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# **Development and Validation of a Patient-Based Measure of Outcome for Coronary Revascularisation**

Thesis submitted to the University of London  
for the degree of Doctor of Philosophy, April 2001

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## Abstract

**Background:** Disease-specific patient-based questionnaires are being used increasingly to evaluate treatment outcomes in coronary heart disease (CHD) from the patient's perspective. However, most have been developed to evaluate health-related quality of life (HRQoL) in medically rather than surgically treated patients and many have not been rigorously evaluated against required standards. There are currently no validated questionnaires to measure patient-based outcomes after coronary revascularisation, the surgical treatment for CHD.

**Objectives:** To develop a new patient-based instrument, the Coronary Revascularisation Outcome Questionnaire (CROQ), to measure health outcomes and HRQoL before and after coronary artery bypass graft surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA). To evaluate the psychometric properties of the CROQ using classical psychometric methods.

**Design:** Psychometric study.

**Subjects:** A total of 725 (79% male) patients undergoing CABG and 643 (71% male) patients undergoing PTCA at three hospitals in the UK.

**Methods:** Qualitative methods (literature review, review of existing instruments, patient interviews, and expert opinion) were used to develop two versions of the CROQ (CROQ-CABG and CROQ-PTCA). Two field tests were then conducted by postal survey to patients before and 3-months after revascularisation firstly, to identify possible items for elimination (item reduction) and secondly, to evaluate the psychometric properties (reliability, validity, responsiveness) of the item-reduced CROQ in independent samples.

**Results:** The CROQ was acceptable to patients, satisfied tests of scaling assumptions, showed good internal consistency, test-retest reliability, validity, and responsiveness.

**Conclusions:** The CROQ is a new, psychometrically rigorous patient-based measure of outcome for coronary revascularisation. The CROQ has many potential uses in evaluative research, such as in clinical trials of effectiveness, and as a routine clinical audit tool to assist providers of CABG and PTCA in monitoring the outcomes of care.

## Table of Contents

	Page
Title Page .....	1
Acknowledgements .....	2
Abstract .....	4
Table of Contents.....	6
List of Tables.....	15
List of Figures .....	19
List of Appendices.....	19

### CHAPTER 1: INTRODUCTION

1.1	Study rationale .....	24
1.2	Evaluating treatment outcomes.....	25
1.3	Patient-based assessments .....	31
	1.3.1 What are patient-based assessments?.....	31
	1.3.2 From psychometrics to health measurement.....	35
	1.3.3 Measures of health-related quality of life .....	38
	1.3.4 Application of patient-based assessments of HRQoL.....	41
1.4	Coronary heart disease .....	45
	1.4.1 Epidemiology and costs.....	45
	1.4.2 Manifestations and diagnosis .....	47
	1.4.3 Psychosocial factors .....	49
	1.4.3.1 Psychosocial risk factors.....	50
	1.4.3.2 Psychosocial predictors of outcome .....	52
	1.4.4 Treatment .....	53
	1.4.4.1 Medical treatment.....	53

1.4.4.2	Coronary revascularisation .....	54
1.4.4.3	Effectiveness of treatments.....	59
1.4.5	Methods for evaluating treatment outcomes in CHD .....	61
1.4.5.1	Clinical outcomes.....	62
1.4.5.2	Patient-based outcomes .....	64
1.5	Summary.....	71

**CHAPTER 2: EVALUATING PATIENT-BASED QUESTIONNAIRES:  
PSYCHOMETRIC CRITERIA, SCORING AND PRACTICAL  
ASPECTS**

2.1	Psychometric properties.....	73
2.1.1	Conceptual and measurement model.....	73
2.1.2	Acceptability .....	73
2.1.3	Reliability .....	74
2.1.3.1	Internal consistency .....	74
2.1.3.2	Test-retest reliability .....	75
2.1.3.3	Inter-rater reliability.....	76
2.1.3.4	Parallel (alternate) forms reliability .....	76
2.1.4	Tests of scaling assumptions .....	76
2.1.5	Validity .....	77
2.1.5.1	Content validity.....	77
2.1.5.2	Criterion-related validity .....	78
2.1.5.3	Construct validity .....	78
2.1.5.3.1	Construct validity: within-scale analyses .....	79
2.1.5.3.2	Construct validity: comparison with external criteria.....	80

2.1.6	Responsiveness .....	81
2.1.7	Interpretability .....	83
2.1.8	Cultural and language adaptations .....	84
2.2	Methodological issues related to scoring.....	84
2.2.1	Summated-rating scaling assumptions .....	84
2.2.2	Items with a varying number of response categories.....	85
2.3	Practical aspects .....	86
2.3.1	Feasibility.....	86
2.3.2	Appropriateness.....	87
2.3.3	Methods for instrument development.....	87
2.3.3.1	Pre-testing .....	87
2.3.3.2	Preliminary field test (item reduction).....	88
2.3.3.3	Final field test (psychometric evaluation).....	88
2.4	Summary.....	89

### **CHAPTER 3: CRITICAL REVIEW OF CARDIAC-SPECIFIC PATIENT-BASED QUESTIONNAIRES**

3.1	Methods .....	90
3.1.1	Search strategy.....	90
3.1.2	Selection of measures for critical review.....	92
3.2	Results .....	93
3.2.1	Results of searches .....	93
3.2.2	Measures for critical review .....	94
3.3	Critical review of selected cardiac-specific patient-based questionnaires .....	96
3.3.1	Coronary revascularisation .....	96

3.3.2	Angina .....	99
3.3.3	Myocardial infarction.....	100
3.3.4	Heart failure .....	101
3.3.5	General cardiac (non-specific) .....	103
3.4	Summary.....	105

## **CHAPTER 4: QUESTIONNAIRE DEVELOPMENT: METHODS & RESULTS**

4.1	Refining the conceptual model and generating items.....	108
4.1.1	Qualitative interviews with patients.....	108
4.1.1.1	Recruitment .....	108
4.1.1.2	Interview techniques.....	109
4.1.1.3	Main findings.....	110
4.1.2	Expert opinion and consultation.....	113
4.2	CROQ conceptual model (pre-test version).....	113
4.3	Development of the pre-test version of the CROQ.....	115
4.3.1	Borrowed items.....	116
4.3.2	New items.....	117
4.3.3	Descriptive and demographic questions.....	118
4.3.4	Questionnaire format and instructions .....	119
4.4	Questionnaire pre-testing.....	119
4.4.1	Methods.....	119
4.4.2	Results.....	121
4.5	Summary.....	123

## **CHAPTER 5: PSYCHOMETRIC EVALUATION OF THE CROQ: METHODS**

<b>5.1</b>	<b>Data collection and management.....</b>	<b>124</b>
5.1.1	Sampling frame and recruitment.....	124
5.1.1.1	Inclusion and exclusion criteria.....	126
5.1.2	Questionnaire administration.....	126
<b>5.2</b>	<b>Item reduction.....</b>	<b>128</b>
5.2.1	Item reduction strategy.....	128
5.2.2	Item elimination.....	130
5.2.3	Tests of scaling assumptions.....	133
<b>5.3</b>	<b>Preliminary and final psychometric evaluations.....</b>	<b>134</b>
5.3.1	Acceptability.....	134
5.3.2	Internal consistency and test-retest reliability.....	134
5.3.3	Calculation of summary scores.....	135
5.3.4	Tests of scaling assumptions.....	136
5.3.5	Validity.....	136
5.3.5.1	Content validity.....	136
5.3.5.2	Construct validity: within-scale analyses.....	137
5.3.5.2.1	Internal consistency.....	137
5.3.5.2.2	Intercorrelations between scales.....	137
5.3.5.2.3	Factor analysis.....	137
5.3.5.2.4	Known groups / hypothesis testing (within scale analyses).....	138
5.3.5.3	Construct validity: comparison with external criteria.....	138
5.3.5.3.1	Convergent and discriminant validity.....	138

5.3.5.3.2	Known groups / hypothesis testing (analyses against external criteria) .....	139
5.3.6	Responsiveness .....	139
5.4	Summary .....	140

## **CHAPTER 6: PSYCHOMETRIC EVALUATION OF THE CROQ: RESULTS**

6.1	Preliminary field test .....	141
6.1.1	Respondent characteristics .....	141
6.1.2	Response rates.....	142
6.1.2.1	Pre-revascularisation samples.....	142
6.1.2.2	Post-revascularisation samples .....	143
6.1.3	Item reduction.....	144
6.1.3.1	Phase one: item reduction of core pre- / post-revascularisation items .....	144
6.1.3.2	Phase two: item reduction of common post-revascularisation only items.....	145
6.1.3.3	Phase three: item reduction of procedure- specific complication items .....	145
6.1.4	CROQ (final version) .....	146
6.1.5	Preliminary psychometric evaluation .....	146
6.2	Final field test .....	146
6.2.1	Respondent characteristics .....	147
6.2.2	Acceptability.....	148
6.2.2.1	Response rates.....	148
6.2.2.1.1	Pre-revascularisation samples.....	148
6.2.2.1.2	Post-revascularisation samples .....	148
6.2.2.2	Item and scale non-response.....	150

6.2.2.3	Item floor and ceiling effects .....	150
6.2.2.4	Scale floor and ceiling effects .....	150
6.2.3	Reliability .....	151
6.2.3.1	Internal consistency .....	151
6.2.3.2	Test-retest reliability .....	152
6.2.4	Tests of assumptions for summated-rating .....	153
6.2.5	Tests of scaling assumptions .....	153
6.2.5.1	Pre-revascularisation .....	154
6.2.5.2	Post-revascularisation .....	155
6.2.6	Validity .....	155
6.2.6.1	Content validity .....	155
6.2.6.2	Construct validity: within scale analyses .....	156
6.2.6.2.1	Internal consistency .....	156
6.2.6.2.2	Intercorrelations between scales .....	156
6.2.6.2.3	Factor analysis .....	158
6.2.6.2.4	Known group differences/hypothesis testing (within scale analyses) .....	160
6.2.6.3	Construct validity: comparison with external criteria .....	161
6.2.6.3.1	Convergent and discriminant validity (pre-revascularisation) .....	161
6.2.6.3.2	Convergent and discriminant validity (post-revascularisation) .....	163
6.2.6.3.3	Known groups / hypothesis testing (analyses against external criteria) .....	165
6.2.7	Responsiveness .....	165
6.2.7.1	Relative responsiveness .....	167

## **CHAPTER 7: DISCUSSION**

7.1	Summary of results .....	169
7.2	Study strengths .....	170
7.2.1	Patient involvement in instrument development .....	170
7.2.2	Extensive two-stage field testing .....	172
7.2.3	Large samples .....	173
7.2.4	Tests of scaling assumptions.....	173
7.2.5	Item reduction analyses using explicit criteria.....	174
7.2.6	Responsiveness analyses .....	175
7.2.7	Inclusion of specific patient groups.....	176
7.2.7.1	Women .....	176
7.2.7.2	Elderly people.....	177
7.3	Study limitations .....	178
7.3.1	Selection bias .....	179
7.3.2	Observation (information) bias.....	181
7.3.3	Generalisability .....	183
7.3.3.1	Comparison with other studies using the SF-36 .....	185
7.3.3.1.1	Pre-revascularisation.....	185
7.3.3.1.2	Post-revascularisation .....	186
7.4	Methodological issues .....	187
7.4.1	Scoring questionnaires with varying numbers of response categories .....	187
7.4.2	Treating ordinal-level data as interval.....	190
7.4.3	Item reduction strategy for a pre- and post-intervention instrument .....	190

7.5	Practical issues in developing the CROQ.....	192
7.5.1	Implementing a systematic sampling strategy .....	192
7.5.2	Verifying that patients are alive.....	195
7.5.3	Being a researcher in a clinical context .....	195
7.6	Study implications .....	197
7.6.1	Research .....	197
7.6.2	Clinical audit / quality improvement .....	199
7.6.2.1	Patient-based outcomes in coronary revascularisation as measured by the CROQ.....	201
7.7	Future research.....	207
7.7.1	Further validation of the CROQ .....	207
7.7.2	Developing norms.....	209
7.7.3	Long-term outcomes.....	210
7.7.4	Prediction of health outcomes .....	211
7.7.5	Developing methods for the interpretation of scores .....	211
7.7.6	Using self-report to evaluate adverse effects.....	213
7.7.7	Cultural and language adaptations .....	214
7.8	Conclusions.....	215
	<b>References.....</b>	<b>217-226</b>
	<b>Tables.....</b>	<b>266-378</b>
	<b>Figures .....</b>	<b>379-383</b>
	<b>Appendices.....</b>	<b>384-568</b>

## List of Tables

Table 1.1	Mortality rates for coronary heart disease in England and Wales by age (1999) .....	267
Table 1.2	Mortality rates for coronary heart disease in the UK by country, region, and sex (1991-97).....	268
Table 1.3a	Prevalence rates of treated coronary heart disease in England and Wales by age and sex (1994-98).....	269
Table 1.3b	Prevalence rates of treated coronary heart disease in Scotland by age and sex (1998).....	269
Table 1.4	UK trends in coronary artery bypass graft surgery .....	270
Table 1.5	UK percutaneous coronary intervention procedures .....	271
Table 1.6	Content domains included in conceptual models of HRQoL in coronary revascularisation.....	272
Table 1.7	Selected examples of change in HRQoL after coronary revascularisation.....	273
Table 3.1	Search strategy for computerised bibliographic databases ...	277
Table 3.2	Cardiac-specific patient-based questionnaires: psychometric properties .....	278
Table 3.3	Selected reliable and valid cardiac-specific patient-based questionnaires: item reduction, responsiveness and validated language versions.....	296
Table 3.4	Content domains included in reliable and valid cardiac-specific patient-based questionnaires.....	299
Table 4.1	Qualitative interview topic list .....	302
Table 4.2:	Selected excerpts from patient interviews grouped by content domain.....	304
Table 4.3	Phrasing of CROQ items for the three phases of questionnaire development .....	307
Table 5.1	Criteria used in the psychometric evaluation of the CROQ ...	314
Table 6.1a	Respondent characteristics: CROQ-CABG (preliminary field test) .....	315

Table 6.1b	Respondent characteristics: CROQ-PTCA (preliminary field test) .....	317
Table 6.2	Response rates: CROQ pre-revascularisation (preliminary field test) .....	319
Table 6.3	Response rates: CROQ post-revascularisation (preliminary field test) .....	320
Table 6.4	Item reduction analyses.....	321
Table 6.5a	Respondent characteristics: CROQ-CABG (final field test) .....	328
Table 6.5b	Respondent characteristics: CROQ-PTCA (final field test) .....	330
Table 6.6	Response rates: CROQ pre-revascularisation (final field test) .....	332
Table 6.7	Response rates: CROQ post-revascularisation (final field test) .....	333
Table 6.8a	Item descriptive statistics: CROQ-CABG pre-revascularisation (final field test) .....	334
Table 6.8b	Item descriptive statistics: CROQ-PTCA pre-revascularisation (final field test) .....	335
Table 6.9a	Item descriptive statistics: CROQ-CABG post-revascularisation (final field test) .....	336
Table 6.9b	Item descriptive statistics: CROQ-PTCA post-revascularisation (final field test) .....	338
Table 6.10	Scale descriptive statistics: CROQ pre-revascularisation (final field test) .....	340
Table 6.11	Scale descriptive statistics: CROQ post-revascularisation (final field test) .....	341
Table 6.12	Reliability: CROQ pre-revascularisation (final field test) .....	342
Table 6.13	Reliability: CROQ post-revascularisation (final field test) .....	343
Table 6.14a	Item convergent and discriminant correlations: CROQ-CABG pre-revascularisation (final field test) .....	344

