7	-	Return to work	Healthcare use	Across groups and general population
Merlani 2007 Switzerland	Surgical ICU	24	EQ-5D	Functional state measure, place of residence	Author-derived items	General population

Combes 2008(France)	Cardiogenic shock	Median 11	-	-	-	General population and matched controls
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<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional ability</b>	<b>Other</b>	<b>Comparison group</b>
Hofhuis 2008 (Netherlands)	General ICU	Pre(proxy) 3,6	-	-	-	General population
Graf 2008(Germany)	General ICU	60	-	-	Hospital costs, QALYs	General population
Ringdal 2008(Sweden)	General ICU	6,18	-	-	HADS, ICU memory tool	Across groups and general population
Cuthbertson 2009(UK)	General ICU	12	EQ-5D	-	HADS	Across treatment groups and general population
Wright 2009(UK)	Pancreatitis	3,6,12	-	Six minute walk test	-	General population
Kancir 2010(Denmark)	Renal failure	6	-	ADL index	-	Across groups and general population

## Appendix 12: The EQ-5D

By placing a tick in one box in each group below, please indicate which statement best describes your own health state today. Do not tick more than one box in each group.

### Mobility

- I have no problems walking about
- I have some problems in walking about
- I am confined to bed

### Self-care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

### Usual activities

(e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

### Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

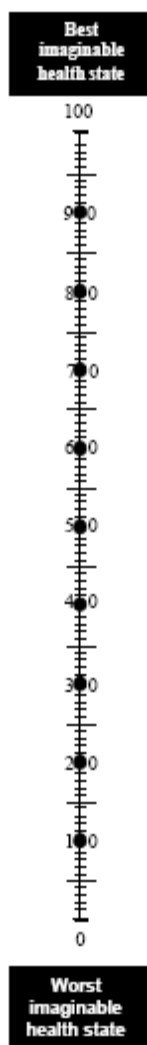
### Anxiety/Depression

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked by 0. We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line on the scale to indicate how good or bad your health state is.



### Appendix 13: The EQ-5D in critical care outcome studies

First author (origin)	Patient group	Follow up (months)	Other QoL measure	Functional measure	Other	Comparison groups
Diaz-Prieto 1998(Spain)	General ICU	N/A	-	-	-	Proxy estimations
Badia 2001(Spain)	General ICU	12	-	-	-	Across groups
Sznajder 2001(France)	General ICU	N/A	-	-	-	Cost-effectiveness analysis
Granja 2002(Spain)	General ICU	6	-	Return to work	-	Pre-ICU (recalled) HRQoL, across groups
Granja 2002(Spain)	Cardiac arrest	6	-	Return to work	-	Critically ill matched controls
Garcia 2003(Spain)	General ICU	18	-	Return to work	-	Across groups
Granja 2003(Spain)	ARDS	6	-	-	-	Pre-ICU (recalled) and critically ill controls
Lizana 2003(Brussels)	General ICU	18	-	Return to work	-	Across groups and recalled HRQoL
Granja 2004(Portugal)	Sepsis	12	-	Return to work	-	Pre-ICU (recalled) and critically ill controls

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional measure</b>	<b>Other</b>	<b>Comparison groups</b>
Kaarlola 2004(Finland)	Surgical ICU	Not known	SF-36	Return to work, place of residence	-	General population
Alhstrom 2005(Finland)	Renal failure	Median 29	-	-	Derivation of QALYs, cost analysis	General population
Cuthbertson 2005(UK)	General ICU	12	SF-36	Return to work	-	Pre-ICU (proxy) HRQoL, general population.
Orwelius 2005(Sweden)	General ICU	6	SF-36	-	-	Co-morbidity matched local general population
Capuzzo 2006(Italy)	General ICU	3	-	-	-	Pre-ICU (recalled) HRQoL and across groups
Edwards 2006(UK)	General ICU	N/A	-	-	Cost utility analysis	N/A
Jagodic 2006(Slovenia)	Sepsis and trauma	24	-	-	-	General population
Kaarlola 2006(Finland)	General ICU	36	-	-	Derivation of QALYs	Critically ill matched controls

<b>First author (origin)</b>	<b>Patient group</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Functional measure</b>	<b>Other</b>	<b>Comparison groups</b>
Merlani 2007 (Switzerland)	Abdominal pathology	24	SF-36	Functional status measure, place of residence	Preferences for ICU care	Across groups, general population
Ulvik 2008(Norway)	Trauma	24-84	-	-	-	Across groups, general population
Kaarlsson 2009(Finland)	Sepsis	Median 17	-	-	-	Pre-ICU (proxy) HRQoL

### Appendix 14: Use of the SF-36 among survivors of ARDS

<b>First author</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Physical function measure</b>	<b>Psychological measure</b>	<b>Neurocognitive measure</b>	<b>Other</b>
Schelling 1998(Germany)	Median 48	-	Return to work	PTSD Inventory	-	-
Davidson 1999(USA)	Median 23	St George's Respiratory Questionnaire	-	-	-	-
Hopkins 1999(USA)	12	-	-	-	Weschler Memory Scale, Rey Auditory Verbal Learning test, Rey- Osterrieth Complex Figure Test, Trail Making Tests, Verbal Fluency Test	-
Schelling 2000(USA)	62.5	-	Pulmonary function tests, return to work	-	-	-
Rothenhausler 2001(Germany)	Mean 77±38	-	Return to work	-	Cognitive performance	-
Herridge 2003(Canada)	3, 6,12	-	Pulmonary function, CXR, 6 minute walk test, return to work	-	-	-
Orme 2003(USA)	12	Sickness Impact Profile	Pulmonary function tests	Beck Depression/ Anxiety Scale		

**Appendix 14 (cont'd): Use of the SF-36 among survivors of ARDS**

<b>First author</b>	<b>Follow up (months)</b>	<b>Other QoL measure</b>	<b>Physical function measure</b>	<b>Psychological measure</b>	<b>Neurocognitive measure</b>	<b>Other</b>
Hopkins 2004(USA)	12, 24	-	-	Beck Depression/ Anxiety Scale	Weschler Memory Scale, Rey Auditory Verbal Learning test, Rey- Osterrieth Complex Figure Test, Trail Making Tests, Verbal Fluency Test	-
Heyland 2005(Canada)	3, 6,12	St George's Respiratory Questionnaire	Pulmonary function, Zubrod scale	-	-	Hospital costs
Hopkins 2005(Canada)	24	-	-	Battery of neurocognitive and psychological tests	-	-
Cheung 2006(Canada)	3,6,12,18,24	-	Pulmonary function tests, six minute walk test, return to work	-	-	Health care use, costs
Deja 2006(Germany)	57±32	-	-	PTSS-10	-	Questionnaire for Social Support, Symptom Checklist 90-R
Parker 2006(Canada)	12	St George's Respiratory Questionnaire	Spirometry	-	-	-
Scales 2006(Canada)	Proxy,3	-	-	-	-	-

### Appendix 15: Decrements in HRQoL (by dimension) among survivors of ARDS

Study (year)	Comparison	Follow up (months)	Physical function	Role physical	Bodily pain	General health	Vitality	Social function	Role emotional	Mental health
Weinert (1997)	General population	12	*↓	*↓	*↓	*↓	*↓	*↓	*↓	*↓
Schelling (1998)	Critically ill controls	48	*↓	*↓	*↓	*↓	*↓	*↓	*↓	*↓
Davidson (1999)	Critically ill controls	12	*↓	*↓	*↓	*↓	*↓	*↓	—	
Hopkins (1999)	General population	12	↓*	↓*	*↓	*↓	↓*	↓*	*↓	*↓
Schelling (2000)	General population	Median 62.5	*↓	*↓	—	*↓	—	—	—	—
Rothenhausler (2001)	General population	Median 72	*↓	*↓	*↓	*↓	*↓	*↓	*↓	
Orme (2003)	Critically ill controls	12	*↓	*↓	*↓	*↓	*↓	-	-	-
Herridge (2003)	General population	3	↓	↓	↓	↓	↓	↓	↓	↓
		6	↓*	Unchanged	↓*	↓*	↓*	↓*	↓*	↓*
		12	↓*	↓*	↓*	↓**	Unchanged	Unchanged	↓***	↓*