Table 6.14b	Item convergent and discriminant correlations: CROQ-PTCA pre-revascularisation (final field test) .....	345
Table 6.15a	Item convergent and discriminant correlations: CROQ-CABG post-revascularisation (final field test) .....	346
Table 6.15b	Item convergent and discriminant correlations: CROQ-PTCA post-revascularisation (final field test).....	348
Table 6.16	Intercorrelations between scales: CROQ pre-revascularisation (final field test).....	350
Table 6.17	Intercorrelations between scales: CROQ post-revascularisation (final field test) .....	351
Table 6.18a	Principal axis factor analysis: CROQ-CABG core items pre-revascularisation (final field test) .....	352
Table 6.18b	Principal axis factor analysis: CROQ-PTCA core items pre-revascularisation (final field test).....	353
Table 6.19a	Principal axis factor analysis: CROQ-CABG core items post-revascularisation (final field test) .....	354
Table 6.19b	Principal axis factor analysis: CROQ-PTCA core items post-revascularisation (final field test) .....	355
Table 6.20a	Principal axis factor analysis: CROQ-CABG post- revascularisation outcome only items (final field test) .....	356
Table 6.20b	Principal axis factor analysis: CROQ-PTCA post-revascularisation outcome only items (final field test)....	357
Table 6.21	Known group differences: CROQ global improvement post-revascularisation (final field test) .....	358
Table 6.22	Known group differences: CROQ bothered by chest pain post-revascularisation (final field test) .....	359
Table 6.23	Construct validity: comparison with other HRQoL measures at pre-revascularisation (final field test).....	360
Table 6.24	Construct validity: correlations between CROQ and SF-36 dimension scores at pre-revascularisation (final field test) ....	361
Table 6.25	Discriminant validity: correlations between CROQ and age, sex, social class at pre-revascularisation (final field test) .....	362

Table 6.26	Convergent validity: correlations between CROQ and CCS and NYHA at pre-revascularisation (final field test).....	363
Table 6.27	Construct validity: comparison with other HRQoL measures at post-revascularisation (final field test).....	364
Table 6.28	Construct validity: correlations between CROQ and SF-36 dimension scores at post-revascularisation (final field test)...	365
Table 6.29	Discriminant validity: correlations between CROQ and age, sex, social class at post-revascularisation (final field test).....	366
Table 6.30	Known group differences: mean CROQ-CABG symptom scores by CCS, NYHA and ejection fraction at pre-revascularisation (final field test).....	367
Table 6.31	Responsiveness: CROQ pre- to 3-months post-revascularisation (final field test).....	368
Table 6.32	Responsiveness: CROQ pre- to 3-months post-revascularisation for subsample who reported global improvement (final field test) .....	369
Table 6.33	Responsiveness: CROQ pre- to 9-months post-revascularisation (final field test) .....	370
Table 6.34	Responsiveness: comparison of CROQ change scores for different levels of global improvement (final field test).....	371
Table 6.35	CROQ longitudinal change: 3 to 9 months post-revascularisation (final field test) .....	372
Table 6.36	Relative responsiveness: CROQ and SF-36 (final field test) .....	373
Table 6.37	Responsiveness: SF-36 dimension scores (final field test) .....	374
Table 6.38	Relative responsiveness: CROQ and SAQ (final field test) .....	375
Table 7.1	Generalisability of CROQ sample.....	376
Table 7.2	Comparison with other studies: SF-36 scores (pre-revascularisation).....	377
Table 7.3	Comparison with other studies: SF-36 scores (post-revascularisation).....	378

## List of Figures

Figure 4.1	CROQ conceptual model (pre-test version).....	380
Figure 6.1	CROQ conceptual model (final version).....	381
Figure 6.2	Mean CROQ-CABG cores at pre- and 3-months post-revascularisation in responsiveness subsample n=198.....	382
Figure 6.3	Mean CROQ-PTCA scores at pre- and 3-months post-revascularisation in responsiveness subsample n=107.....	383

## List of Appendices

Appendix 3.1	Cardiac-specific patient-based questionnaires: general characteristics.....	385
Appendix 4.1	Letter of invitation for interview.....	396
Appendix 4.2	Patient consent form for interviews .....	397
Appendix 4.3	Frequency of comments made by CABG and PTCA patients for each content domain .....	398
Appendix 4.4	Pre-test version of post-revascularisation CROQ-CABG questionnaire.....	402
Appendix 4.5	Pre-test version of post-revascularisation CROQ-PTCA questionnaire .....	412
Appendix 4.6	CROQ items (pre-test version).....	422
Appendix 4.7	3-months post-revascularisation CROQ-CABG questionnaire (preliminary field test).....	429
Appendix 4.8	3-months post-revascularisation CROQ-PTCA questionnaire (preliminary field test).....	439
Appendix 4.9	Pre-revascularisation CROQ-CABG questionnaire (preliminary field test) .....	448
Appendix 4.10	Pre-revascularisation CROQ-PTCA questionnaire (preliminary field test) .....	455
Appendix 5.1	Letter of invitation 1: pre-revascularisation (preliminary field test) .....	462

Appendix 5.2	Letter of invitation 1: pre-revascularisation (final field test).....	463
Appendix 5.3	Patient information sheet 1: pre-revascularisation (preliminary field test).....	464
Appendix 5.4	Patient information sheet 1: pre-revascularisation (final field test).....	465
Appendix 5.5	Patient consent form: pre-revascularisation (preliminary and final field tests).....	466
Appendix 5.6	Pre-revascularisation CROQ-CABG questionnaire (final field test).....	467
Appendix 5.7	Pre-revascularisation CROQ-PTCA questionnaire (final field test).....	473
Appendix 5.8	Letter of invitation 2: 3-months post-revascularisation (preliminary field test).....	479
Appendix 5.9	Letter of invitation 2: 3-months post-revascularisation (final field test).....	480
Appendix 5.10	Letter of invitation 3: 9-months post-revascularisation (final field test).....	481
Appendix 5.11	3-months post-revascularisation CROQ-CABG questionnaire (final field test).....	482
Appendix 5.12	3-months post-revascularisation CROQ-PTCA questionnaire (final field test).....	490
Appendix 5.13	Patient information sheet 2: 3-months post- revascularisation (preliminary field test).....	498
Appendix 5.14	Patient information sheet 2: 3-months post- revascularisation (final field test).....	499
Appendix 5.15	Patient information sheet 3: 9-months post- revascularisation (final field test).....	500
Appendix 5.16	Letter of invitation: 3-months post-revascularisation only (preliminary and final field tests).....	501
Appendix 5.17	Patient information sheet: 3-months post- revascularisation only (preliminary and final field tests).....	502

Appendix 5.18	Patient consent form: 3 months post-revascularisation only (preliminary and final field tests) .....	503
Appendix 5.19	3-week reminder letter: 3-months post-revascularisation (preliminary and final field tests).....	504
Appendix 5.20	5-week reminder letter: 3-months post-revascularisation (preliminary and final field tests) .....	505
Appendix 5.21	Formulae for scoring and transforming the CROQ .....	506
Appendix 6.1a	Item descriptive statistics: CROQ-CABG pre-revascularisation (preliminary field test).....	508
Appendix 6.1b	Item descriptive statistics: CROQ-PTCA pre-revascularisation (preliminary field test).....	509
Appendix 6.2a	Item descriptive statistics: CROQ-CABG post-revascularisation (preliminary field test) .....	510
Appendix 6.2b	Item descriptive statistics: CROQ-PTCA post-revascularisation (preliminary field test) .....	512
Appendix 6.3	Scale descriptive statistics: CROQ pre-revascularisation (preliminary field test) .....	514
Appendix 6.4	Scale descriptive statistics: CROQ post-revascularisation (preliminary field test).....	515
Appendix 6.5	Reliability: CROQ pre-revascularisation (preliminary field test).....	516
Appendix 6.6	Reliability: CROQ post-revascularisation (preliminary field test).....	517
Appendix 6.7a	Item convergent and discriminant correlations: CROQ-CABG pre-revascularisation (preliminary field test).....	518
Appendix 6.7b	Item convergent and discriminant correlations: CROQ-PTCA pre-revascularisation (preliminary field test).....	519
Appendix 6.8a	Item convergent and discriminant correlations: CROQ-CABG post-revascularisation (preliminary field test) .....	520
Appendix 6.8b	Item convergent and discriminant correlations: CROQ-PTCA post-revascularisation (preliminary field test) .....	522

Appendix 6.9	Intercorrelations between scales: CROQ pre-revascularisation (preliminary field test) .....	524
Appendix 6.10	Intercorrelations between scales: CROQ post-revascularisation (preliminary field test) .....	525
Appendix 6.11a	Principal axis factor analysis: CROQ-CABG core items pre-revascularisation (preliminary field test) .....	526
Appendix 6.11b	Principal axis factor analysis: CROQ-PTCA core items pre-revascularisation (preliminary field test) .....	527
Appendix 6.12a	Principal axis factor analysis: CROQ-CABG core items post-revascularisation (preliminary field test) .....	528
Appendix 6.12b	Principal axis factor analysis: CROQ-PTCA core items post-revascularisation (preliminary field test) .....	529
Appendix 6.13a	Principal axis factor analysis: CROQ-CABG post-revascularisation outcome only items (preliminary field test).	530
Appendix 6.13b	Principal axis factor analysis: CROQ-PTCA post-revascularisation outcome only items (preliminary field test).	531
Appendix 6.14	Known group differences: CROQ global improvement post-revascularisation (preliminary field test) .....	532
Appendix 6.15	Known group differences: CROQ bothered by chest pain post-revascularisation (preliminary field test) .....	533
Appendix 6.16	Responsiveness: CROQ pre- to 3-months post-revascularisation (preliminary field test) .....	534
Appendix 6.17	Responsiveness: CROQ pre- to 3-months post-revascularisation for subsample who reported global improvement (preliminary field test) .....	535
Appendix 6.18	Responsiveness: comparison of CROQ change scores for different levels of global improvement (preliminary field test)	536
Appendix 6.19a	Percentage endorsement of the CROQ-CABG at pre-revascularisation (final field test) .....	537
Appendix 6.19b	Percentage endorsement of the CROQ-PTCA at pre-revascularisation (final field test) .....	541
Appendix 6.20a	Percentage endorsement of the CROQ-CABG at 3-months post-revascularisation (final field test) .....	545

Appendix 6.20b	Percentage endorsement of the CROQ-PTCA at 3-months post-revascularisation (final field test) .....	551
Appendix 6.21a	Percentage endorsement of the CROQ-CABG at 9-months post-revascularisation (final field test) .....	557
Appendix 6.21b	Percentage endorsement of the CROQ-PTCA at 9-months post-revascularisation (final field test) .....	563

# CHAPTER 1

## INTRODUCTION

### 1.1 Study rationale

All health care interventions need to be evaluated to ensure that patients receive the best available care. Health care outcomes have traditionally been evaluated on the basis of mortality and morbidity. However, this limited approach to the evaluation of outcome has changed over the past few decades. The current focus is on establishing the effectiveness of health care based on scientific evidence using a wider range of outcome measures. A new discipline within health services research, health measurement, focuses on evaluating health outcomes from the patient's perspective using scientifically validated instruments. These health outcome instruments need to be rigorously evaluated against explicit criteria for use in evidence-based health care.

Coronary heart disease (CHD) is the most common single cause of death in the UK and is associated with considerable illness and disability. For a disease of such public health importance, it is essential to have appropriate outcome measures to evaluate the impact of treatment from the patient's perspective. There are currently no rigorously validated questionnaires developed specifically to measure patient-based outcomes after coronary revascularisation, the surgical treatment for CHD. Although numerous disease-specific measures have been developed for CHD, there are two limitations with using existing measures to evaluate outcomes after coronary revascularisation. First, many of the current CHD-specific instruments have not been developed and validated against rigorous scientific standards. Second, those with established psychometric properties have largely been developed for use with medically not surgically treated patients, and are conceptually inappropriate for the comprehensive measurement of the impact of coronary revascularisation. This thesis describes the development and scientific evaluation of a new patient-based measure of outcome for coronary revascularisation.

## 1.2 Evaluating treatment outcomes

The evaluation of health care interventions is an integral part of evidence-based medicine. In recent years there have been two important changes in the approach to the evaluation of health outcomes. Firstly, a more systematic and rigorous scientific approach to evaluation has been adopted and secondly, patient-based assessments of outcome have been increasingly incorporated into the evaluation of health care.

Traditionally, the evaluation of health care consisted of clinical judgment as to whether or not a treatment had been a success. Clinicians' assessments about treatment successes were often based on personal experience and anecdotal evidence rather than sound scientific evidence. The concern that many procedures are of no benefit, or may even be harmful, and the increasing awareness that health care resources are scarce, have been important factors in encouraging rigorous evaluation of health care interventions.<sup>1</sup> The current focus is on establishing the effectiveness of treatments and interventions based on critical, objective, and rigorous scientific evidence using a wide range of outcome measures.<sup>2</sup> This is one reason why the measurement of health outcomes has become a key issue in health services research;<sup>3</sup> health care interventions need to be evaluated to ensure that patients receive the best available care.

In the UK, the creation of the internal market and the division of health care into purchaser and provider organisations directly influenced the evaluation of health care and health outcomes research. Changes outlined in the 1989 White Paper *Working for Patients*<sup>4</sup> led to a greater need for purchasers to obtain evidence of cost-effectiveness in the contracting process.<sup>3</sup> Clinical audit, the systematic assessment and improvement of care, was introduced as a means of monitoring the structure, process and outcome of health care. It involves routine monitoring of health care, thus recognising the need for more systematic study of the relationship between health care and outcomes.

Health care outcomes are central to the definition of the quality of care.<sup>5</sup> By linking the care patients receive to health outcomes, outcomes research has become the

key to developing better ways to monitor and improve the quality of care. The growing interest in the assessment of health outcomes reflects increased awareness of the variations in effectiveness of interventions and the quality of care. In the 1997 White Paper, *The New NHS*,<sup>6</sup> the Government outlined its commitment to a new agenda devoted to improving quality standards, efficiency, openness and accountability in the NHS. It promoted the use of national standards for services supported by consistent evidence-based guidelines to raise quality standards. Evidence-based medicine encourages clinical decision-making from the best available evidence from systematic research.<sup>7</sup>

The Government has launched a series of new initiatives and monitoring systems to assess and improve quality and performance in the NHS. The process of Clinical Governance was introduced to provide a mechanism for quality assurance of clinical decisions.<sup>8</sup> The National Institute for Clinical Effectiveness (NICE) was set up to provide consistent guidance to clinicians about the clinical and cost-effectiveness of new and existing interventions.<sup>9</sup> A series of National Service Frameworks have been proposed to define standards for service provision in an attempt to tackle unacceptable variations in quality across the country.<sup>10</sup> The *National Service Framework for Coronary Heart Disease*<sup>11</sup> was one of the first published, reflecting the government's commitment to improving the quality of care in this area. The Performance Assessment Framework<sup>9</sup> was designed to encourage the NHS to address performance across the whole range of its activities. It focuses on six key areas, including health outcomes and patient and carer experience, to judge how well each part of the NHS is doing in delivering quality services. The Commission for Health Improvement (CHI), a new statutory body, was set up to provide independent assessments of local action to improve quality.<sup>9</sup> The Commission visits NHS Trusts to ensure that clinical governance arrangements are in place and that NICE guidance is implemented throughout the NHS. Its role is also to check the implementation of National Service Frameworks. The use of clinical indicators and high level performance indicators<sup>12</sup> is being encouraged nationally to measure aspects of clinical care and performance that affect quality. These indicators are intended to help NHS organisations to compare

performance with similar organisations and with the national average, identify areas for further investigation and possible action, share information and good practice to achieve the best results for patients, and provide information to the public about local health service performance.<sup>12</sup>

With the recognition of the importance of rigorous evaluation, there has been a change in the type and breadth of health outcomes that are measured. Evaluation has moved beyond the measurement of traditional clinical outcomes, such as mortality and morbidity, towards increasingly diverse aspects of outcome, such as health-related quality of life and patient reports of satisfaction. This change in approach to outcomes measurement over the past few decades is a result of several factors, some of which are described below.