Study (year)	Comparison	Follow up (months)	Physical function	Role physical	Bodily pain	General health	Vitality	Social function	Role emotional	Mental health
Hopkins (2004)	General population	12	*↓	*↓	↓	↓	*↓	*↓	↓	*↓
		24	Unchanged	↓*	Unchanged	Unchanged	Unchanged	Unchanged	Unchanged	↓**
Heyland (2005)	General population	3	↓	↓	↓	↓	↓	↓	↓	↓
		6	↓*	↓*	↓*	↓**	↓*	↓*	↓*	Unchanged
		12	↓*	↓*	↓*	↓*	↓*	↓*	↓*	↓*
Cheung (2006)	General population	12	*↓	*↓	*↓	*↓	*↓	*↓	-	-
		24	*↓	*↓	*↓	*↓	*↓	*↓	-	-

↓ Reported decrement

\*↓ Statistically significant decrement

↓\* Remains below normative population, but increased from previous score

↓\*\* Remains below normative population, but decreased from previous score

↓\*\*\* Greater than normative score

N.b. It is not known whether these scores are statistically significant

## Appendix 16: Strengths and weaknesses of the quantitative approach to HRQoL measurement

<i>Strengths</i>	<ul style="list-style-type: none"> <li>• Testing hypotheses that are constructed before the data are collected.</li> <li>• Testing and validating already constructed theories about how (and to a lesser degree, why) phenomena occur.</li> <li>• Can generalize a research finding when it has been replicated on many different populations and subpopulations.</li> <li>• Can generalize research findings when the data are based on random samples of sufficient size.</li> <li>• Useful for obtaining data that allow quantitative predictions to be made.</li> <li>• The researcher may construct a situation that eliminates the confounding influence of many variables, allowing one to more credibly assess cause-and-effect relationships.</li> <li>• Data collection using some quantitative methods is relatively quick.</li> <li>• Provides precise, quantitative, numerical data.</li> <li>• Data analysis is relatively less time consuming (using statistical software).</li> <li>• The research results are relatively independent of the researcher (e.g., effect size, statistical significance).</li> <li>• It may have higher credibility with people in power (e.g., administrators, politicians, people who fund programmes).</li> <li>• It is useful for studying large numbers of people.</li> </ul>
<i>Weaknesses</i>	<ul style="list-style-type: none"> <li>• The researcher's theories may not reflect participants' understandings.</li> <li>• The researcher's categories may not reflect participants' understandings.</li> <li>• Knowledge produced may be too abstract and general for direct application to specific local situations, contexts, and individuals.</li> <li>• The researcher may miss out on other phenomena because of the focus on theory or hypothesis testing rather than on theory or hypothesis generation (the confirmation bias).</li> </ul>

Adapted from Johnson RB and Onwuegbuzie AJ (2004). Mixed Methods Research: A

research paradigm whose time has come. *Educational Researcher*; 33: 14-26

## Appendix 17: Attributes and criteria for reviewing HRQoL instruments

Attribute	Review criteria
<p><b>1. Conceptual and measurement model:</b> The rationale for and description of the concept and the populations that a measure is intended to assess and the relationship between these concepts</p>	<ul style="list-style-type: none"> <li>-Concept to be measured</li> <li>-Conceptual and empirical bases for item content and combinations</li> <li>-Target population involvement in content derivation</li> <li>-Information on dimensionality and distinctiveness of scales</li> <li>-Evidence of scale variability</li> <li>-Intended level of measurement</li> <li>-Rationale for deriving scale scores</li> </ul>
<p><b>2. Reliability:</b> The degree to which an instrument is free from random error</p>	
<p>(a) <i>Internal consistency:</i> The precision of a scale, based on the homogeneity of the scale's items at one point in time.</p>	<ul style="list-style-type: none"> <li>-Methods to collect reliability data</li> <li>-Reliability estimates and standard errors for all score elements or standard error of the mean over the range of scale and marginal reliability of each scale</li> <li>-Data to calculate reliability coefficients or actual calculations of reliability coefficients</li> <li>-Above data for each major population of interest, if any</li> </ul>
<p>(b) <i>Reproducibility:</i> Stability of an instrument over time (test-retest) and inter-rater agreement at one point in time.</p>	<ul style="list-style-type: none"> <li>-Methods employed to collect reproducibility data</li> <li>-Well argued rationale to support the design of the study and the interval between first and subsequent administration to support the assumption that the population is stable</li> <li>-Information on test-retest reliability and inter-rater reliability based on intraclass correlation coefficients</li> <li>-Information on the comparability of the item parameter estimates and on measurement precision over repeated administrations</li> </ul>
<p><b>3. Validity:</b> The degree to which the instrument measures what it purports to measure.</p>	<ul style="list-style-type: none"> <li>-Rationale supporting the particular mix of evidence presented for the intended uses</li> <li>-Clear description of the methods employed to collect validity data</li> <li>-Composition of the sample used to examine validity (in detail)</li> <li>-Above data for each major population of interest</li> </ul>
<p>(a) Content-related: Evidence that the domains of an instrument are appropriate relative to its intended use.</p>	
<p>(b) Construct-related: evidence that supports a proposed interpretation of scores based on theoretical implications associated with the constructs being measured.</p>	

## Appendix 17 (cont'd): Attributes and criteria for reviewing HRQoL instruments

Attribute	Review criteria
<p><b>3. Validity</b> (c) Criterion-related: evidence that shows the extent to which scores of the instrument are related to a criterion measure.</p>	
<p><b>4. Responsiveness:</b> An instrument's ability to detect change overtime.</p>	<ul style="list-style-type: none"> <li>-Evidence on the changes in scores of the instrument</li> <li>-Longitudinal data that compare a group that is expected to change with a group that is expected to remain stable</li> <li>-Population(s) on which responsiveness has been tested, including the time intervals of assessment, the interventions or measures involved in evaluating change, and the populations assumed to be stable</li> </ul>
<p><b>5. Interpretability:</b> The degree to which one can assign easily understood meaning to an instrument's quantitative scores.</p>	<ul style="list-style-type: none"> <li>-Rationale for selection of external criteria of populations for purposes of comparison and interpretability of data</li> <li>-Information regarding the ways in which data from the instrument should be reported and displayed</li> <li>-Meaningful 'benchmarks' to facilitate interpretation of the scores</li> </ul>
<p><b>6. Burden:</b> The time, effort, and other demands placed on those to whom the instrument is administered (respondent burden) or on those who administer the instrument (administrative burden).</p>	<p><b>(a) Respondent burden</b></p> <ul style="list-style-type: none"> <li>-Information on: (a) average and range of the time needed to complete the instrument (b) reading and comprehension level and (c) any special requirements or requests made of respondent</li> <li>-Evidence that the instrument places no undue physical or emotional strain on the respondent</li> <li>-When or under what circumstances the instrument is not suitable for respondents</li> </ul> <p><b>(b) Administrative burden</b></p> <ul style="list-style-type: none"> <li>-Information about any resources required for administration of the instrument</li> <li>-Average time and range of time required of a trained interviewer to administer the instrument in face-to-face interviews, by telephone, or with computer-assisted formats</li> <li>-Amount of training and level of education or professional expertise and experience needed by administrative staff</li> </ul>
<p><b>7. Alternatives modes of administration:</b> These include self-report, interviewer-administered, trained observer rating, computer-assisted interviewer-administered or performance-based measures.</p>	<ul style="list-style-type: none"> <li>-Evidence on reliability, validity, responsiveness, interpretability and burden for each mode of administration</li> <li>-Information on the comparability of alternative modes</li> </ul>

## Appendix 17 (cont'd): Attributes and criteria for reviewing HRQoL instruments

Attribute	Review criteria
<p><b>8.Cultural and language adaptations or translations:</b> This involves two primary steps</p> <p>1.Assessment of conceptual and linguistic equivalence</p> <p>2.Evaluation of measurement properties</p>	<ul style="list-style-type: none"> <li>-Methods to achieve conceptual equivalence</li> <li>-Methods to achieve linguistic equivalence</li> <li>-Any significant differences between the original and translated versions</li> <li>-How inconsistencies were reconciled</li> </ul>

Adapted from the Scientific Advisory Committee of the Medical Outcomes Trust (2002). Assessing health status and quality-of-life instruments: Attributes and review criteria. *Quality of Life Research*: 11; 193–205.