The acceptance of the World Health Organisation's broader definition of health in 1948 as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity"<sup>13</sup> has encouraged health service researchers to look beyond clinical indicators of disease. It has encouraged a shift of focus away from the narrow and negative disease-based definition, towards a more positive concept of health. This positive definition of health encourages researchers to assess functional, social, cultural, subjective and social-psychological variables that have an impact on role performance, independent living and perceived well-being.<sup>14</sup> The traditional biomedical model of ill health is based on the belief that ill health is an objective and measurable state. Ill health is a pathological abnormality indicated by signs and symptoms. It is based on a pathophysiological understanding of the consequences of disease, defining disease by organ-systems and pathogenic mechanisms such as neoplasm or infection.<sup>15</sup> In contrast *illness* refers to a person's subjective experience of ill health and is indicated by reported symptoms and subjective accounts of pain, distress, discomfort and so on. It is an important distinction that a person might feel ill without medical science being able to detect disease.<sup>16</sup> Illness is a social phenomenon rather than a physical entity or property of individuals.<sup>17</sup> Disease (the biophysical state) and illness (the social state) are distinct entities and "illness became the providence of sociology".<sup>18</sup>

To evaluate health outcomes, it is important to go beyond the measurement of presence/absence and severity of symptoms of the disease, and to show how manifestations of an illness or treatment are experienced by individuals. There is increasing recognition that patients are not always passive, as they are regarded in the traditional biomedical model, and indeed often take an active role in their treatment. Interpretative sociology has developed a view that people act as agents, rather than being merely the products of the contexts in which they live.<sup>19</sup> Qualitative studies are increasingly being used to report on the lived reality of chronic illness, exploring the diversity of everyday experience which lie beyond indices of disability and mortality.<sup>19</sup> Chronic illness passes through stages with the course of time which may have different *meanings* as the individual ages and their position in life changes. Individuals need to make trade-offs between adherence to medical regimes and the social impact they have on daily life. Adherence to medical regimes can influence the course of disease. There is a need for a multidimensional view of the impact of disease on every-day life. Bury distinguishes two types of 'meaning' in chronic illness.<sup>19</sup> The 'meaning' of illness lies in the *consequences* for the individual, i.e. the effect of the onset of disruptive symptoms on everyday functioning. The 'meaning' of chronic illness is also seen in terms of its *significance*, as different conditions carry with them different connotations and imagery. These differences may have a profound effect on how individuals regard themselves and how they think others perceive them. Experiences are not only influenced by the social context in which the person lives, but by the nature of the symptoms, and their perception by self and others.<sup>19</sup>

Whilst there is no agreement on a definition of *health*, there is wide consensus that it includes physical, mental and social components.<sup>20</sup> The WHO's classification of Impairments, Disabilities and Handicaps,<sup>21</sup> provides a useful framework for considering the consequences of health and disease. Impairment refers to any loss or abnormality of psychological, physiological or anatomical function. Disability refers to any restriction or lack of ability to perform an activity in ways considered normal for an individual. Handicap results from impairment or disability that limits the fulfilment of a role that is normal for that individual.

Another reason for the shift away from strictly clinical measures of outcome is that although mortality is an appropriate outcome to measure if the health technology in question is intended to save lives, most technologies aim to prevent, cure or alleviate the effects of diseases and conditions which do not threaten life.<sup>22</sup> Indeed, many interventions have little effect on mortality.<sup>16</sup> As advances in medical technology have made death a relatively rare event, it is no longer considered an appropriate indication of outcome if used in isolation. Advances in medical care and technology have led to a shift in attention from acute illness to chronic disease, where the goal of therapy is not cure but symptom alleviation and improved functional capacity.<sup>23 24</sup> Most health care is provided to relieve symptoms, restore functioning, reduce pain or discomfort, and assist patients in coping with disease. Measures of mortality and morbidity are thus inadequate in measuring these aspects of outcomes. The ageing of the population has also led to an increasing emphasis on the treatment of chronic diseases, which are more likely to have an impact on diverse aspects of a patient's life.<sup>25 26</sup> Therapeutic interventions in chronic diseases, such as chemotherapy for cancer, can cause serious side-effects and functional impairment which need to be evaluated.<sup>27</sup> Some treatments have both beneficial and harmful effects. For example, some drugs used to treat cancer can prolong survival but are so toxic that they may lead to nausea and depression. In the evaluation of treatment outcomes in chronic disease, measures of outcome need to be able to detect small or subtle changes in physical and mental health.

Traditional clinical measures of morbidity are often poorly related to subjective accounts of health and well-being.<sup>28-34</sup> As Jenkinson states, "it is possible to feel ill without any signs of underlying disease, and possible to have disease without any subjective awareness of illness".<sup>31, p.2</sup> For example, Juniper *et al.*<sup>30</sup> found only modest correlations between clinical assessments of asthma and how patients felt and functioned in daily activities. Similarly, Leidy and Coughlin<sup>33</sup> found no relationship between forced expiratory volume and patients' self-reports of asthma using the Asthma Quality of Life Questionnaire. Guyatt *et al.*<sup>28</sup> reported poor correlations (.30 or lower) between cycle ergometer results and scores on functional status questionnaires in patients with chronic heart and lung disease.

Clinical measures of mortality and morbidity clearly do not reflect the whole concept of health. Reliance on clinical measures alone is now considered to be of limited value in the evaluation of the effectiveness of treatments.<sup>35</sup>

In recent years, patients have become increasingly involved in treatment decisions.<sup>36</sup> There is growing acceptance that patients and carers are “experts” in their own conditions; that is, they know what it is like to live with or care for someone with a particular health problem and often know what is best for recovery.<sup>32 36</sup> It is for these reasons that outcomes of importance to the patient have been incorporated increasingly into health outcome assessments. Patients are the best informant about symptoms, feelings, and the ways in which illness affects what is important to them.<sup>37</sup> Patients’ preferences for treatment options have also been shown to differ from those of health care professionals. Slevin *et al.*,<sup>38</sup> for example, reported differences between patients and medical staff in treatment choices for chemotherapy regimens; contrary to the expectations of medical staff, patients were willing to accept toxic chemotherapy for a minute chance of possible benefit. Wynne<sup>39</sup> reported that patients with multiple sclerosis in a randomised controlled trial of hyperbaric oxygen therapy, used different criteria than clinicians to judge the success of their treatment.

The UK government has also promoted the involvement of patients in planning and evaluating care. In 1983, the *National Health Service Management Inquiry*<sup>40</sup> known as the Griffiths’ report, recommended that information about patients’ experiences and perceptions be gathered to demonstrate how well the service was being delivered locally. The aim was to ensure that services are planned and delivered in response to such information. The 1989 White Paper *Working for Patients*<sup>4</sup> aimed to make the NHS more responsive to patients’ needs and thus of a better quality. In 1991 the *Patient’s Charter*<sup>41</sup> was launched setting out patients’ rights to care in the NHS and introducing national standards (e.g. respect for privacy, dignity, and religious and cultural beliefs). The *Patient’s Charter* has since been updated<sup>42</sup> with a greater emphasis on ensuring that users are involved in decision-making. The White Paper *The New NHS*<sup>6</sup> committed the Government to

carry out an annual national survey (National Survey of Patient and User Experience) that would allow systematic comparisons of the experience of patients and their carers over time and between different parts of the country. The survey is a key part of the quality agenda set out in *The New NHS* and will be used to help monitor the delivery of quality standards locally, in line with the framework set out in *A First Class Service*.<sup>9</sup> The survey will enable local managers and health professionals to take direct account of users' views in improving services. Part of the survey looks in depth at patients' experiences in selected areas. The initial survey of CHD patients covered a wide range of issues including access, communications, patients' views about doctors and nurses and how involved patients were in the care that they received. The *Patient Partnership Strategy* aims to improve service quality by providing patients with information enabling them to make informed decisions about their health and health care.<sup>36</sup>

### **1.3 Patient-based assessments**

The now widespread use of patient-based assessments in evaluating health care interventions has also led to greater patient involvement. The following section describes what is meant by the term *patient-based assessments* and outlines the origins of health measurement.

#### **1.3.1 What are patient-based assessments?**

Patient-based assessments of outcome provide an evaluation of the impact of treatment from the patient's point of view. They include questionnaires (self- and interviewer-administered) to elicit responses from patients about their health condition and / or treatments. Terms that are widely used in reference to these patient-based assessments include *quality of life (QoL)*, *health-related quality of life (HRQoL)*, *health status*, *subjective well-being*, *functional status*, and *patient satisfaction*. Several of these terms are used interchangeably, causing considerable confusion. The terms are often used loosely and many authors fail to define the terms they use.

HRQoL was first mentioned in the medical literature in 1966,<sup>32</sup> and the term *quality of life* was first listed in Index Medicus in 1977.<sup>3</sup> Since the late 1980s, the assessment of HRQoL has increased rapidly, with over 1000 new articles each year indexed under this term.<sup>43</sup> A range of different types of instruments are indexed under the term QOL. For example, some instruments focus exclusively on physical function such as mobility and activities of daily living and as such can be viewed as functional status instruments. Whereas others assess the impact of health on a broad spectrum of the individual's life, for example family life and life satisfaction, and as such might be best described as QOL instruments.<sup>44</sup> The use of the term QOL is often inappropriate and misleading as it suggests an abstract or philosophical set of judgements relating to life in the broadest sense i.e. factors outside of the person such as living standards, political or physical environment. The vast majority of so-called QOL instruments do not assess these wider aspects and as such the term QOL is inappropriate.

QOL and HRQoL should not be used interchangeably: there is a need to

“distinguish those features of quality of life which will yield to medical influence from its other features which depend upon economics, politics, or culture within the broader society..... otherwise quality of life may become so banalized that it will lose its original meaning, intent, and even possible usefulness”.<sup>45, p.4</sup>

Several researchers have helped to narrow the definition of HRQoL. Mosteller *et al.*'s<sup>46</sup> minimum core set of health concepts includes measures of physical, social, and role functioning, general mental health, and health perceptions. An international group of HRQoL researchers reached a consensus on the fundamental dimensions essential to any HRQoL assessment: physical, psychological, and social functioning, and global perceptions of function and well-being.<sup>20</sup> Researchers interested in measuring outcomes in specific conditions suggest the additional inclusion of disease-specific symptoms and somatic discomfort.<sup>25</sup>

HRQoL has been poorly defined in the literature and a single definition “remains illusive”.<sup>47</sup> Several contrasting definitions are described below. Calman<sup>48</sup> defined QOL as the difference, or the gap, at a particular period of time, between the hopes and expectations of the individual and that individual’s experiences. Gill and Feinstein<sup>49</sup> defined quality of life, rather than being a description of patients’ health status, as a reflection of the way that patients perceive and react to their health status and to other non-medical aspects of their lives. Patrick and Erickson<sup>50</sup> have defined HRQoL as “the value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment or policy”. Farquhar<sup>51</sup> reviewed the range of definitions of QOL and developed a typology distinguishing between global, component and focused definitions. Global definitions express QOL in general terms such as degree of satisfaction with life; component definitions break down QOL into specific parts such as health, life satisfaction and psychological well-being; and focused definitions emphasise only one or two of the range of possible component parts. The common link between all these definitions is that they all address aspects of the patient’s subjective experience of health and the consequences of illness; they all elicit perceptual information from the patient.<sup>44</sup>

Within the growing literature on health outcomes, there is little agreement about the meaning of the term QOL, with rival factions urging the adoption of a different approach using different types of measures. This has led some researchers, such as Hunt,<sup>52</sup> to caution against using QOL as an outcome which can influence patients’ lives, but that the “soliciting of patients’ perceptions of their health state and functioning” should continue to be an important component of outcomes research. The term HRQoL is used throughout this thesis to operationalise the definition given by Wenger *et al* as:

those attributes valued by patients, including their resultant comfort or sense of well-being; the extent to which they are able to maintain reasonable physical, emotional, and intellectual function; and the degree to which they retain their ability to participate in valued activities within the family, in the workplace, and in the community.<sup>53, p.884</sup>

The term HRQoL is taken to exclude the widely valued aspects of life, such as income, freedom, and quality of the environment, that are not generally considered as 'health'.<sup>54</sup> However, it should also be recognised that when a patient becomes ill, almost all aspects of life can become health-related.<sup>54</sup> HRQoL encompasses the dimensions of QOL which are affected by a disease and its treatment and which have the potential to be changed by the therapeutic situation.<sup>55</sup> Throughout this thesis, the Coronary Revascularisation Questionnaire is referred to as a patient-based measure of outcome as it measures both HRQoL and other health outcomes, such as readmission to hospital. It assesses the patient's perception of the impact of the disease and treatment on their functioning.

Patient satisfaction is another ill-defined term<sup>56</sup> that falls under the umbrella term of patient-based assessments. It is an important indicator of the quality of health care and is commonly used in the process of monitoring and improving care. It is a separate concept from HRQoL, but one that can influence HRQoL. Dissatisfaction has been linked to poorer health outcomes,<sup>57</sup> poorer compliance with treatment<sup>58</sup> and poor attendance for follow-up care,<sup>59</sup> all of which can affect health outcomes and HRQoL. It is important to measure the impact of services in terms of both patient satisfaction and health outcomes.<sup>56</sup>

It is now increasingly accepted that patient-based assessments of HRQoL and satisfaction provide invaluable information about the impact of medical interventions.<sup>3 35 44 47 50 60 61</sup> These instruments provide useful and important additional information to traditional physiological or biological indicators of health status because they describe what the patient has experienced as a result of health care.<sup>61</sup> Patient-based assessments are not designed to replace traditional clinical endpoints, but are intended to complement existing measures and to provide a more complete picture of health state than can be gained by clinical measures alone.<sup>35 47</sup> Enhancing HRQoL is as important as other goals of health and medical care, such as preventing disease, effecting a cure, alleviating symptoms or pain, averting complications, providing humane care, and prolonging life.<sup>50</sup>

The discipline of health measurement concerns the development of methods for measuring patient-based health outcomes, such as HRQoL. Whilst the field of health measurement is relatively new, it derives directly from the well-established theories and methods of psychometrics. The next section outlines the development of health measurement.

### 1.3.2 *From psychometrics to health measurement*

The foundation of health measurement is in the field of psychometrics. The development of psychometrics can be traced to the mid 1800s; by the mid 1950s the methodologies for the scientific evaluation of measuring instruments were well established. However, until recently, there was little transfer of this knowledge from the social sciences to medicine.

McDowell and Newell<sup>62</sup> provide a historical overview of the development of methods to measure subjective phenomena. Psychophysics, a sub-discipline of experimental psychology, demonstrated that subjective judgements are a valid approach to measurement. Psychophysics is concerned with the way in which people perceive and make judgements about physical phenomena, for example the loudness of a sound or the intensity of pain. In the 1860s, one of the pioneering psychophysicists, Gustav Fechner, searched for a mathematical relationship between the intensity of a stimulus and its perception. He concluded that small differences at lower levels of a stimulus are easier to detect than at higher levels and that this relationship can be expressed as a natural logarithm. Over the next 70 years, evidence from various sources showed that the logarithmic relationship did not fit all types of stimuli. However, it was not until the mid-1950s that Stevens' power law replaced the logarithmic approach. Stevens' power law recognised that people can provide consistent numerical estimates of sensory stimuli and that the relationship between stimulus and response is not linear. Stevens' view differed from that of Fechner in that he stated that the exact form of the relationship varied from one sensation to another.

Stevens' power law has been subjected to numerous tests which have produced some convincing evidence that people can make subjective judgements in a remarkably consistent manner, even when asked to make abstract comparisons - comparisons of the type that are frequently incorporated into subjective health measurements. Research to validate the power law suggests that people can make accurate judgements of stimuli on a ratio scale rather than merely on an ordinal scale of measurement. This implies that people can consistently judge how many times stronger one stimulus is than another.

Psychometrics, which grew out of psychophysics, produced the methods to measure other behavioural phenomena. In the 1950s, psychologists working in the field of psychometrics adapted the principles of psychophysical methods to measure constructs such as intelligence and personality, for which there is no physical scale. Psychometrics developed at the beginning of the twentieth century with Binet's intelligence test to measure mental age. The idea of standardised intelligence testing spread rapidly and was applied to different situations. The need for large-scale group testing to screen new World War I recruits *en masse* added momentum to the psychological testing movement.<sup>63</sup> Tests were developed to measure educational achievement, aptitude, personality and psychopathology. The massive interest in psychological testing was motivated by the practical need for ways to measure diverse outcomes such as how to identify children with special education needs, psychiatric patients in need of treatment, and personnel for certain jobs. Accompanying this practical need was the development of a more specific interest in the methodology and technology of testing, which led to psychometrics coming to prominence in the 1940s-60s.

Health, like intelligence and personality, cannot be measured directly as there is no physical scale to measure it. There will always be debate about how best to measure health due to its complex and abstract nature.<sup>62</sup> The measurement of health relies on the use of health indicators to represent different elements. Health services researchers often need to measure something which has not previously been evaluated, for example severity of chest pain or satisfaction with treatment.<sup>64</sup>

Objective measurements, such as weight and height, refer to "tangible phenomena, occurring as external realities" and can be measured by generally accepted standards and criteria that make them "scientifically attractive".<sup>65</sup> Subjective measurements, such as intensity of pain and satisfaction with treatment, lack such criteria. However, these subjective measurements are important in health care because patients' personal responses to phenomena like pain are often the most important outcomes of clinical treatment.<sup>65</sup>

As laboratory data and physically observable findings are the traditional methods for evaluating health care, patient self-reports of outcomes have been labelled as subjective, unreliable and 'soft'.<sup>66</sup> However, through the use of psychometric methods, instruments can be developed which are reliable and valid and which may even perform better on tests of reliability than many traditional medical tests.<sup>66</sup> <sup>67</sup> Read<sup>68</sup> criticises clinicians' inappropriate use of terms such as reliable and reproducible to describe their 'hard' clinical data. Notes in medical records may be subject to numerous types of measurement error and bias,<sup>67</sup> which standardised subjective measures are not prone to. There can be no excuse for rejecting HRQoL assessment as unsatisfactory 'soft' information if scientifically rigorous measures are used. Neither should HRQoL assessment be rejected because it is considered difficult to measure. There is strong evidence that patients can provide reliable and valid judgements of outcomes and that these perceptions are important and relevant.<sup>3 25 27 44 47 55 67 69-73</sup>

Clinimetrics,<sup>65 74</sup> a field related to psychometrics, refers to indices or rating scales of clinical phenomena such as symptom severity, co-morbidity and functional disability. In contrast to psychometrics, clinimetrics usually concerns the measurement of multiple attributes with a single index score. The aim is usually to develop an index which is "clinically sensible" with desirable properties for prognosis and prediction.<sup>27</sup> The most important attributes of sometimes complex clinical phenomena are combined without expecting the items to be homogeneous. Clinimetric indices usually consist of a single-item "global" rating to facilitate ease of use in the clinical setting.<sup>65</sup> Whilst clinimetric indices have the advantage of

being easy to develop, short and easily applied, they are frequently developed on an *ad hoc* basis with little attention to their measurement properties (reliability, validity and responsiveness). Many indices that are widely accepted and have proven to be useful may in fact lack evidence of their reproducibility and validity.<sup>65</sup> The two most widely used clinimetric indices in cardiology, the New York Heart Association<sup>75</sup> and the Canadian Cardiovascular Society<sup>76</sup> classifications of angina and dyspnoea on exertion are no exception.

Since health measurement was recognised as a new discipline in the late 1980s several books have been published in this field. In 1989, Streiner and Norman published the first textbook on the methodological aspects of health measurement,<sup>77</sup> which was revised in 1995.<sup>64</sup> Around the same time, a number of health measurement books were also published that summarised and evaluated the wide range of clinical and research instruments used to evaluate patient-based outcomes in health care settings.<sup>3 16 62 78</sup> These texts are a valuable source for identifying appropriate and validated instruments for use in health care research.

### 1.3.3 *Measures of health-related quality of life*

Traditionally, HRQoL was evaluated by indirect inference from medical variables.<sup>68</sup> For example, improved exercise tolerance was used as a sign of symptom relief and consequently improved HRQoL for cardiac patients. The move towards patient-centred outcomes began with the introduction in 1947 of the Karnofsky Performance Scale, a clinician-rated scale of patients' functional abilities.<sup>79</sup> Clinicians were interested in looking beyond the functional capacity of the patient in the clinical setting towards the impact of disease and treatment on a patient's daily life. Following this, a number of activities of daily living (ADL) scales were developed, for example the Barthel Index.<sup>80</sup> For practical reasons, clinicians usually provided information about HRQoL. However, clinician and patient perceptions of HRQoL and outcome are generally poorly correlated.<sup>16 26 27 37 61 81-84</sup> This may be because clinicians usually judge patients' clinical responses rather than how the clinical responses might be altered by a patient's value system or beliefs.<sup>83</sup> Patients provide the most accurate measure of HRQoL.<sup>20 27 61</sup>

In the late 1970s and early 1980s, a few general health status measures linking functional capacity to HRQoL were developed, for example the Sickness Impact Profile (SIP)<sup>85</sup> and the Nottingham Health Profile (NHP).<sup>86</sup> These self-administered instruments were the first to focus on physical functioning, psychological health, perceived distress and life satisfaction. Since the late 1980s, there has been a tremendous surge in the development of new patient-based measures of outcome and the emergence of 'gold standard' instruments, such as the SF-36 Health Survey (SF-36).<sup>87-89</sup> The SF-36 is a 36-item generic measure that covers eight dimensions: physical functioning, physical role limitations, bodily pain, general health perceptions, vitality, social functioning, emotional role limitations, and mental health. The SF-36 has been evaluated in many populations and is probably the most widely used measure of health status world-wide.<sup>47</sup>

With the proliferation of treatment options that may have similar effects on mortality and morbidity, HRQoL has become an increasingly important measure of outcome. Since the 1980s, measures of HRQoL and patient satisfaction have been used increasingly to evaluate patients' perceptions of outcome after a wide range of treatments. Researchers are developing new tools to monitor the quality of care, which incorporate patients' experiences, self-perceived needs and health status. There has recently been a proliferation of measures with little attention paid to their measurement (psychometric) properties. Instruments must be reliable, valid and responsive to change if we want to be confident about their use,<sup>64 90</sup> and also need to be useful and interpretable in the clinical setting.<sup>91</sup> Chapter 2 presents the key psychometric properties (including acceptability, reliability, validity, and responsiveness) that need to be assessed when evaluating a patient-based questionnaire and provides recommended criteria for each property. It also describes some practical aspects in evaluating patient-based instruments.

There are two main types of HRQoL instruments - generic and disease-specific.<sup>54</sup>  
<sup>92</sup> The usefulness of each of these approaches depends on the purpose of measurement. Generic measures provide comprehensive, general evaluations of HRQoL applicable to patients with any acute or chronic condition. They enable

comparison of outcome across different patient populations and interventions, which is useful for cost-effectiveness analysis, and can provide the opportunity to make policy decisions across a variety of diseases.<sup>92</sup> Whilst generic measures are likely to be robust as they have been tested in different contexts, they lack the range, sensitivity, and flexibility to deal with the particular problems of specific conditions.<sup>93 94</sup> Generic measures, such as the SF-36 and the NHP, are widely used in research studies and clinical trials.

Disease-specific measures of HRQoL provide useful additional information about response to specific conditions and treatments and can enable greater discrimination between treatments.<sup>70</sup> Disease-specific measures are more sensitive for the detection and quantification of small changes that are important to clinicians and patients.<sup>54 70 92 93</sup> They can reduce patient burden and increase acceptability by including only relevant dimensions.<sup>93 95 96</sup> However, the inability to compare results with other disease groups can be seen as a disadvantage. Comprehensive assessment of health outcomes should incorporate both generic and disease-specific instruments as they complement each other.<sup>46 92 95</sup> Generic measures enable comparison with other studies, thus enhancing the generalisability of findings, whereas the use of disease-specific measures ensures good content validity and increased responsiveness to change in specific populations.<sup>92 97</sup>

Utility or preference measures are HRQoL instruments that are designed specifically for economic evaluations.<sup>98 99</sup> These measures provide a single health index scored from 0 to 1, where 1 reflects full health and 0 dead. These measures can be used to calculate quality-adjusted life-years (QALYs) to assess the cost-effectiveness of interventions. QALYs integrate mortality and morbidity to give a value of health status in terms of the equivalent of well years of life. Widely-used utility measures and techniques include the Rosser Index,<sup>100</sup> Quality of Well Being Scale,<sup>99</sup> time trade-off,<sup>98</sup> and standard gamble<sup>101</sup> techniques and the EuroQoL EQ-5D.<sup>102</sup> Utility measures are being used increasingly in clinical trials to evaluate the cost-effectiveness of treatment.

Other researchers have recently taken a different approach to measuring HRQoL.<sup>103-106</sup> Instead of using fixed format questions, patients are asked to select areas of their life that have been adversely affected by their condition and to assess the extent of this impact. This individualised method allows respondents to define HRQoL in a way that is meaningful for them and to select and weight their own chosen areas for relative importance, and avoids imposing pre-existing definitions of health state.<sup>106</sup> Responses can be scored to form a single index suitable for utility assessments. Examples of the individualised approach include the Schedule for the Evaluation of Individual Quality Of Life (SEIQoL),<sup>103-105</sup> the Patient Generated Index (PGI),<sup>106</sup> and the Patient Specific Index (PSI).<sup>107</sup> These individualised instruments have not yet been widely used.

#### *1.3.4 Application of patient-based assessments of HRQoL*

Patients' evaluations of their health status and HRQoL are becoming increasingly important in several contexts: determining the appropriateness and quality of health care; evaluating the clinical and cost effectiveness of health care interventions; clinical decision-making; evaluating health policy programmes; health care planning and for prioritising health care treatments and containing costs.<sup>23 71 93 108-112</sup> The main applications of patient-based measures of HRQoL are briefly described below.

An important application of HRQoL instruments is their use as outcome measures in evaluative research. HRQoL instruments are being used increasingly in clinical trials alongside more traditional measures of outcome, such as mortality and morbidity, to provide a more comprehensive assessment of treatment and to improve knowledge of treatments.<sup>113 114</sup> Some clinical trial organisations have introduced the assessment of HRQoL as a standard part of new trials.<sup>27</sup> The majority of clinical trials use generic instruments, but in recent years there has been progress towards including disease-specific instruments. Patient-based instruments are usually used as secondary outcome measures, but several trials have used them as the primary outcome. For example, Croog *et al.*<sup>115</sup> demonstrated major differences in HRQoL between three anti-hypertensive

therapies and Bulpitt<sup>73</sup> measured the effects of drug treatments (ACE inhibitors) on HRQoL in patients with heart failure.

Patient-based measures of HRQoL can also be used in audit, quality assurance, and routine evaluation of health care treatments and providers of treatment.<sup>35 113 114</sup> Practitioners, providers, purchasers and policy makers are increasingly seeking to enhance the level of sophistication of commissioning and audit in the NHS. Routine audit using reliable and valid outcome measures provides valuable information for evaluating the effectiveness of health care treatments and can assist clinicians in monitoring the outcomes of care. Clinical audit is a means of ensuring high quality health care by identifying and rectifying deficiencies in health care provision; these deficiencies can be identified by using patient-based measures of outcome. Patient-based measures of HRQoL and satisfaction can also be used to monitor quality within and between provider institutions. Involving service users and carers is an important part of improving service quality in the NHS as it provides a different view of problems.<sup>36</sup> Listening and responding to the needs of those who use the NHS is an important part of making effective change.<sup>36</sup> The views and experiences of patients are vital indicators of and contributors to service quality.

HRQoL data can also be used to assist health professionals in individual patient care. The data can be used to provide information about patients' progress and response to treatment, assessing need, and setting treatment goals for screening patients.<sup>26 114 116</sup> HRQoL measures can quantify the magnitude and duration of problems experienced by patients and the extent to which such problems affect everyday functioning. This in turn, can help to identify key areas in which additional support and or rehabilitation should be directed in clinical practice.<sup>37</sup> They can also be used to screen for health or psychosocial problems that may not otherwise have become apparent from the clinical consultation.<sup>44 117</sup> By presenting patients with information about HRQoL together with clinical data, patients might be able to judge better which treatment they would prefer. Patients could also be better informed about the range of problems which they can expect in the

immediate and long-term from a particular illness and its treatment.<sup>27</sup> Realistic expectations might help to improve health outcomes.<sup>118</sup>

There is some evidence that it is feasible to incorporate short measures into routine practice,<sup>119</sup> and that clinicians find the information useful and informative.<sup>120</sup> However, trials evaluating the impact of providing this information to clinicians have found little evidence that clinical decisions are changed as a result of the additional information.<sup>120</sup> Deyo and Patrick suggest that patient-based measures of outcome may have failed to infiltrate clinical practice because information needs to be processed rapidly, it is not clear how to present the data in a useful format and clinicians do not know how best to use the evidence.<sup>121</sup>

Commissioners and purchasers of health care increasingly require evidence of the effectiveness of interventions before placing contracts. Policy makers are interested in the effects of medical interventions on HRQoL because the case-mix of patients affects use of services and expenditure patterns.<sup>28</sup> Commissioning agencies can use HRQoL data in conjunction with measures of other treatment outcomes and costs to compare the cost-effectiveness of different methods of treatment. Those responsible for the allocation of resources to treatments should attempt to maximise the amount of health gain by balancing the ratio between benefits and costs. Ebrahim<sup>15</sup> emphasises the importance of careful selection of HRQoL instruments for measurement in clinical (i.e. individual) and public health (i.e. population) settings. He warns that such wide-ranging purposes of measurement are unlikely to be satisfied by a single scale or indicator.

HRQoL assessments can also be used to provide an indication of ill health and need in specific groups in population surveys,<sup>114</sup> as a basis for determining appropriate and efficient allocation of resources for health care,<sup>35</sup> and as a basis for assessing the impact of policy initiatives.<sup>93 108</sup> HRQoL instruments provide more specific information about perceived need beyond existing measures of need such as mortality or socio-demographic data. Surveys have been conducted on specific geographical populations and social groups to provide evidence of inequalities in

health status between specific groups.<sup>109 122</sup> For example, Ahmad *et al.*<sup>109</sup> measured the influence of ethnicity and unemployment on perceived health in a sample of general practice attenders. Population-based surveys can also be used to measure the impact of changes in health care provision over time as a result of policy initiatives. In the population setting, instruments need to provide specific information that indicates needs for particular kinds of health or other services; these are rarely included in validated instruments. There is little evidence that patient-based assessments add to other sources of health status in informing population-level decision-making.<sup>44</sup>

The two most widely adopted applications are the use of patient-based assessments in evaluative research, such as clinical trials, and in clinical audit as indicators of the quality of care provided. With increasing use and greater familiarity with these instruments, it is possible that they will be used on an even wider scale and be used routinely in clinical practice.

Patient-based assessments have been used extensively in the evaluation of treatments for CHD. CHD is a chronic disease of great public health importance as it is the most common single cause of death in the UK and causes considerable illness and disability. As such, it has attracted much rigorous research into the relative effectiveness of various treatments. The government has identified CHD as an area of high priority<sup>11 123</sup> and is committed to improving the standard of care for this disease. It is now clearly recognised that patient-based assessments provide useful information to help evaluate the effectiveness of treatments in CHD, as the goal of treatment is to improve HRQoL rather than cure. Consequently, many patient-based instruments have been developed and used to measure the impact of CHD from the patient's perspective.

Subsequent sections of this chapter describe the changing approach to health outcome measurement in CHD - the increasing use of patient-based assessments and the adoption of a systematic and rigorous scientific methodology. This thesis concerns the development of a new patient-based measure of outcome for

coronary revascularisation, the surgical treatment for CHD. The next section briefly describes the epidemiology and costs of CHD, psychosocial aspects of the disease, and methods of treatment, before presenting the range of outcome measures (clinical and patient-based) that have been used to evaluate health outcomes in CHD. Chapter 3 provides a critical review of the psychometric properties of disease-specific, patient-based measures of outcome in CHD.