## Appendix 18: Reporting the results of QoL assessments in clinical trials

Item	Recommendation
<b>Title and authors</b>	<p>Concise, informative and correct title</p> <p>Nature of the study e.g. randomised, controlled, pilot, etc</p> <p>Authors and their institutional affiliations</p> <p>Key words for indexing purposes</p>
<b>Abstract</b>	<p>Purpose</p> <p>Patients and methods</p> <p>Key results</p> <p>Main conclusion(s)</p>
<b>Introduction</b>	<p>Objective(s)</p> <p>Reason (rationale)</p> <p>Appropriately comprehensive literature review and references</p> <p>Pre-trial QoL hypotheses</p> <p>Description of the disease(s) and treatment(s)</p>
<b>Patients and methods</b>	<p><b>Population and sample:</b></p> <p>Description of the population sample</p> <p>Inclusion and exclusion criteria</p> <p>Source of patient sample</p> <p>Requirement for consent form</p> <p>Planned effect size and required sample size</p> <p>Estimate of alpha error (test size) and power</p> <hr/> <p><b>QoL instrument selection:</b></p> <p>Type of assessment and its justification</p> <p>Method and instruments(s) used</p> <p>Psychometric properties, if not a well-known instrument</p> <p>Time frame of questions</p> <p>Scoring procedure</p> <p>Cross cultural adaptation if applicable</p> <hr/> <p><b>Trial size:</b></p> <p>Anticipated effect size</p> <p>Test size (alpha error) including one or two-sided power</p> <p>Number of subjects in each arm</p>

## Appendix 18 (cont'd): Checklist for reporting the results of QoL assessments in clinical trials

Item	Recommendation
<b>Patients and methods</b>	<p><b>Endpoints:</b></p> <p>Dimensions or items used as endpoints</p> <p>Other endpoints of the study</p>
	<p><b>Timing of study assessments:</b></p> <p>Schedule of assessments before, during and after treatment (or other intervention), including frequency of follow-up assessments</p>
	<p><b>Data:</b></p> <p>Method of collecting data</p> <p>Procedures for quality control</p> <p>Definition of adequate data</p> <p>Definition of missing data</p>
	<p><b>Method of analysis:</b></p> <p>Missing data defined and explained</p> <p>Statistical methods</p> <p>Endpoints analysed</p> <p>Adjustments made (if any) for multiple comparisons</p> <p>Definition of a clinically important difference</p> <p>Planned effect size and required sample size</p> <p>Estimate of alpha error (test size) and power</p> <p>Adjustment for multiple comparisons</p>
<b>Results</b>	<p><b>Presentation of data:</b></p> <p>All QoL presented</p> <p>Time required for accrual</p> <p>Median follow-up time</p>
	<p><b>Patient data: number of patients</b></p> <p>Accrued and their demography</p> <p>Eligible and entered</p> <p>Excluded from analysis with reasons</p> <p>With inadequate data</p> <p>With missing data with reasons</p> <p>Adequately followed</p> <p>Lost to follow up</p>

## Appendix 18 (cont'd): Checklist for reporting the results of QoL assessments in clinical trials

Item	Recommendation
<b>Results</b>	<b>Patient data: number of patients (cont'd)</b>
	Who died during the trial Adequately treated according to protocol Failed to complete the treatment according to protocol Who received treatments not specified in the protocol
	<b>Scheduling of instrument administration:</b> Actual schedule followed
	<b>Missing data and compliance:</b> Missing data documented fully with reasons ( e.g. death) Missing for other reasons, missing due to incomplete response to items on questionnaires Compliance data i.e. number of questionnaires Completed out of the number expected, number of items completed out of the number expected
	<b>Statistical analysis:</b> Main hypotheses Description of secondary (exploratory) analyses Number of interim analyses, if any Censoring mechanisms
<b>Discussion and conclusions</b>	Importance of any observed changes in QoL Generalisability of the results Clinical meaning of the results Relationship of the results to those of other, similar studies Summary of therapeutic results How results advance knowledge in the field
<b>References</b>	All necessary references Format conforms with journal style Key words
<b>Appendices</b>	Copy of instruments used in the study, if appropriate/applicable and characteristics

Adapted from Staquet M, Berzon, R, Osoba, D and Machin D (1996). Guidelines for reporting the results of quality of life assessments in clinical trials. *Quality of Life Research*; 5: 496-502

## Appendix 19: Strengths and weaknesses of qualitative approaches to HRQoL

<b><i>Strengths</i></b>	<ul style="list-style-type: none"> <li>• The data are based on the participants' own categories of meaning.</li> <li>• Useful for studying a limited number of cases in depth.</li> <li>• Useful for describing complex phenomena.</li> <li>• Provides individual case information.</li> <li>• Can conduct cross-case comparisons and analysis.</li> <li>• Provides understanding and description of people's personal experiences of phenomena.</li> <li>• Can describe, in rich detail, phenomena as they are situated and embedded in local contexts.</li> <li>• The researcher identifies contextual and setting factors as they relate to the phenomenon of interest.</li> <li>• The researcher can study dynamic processes (i.e. documenting sequential patterns and change).</li> <li>• The researcher can use the primarily qualitative method of "grounded theory" to generate inductively a tentative but explanatory theory about a phenomenon.</li> <li>• Can determine how participants interpret "constructs"</li> <li>• Data are usually collected in naturalistic settings in qualitative research.</li> <li>• Qualitative approaches are responsive to local situations, conditions, and stakeholders' needs.</li> <li>• Qualitative researchers are responsive to changes that occur during the conduct of a study (especially during extended fieldwork) and may shift the focus of their studies as a result.</li> <li>• Qualitative data in the words and categories of participants lend themselves to exploring how and why phenomena occur.</li> <li>• One can use an important case to demonstrate vividly a phenomenon to the readers of a report.</li> <li>• Determine idiographic causation (i.e., determination of causes of a particular event).</li> </ul>
<b><i>Weaknesses</i></b>	<ul style="list-style-type: none"> <li>• Knowledge produced may not generalize to other people or other settings (i.e., findings may be unique to the relatively few people included in the research study).</li> <li>• It is difficult to make quantitative predictions.</li> <li>• It is more difficult to test hypotheses and theories.</li> <li>• It may have lower credibility with some administrators and commissioners of programs.</li> <li>• It generally takes more time to collect the data when compared to quantitative research.</li> <li>• Data analysis is often time consuming.</li> <li>• The results are more easily influenced by the researcher's personal biases and idiosyncrasies.</li> </ul>

Adapted from Johnson RB and Onwuegbuzie AJ (2004). Mixed Methods Research:

A research paradigm whose time has come. *Educational Researcher*; 33: 14-26

### Appendix 20a: Criteria for evaluating qualitative research (methods)

<b>Methods</b>	1. Are the methods appropriate to the question being asked?	a. Does the research seek to understand processes or structures, or illuminate subjective experiences or meanings?	b. Are the categories or groups being examined of a type which cannot be pre-selected, or the possible outcomes cannot be specified in advance?	c. Could a quantitative approach have addressed the issue better?
	2. Is the connection to an existing body of knowledge or theory clear?	a. Is there adequate reference to the literature?	b. Does the work cohere with, or critically address, existing theory?	
	3. Are there clear accounts of the criteria used for the selection of subjects, and of the data collection and analysis?			
	4. Is the selection of cases theoretically justified?	a. The unit of research may be people, events, institutions, etc. Is it clear what population the sample refers to?	b. Is consideration given to whether the units chosen were unusual in some important way?	
	5. Does the sensitivity of the methods meet the needs of the research questions?	a. Does the method accept the implications of an approach which respects the perceptions of those studied?	b. To what extent are any definitions or agendas taken for granted, rather than being critically examined or left open?	c. Are the limitations of any structured interview method considered?
	6. Has the relationship between researcher and subject been considered, and is there evidence that the research was presented and explained to its subjects?	a. If more than one researcher was involved, has comparability been considered?	b. Is there evidence about how the subjects perceived the research?	c. Is there any evidence about how any group processes were conducted?
	7. Was the data collection and record-keeping systematic?	a. Were careful records kept?	b. Is the evidence available for independent examination?	c. Were full records or transcripts of conversations used if appropriate?

Adapted from Seale C (2000). Criteria for the Evaluation of Qualitative Research Papers: 189-190. In *The Quality of Qualitative Research*. Sage, London.

### Appendix 20b: Criteria for evaluating qualitative research (analysis)

<b>Analysis</b>	1. Is reference made to accepted procedures for analysis?	a. Is it clear how the analysis was done?	b. Has its reliability been considered, ideally by independent repetition?
	2. How systematic is the analysis?	a. What steps were taken to guard against selectivity in the use of data?	b. In research with individuals, is it clear that there has not been selection of some cases and ignoring less interesting ones?
	3. Is there adequate discussion of how themes, concepts and categories were derived from the data?	a. It is sometimes inevitable that externally given or predetermined descriptive categories are used, but have they been examined for their real meaning or any possible ambiguities?	
	4. Is there adequate discussion of the evidence both for and against the researcher's evidence?	a. Is negative data given? Has there been any search for cases which might refute the conclusions?	
	5. Have measures been taken to test the validity of the findings?	a. For instance, have methods such as feeding them back to respondents, triangulation, or other procedures such as grounded theory been used?	
	6. Have any steps been taken to see whether the analysis would be comprehensible to respondents, if this is possible and relevant?	a. Has the meaning of their accounts been explored with respondents? Have apparent anomalies and contradictions been discussed withy them, rather than assumptions being made?	