## **1.4 Coronary heart disease**

### **1.4.1 *Epidemiology and costs***

CHD is the single most common cause of death in the UK and is associated with considerable illness and suffering.<sup>124</sup> It is a major public health problem due to its high prevalence and the significant health care expenditure directed towards its prevention and treatment. It kills more than 110,000 people a year in England, of whom more than 41,000 are under 75 years of age.<sup>11</sup> Although CHD mortality rates are falling, rates in the UK are still amongst the highest in the world,<sup>124</sup> with 26% of all deaths in England in 1992<sup>125</sup> and 148,186 deaths in 1996 attributable to CHD.<sup>124</sup>

In the UK mortality rates from CHD are considerably higher amongst males than females, though in recent years rates have been decreasing in both men and women. CHD is traditionally considered a male disease, but one in four men and one in five women die from heart disease in the UK.<sup>124</sup> Female deaths from CHD account for almost 46% of all CHD deaths; CHD is the single most frequent cause of death in women, both above and below the age of 65 years.<sup>125</sup> Table 1.1 shows the mortality rates in England and Wales for CHD in 1999 for males and females by age group. For each age group, mortality rates are higher for males than females, except ages 15-24 years. The magnitude of difference between the sexes peaks at 45-54 years, when mortality rates in males are 4.7 times higher than in females. With increasing age, the difference between the sexes falls and in the age group 85 years and over, mortality rates for males are only 1.4 times higher than for women.

Variations in CHD mortality rates have increased in certain social and ethnic groups and across regions.<sup>11</sup> CHD is more prevalent in manual than non-manual workers in the UK and there have been widening differences in death rates between these groups.<sup>124 126</sup> In the UK during the period 1991 to 1993, men in social Class V were 3.1 times more likely to die for CHD than those in Social Class I.<sup>127</sup> However there was a geographic difference in this social gradient. As for all-causes, the Social Class gradient was flatter in England than in Wales, Scotland and Northern Ireland. Within England, gradients in the southern regions were flatter than those in the north.<sup>127</sup> Since the 1970s, there has been a greater reduction in CHD deaths among non-manual groups than among manual groups.<sup>126</sup> This pattern is also reflected in morbidity rates, with angina and heart attacks being more common in people in manual occupations.<sup>128</sup> South Asians living in the UK (Indians, Bangladeshis, and Sri Lankans) have particularly high rates of CHD. The British Heart Foundation reported an increase in the proportion of South Asians dying from and living with CHD between 1997 and 1998.<sup>124</sup>

Table 1.2 presents age-standardised mortality rates for CHD in the UK by country and region for males and females (1991-97). This table shows the considerable geographic variation in mortality from CHD.<sup>127</sup> Scotland, Northern Ireland and Wales all have higher mortality from CHD than England for both males and females. Across age groups the pattern was very similar to this, although the rates were low for those aged 15-44 years, particularly for females. Within England there was a north-south divide in mortality from CHD, similar to that seen for all cause mortality; rates are significantly higher in northern parts of England than the overall UK rate, whereas they are lower in southern parts of England.

Improvements in medical treatments for CHD have led to reduced mortality, but the disease also causes considerable illness and disability. The proportion of ill health caused by CHD may be rising.<sup>124</sup> Routine UK hospital data show that 3% of all admissions are for CHD.<sup>11 124</sup> Every year, more than 1.4 million people suffer from angina and 300,000 have heart attacks.<sup>11</sup> Table 1.3a presents prevalence rates for treated CHD in England and Wales by age and sex in 1994-8. Rates are higher in

Wales than in England, and among males compared to females. Table 1.3b presents prevalence rates for treated CHD in Scotland by age and sex in 1998. In Scotland, rates are higher among males compared to females at all ages.<sup>129</sup>

CHD is the most costly disease in the UK, accounting for 2.5% of total NHS expenditure,<sup>123</sup> and adding a burden of £10 billion per year to the UK economy.<sup>130</sup> CHD cost the UK health care system about £1,600 million in 1996 (more than any other disease).<sup>130</sup> However, these costs grossly underestimate the total cost of the disease as the majority of costs fall outside healthcare. Costs due to illness caused by CHD (65 million lost working days per year)<sup>128</sup> and the economic effects on caregivers are not included in these cost estimates. These production losses have been estimated to cost an extra £8,500 billion in 1996 to the UK economy.<sup>130</sup> In 1995, CHD was identified as a key area for improvement by Health of the Nation<sup>123</sup> and in 2000, the UK government established its first comprehensive national program for tackling heart disease, laid out in the National Service Framework for CHD.<sup>131</sup> This 10-year programme of modernisation aims to transform the prevention, diagnosis and treatment of CHD and to save 20,000 lives a year when fully implemented.

#### *1.4.2 Manifestations and diagnosis*

CHD develops as a result of narrowing of the blood vessels (coronary arteries) which supply the heart muscle with oxygen and its energy supply. Coronary arteries narrow due to the accumulation of fat deposits (atherosclerosis) in their walls, thus limiting blood flow to the heart muscle. In the vast majority of cases, CHD is the result of the build-up of atherosclerosis in the coronary arteries. The cause of atherosclerosis is not fully understood, but a number of risk factors have been identified: increasing age, family history of CHD, smoking, high blood pressure, obesity, diabetes, high cholesterol, physical inactivity, diet and stress.<sup>132</sup> <sup>133</sup> When the blockage is severe, it produces chest pain on exertion and can produce a heart attack when some of the heart muscle dies. Ejection fraction is a term used to describe how well the heart is pumping. A good heart ejects 50-70% of blood with each beat from the ventricle, its main pumping chamber.

The major clinical manifestations of CHD are angina pectoris, myocardial infarction (heart attack), sudden cardiac death, silent ischaemia (reduced blood flow to the heart muscle in the absence of chest pain), and ischaemic cardiomyopathy.<sup>133</sup> Silent ischaemia and ischaemic cardiomyopathy are the less common presentations of CHD. Angina pectoris (chest pain) is the symptom that brings most patients with CHD to medical attention. It is typically described as pain in the chest, but can also be experienced as radiating pain in the arms, shoulders, neck, back, epigastrium and jaw.<sup>134 135</sup> These radiating pains are described as atypical. Some patients do not describe angina as pain, but instead use the following adjectives to describe the sensation: "discomfort", "tightness", "dull ache", "fullness", "squeezing", "pressing", "strangling", "constricting", "bursting", or "burning sensation".<sup>134 135</sup> Some studies suggest that women describe their experience of angina differently from men,<sup>136-139</sup> and that they do not always fit the classic textbook symptoms, which were modelled on male patients when CHD was believed to be essentially a male disease.

Angina occurs when the heart muscle does not get sufficient oxygen for its energy expenditure. It is for this reason that symptoms are frequently induced on exertion and are relieved after several minutes of rest. Angina is often worse in cold weather or after food.<sup>135</sup> Angina is termed *unstable* if it is induced by progressively less physical exertion over a short time period, often developing in episodes of angina brought on by minimal exertion or at rest. A heart attack (myocardial infarction) occurs when the heart muscle is damaged from the blood supply being completely cut off due to a spasm or blood clot in the coronary arteries (coronary thrombosis). Heart attacks and angina can cause electrical conduction disturbances in the heart, which can result in abnormal heart rhythms (arrhythmias), such as ventricular fibrillation. Ventricular fibrillation is a fatal condition if it is not treated within minutes of occurrence. Repeated heart attacks, when substantial portions of heart muscle have died, can lead to ischaemic cardiomyopathy (heart failure). Heart failure is predominantly caused by CHD, but there are several causes, including hypertension, cardiomyopathy and heart valve disease.<sup>140</sup> It is usually a chronic condition requiring drug therapy to help reduce

the load to allow the heart to work effectively. In end-stage heart failure, heart transplantation becomes necessary.

The diagnosis of CHD and angina is usually made on the basis of the clinical history and an assessment of risk factors for atherosclerosis. However, clinical tests are used to confirm the diagnosis. The electrocardiogram (ECG) is usually used to confirm the diagnosis of CHD by recording the heart's electrical activity. An ECG during exercise on a treadmill or exercise bicycle can be used to identify abnormal heart function or rhythm not present at rest. Sometimes, thallium scans are used for diagnosis, which involve the injection of small doses of radio-isotopes into the blood during exercise. However, the most accurate test involves cardiac catheterisation, where a catheter is threaded through an artery in the arm or leg into the coronary arteries. An x-ray dye is then injected during x-ray filming which is used to identify narrowing of the coronary arteries. Cardiac catheterisation carries a small risk of producing a heart attack or heart rhythm disturbance, so is only undertaken when precise diagnosis is essential (e.g. when interventional treatment is being considered).

#### 1.4.3 *Psychosocial factors*

The importance of psychosocial variables in the development of CHD and in the prognosis of patients with established CHD has attracted considerable research.<sup>141</sup> Traditional risk factors for example, smoking, hypertension, hypercholesterolemia, obesity, physical activity, diabetes and hormonal factors do not fully explain the occurrence of CHD. Numerous studies have focused on Type-A behaviour pattern, hostility, depression, anxiety, and social isolation as possible risk factors for the development of CHD and as predictors of outcome for patients with established CHD.<sup>142</sup> This section provides a brief overview of the psychosocial factors which play an important role in the development of CHD and in predicting outcome after treatment.

#### 1.4.3.1 Psychosocial risk factors

The psychological variable that has received the most attention as a risk factor for CHD is Type-A behaviour pattern. Type-A individuals typically display hard-driving competitiveness, a persistent sense of time urgency, and easily evoked hostility. Results from research studies have produced inconsistent findings as to whether Type-A is an independent risk factor for CHD.<sup>141 143</sup> One possible reason for inconsistent findings is the global definition of Type-A. For this reason, the focus has shifted towards the hostility component of this behaviour pattern as the 'toxic' risk factor for CHD. Although there is some evidence that high levels of hostility and anger are associated with CHD and adverse health outcomes,<sup>144</sup> results are conflicting due to the lack of a standardised assessment methodology.<sup>141</sup> Type-D (distressed) personality, characterised by chronic suppression of negative emotions, has also been reported to be a significant predictor of long-term mortality in patients with established CHD that is independent of biomedical risk factors.<sup>145</sup> Personality is important as it can promote disease indirectly through health-related behaviours. Failure to alter risk factors and poor treatment adherence are related to a greater extent of coronary disease and an increased risk of death in patients with CHD.<sup>146</sup>

Depression, anxiety and hostility have all been demonstrated to be associated with the risk of CHD<sup>143 147-151</sup> and of adverse outcomes after coronary events such as myocardial infarction.<sup>152 153</sup> Multiple studies have shown that high levels of depressive symptoms increase the risk of mortality in patients with established CHD. Many studies have focused on the association between depression and mortality in myocardial infarction patients.<sup>152 153</sup> For example, Frasure-Smith *et al.*<sup>152</sup> reported that patients who met DSM-III-R criteria for major depression were three to four times more likely to die during the first 6 months following myocardial infarction than non-depressed patients and these effects were independent of disease severity. Directing interventions toward depressed post-MI patients whilst hospitalised could result in reduced mortality; however, this has yet to be demonstrated. Barefoot *et al.*<sup>154</sup> assessed depression in a group of patients with established CHD, and did a follow-up of subsequent mortality. They reported that

depression may be persistent or frequently recurrent in patients with CHD and is associated with disease progression and triggering of acute events.

Anxiety is characterised as a strong negative emotion with a component of fear and is associated with perceptions of unpredictability, accompanied by a marked apprehension concerning the future.<sup>147</sup> Individuals who are in situations that are more likely to induce anxiety, for example those with stressful jobs, or low socio-economic status, may be at increased risk of CHD.<sup>147</sup> Rates for CHD vary markedly between occupations;<sup>142</sup> manual workers have higher morbidity and mortality rates than non-manual workers.<sup>124 128</sup>

Depression may be associated with social isolation, which may also serve as an independent risk factor. Lack of social support (the subjective experience of other people as agents of help) could exacerbate the role of psychosocial stress in the progression of CHD.<sup>155</sup> Conversely, social support, or the degree to which one is connected to others in the community, has been identified as an inverse risk factor for CHD. For example, studies with coronary artery bypass graft surgery (CABG) patients have found positive relationships between perceived social support availability and recovery from surgery.<sup>156-158</sup> Social support has been measured in a variety of ways, including the number of relationships and frequency of social contacts. In their review of studies evaluating the role of psychosocial risk factors, Alan and Scheidt<sup>141</sup> conclude that of all the risk factors, the social support literature is the most consistent in establishing a relationship between behavioural factors and CHD. The results provide a powerful rationale for support groups for CHD patients.

Depression and anxiety are commonly the consequence of CHD. Psychological morbidity prior to CABG can be high. For example one study reported that a third of patients had clinically significant levels of anxiety and depression.<sup>159</sup> Another reported that 47% and 28% of patients on the waiting list for CABG scored in the clinically significant range of depression and anxiety, respectively, on the Hospital

Anxiety and Depression Scale prior to CABG.<sup>160</sup> Depression is also estimated to precede myocardial infarction in 33-50% of patients.<sup>161</sup>

#### 1.4.3.2 Psychosocial predictors of outcome

A subgroup of patients experience poor psychosocial outcomes after CABG. Despite general improvements in psychological functioning, approximately one patient in four has an unfavourable psychological situation 1 year after CABG.<sup>159 162</sup> For example, Heller *et al.*<sup>163</sup> found the following forms of psychological distress in one third of patients 1 year after open heart surgery: anxiety, depression, somatic preoccupation, poor self-esteem, passive dependency, paranoid tendency, and withdrawal from social life. Improvement in physical condition in terms of symptom relief is not necessarily accompanied by improvement in psychosocial condition.

It has been suggested that psychosocial factors can predict psychosocial outcomes after CABG.<sup>164</sup> Magni<sup>165</sup> found that patients with high preoperative scores on the Zung Depression Scale were at high risk of depression 1 year after successful CABG. Pinna Pintor *et al.*<sup>166</sup> reported that patients who experienced postoperative cardiac events had significantly higher preoperative levels of anxiety and depression than those without. Jenkins *et al.*<sup>167</sup> found that low preoperative levels of anxiety and depression and good social support can predict freedom from cardiac symptoms 6 months after CABG. Perski *et al.*<sup>168</sup> found that patients who reported a high level of distress before CABG on the emotional scale of the NHP (anxiety, depression and tiredness) assessed their own status (in terms of angina and HRQoL) as much worse both before and 1 year after revascularisation compared with initially non-distressed patients. Distressed patients also had significantly higher rates of cardiac events in a 3-year follow-up period compared with non-distressed patients. Grossi *et al.*<sup>169</sup> also found that preoperative negative emotional state (measured by the State-Trait Anxiety Inventory), predicted poor HRQoL 1 year after CABG and that patients in the preoperative moderate and high anxiety groups perceived a higher degree of residual angina than the non-anxious group.

Findings from these studies have important implications for the selection and preparation of patients for surgery and identification of those who might benefit from extra rehabilitation.<sup>164</sup> Preoperative identification of patients at high risk for poor psychosocial outcome after treatment might help to target early psychosocial interventions aimed at improving HRQoL in this patient group. Successful intervention could significantly improve psychosocial outcomes in these patients. Research is necessary to identify other risk factors so that prevention strategies can be targeted at the right individuals. Psychosocial and lifestyle interventions can have enormous potential for modifying the course of CHD.<sup>141</sup> Education, counselling, and psychosocial interventions can result in improved psychological well-being; training in behaviour modification, stress management, and relaxation techniques is effective in lowering self-reported emotional stress, and in modifying Type-A behaviour.<sup>161</sup>

Psychosocial factors clearly play an important role in the development of CHD and predicting outcome after treatment. Further rigorous research using rigorous outcome measures is needed to help establish the causal relationships between specific psychosocial variables and CHD. The next section describes the main treatments for CHD.

#### *1.4.4 Treatment*

Treatments for CHD include attention to risk factors, medical therapy and coronary revascularisation. Although preventing CHD is important, this thesis is concerned only with treatments for established CHD.

##### *1.4.4.1 Medical treatment*

Medical therapy is the first line treatment for CHD, and surgical intervention the second. Pharmacological therapy for angina includes five categories of drugs: beta-blockers, calcium blockers, nitrates, aspirin and other antiplatelet drugs, and antilipid drugs. Most of these drugs act by dilating the blood vessels in the body and reducing the amount of work the heart has to perform, i.e., they reduce the demands made on the heart and its need for oxygen.<sup>133</sup> Sublingual glyceryl

trinitrate (GTN) is the standard treatment for immediate symptom control; the other drugs can be classed as background antianginal medication used to help prevent angina attacks.<sup>135</sup> GTN is used during an angina attack or prior to a task which might induce an attack. It is taken under the tongue as a tablet or spray, where it is quickly absorbed to provide fast symptom relief. Drug therapy for angina can be successful for some patients for a number of years, but many patients need interventional therapy to alleviate their symptoms.

#### 1.4.4.2 Coronary revascularisation

There are two main interventional treatments for CHD, coronary artery bypass graft surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA). These two surgical methods for improving the blood flow through the narrowed coronary arteries are referred to collectively as coronary revascularisation. They are nearly always performed to alleviate symptoms and improve quality of life, and in some cases to extend survival.<sup>135 170</sup>

For many years, CABG was the accepted surgical method for the treatment of CHD. Standard CABG involves an incision in the chest to cut the breastbone (sternum) lengthways, which provides good access to the heart. During the procedure, it is necessary to stop the heart and the flow of blood through the heart and lungs. A heart/lung bypass machine artificially takes over the heart's job of pumping and the lungs' job of breathing. A blood vessel (usually from the leg or arm) or the internal mammary artery from inside the chest wall is used as the graft. The graft is attached to the aorta, the main blood vessel of the heart, and to the coronary artery to bypass the site of the blockage. Patients usually receive three grafts, but some require more and others less.<sup>171</sup> Clinical complications after CABG include mortality, myocardial infarction, chest wall pain, palpitations, atrial arrhythmias, fluid retention and peripheral oedema, pleural effusions, low grade pyrexias, leg wound pain and inflammation, wound infections, sternal dehiscence, ventricular arrhythmias, heart block, pulmonary oedemas and acute lung injury, deep vein thrombosis, and pulmonary embolus.<sup>132</sup>

Due to the invasive nature of the CABG procedure, full recovery can take some time. The majority of patients stay in hospital between 6 and 10 days after surgery.<sup>171</sup> Patients are then advised not to exert themselves during the first 6 weeks after surgery to enable their wounds to heal. Around 3 months after CABG, most patients should have returned to at least their former level of functioning prior to surgery. However, there are several reports of "recovery problems" after CABG<sup>172-178</sup> which can persist for long periods after surgery.<sup>174 175 179</sup> Many patients report pain and numbness in their leg or arm from where the veins or arteries were removed to be used as grafts. These sensations may continue for as long as 12 months after CABG in some patients.<sup>175</sup> Some patients also experience problems with wound healing in the chest, legs and arms.<sup>175 180</sup> Problems experienced by patients after discharge are less well documented in the literature than pre-discharge problems.<sup>178</sup> However, problems associated with CABG such as chest and leg wounds can cause great distress.<sup>175</sup> Patients can find it difficult to distinguish between sternal discomfort as a result of CABG and angina pain;<sup>181</sup> fear of recurrent angina and of a failed operation can also be distressing.

Cognitive impairment after CABG is a common adverse event and has been extensively documented. Impairments include short-term subtle cognitive deficits, such as problems with short-term memory, concentration, attention, new learning ability, thinking clearly, processing information, and making decisions,<sup>182-184</sup> as well as major neurological complications, such as stroke and transient ischaemic attacks.<sup>185</sup> Impairments can be subtle and detectable only through neuropsychological testing, which is sensitive in identifying cognitive complications. Neuropsychological testing typically includes evaluating memory, attention, visuo-constructional ability, and motor and psychomotor speed;<sup>186</sup> examples include the Wechsler Memory Scale,<sup>187</sup> Wechsler Adult Intelligence Scale-Revised,<sup>187</sup> and the Reitan Trail Making Test.<sup>188</sup> Questions concerning cognitive functioning are rarely included in self-administered questionnaires. This might be because formal neuropsychological testing is usually required to detect subtle changes in cognition, or because there is growing evidence that there is a poor relationship between self-reports of cognitive function and actual changes in cognition.<sup>182</sup>

Patients with high levels of depressed mood or anxiety might also report deterioration in cognitive functioning, such as the ability to concentrate.<sup>182 189 190</sup>

Perioperative cognitive dysfunction can be attributed to transient effects of anaesthesia, medication, and the need for circulatory support during surgery.<sup>191-193</sup> Cognitive impairment usually resolves in the first few months after CABG, but it can persist as long as 6<sup>191</sup> 194 and 12<sup>195</sup> months after CABG. For a subgroup of patients, cognitive dysfunction may persist in the long-term.<sup>191 192</sup> There is controversy about the degree and duration of cognitive impairment.<sup>185</sup> In a review of 35 studies, Borowicz *et al.*<sup>186</sup> reported the incidence of short-term cognitive deficits (studied less than 2 weeks postoperatively) to range between 26% and 79% and long-term deficits (studied more than 1 month postoperatively) to range from 0% to 37%. They suggest that differences in study design, sampling and outcome definitions have led to these variations in incidence rates. A very recent study<sup>196</sup> measured cognitive functioning before discharge, and 6 weeks, 6 months, and 5 years after CABG. The findings confirmed the relatively high prevalence and persistence of cognitive decline after CABG and suggested a pattern of early improvement followed by later decline (at 5 years) that is predicted by the presence of early postoperative cognitive decline.

Recent advances in cardiac surgery have resulted in the development of some novel procedures that are currently being evaluated. CABG performed directly on the beating heart, without the use of cardiopulmonary bypass via a median sternotomy, is now a well-established procedure that is used extensively by some surgeons.<sup>197 198</sup> Other surgeons are performing CABG using smaller incisions and utilising cardiopulmonary bypass and aortic clamping (port access procedures). Recently, minimally invasive CABG procedures (MIDCAB), which do not require the use of cardiopulmonary bypass or median sternotomy, have been introduced. In such procedures, the surgeon operates directly on the beating heart through a small (10-12 cm) incision in the chest. There is no need for a heart/lung bypass machine as the heart and lungs continue to function independently. Early results suggest that these procedures are effective for selected patients,<sup>199</sup> but as they are

only performed in a few specialist centres they are not part of routine treatment. Postoperative hospital stay can be reduced to 2 days, possibly due to avoidance of cardiopulmonary bypass rather than to the position or length of the incision.<sup>199</sup> Beating heart surgery appears to produce a lower incidence of cognitive dysfunction in short-term follow-up than conventional CABG using cardiopulmonary bypass.<sup>200</sup>

In the late 1970s, PTCA was developed as a less invasive method of coronary revascularisation. It involves the insertion of a fine catheter into a vein in the groin then up through the coronary artery and across the blocked section. A balloon mounted on the end of the catheter is inflated to stretch the vessel and squeeze and disrupt the material blocking it. The balloon is then deflated and removed, resulting in an enlarged channel through which blood can flow to the heart muscle. PTCA is carried out under local anaesthesia and patients are mobilised the following day. The advantages of PTCA over CABG are a shorter hospital stay,<sup>201</sup> less discomfort for the patient, rapid convalescence and return to work,<sup>202</sup> and lower initial procedural costs.<sup>203</sup> The most important long-term limitation of PTCA is restenosis (>50% diameter stenosis at follow-up angiography). Restenosis occurs in 30-50% of patients, usually within the first 4 months after PTCA, with 20-30% of patients requiring further revascularisation of the diseased vessel.<sup>204</sup> Knowledge of high restenosis rates can lead to anxiety about symptoms returning or the need for further heart operations. These concerns about reocclusion may contribute to poorer psychological functioning.<sup>205</sup> The unknown long-term outcome and the high restenosis rate can create a situation of high uncertainty for PTCA patients.<sup>206</sup>

In 1986, the method of implanting intracoronary stents during PTCA was developed. Stents are tiny metal devices that are delivered by a catheter in a collapsed state to the site of an obstruction and then expanded so as to mechanically support the atherosclerotic lesion and mechanically prevent collapse of the vessel or regrowth of atherosclerosis.<sup>133</sup> Stenting has improved PTCA by reducing the chance of acute closure and restenosis.<sup>207</sup> Consequently, rates of

emergency CABG for acute closure and re-interventions for restenosis have been reduced.<sup>208</sup> Results from randomised controlled trials show that coronary stenting significantly reduces 6-month restenosis rates and improves clinical outcomes.<sup>209-211</sup> The use of stents has increased from 2.6% per PTCA in 1991 to approximately 69% in 1998, thus substantially reducing the need for re-interventions and emergency CABG.<sup>212</sup> Interventional cardiologists perform PTCA in cardiac catheterisation laboratories with very low complication rates. The mortality rate is approximately 0.5%, MI occurs as a complication in about 1%, and emergency CABG is needed due to acute closure of a vessel in about 1% of patients.<sup>133</sup>

The use of coronary revascularisation procedures is increasing in the UK. The Society of Cardiothoracic Surgeons reported a 111% increase in CABG procedures in the UK between 1985 and 1995 (see Table 1.4). In 1997/8, 25,639 procedures were performed.<sup>171</sup> Similarly, the British Cardiovascular Intervention Society, reported a 2.8-fold increase in all percutaneous coronary interventions between 1991 and 1999 (see Table 1.5).<sup>212</sup>

The rate of coronary revascularisation is increasing at a slower rate in the UK than in several other countries.<sup>11 135</sup> There is currently insufficient coronary revascularisation provision in England, and waiting times for diagnosis and treatment are considerably longer than in other countries.<sup>11 213</sup> Time on the waiting list has been found to be significantly related to anxiety, depression, impairment of work, family relationships and social functioning,<sup>160 214</sup> and perceived HRQoL.<sup>215</sup>

There is inequitable provision of services for CHD.<sup>11 213 216</sup> There are marked geographical,<sup>217 218</sup> gender<sup>219-222</sup> and ethnic<sup>223</sup> variations in cardiac diagnostic and therapeutic intervention rates. The rates of coronary revascularisation in areas with the highest prevalence of CHD are often lower than rates in areas with a much lower burden of CHD.<sup>11</sup> Considerable systematic variations across districts in rates of CABG in the UK have been reported, with demand factors such as the level of need in the population, measured by CHD mortality, inversely associated with the

rate of intervention.<sup>224</sup> Fewer women<sup>220 221</sup> and Asians<sup>223</sup> are referred for coronary angiography and cardiac surgery.

In October 1999, the Secretary of State announced a £50 million boost to cardiac surgery to increase the number of heart operations nationally by 10% (3,000) by 2002.<sup>11</sup> In March 2000, a further £50 million was committed to “kick-start the crusade against heart disease”.<sup>131</sup> The NHS National Framework for CHD<sup>11</sup> aims to increase the national rate of both CABG and PTCA to 750 per million population. It also aims to reduce inequalities and increase all health authorities to an equivalent rate relative to the burden of disease. A national goal has been set for treating high-risk priority CABG and all angioplasty patients within 3 months of the decision to operate, and all other CABG patients within 6 months.<sup>11</sup>

#### 1.4.4.3 Effectiveness of treatments

In studies evaluating the effectiveness of treatments for CHD, the two changes in the approach to health outcome measurement described in Section 1.2 can be seen: the adoption of a systematic and rigorous scientific approach to evaluation of outcomes and the incorporation of patient-based assessments of outcome into the evaluation process.

Numerous randomised controlled trials have been performed to evaluate the clinical and cost-effectiveness of treatments for CHD; many are ongoing. The purpose is to gather rigorous, evidence-based findings of the relative effectiveness of various treatments in the short-, medium- and long-term. The majority of trials have focused on the use of clinical outcomes, such as mortality and morbidity, but in recent years patient-based assessments have been used as secondary outcome measures. Many trials now use standardised generic HRQoL instruments. For example, the first RITA trial<sup>225</sup> of outcomes after CABG and PTCA used the NHP, and RITA-2 used the SF-36 to compare PTCA with medical treatment.<sup>226</sup> Fewer trials are using validated disease-specific instruments, although their use is increasing to meet the need for more comprehensive measurements of treatment outcome to help establish relative effectiveness. This section presents the main

research findings of some of the key clinical trials to evaluate the effectiveness of treatments for CHD, and describes the outcome measures used.

CABG has been shown to be superior to medical treatment in terms of symptom relief and survival.<sup>227-230</sup> A systematic review reported improved survival rates in CABG compared with medically treated patients at 5 and 10 years.<sup>231</sup> Compared with patients treated medically, PTCA patients show better symptom relief and exercise test performance, reduced need for nitroglycerin medication and more improvement in psychological well-being.<sup>226 232 233</sup> However, PTCA has not been shown to reduce the incidence of mortality or rate of myocardial infarction in patients with stable angina.<sup>232 233</sup>

CABG has been shown to be effective in patients who have left main artery disease, three-vessel disease and left ventricular dysfunction.<sup>228 234-237</sup> CABG has not been shown to prevent myocardial infarction or to postpone cardiovascular death in certain subsets of patients, but increasing numbers are being operated on for these reasons.<sup>238</sup> PTCA has proven to be effective in patients with single vessel disease,<sup>209 210 239</sup> but the clinical benefit of PTCA as compared with CABG for patients with multivessel coronary artery disease has not been fully established, despite the use of PTCA on these patients since the early 1980s.<sup>239 240</sup>

Several randomised controlled trials are currently being undertaken to evaluate the relative clinical effectiveness of CABG versus PTCA.<sup>240-248</sup> In a meta-analysis of nine randomised controlled trials comparing initial treatment by CABG versus PTCA,<sup>203</sup> Henderson concluded that whilst both procedures are effective treatments for angina, CABG is slightly more effective during the first 1-3 years after revascularisation. However, the advantage of CABG over PTCA reduces over time, probably because of occlusion of saphenous vein grafts in CABG patients and treatment of incomplete revascularisation and restenosis in PTCA patients. In all trials, patients treated with PTCA required additional revascularisation procedures more often than did those treated with CABG, confirming the findings of an earlier meta-analysis.<sup>248</sup> About one-third of patients

assigned to initial treatment by PTCA required an additional revascularisation procedure within 1 year, but thereafter the re-intervention rate was lower.<sup>203</sup> However, the long term effects of PTCA and CABG on clinical outcome are yet to be evaluated. Individual trials may have limited statistical power to detect differences in mortality between the two procedures.<sup>203</sup> However, two other meta-analyses report no evidence of a treatment difference in mortality between the procedures.<sup>248 249</sup> Subanalyses have found no difference in HRQoL (measured by the RAND Mental Health Inventory) or return to employment over 3 to 5 years of follow-up.<sup>250</sup>

The results of economic analyses are remarkably consistent, with CABG shown to be initially twice the cost of PTCA.<sup>203</sup> This reflects a greater requirement for specialised nursing and inpatient care during the initial surgical procedure. However, this cost difference decreases during subsequent follow-up, because of the greater need for additional procedures in the PTCA group, with little difference in cost between the two procedures over 3-5 years.<sup>251</sup> A more recent cost benefit analysis showed that the need for repeat procedures reduces the initial cost advantage of PTCA over CABG until this becomes insignificant at about 5 years.<sup>252</sup>

There are several clinical trials evaluating the effectiveness of minimally invasive CABG procedures in comparison to standard CABG, PTCA and medical treatment, but these studies are ongoing. Preliminary case series<sup>199 253 254</sup> indicate that MIDCAB is safe, relatively inexpensive and less invasive compared with CABG, and potentially more effective than PTCA for patients with proximal stenosis of the left anterior descending artery. Long-term outcomes of these procedures need to be evaluated.<sup>253</sup>

#### *1.4.5 Methods for evaluating treatment outcomes in CHD*

Previous sections of this chapter describe the changing approach to health outcome assessment with an increasing emphasis on patient-based measures of outcome. This section describes the range of outcome measures that have been used to evaluate outcomes in CHD (clinical and patient-based).