Adapted from Seale C (2000). Criteria for the Evaluation of Qualitative Research Papers: 190-191. In *The Quality of Qualitative Research*. Sage, London.

### Appendix 20c: Criteria for evaluating qualitative research (presentation)

<b>Presentation</b>	1. Is the research clearly contextualised?	a. Has all the relevant information about the setting and subjects been supplied?	b. Are the variables being studied integrated in their social context, rather than abstracted and contextualised?	
	2. Are the data presented systematically?	a. Are quotations, field notes, etc identified in such a way that enables the reader to judge the range of evidence used?		
	3. Is a clear distinction made between the data and their interpretation?	a. Do the discussions follow from the data?		
	4. Is sufficient of the original evidence presented to satisfy the reader of the relationship between the evidence and the conclusions?	a. Though the presentation of discursive data always requires more space than numerical data, is the paper as concise as possible?		
	5. Is the author's own position clearly stated?	a. Is the researcher's perspective described?	b. Has the researcher examined his or her own role, possible bias and influence on the research?	
	6. Are the results credible and appropriate?	a. Do they address the research questions (s)	b. Are they plausible and coherent?	c. Are they important, either theoretically or practically?

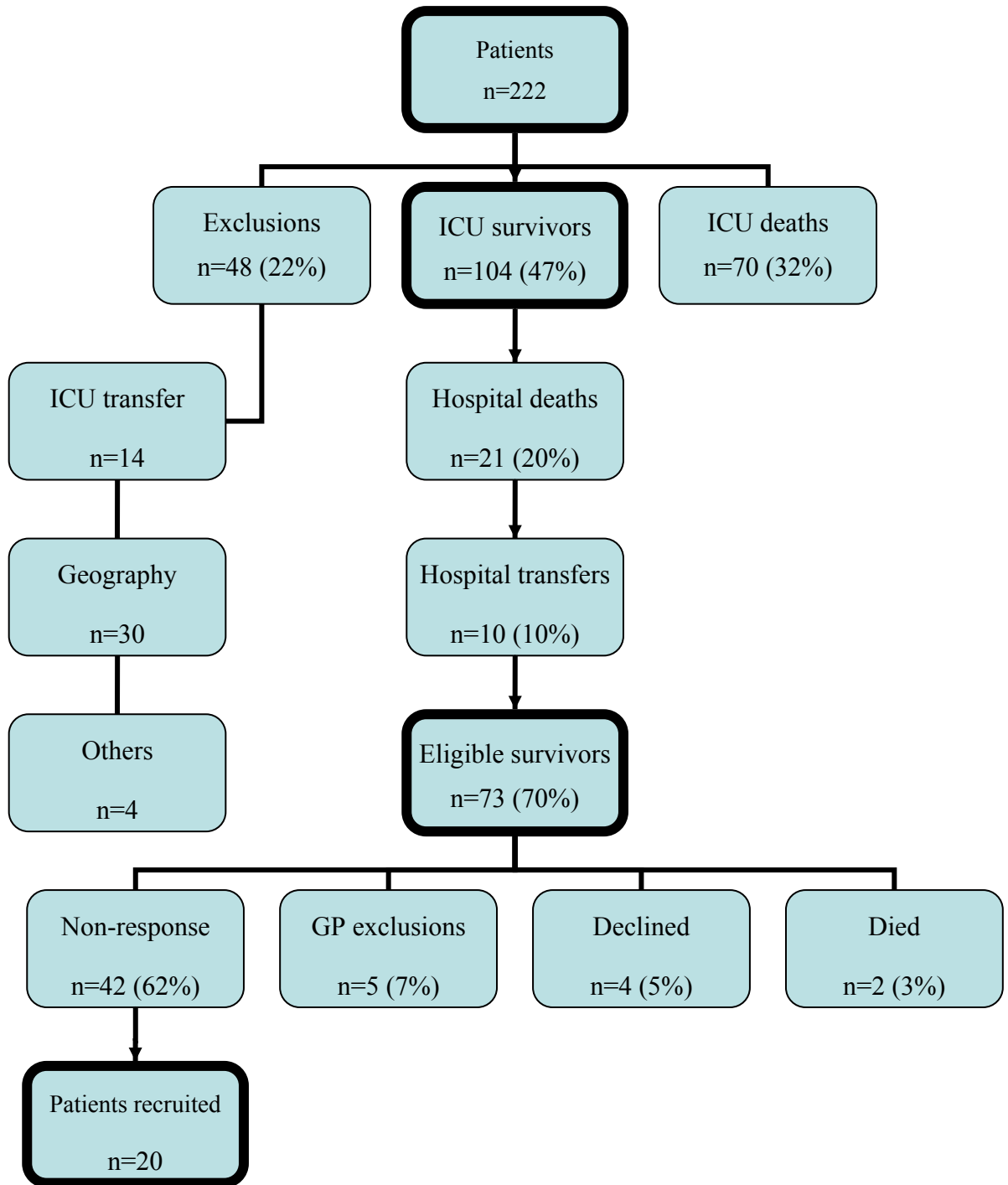
Adapted from Seale C (2000). Criteria for the Evaluation of Qualitative Research Papers: 191-192. In *The Quality of Qualitative Research*. Sage, London.

## Appendix 21: Strengths and weaknesses of mixed methods approaches to HRQoL

<i>Strengths</i>	<ul style="list-style-type: none"> <li>• Words, pictures, and narrative can be used to add meaning to numbers.</li> <li>• Numbers can be used to add precision to words, pictures, and narrative.</li> <li>• The researcher can generate and test a grounded theory.</li> <li>• Can answer a broader and more complete range of research questions because the researcher is not confined to a single method or approach.</li> <li>• The specific mixed research designs discussed in this article have specific strengths and weaknesses that should be considered (e.g. in a two-stage sequential design, the Stage 1 results can be used to develop and inform the purpose and design of the Stage 2 component).</li> <li>• A researcher can use the strengths of an additional method to overcome the weaknesses in another by using both in a research study.</li> <li>• Can provide stronger evidence for a conclusion through convergence and corroboration of findings.</li> <li>• Can add insights and understanding that might be missed when only a single method is used.</li> <li>• Can be used to increase the generalisability of the results.</li> <li>• Qualitative and quantitative research used together produce more complete knowledge necessary to inform theory and practice.</li> </ul>
<i>Weaknesses</i>	<ul style="list-style-type: none"> <li>• Can be difficult for a single researcher to carry out both qualitative and quantitative research, especially if two or more approaches are expected to be used concurrently.</li> <li>• The researcher has to learn about multiple methods and approaches and understand how to mix them appropriately.</li> <li>• Methodological purists contend that one should always work within either a qualitative or a quantitative paradigm.</li> <li>• More expensive.</li> <li>• More time consuming.</li> <li>• Some of the details of mixed research remain to be worked out fully by research methodologists (e.g. problems of paradigm mixing, how to qualitatively analyze quantitative data, how to interpret conflicting results).</li> </ul>

Adapted from Johnson RB and Onwuegbuzie AJ (2004). Mixed Methods Research: A research paradigm whose time has come. *Educational Researcher*; 33: 14-26

## Appendix 22: Eligibility of patients for study inclusion at RIE and WGH (1.1.06-21.11.07)



## Appendix 23: Copy of GP letter

Dept. of Anaesthesia and Critical Care (Research)

Room GU 309

Chancellor's Building

Royal Infirmary of Edinburgh

51 Little France Crescent

Edinburgh

EH16 4SA

Tel: 0131 242 6396

Dear Dr \_\_\_\_\_

Regarding your patient: \_\_\_\_\_ (DOB XX.XX.19XX)

Mr/Mrs \_\_\_\_\_ was recently discharged from the Intensive Care Unit of the Royal Infirmary of Edinburgh and required prolonged mechanical ventilation ( $\geq 14$  days' duration) as part of his/her treatment. I am writing to ask if there is any reason why I should not approach this patient to request participation in the following study: "An exploratory study into quality of life measures among survivors of critical illness and prolonged mechanical ventilation"

This study involves administering a number of health-related quality of life questionnaires and participation in a semi-structured interview regarding the recovery process. Questionnaire completion and interview should take around an hour. The primary aim of the study is to explore the prevalence of health concerns of this patient group during the recovery process and their relative importance in daily life. This pilot study will inform a much larger prospective study which will identify changes in health service provision that might improve recovery rates and help improve patient-centred evaluation of interventional trials. The study is observational and does not alter routine therapy.