#### 1.4.5.1 Clinical outcomes

There have been two major reviews of the literature of the methods used to evaluate outcome and recovery in cardiac patients, including coronary revascularisation.<sup>175 255</sup> The most frequently used measures are those related to mortality / length of survival, followed by morbidity / serious complications, physical condition (exercise testing, cardiac function, angiography), patency of grafts, symptoms (pain, dyspnoea), and return to work.<sup>175</sup> Survival, clinical test results, return to work, and clinical ratings of outcome are the most frequently used methods because they are easily measured. The frequency of angina attacks and the quantity of nitroglycerin are also commonly used as outcome measures for the treatment of angina pectoris.<sup>256</sup>

Clinical outcomes after coronary revascularisation are measured in terms of clinical events (such as death, myocardial infarction, cerebrovascular accidents), complications (such as arrhythmias, atrial fibrillation, infection, and need for pleural effusion), clinical status assessed by diagnostic testing (e.g. ECG results, ejection fractions, graft patency, the number of diseased vessels shown on angiograms), and functional status measured by exercise testing.

Several professional societies hold audit databases of clinical outcomes after cardiac interventions, based on information received from hospitals (e.g. the Society of Cardiothoracic Surgeons Surgical Register, the British Cardiovascular Intervention Society Intervention Register). Several methods of risk stratification before CABG have been developed based on clinical parameters, including Parsonnet,<sup>257</sup> Euroscore,<sup>258</sup> and UK Bayes.<sup>171</sup> The NHS funded Central Cardiac Audit Database is a pilot project to illustrate the feasibility of implementing a national risk stratified outcome audit for all cardiac interventions including CABG and PTCA.<sup>11</sup> NICE will soon recommend a method for a national audit for coronary revascularisation for use throughout the NHS.<sup>11</sup>

Whilst mortality has been used as a key outcome indicator for coronary revascularisation in many studies, it is evident that mortality is no longer an

adequate measure of outcome.<sup>259</sup> Mortality has become a relatively rare event after coronary revascularisation, with the overall average mortality for elective CABG or PTCA in stable angina being around 1%.<sup>135</sup> The UK mortality rate in 1997 for all patients who underwent CABG was 3%, but included patients with unstable angina and emergencies.<sup>135</sup> Coronary revascularisation procedures significantly improve survival relative to medical therapies for only selected subgroups of patients.<sup>228 260 261</sup> Prolonged life after CABG has been demonstrated for patients who have left main coronary artery disease, triple vessel disease and left ventricular dysfunction, but enhanced survival for other patient groups remains controversial.<sup>262</sup> Recognition of the limited improvements in survival for some patients after coronary revascularisation has been a key factor in raising the awareness of the importance of assessing changes in HRQoL after CABG and PTCA.<sup>260</sup>

As a result of improvements in revascularisation techniques, attention has shifted away from survival rates to improvement in symptomatic and functional status. It is widely recognised that coronary revascularisation improves functional status and reduces chest pain and the need for anti-anginal drugs.<sup>227 228 263</sup> Outcome assessment has focused largely on improvement in physical activities and the alleviation of symptoms,<sup>264-267</sup> with the assumption that decreased angina and improved functional capacity translate into improved social and psychological adjustment.<sup>181</sup> Early efforts to include performance or activity measures in clinical studies include the New York Heart Association classification (NYHA),<sup>75</sup> the Canadian Cardiovascular Society Classification (CCS) of angina on exertion,<sup>76</sup> and the Specific Activity Scale (SAS).<sup>264</sup> The CCS and the NYHA scales are still widely used in routine clinical practice. However, these functional measures are limited by their weak measurement properties (reliability, validity and responsiveness). For example, measures such as the NYHA and CCS classifications of angina have shown considerable imprecision and interobserver variability.<sup>3 29 264 268 269</sup> The four coarse grades of the NYHA are unable to show distinct changes in functional capacity that can occur while the patient retains the same rating.<sup>256 270</sup> Compared

with the CCS, the SF-36 Physical Functioning scale has shown to be more responsive to change after PTCA.<sup>271</sup>

Whilst physiological measures provide information to the clinician, they are of limited interest to patients.<sup>54</sup> Results from clinical assessments do not reflect patients' ability to cope or their HRQoL because they are not related to people's everyday life and environment.<sup>272 273</sup> In patients with chronic heart disease, exercise capacity in the laboratory is only weakly related to exercise capacity in daily life.<sup>28</sup> The treadmill exercise test is an attempt to reproduce the daily exertional pattern of patients in a controlled environment. However, it is an artificial setting that does not take into account the realities of life, and is thus an inadequate measure of possible lifestyle activities.<sup>256 272 274</sup> Patients alter their lifestyle to prevent or minimise anginal pain,<sup>272</sup> for example, they may avoid strenuous activities that have caused previous attacks. The frequency of angina attacks as a measure of outcome is also inadequate as patients might have the same number of attacks, but only as a result of having reduced their level of activity. Self-reported activity may be a better predictor of exercise treadmill performance than a clinician's interpretation of functional capacity.<sup>275</sup> Objective measures of ischaemia, such as electrocardiogram ST-segment depression on exercise testing, can be inaccurate because of false-positives and negatives and are poorly correlated with the patient's assessment of angina.<sup>272</sup> Clinical measures such as exercise capacity have also been shown to correlate poorly with the number of diseased vessels and with left ventricular ejection fraction.<sup>29</sup> Clinical outcome measures do not adequately reflect the impact of treatment for CHD on patients' daily lives, health and HRQoL.

#### 1.4.5.2 Patient-based outcomes

A plethora of studies have used patient-based assessments to measure outcome in CHD.<sup>181 260 262 276-281</sup> CHD is a condition that is very well-suited to evaluating HRQoL as treatments are usually directed toward symptom relief and improving HRQoL rather than cure.<sup>282</sup> Although there is extensive research on HRQoL in patients with CHD, few investigators are willing to commit to a definition of HRQoL

in the cardiac literature.<sup>283</sup> Whilst there are several conceptual models of HRQoL in heart disease,<sup>24 179 260 284-290</sup> Wenger *et al.*'s model<sup>24</sup> is the most comprehensive. HRQoL in cardiovascular disease is defined in terms of three interrelated major components:

- Functional capacity: Ability to carry out the activities of daily life (mobility, independence, self-care)  
Social function (social interaction, marital satisfaction)  
Intellectual function (memory, alertness, and judgement)  
Emotional function (mood changes, anger, guilt, hostility, depression, helplessness, sick-role behaviour, satisfactions, expectations)  
Ability to maintain a satisfactory standard of living, income, employment, insurance eligibility
- Perceptions: Perceptions of general health status  
Perceptions of well-being (life satisfaction)
- Symptoms: Symptoms of the disease (pain, dyspnoea, amount of medication, alteration of activity to limit symptoms, hospitalisations)  
Symptoms induced by treatment or concurrent illness  
Symptoms reduced or abolished by the intervention.

With the exception of models for hypertension, such as that developed by Bulpitt and Fletcher for the Hypertension Questionnaire,<sup>288</sup> the Wenger *et al.* model is the only one to distinguish symptoms induced by treatment from symptoms of the disease. This is a useful and relevant distinction for the measurement of outcome in coronary revascularisation, as it incorporates new symptoms and problems associated with CABG and PTCA, such as pain from opening the chest or bruising in the groin area.

Table 1.6 summarises the main content domains that have been included in conceptual models of HRQoL in coronary revascularisation. Three core domains have been identified in each of these models: physical/, psychological/, and social/ functioning.<sup>179 260 284-287 289 290</sup> These same core domains are usually included in HRQoL instruments. However, some conceptual models have additional domains including neuro-psychological (intellectual functioning),<sup>260 285-287</sup> symptom relief,<sup>179</sup>

260 286 287 289 mood (general well-being),<sup>284 287 289</sup> socio-economic status (return to work),<sup>260 284 286 287 289 290</sup> and satisfaction and expectations.<sup>24 179 285 287</sup>

Early assessments of HRQoL after CABG were based solely on the relief of angina<sup>291 292</sup> or return to work.<sup>293 294</sup> For many years, return to work was used as a surrogate for HRQoL<sup>53</sup> and probably arose from the debates related to the economics and the cost-benefit ratio of cardiac surgery and the ease of its measurement.<sup>295</sup> It has become increasingly recognised that the decision not to work is often the patient's choice and is not necessarily related to surgical outcome, but to multiple physical, social, economic, occupational and psychological factors.<sup>53 181 278 287 296-298</sup>

A plethora of studies have used generic measures of HRQoL to evaluate outcomes after coronary revascularisation; several authors have reviewed the main findings of this large literature.<sup>181 260 276 278 279</sup> HRQoL after cardiac surgery has become the focus of international interest.<sup>285 299</sup> Although PTCA has received relatively less attention than CABG, research on CABG is conceptually relevant to HRQoL in angioplasty patients because PTCA and CABG are both coronary revascularisation procedures.<sup>255 260 284</sup> Generic patient-based measures of outcome have been used before and after coronary revascularisation to assess health status (e.g. SF-36,<sup>87 271 300-305</sup> NHP,<sup>176 225 306-308</sup> General Health Questionnaire,<sup>309 310</sup>), psychological aspects of HRQoL (e.g. Psychological General Well-being Index,<sup>311 312</sup> Psychosocial Adjustment to Illness Scale,<sup>159 313-315</sup> Profile of Moods States,<sup>284 316</sup> Spielberger's State-Trait Anxiety Inventory,<sup>166 255 317</sup> Zung's Self Rating Depression Scale,<sup>166 318</sup>), and social interaction (e.g. Social Support Scale,<sup>297</sup> Social Activities Questionnaire<sup>319</sup>).

Numerous studies have demonstrated improvements in HRQoL,<sup>159 166 205 225 255 271 289 290 297 310 314 315 320-325</sup> functional capacity,<sup>159 176 179 205 239 300 310 320 326</sup> emotional / psychological<sup>162 176 181 310 326</sup> and social functioning<sup>159 176 179 205 310 320 327 328</sup> after CABG and PTCA. Table 1.7 illustrates how generic measures have been used to evaluate changes in HRQoL after coronary revascularisation. Included in this table

are selected examples of studies in which the most widely-used generic measures of HRQoL, including the SF-36, NHP, GHQ, have been applied. The table also includes selected examples of studies in which other widely-used measures that evaluate specific components of HRQoL, such as functional status, psychosocial adjustment, mood, well-being and social activities, have been applied. There is no question that CABG and PTCA have beneficial effects on HRQoL in terms of improved physical, psychological and social functioning.

With the recognition that health status and health outcomes are multidimensional, there is a growing trend to use several generic questionnaires that measure different domains in an attempt to capture all important dimensions.<sup>289 320</sup> Jenkins *et al.*,<sup>167 320</sup> for example, evaluated an extensive battery of 58 scales and items to evaluate the benefits of CABG. The battery included measures of: cardiac symptoms, psycho-neurological/ emotional/ physical/ role functioning and occupational, social, family, sexual, and attitudinal variables. Although this battery approach may be useful for research, it is impractical for routine use due to the increased burden on the patient and the demands of a busy clinical setting.

Whilst generic measures have been shown to be responsive to clinical change in coronary revascularisation patients,<sup>176 271 273 329</sup> they are not designed to detect changes in health that are specific to CABG or PTCA. As generic measures are designed for use across different patient populations, they do not address specific areas of health change related to coronary revascularisation, such as cardiac symptoms, or adverse effects and satisfaction with treatment. It is important to measure these treatment-specific outcomes in a patient-based evaluation of the impact of coronary revascularisation.

As in other conditions, generic measures have been shown to be less responsive to clinical change in CHD than disease-specific measures. One study that compared the SF-36 with the Seattle Angina Questionnaire<sup>325</sup> (SAQ) found that the SF-36 was relatively insensitive to large changes in cardiac status assessed by the CCS compared to the SAQ, and that it showed only limited responsiveness to

adjustment in anti-anginal medication.<sup>282</sup> Cleary *et al.* administered a battery of measures to patients undergoing PTCA and reported the disease-specific symptom scales to be more responsive than the generic scales.<sup>289</sup> Spertus *et al.* found the SAQ to be more responsive than the SF-36 to clinical change in angina patients.<sup>329</sup> These results are not surprising, as disease-specific measures are developed to capture the effects of a specific treatment, whereas generic measures provide an assessment of general HRQoL, including co-existing diseases and health problems. Disease-specific questionnaires that ask specific questions about changes in a patient's heart condition are likely to be more responsive than generic questions that measure change in general health status. In the evaluation of treatments for CHD, disease-specific measures provide more detailed information about treatment-specific changes in functional status and HRQoL. As with other patient groups, there is a need for more head-to-head comparisons of the relative responsiveness of different instruments.

Numerous disease-specific questionnaires have been developed to measure outcome in patients with CHD.<sup>166 176 214 215 255 266 267 286 289 292 325 326 330-364</sup> These measures range in quality in terms of psychometric properties and methods of instrument development. Chapter 3 provides a critical review of these cardiac-specific patient-based questionnaires. The majority of these questionnaires has been developed to measure outcomes in medically rather than surgically treated patients, for example patients with angina, heart failure, and post myocardial infarction.

Some cardiac-specific instruments have been developed specifically for use with patients undergoing coronary revascularisation.<sup>166 176 214 215 255 286 289 326 330-336</sup> However, the majority of the coronary revascularisation measures were developed *ad hoc* for descriptive use in a single study and no steps were taken to evaluate their measurement properties. The psychometric properties of these questionnaires are critically reviewed in Chapter 3. Whilst there is increasing recognition that it is important to measure the impact of adverse events after coronary revascularisation from the patient's perspective,<sup>172-178</sup> there are no

available validated scales to measure these aspects of outcome. A few instruments have included items about complications,<sup>176 179 326</sup> such as chest or leg wound discomfort, but none of these measures have been scientifically evaluated for their psychometric properties. Information generated from these instruments about complications has only been used for descriptive purposes. There have been no attempts to routinely ask patients about these complications using a systematic standardised method. The majority of research into the impact of complications after coronary revascularisation has been conducted using qualitative research methods.<sup>172-175 178</sup>

Due to the lack of a comprehensive validated disease-specific instrument for coronary revascularisation, some study investigators have used cardiac-specific measures that were originally developed for evaluating outcomes in medically treated patients. For example, Fruitman *et al.*,<sup>365</sup> MacDonald *et al.*,<sup>301</sup> and Seto *et al.*<sup>305</sup> used the Seattle Angina Questionnaire and the SF-36 to measure HRQoL in elderly patients after coronary revascularisation. There are important methodological limitations in using such instruments, developed specifically for measuring outcomes in medically treated patients, to assess outcomes in surgical patients. If a disease-specific measure is used with a different patient group from that in which it was developed, the instrument needs to be re-evaluated in the new patient group to confirm its psychometric properties. It is not scientifically valid to use a measure that is developed in a specific patient population and assume that its psychometric properties are retained when used in a different patient group. A full psychometric validation is necessary to establish the measurement properties in the new patient group. Re-validation in the relevant patient sample has not been carried out in the studies described above.

Another limitation of existing measures concerns conceptual relevance. HRQoL instruments developed to measure specific outcomes for a particular patient group might not be conceptually relevant to a different patient group, even within the same condition. Domains of interest can vary with the stage or severity of illness; different dimensions of HRQoL may be of interest to the CHD patient with stable

angina as compared with a patient who is recovering from myocardial infarction or who has undergone coronary revascularisation.<sup>53</sup> Similarly, issues that are pertinent to a group of patients at a particular point in time, such as CHD patients prior to revascularisation, might not remain relevant after treatment.

The Seattle Angina Questionnaire, for example, comprises a series of questions about the impact of chest pain (angina) on exertional capacity and enjoyment of life. For patients who have undergone successful CABG or PTCA, angina pain has been relieved. Asking patients about the effects of having a symptom that they no longer experience without provision of a response option to indicate that they currently do not have angina can be frustrating to the respondent. Indeed, even the term *chest pain* can have a different meaning for patients after coronary revascularisation. Patients experience a new type of chest pain as a result of having their chest opened. Questionnaires developed for use with medically treated patients that ask about chest pain (angina) might be misunderstood by CABG patients as the new procedural-related pain sensation that they are experiencing. Another conceptual limitation is that instruments developed to measure outcome in medically treated patients do not include items specific to coronary revascularisation procedures, such as adverse effects and satisfaction with outcome.