I would be grateful if you would forward the enclosed letter of invitation to the patient in the pre-paid envelope provided, if you feel it is appropriate to do so. I have enclosed a copy of the Patient's Information Sheet for your reference. If, sadly, the patient has subsequently died, or you consider it inappropriate to approach the patient for potential inclusion, I'd be grateful if you would return the enclosed form to me in the pre-paid envelope. If you would like more information, please don't hesitate to contact me at the above address. Thank you for your assistance in this research.

Yours sincerely

Pam Ramsay

(Principal Investigator)

## **Appendix 24: Copy of Patient Information Sheet**

Version 1 (4<sup>th</sup> of April, 2005)

**Title of Project:** An exploratory study into quality of life measures among survivors of critical illness and prolonged mechanical ventilation

### **Summary of the study:**

- You were recently discharged from the Intensive Care Unit of the Royal Infirmary of Edinburgh
- As part of your treatment while you were ill, you were on a ventilator (“breathing machine”) for a prolonged period of time (more than 14 days).
- Often, patients who have needed to be on the breathing machine for this period of time take a long time to recover from their illness.
- We are very interested in finding out more about your health concerns following discharge from hospital. This will allow us to offer more useful support to patients in the future who have had similar experiences to your own.
- We are also very interested in finding out which aspects of the recovery process have been most troublesome for you. This will help us to develop ways in which we might improve the recovery process of patients who have had similar experiences.
- We would like to do this by asking you to discuss your recovery with a member of our research team.
- This may take up to an hour of your time.
- To do this, we would like to invite you to the Wellcome Trust Clinical Research Facility at the Royal Infirmary of Edinburgh. We will provide transport by taxi to and from your home.
- If it is more convenient for you, a member of our research team can visit you at home.

**Person in charge of the research:**

Ms Pam Ramsay  
Research Fellow  
Dept of Anaesthetics and Critical Care (Research)  
Room GU 309  
Chancellor's Building  
Royal Infirmary of Edinburgh  
Little France  
Edinburgh  
EH16 4SA  
Tel. 0131 242 6396

**Introduction to the project**

You were recently discharged from the Intensive Care Unit, and are hopefully recovering well at home. As part of normal treatment during your illness, you required a long period of support (more than 14 days) on a ventilator ("breathing machine"). It is common for patients who have been very seriously ill and who have required this level of breathing support to have a number of health problems following their return home. For some patients, the recovery process is difficult and may take quite some time. Others recover relatively quickly and resume normal life. We currently know very little about how well or how quickly people recover. We would like to know more about this, so that in the future we might offer specific support and develop ways of improving the rate of recovery for patients who have had similar experiences to your own.

The aim of this research is for us to gain a better understanding of the problems patients experience following a critical illness. We would like to know more about how well you are recovering, and which aspects of your recovery have been particularly frustrating or upsetting for you. In order to do this, we would like to invite you to discuss various aspects of the recovery process with a member of our research team.

So that we might analyse this discussion in more detail at a later date, we would like to tape-record the discussion. Your details will be kept entirely anonymous in accordance with many of the rules surrounding this type of research.

In order for us to gain a fuller understanding of any issues you may have, a member of our research team will ask you specific questions, and you will also have the opportunity to discuss any important problems you have experienced in your recovery to date. In total, this may take up to an hour of your time. We will not contact you again, unless you have any specific problems you would like to discuss with us.

We would like to invite you to the Wellcome Trust Clinical Research Facility at the Royal Infirmary of Edinburgh for the purposes of “informal interview”. We will provide transport (by taxi) to and from the Royal Infirmary. If it is more convenient for you, a member of our research team will visit you at home.

#### **What will happen if I consent to take part in the study?**

This is an observational study, which means that if you agree to take part it will not change your treatment in any way.

#### **What will be done with the information obtained?**

At the end of the study we will analyse the information we have collected, with the aim of finding out which health problems are the most common and the most troublesome amongst patients who have had similar experiences to your own. We will work very closely with staff of the University of Edinburgh to do this. The information will be used to help us develop more effective ways of supporting patients through the recovery process.

We may need to examine your medical notes during the study to document information about your illness. Data collection will only be done by doctors and nurses directly involved in the study and the information collected will be kept anonymous. If you would like to receive the results of this study when they are available, we can arrange to send them to you.

**Do I have to agree?**

No. You do not have to agree to take part in this study. In addition, you can withdraw your participation in the study at any time without having to give a reason.

**What do I have to do now?**

You can think about whether you are happy to take part in the study. If you have more questions we will be happy to discuss them with you. You may discuss the study with a member of our research team by telephone (details on page 1) or by letter if you prefer. If you agree, we will ask you to sign a form that confirms that we have explained the study to you, that you were able to ask any questions, and that you were happy to participate. You will receive a copy of the consent form to keep. If you agree to the study, we will write to your General Practitioner to inform them that you have taken part in this study. This is routine practice, but we will only do this if you agree.

**Disclaimer**

If you are harmed through taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been treated during the course of this study, the normal Health Service complaints mechanism may be available to you or your relatives.

**Additional Information**

If you would like to discuss this study with a doctor who is not involved in it we can arrange this. The doctor who has agreed to do this is:

Dr David Swann

Consultant in Anaesthetics and Intensive Care

Edinburgh Royal Infirmary

Little France

Edinburgh

EH16 4SA

Tel: (0131) 242 1187/8/9

## Appendix 25: GP checklist

An exploratory study into quality of life measures among survivors of critical illness  
and prolonged mechanical ventilation (Version 2, 15<sup>th</sup> June 2005)

Re Mr/Mrs/Miss \_\_\_\_\_ (DOB \_\_\_\_\_)

*Please tick the box accordingly*

This patient has died

Do you know of any reason why this patient should NOT be approached

for inclusion in this study? (Y/N)

Comments?.....

.....

I have forwarded the Patient Information Sheet to the patient's address

**Please return in the stamped addressed envelope to:**

Pam Ramsay  
Research Co-ordinator in ICU  
Room GU 309  
Chancellor's Building  
Royal Infirmary of Edinburgh  
51, Little France Crescent  
Edinburgh  
EH16 4SA

### Appendix 26: A “potted history” of the research participants

Name	Age	Previous medical history	Admitting illness	ICU stay (days)	Ward stay (days)	Discharge destination	Social circumstances
Albert	78	Enlarged prostate, stroke	Abdominal sepsis	23	69	Convalescence	Married, living with spouse. Retired.
Andy	54	Alcohol excess	Pancreatitis	47	40	Home	Single, living alone. Previously unemployed.
Anne	77	Angina, deep venous thrombosis, diverticular disease, nephrectomy, TB, osteoporosis, pulmonary embolus, rheumatoid arthritis,	Pneumonia	26	18	Home	Married, living in fully adapted sheltered accommodation with spouse and adult children.
Arthur	73	Hiatus hernia	Cardiac failure	38	25	Home	Single, living alone. Retired.
Betty	69	Angina, chronic renal impairment, lupus, hypercholesteraemia, hysterectomy, irritable bowel syndrome, Meniere’s disease, osteoporosis, Reynaud’s disease, Sjogren’s syndrome.	Pneumonia	49	59	Convalescence	Married, living with spouse. Retired.
Christine	53	Nil of note	Septicaemia	32	23	Rehabilitation centre	Married, living with spouse and adult son. Previously in full-time employment.

<b>Name</b>	<b>Age</b>	<b>Previous medical history</b>	<b>Admitting illness</b>	<b>ICU stay (days)</b>	<b>Ward stay (days)</b>	<b>Discharge destination</b>	<b>Social circumstances</b>
Dave	32	Hypercholesteraemia	Pancreatitis	29	10	Home	Married, living with spouse and young son. Previously in full-time employment.
Don	74	Myaesthesia gravis	Myaesthesia gravis	26	32	Rehabilitation centre	Married, living with spouse. Retired.
Elizabeth	61	Alcohol excess, hypertension, hypothyroidism	Oesophageal tear (malignancy)	42	59	Home	Married, living with spouse. Retired.
Frank	60	Alcohol excess, hepatitis, Parkinson's disease	Pneumonia	22	11	Home	Married, living with spouse. Previously in full-time employment.
Ian	56	Alcohol excess, scoliosis, emphysema, arthritis	Pneumonia	30	15	Rehabilitation centre	Divorced, living alone. Unemployed, on Disability Allowance.
Jane	51	Alcohol excess	Pneumonia	32	18	Home	Single, living with friend. Previously unemployed.
James	65	Peripheral vascular disease, bladder cancer	Necrotising fasciitis of the neck	46	35	Home	Married, living with spouse. Retired.
John	49	Alcohol excess	Pneumonia	37	9	Rehabilitation centre	Single, living alone. Previously in full-time employment.

<b>Name</b>	<b>Age</b>	<b>Previous medical history</b>	<b>Admitting illness</b>	<b>ICU stay (days)</b>	<b>Ward stay (days)</b>	<b>Discharge destination</b>	<b>Social circumstances</b>
Ken	71	Hiatus hernia	Ruptured aortic aneurysm	65	46	Rehabilitation centre	Married, living with spouse. Retired.
Lynne	25	Asthma, tonsillectomy	Pneumonia	61	16	Home	Single, living with friends. Previously in full-time employment.
Pat	47	Alcohol excess	Pneumonia (post hip replacement)	27	50	Home	Single, living alone. Previously unemployed.
Robert	74	Alcohol excess, cancer of the nose, chronic obstructive airways disease, knee replacement, diverticular disease	Septic shock	17	14	Home	Married, living with spouse. Retired.
Roy	63	Coronary artery bypass surgery, depression, rheumatoid arthritis, gastrointestinal ulcer	Pneumonia (following hip replacement)	25	17	Home	Divorced, living temporarily with adult son Previously in full-time employment.
Sandra	67	Breast cancer (bilateral mastectomy), cardiac failure hypertension, pulmonary embolus	Pneumonia	19	19	Home	Married, living with spouse. Retired.

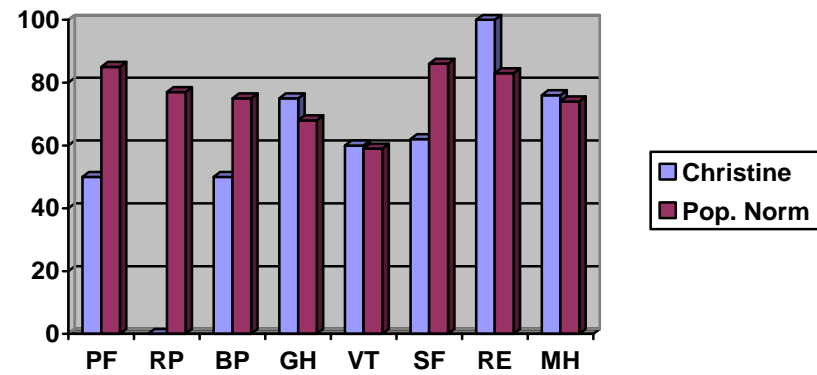
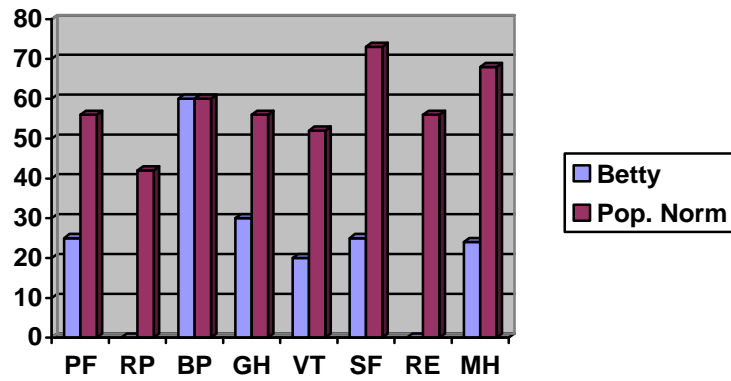
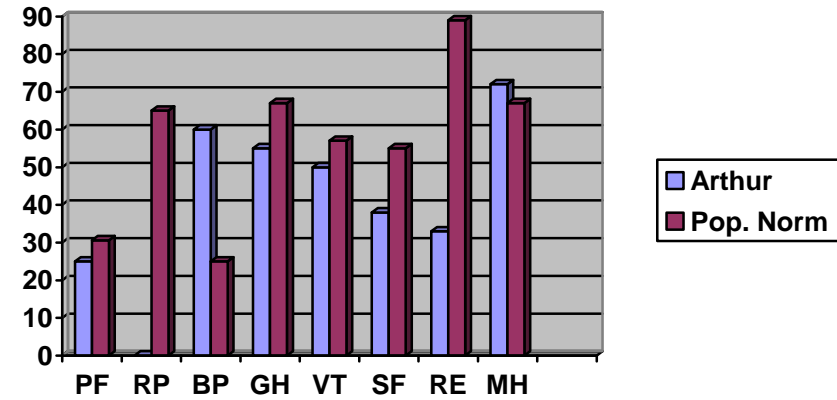
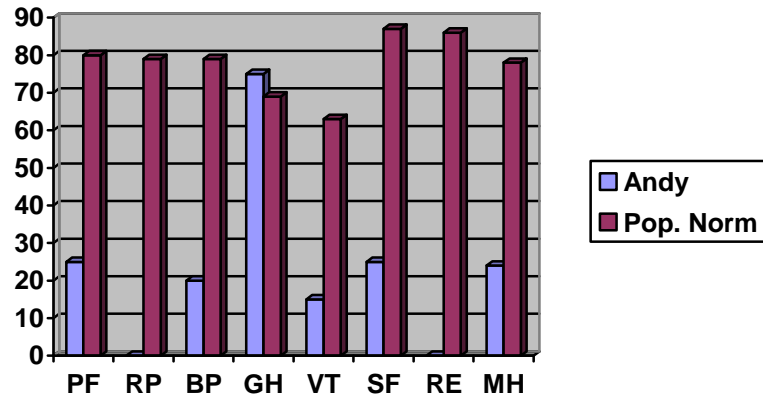
## Appendix 27: The interview topic guide

Stage in the critical illness journey	General questions	“Prompts & Probes”
Life before critical illness	Can you tell me a little bit about what life was like for you before you came ill?	Marital status/living arrangements Employment status Children (young/adult, living nearby) What kinds of things did you like to do in your spare time?
	How would you describe your general health before all of this?	Any long-standing illnesses? How did that/they affect you in your everyday life?  Any other “health” issues, even if they didn’t bother you too much in your everyday life?
ICU admission	What’s your understanding of how you ended up in Intensive Care?	You might not remember much. What have you been able to piece together from what other people have told you?
	What can you remember about your time in Intensive Care?	You might not remember much. What have you been able to piece together from what other people have told you?
Ward life	How did you feel when you were first transferred to the ward?	Some people find see it as a positive step, while others find it more difficult...
	What were your general impressions of the care you received on the ward?	How would you describe your time on the ward?  Can you think of something which was typical of good nursing care? And “not so good” nursing care?
	In terms of helping you getting you back to normal, what kind of help did you get on the ward?	What were your general impressions of the physiotherapy you received, for example?
	What else could/should have been done, in your opinion, at the time? And thinking back?	
Hospital discharge	How did the decision come about that you were ready to go home?	

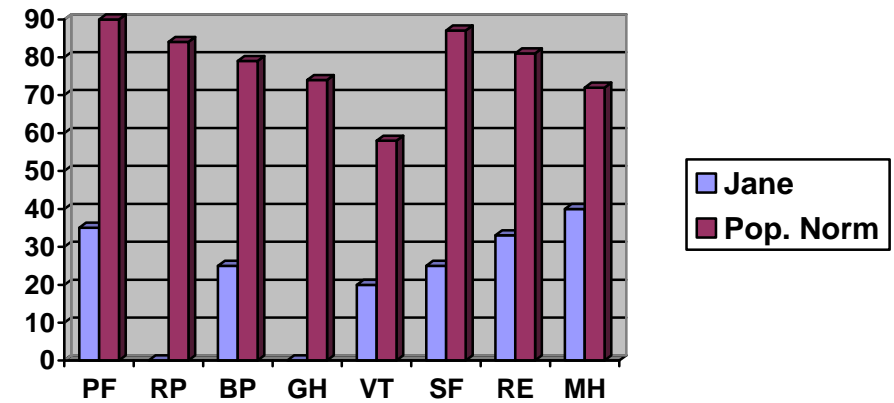
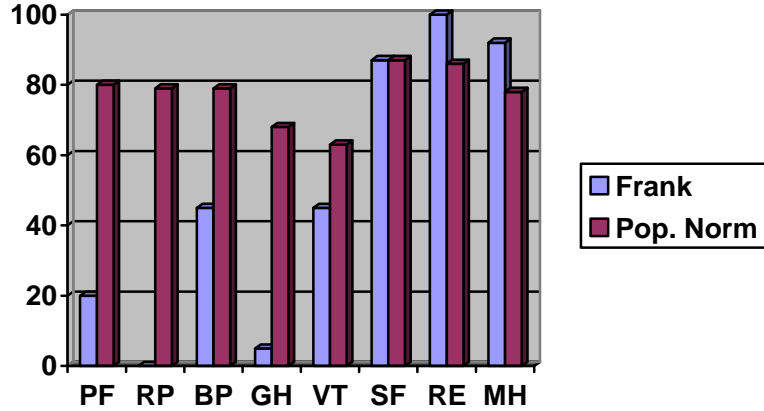
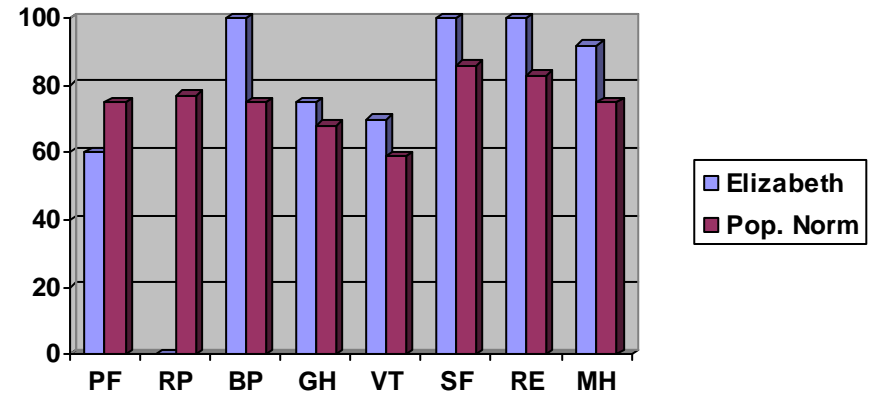
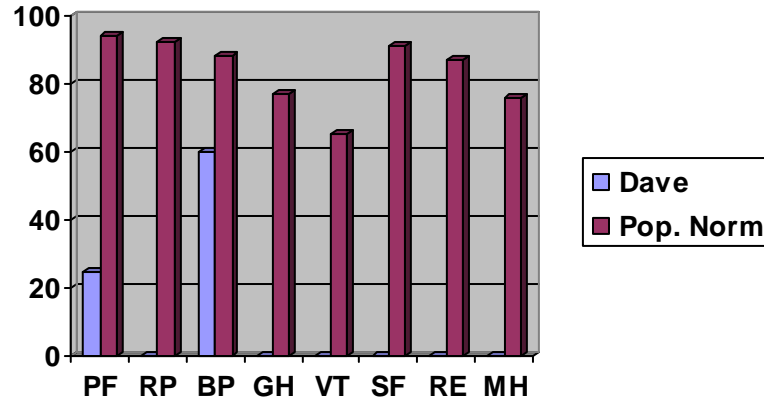
### Appendix 27 (cont'd): The interview topic guide

Stage in the critical illness journey	General questions	“Prompts & Probes”
Hospital discharge	How involved were you in those types of discussions?	Did the staff discuss your home circumstances with you, for example?
	Did you feel <i>ready</i> to go home?	<p>In what way did you feel ready?</p> <p>What sorts of arrangements were made to make sure you had the help you needed when you got home?</p> <p>What else could/should have been done, in your opinion, at the time? And thinking back?</p>
Immediate post-discharge	How did you get on when you first got home?	<p>A lot of people find the first few weeks at home quite difficult...</p> <p>What kind of difficulties did you have?</p> <p>Was it more difficult for you, do you think, because you live alone?</p> <p>What kinds of help did you need from your nearest and dearest?</p>
Now	<p>Thinking back to how things were for you before all of this, what kinds of things are you able/not able to do that you did before?</p> <p>How do you feel now about what happened to you?</p>	In what ways have you been able to get back to the things you did before?
The future	In terms of getting back to how you were before your illness, how much better do you hope or expect to get?	

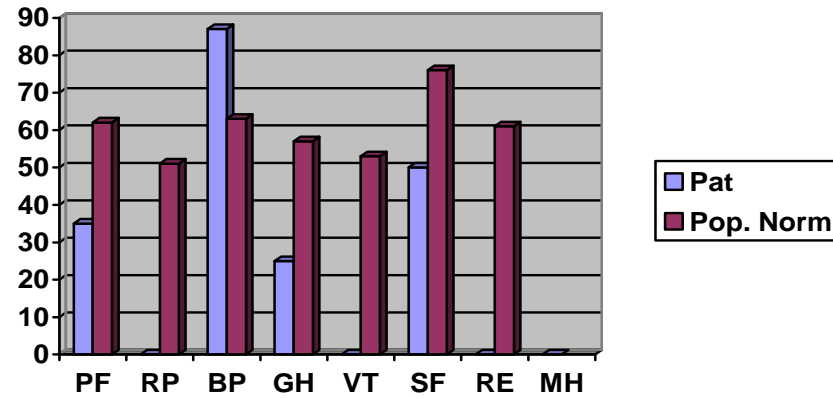
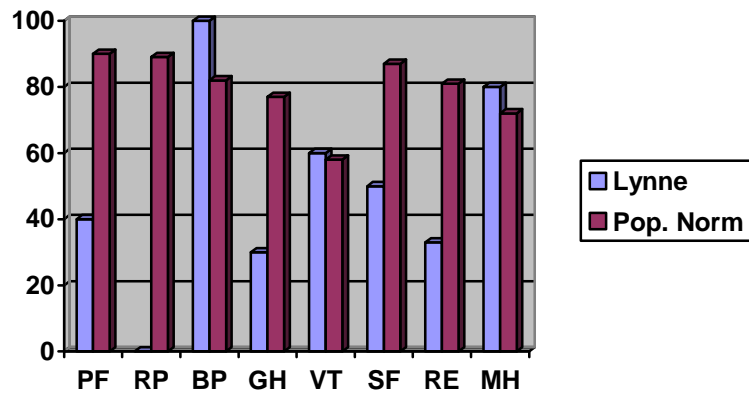
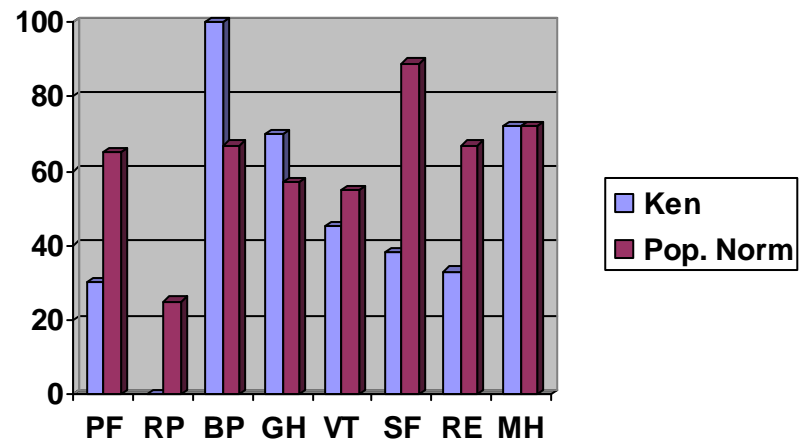
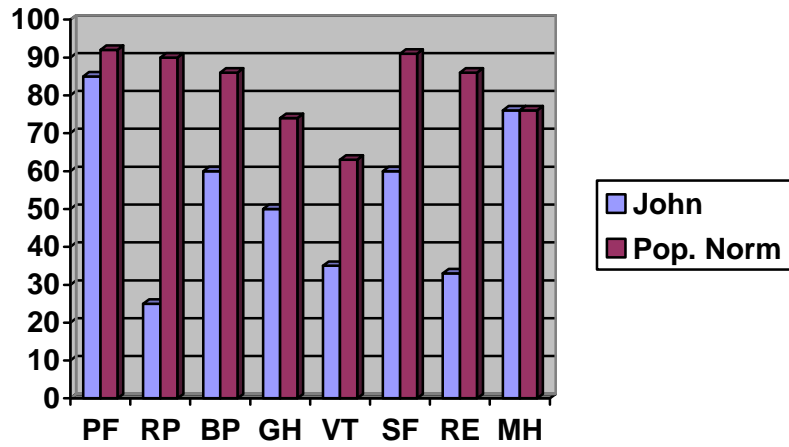
## Appendix 28: Individual level HRQoL data



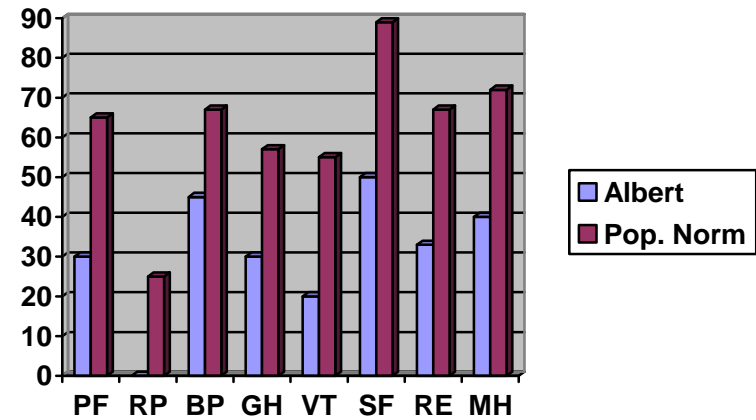
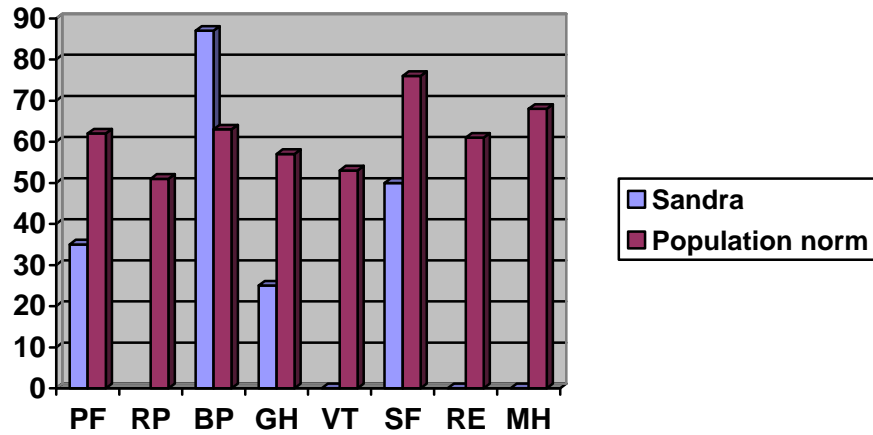
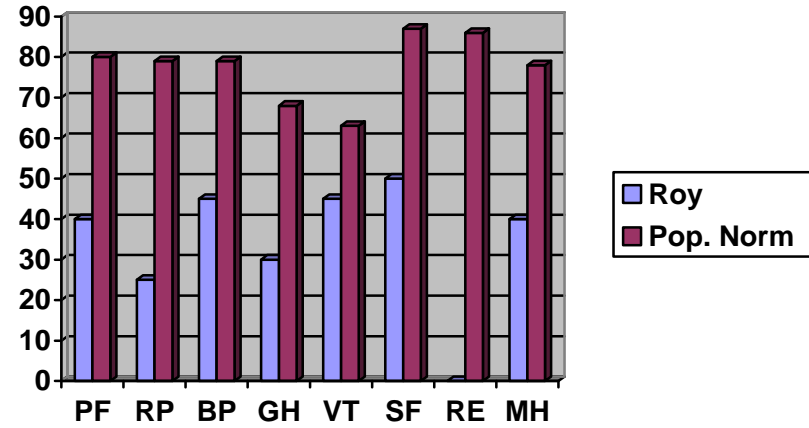
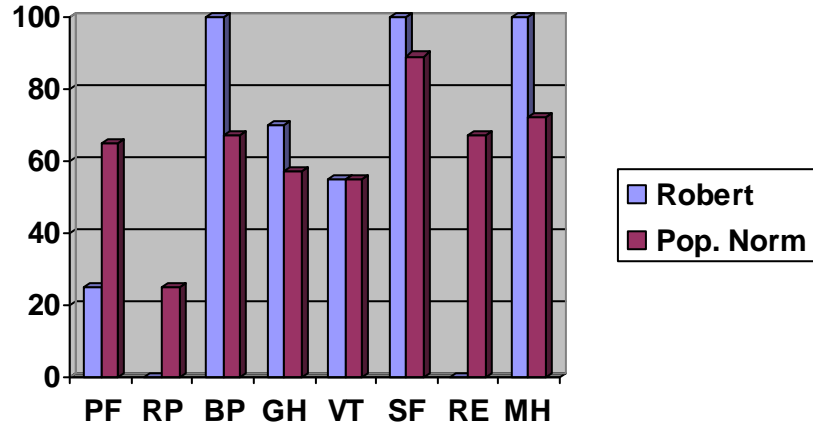
### Appendix 28 (cont'd): Individual level HRQoL data



### Appendix 28 (cont'd): Individual level HRQoL data



### Appendix 28 (cont'd): Individual level HRQoL data



## Appendix 29: Structured probes in cognitive interviewing

Potential source of error	Probe(s)
<b>Instructions;</b> Conflicting, complex or inaccurate instructions, introductions or explanations	Before I get to the actual question, tell me what this introduction is telling you to do?
<b>Clarity;</b> Identify problems related to communicating the <i>intent</i> or <i>meaning</i> of the question to the respondent	
The question is lengthy, awkward, ungrammatical or contains complicated syntax	Can you tell me in your own words what that question was asking?
Technical terms are undefined, unclear or complex	What does the word/term mean to you as it's used in the question?
There are multiple ways to interpret the question or to decide what is to be included/excluded	Tell me what you were thinking when I asked you about that?
Reference periods are missing, not well specified or in conflict	Can you remember what time period the question was asking about?
	You said (answer). What time period does that cover?
<b>Assumptions;</b> Determine if there are problems with assumptions made or the underlying logic	
Inappropriate assumptions are made about the respondent or his/her living situation	How well does that situation apply to you? Can you tell me more about that?
Assumes constant behaviour or experience for situations that vary	Would you say that mostly stays the same, or does it vary or depend?
Double-barrelled questions, containing more than one implicit answer	Tell me more about your opinions on that?

## Appendix 29(cont'd): Structured probes in cognitive interviewing

Potential source of error	Probe(s)
<b>Knowledge/memory;</b> Check whether respondents are likely to not know or have trouble remembering information	
Knowledge; the respondent is unlikely to know the answer to a factual question	How much would you say you know about (topic)?
Attitude; the respondent may not have formed the attitude being asked about	How much thought would you say you've given this?
Recall; the respondent may not remember the information asked for	How easy/difficult is it for you to remember (topic)?
Computation; the question requires a difficult mental calculation	How did you come up with that answer?
<b>Sensitivity/bias;</b> Assess questions for their sensitive nature or wording, and for bias	
Sensitive content; the question asks about a topic that is embarrassing, private, or illegal	Is it ok to talk about (topic) in a survey, or is it uncomfortable?
	In general, how do you feel about this question?
Sensitive wording; the wording should be improved to minimise sensitivity	The question uses the word/term. Does that sound ok to you, or would you choose something different?
A socially acceptable response is implied by the question	How did you come up with that answer?  Do all the answers here seem ok, or did it seem like there's one that's supposed to be the right answer?

## Appendix 29(cont'd): Structured probes in cognitive interviewing

Potential source of error	Probe(s)
<b>Response categories;</b> Assess the adequacy of the range of responses to be recorded	
An open-ended question that is inappropriate or difficult	Was it easy or difficult to decide what answer to give?
Mismatch between question and response categories	How easy or hard was it for you to find your answer on this list?  You said (answer). How well does that apply to you?
Technical terms are undefined, unclear or complex	What does the word/term mean to you as it's used in the question?
Vague response categories are subject to multiple interpretations	Tell me what you were thinking when I asked you about that?
Overlapping response categories	How easy/difficult was it for you to choose an answer?
	Tell me why you chose (answer) instead of some other answer on the list?
Missing eligible responses in response categories	How easy/difficult was it for you to choose an answer?
Illogical order of response categories	How was it for you to go through that list? Did that cause any difficulties?
<b>Other problems not previously identified</b>	Can you tell me more about that?

Adapted from Willis GB (2005) Cognitive interviewing. A tool for improving questionnaire design. Sage, London. p81-83

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