For comprehensive patient-based assessments of coronary revascularisation, a new single instrument covering all relevant domains is needed. This will remove the need for study investigators to administer a series of instruments each measuring a specific domain, such as one measure for depression, another for symptoms, and another for satisfaction. A comprehensive patient-based measure of outcome for coronary revascularisation should include disease-specific symptoms, limitations in daily activities, psychological/ cognitive/ social functioning, and outcomes related to the procedure rather than the condition per se, including readmission to hospital, physical and psychological complications and satisfaction with treatment.

In selecting a patient-based measure of outcome for a specific study, it is essential that careful consideration is directed at issues of conceptual relevance and that the psychometric properties are evaluated. An instrument should be conceptually relevant and psychometrically sound if results are to be interpreted with confidence. As will be shown in Chapter 3, there is clearly a need for a disease-specific, patient-based measure of outcome developed specifically for coronary revascularisation. This thesis presents the development and psychometric evaluation of a new questionnaire, the Coronary Revascularisation Outcome Questionnaire (CROQ).

## **1.5 Summary**

Health care interventions, including medical and surgical treatment, need to be rigorously evaluated to ensure that patients receive the best available care. The outcomes of health care have traditionally been evaluated on the basis of clinical indicators such as mortality and morbidity. However, this limited approach to health outcomes assessment has changed radically over the past few decades. The current focus is on establishing the effectiveness of health care based on scientific evidence using a wider range of outcome measures. The focus of the discipline of health measurement is on evaluating health outcomes from the patient's perspective using scientifically validated instruments.

This chapter focused on CHD and coronary revascularisation to illustrate the changing approach to health outcome measurement. CHD is the most common single cause of death in the UK and causes considerable illness and disability. For a disease of such public health importance, it is essential to have appropriate and scientifically sound outcome measures to evaluate treatment. The relative effectiveness of treatments for CHD has attracted much research. In recent years, patient-based assessments have been used increasingly to evaluate the impact of these treatments from the patient's perspective. Whilst there are validated disease-specific patient-based instruments to measure HRQoL in CHD patients treated medically, none of these are sufficient for comprehensive assessment of all relevant content domains after coronary revascularisation. As will be shown in

Chapter 3, existing instruments specific to coronary revascularisation are either weak in terms of psychometric properties, or conceptually inadequate, or both. There is clearly a need for a new instrument appropriate for measuring HRQoL and health outcomes in coronary revascularisation.

Chapter 2 describes the psychometric criteria and practical aspects for evaluating patient-based questionnaires. Chapter 3 presents a critical review of the psychometric properties of the cardiac-specific patient-based questionnaires in CHD.

## CHAPTER 2

### EVALUATING PATIENT-BASED QUESTIONNAIRES: PSYCHOMETRIC CRITERIA, SCORING AND PRACTICAL ASPECTS

This chapter discusses psychometric criteria, methodological issues related to scoring and practical aspects of evaluating patient-based questionnaires. The methods described in this chapter are used to critically evaluate existing cardiac-specific questionnaires (Chapter 3) and to evaluate the psychometric properties of the CROQ (Chapter 5).

#### 2.1 Psychometric properties

Patient-based questionnaires must be formally evaluated against psychometric criteria to ensure that they are acceptable, reliable, valid and responsive. Current guidelines for the development of patient-based questionnaires and the evaluation of their measurement properties,<sup>3 44 64 69 90 366-368</sup> developed from psychometrics, are briefly described below.

##### 2.1.1 *Conceptual and measurement model*

An instrument should be based on a clear model of what it is intended to measure. The conceptual model is a rationale for and description of the concepts that the instrument is intended to measure and the relationship between these concepts.<sup>90</sup> Each summary scale should measure a single distinct content domain or construct and its scoring procedures should be justified.

##### 2.1.2 *Acceptability*

A questionnaire should be acceptable to respondents. Indicators of data quality such as response rates, item non-response, and the distribution of responses across categories can be used as an indication of respondents' understanding and acceptance of a questionnaire.<sup>369</sup>

The average response rate to mail surveys published in medical journals has been reported to be 68%;<sup>370</sup> however, higher rates are not uncommon.<sup>371 372</sup> The frequent omission of an item suggests that the item might be difficult to understand, distressing, or unacceptable in some other way.<sup>44</sup> The recommended criterion is that missing data for items and scales should not exceed 10%. Acceptability is further evaluated on the basis of floor / ceiling effects (percentage of respondents endorsing the bottom / top of the scale). Ideally, a questionnaire should contain items that can discriminate well and produce an even distribution of responses across the item,<sup>373 374</sup> without too many or too few endorsements of one response alternative.<sup>64</sup> The recommended criterion is that response options should be endorsed between 20% and 80%,<sup>64</sup> and that the distribution should not be skewed (i.e. skewness values should be in the range +1 to -1).

### 2.1.3 *Reliability*

Reliability is the degree to which an instrument is free from random error. A reliable instrument is internally consistent and produces consistent results in repeated use. There are four types of reliability: *internal consistency, test-retest, inter-rater and parallel (alternate) forms.*

#### 2.1.3.1 Internal consistency

*Internal consistency* measures the extent to which items in a scale measure the same concept. It is expressed by Kuder-Richardson formula 20 (KR-20)<sup>375</sup> for dichotomous data and by Cronbach's alpha coefficient<sup>376</sup> for items with more than two response alternatives. Coefficients range between 0 and 1, with higher values indicating higher internal consistency. Alpha coefficients should be above .70 for group comparisons and above .90 for individual assessment.<sup>366</sup> It has been suggested that reliability estimates in the range of .70 to .80 are good enough for most purposes, but where a test is used to make important decisions in clinical settings, values greater than .95 should be sought.<sup>63 377</sup> Although the value of alpha if an item is deleted should not 'substantially increase',<sup>378</sup> no specific values have been suggested for this definition. Coefficient alpha provides a good

estimate of reliability because sampling of content is usually the major source of measurement error for static constructs.<sup>366</sup>

It is important to note that internal consistency reflects both the number of items in a scale and the average correlation between items.<sup>366</sup> If the alpha coefficient is very low, the scale is either too short or the items have little in common and are measuring different constructs. Each scale should measure a single distinct conceptual domain or construct; that is, the scale should be homogeneous. Item-total correlations are used to evaluate the homogeneity of a scale. An item-total correlation is the correlation between an item and its own scale, after the item has been eliminated from the calculation of the scale score. Item-total correlations should be in the moderate range; values of  $>.20$ ,<sup>64</sup>  $>.30$ <sup>366</sup> and  $>.40$ <sup>369</sup> have been recommended. A low item-total correlation indicates that the item may be measuring something different from the other items in the scale.<sup>63</sup>

#### 2.1.3.2 Test-retest reliability

*Test-retest reliability* is the degree to which an instrument reproduces stable scores over time in respondents who are assumed not to have changed on the domain being assessed. It is the relationship between scores obtained by the same person on two or more separate occasions.<sup>377</sup> The same instrument is administered twice separated by a short interval. The test-retest period is usually 2 to 14 days, as this period is short enough to assume that the underlying process is unlikely to have changed and long enough for patients not to remember their first response.<sup>64</sup> Test-retest reliability is usually expressed by Pearson or intraclass correlation coefficients (ICC), with a recommended minimum criterion of  $.70$ .<sup>90</sup> The ICC is the proportion of total variability accounted for by the variability among individuals. High values indicate that not much of the variability is due to variability in measurement on different occasions and that the reproducibility is high.<sup>379</sup> Systematic changes in the mean level of responding (e.g. every individual's score decreasing by a constant) are not reflected by Pearson coefficients.<sup>380</sup> However, ICCs are sensitive to systematic changes and also to the strength of the correlation and as such are increasingly recommended for reporting test-retest reliability.<sup>379</sup>

### 2.1.3.3 Inter-rater reliability

*Inter-rater reliability* refers to the level of agreement between two or more independent raters of the same individual. Cohen's Kappa statistic<sup>381</sup> can be used to estimate exact agreement between raters for a variable measured on a nominal, ordinal or interval-level scale.<sup>382</sup> Kappa compares observed agreement with agreement expected by chance. Cohen's Kappa is appropriate for measuring total agreement and for scales that are rated by an observer. Inter-rater reliability is therefore not relevant for self-report questionnaires that do not involve raters or observers.

### 2.1.3.4 Parallel (alternate) forms reliability

*Parallel (alternate) forms reliability* refers to the agreement between scores on two or more versions of an instrument that are designed to measure the same attribute using different items.<sup>382</sup> If the item content of the two forms is equivalent, the correlation between the scores provides a good estimate of the reliability of the measure. The Pearson product moment correlation coefficient is used as an estimate of reliability. Parallel forms reliability has been widely used in educational, personality and cognitive assessment, where two or more different versions of a questionnaire are needed for repeat assessments (e.g. two word lists to test memory before and after a drug intervention). However, parallel forms reliability is rarely used in HRQoL assessment as few measures have parallel forms due to the practical constraint of having to develop two measures of the same outcome.<sup>63 377</sup>

Reliability is necessary but not sufficient for valid measurement.<sup>366 377 382</sup> It is essential to evaluate validity as an instrument can be reliable, but may not actually be measuring what it is intended to measure.

### 2.1.4 *Tests of scaling assumptions*

Tests of scaling assumptions are performed to ensure that items are correctly grouped in scales.<sup>369 374 383</sup> Items should be more highly correlated with their own scale (item convergent validity) than with other scales (item discriminant validity).

Scaling assumptions can be tested by evaluating items in relation to their hypothesised scale, as well as in relation to other scales.

Ware *et al.*<sup>374</sup> have defined standard criteria to evaluate item convergent and discriminant correlations. A 'scaling success' (SS) indicates that an item correlates significantly higher, by at least two standard errors, with its own scale than with another scale. A 'probable scaling success' (PSS) is defined as an item that correlates higher with its own scale than with another scale, but not significantly, i.e. by less than two standard errors. A 'probable scaling failure' (PSF) indicates that an item correlates higher with another scale than with its own scale but not significantly, i.e. by less than two standard errors. A 'scaling failure' (SF) defines an item that correlates significantly higher, by at least two standard errors, with another scale than with its own scale.

Large datasets are needed to carry out these tests so that estimates of the correlations between items are precise. Sample size determines the standard error of a correlation: the smaller the sample, the larger the standard error. The above criteria for scaling successes and failures are recommended for use with samples of at least 300.<sup>374</sup> In recent years, computer programmes, such as Multitrait / Multi-item Analysis Program-Revised (MAP-R)<sup>374</sup> have been developed to test scaling assumptions.

### 2.1.5 *Validity*

The validity of an instrument concerns the degree to which an instrument measures what it purports to measure. There are three types of validity: content, criterion-related, and construct validity. All address the level of confidence that can be placed in the inferences drawn from scores.<sup>64</sup>

#### 2.1.5.1 Content validity

*Content validity* refers to the extent to which an instrument covers a representative sample of the domains to be measured.<sup>44 64</sup> This is usually assessed by subjective

judgement rather than through a statistical approach. It can be assessed in a number of ways: a comparison of the content of the questionnaire with the content of existing measures of the same domains; expert opinion of what should be measured; and interviews with target respondents.<sup>44</sup> Evidence from lay and expert panel judgements of the clarity, comprehensiveness and redundancy of the items and scales is often used to evaluate content validity. Streiner and Norman<sup>64</sup> recommend that an explicit statement regarding content validity, based on a review by an expert panel, should be a minimum prerequisite for acceptance of a measure. Others propose the need for direct involvement of patients with the specific health problem in generating and confirming the content of the questionnaire.<sup>44</sup> Content validity can also be evaluated by comparing responses to open-ended questions, for example "*Is there anything else you would like to tell us about your condition or treatment that is not covered in this questionnaire?*", with the content covered in the questionnaire. Any new domains identified by several respondents in the open-ended questions would suggest inadequate content validity.

#### 2.1.5.2 Criterion-related validity

*Criterion-related* validity refers to the degree to which the instrument correlates with gold-standard (criterion) measures obtained either at the same point in time (concurrent validity) or subsequently (predictive validity). As there is rarely a gold-standard in HRQoL assessment, construct validity is usually evaluated instead of criterion-related validity.

#### 2.1.5.3 Construct validity

*Construct validity* is evaluated by testing hypotheses about how a measure should 'behave' and about the expected relationships between the measure and other variables or measures of the same construct.<sup>384</sup> An evaluation of construct validity is based on the accumulation of different types of evidence through within-scale analyses and comparison with external criteria. There is no single test to establish construct validity; rather, it is an ongoing process.

2.1.5.3.1 Construct validity: within-scale analyses. A series of within-scale analyses can be used to evaluate construct validity.

*Internal consistency.* Good internal consistency, as evidenced by high inter-item and item-total correlations greater than .30,<sup>366</sup> and high alpha coefficients (greater than .70<sup>90 366</sup>), indicate that a single construct is being measured and that items can be combined into a scale.

*Intercorrelations between scales.* Correlations between scales demonstrate the extent to which scales measure separate but related constructs. High correlations between scales and total scores and moderate intercorrelations between scales indicate that scales are measuring related but separate domains. There should also be evidence of unique reliable variance, indicated by reliability coefficients with values greater than the intercorrelations between scales.<sup>374</sup>

*Factor analysis.* Factor analysis is often performed to confirm or empirically derive the scaling structure of a questionnaire. It can be performed to confirm that items are correctly grouped together, that items in the same scale measure the same construct, that items in different scales measure different constructs, and to identify items that contribute little to their intended scale. Items that measure a particular construct, such as psychological functioning, should load as highly on the same factor as other items in the scale and not on the other factors measuring different constructs, such as physical functioning.

Unrotated Principal Component factor analysis can be used as a starting point to check that all items are measuring the same underlying construct and that they all load on the same first factor. Common criteria for acceptable factor loadings include .30 and .40.<sup>385</sup> Rotated factor analysis (Principal Components or Principal Axis) should then be performed to identify the solution with the simplest structure. The most commonly used method of rotation is Varimax rotation, which attempts to minimise the number of variables that have high loadings on each factor.<sup>385</sup> Eigenvalues indicate how much of the variation in the data is accounted for by each

factor. The criterion of eigenvalues greater than one is the most commonly used method to identify the number of underlying constructs and the number of factors to be extracted; however, in general this rule includes too many factors.<sup>385</sup> Another method is to extract the number of factors above the break in the scree plot. Rotated factor analyses can be repeated by modelling one more and one less factor with eigenvalues greater than one until the clearest structure is identified.

Some items load on more than one factor (crossload) and it is not always clear which factor they belong to. If the value of the difference between the crossloading items is greater than .20, the item is generally assumed to load on the factor for which it had the highest loading.<sup>386</sup> If the difference is less than .20, the item should be 'flagged' as being related to more than one factor. Other recommended criteria are that the Kaiser-Meyer-Olkin (KMO) test of sampling adequacy should be at least 0.5 and Bartlett's test of sphericity (BS) should be significant.<sup>386</sup> KMO indicates whether the association between the variables in the correlation matrix can be accounted for by a smaller number of factors, and BS tests the null hypothesis that no relationship exists between any of the variables i.e. a significant statistic indicates there are discoverable relationships in the data.<sup>386</sup>

*Known groups / hypothesis testing (within scale analyses).* Internal construct validity can also be evaluated by testing hypotheses of differences between groups that are expected to differ on the outcome of interest. For example, patients who report improvement after their operation as measured by a questionnaire would be expected to report fewer symptoms (as measured by the same questionnaire) than those who do not report improvement.

2.1.5.3.2 Construct validity: comparison with external criteria. Construct validity can also be evaluated by examining the relationship between the instrument and external criteria, such as other HRQoL scales and clinical indicators.

*Convergent and discriminant validity.* There are two types of evidence essential for establishing construct validity: convergent and discriminant validity.<sup>387</sup> It is

important to show that scale scores are correlated with independent measures of the same domain (convergent validity), and that there is minimal association with measures of unrelated constructs (discriminant validity). Convergent and discriminant validity are expressed by Pearson product moment correlation coefficients.

Items and scales should be moderately correlated with external criteria that measure similar constructs. The expected magnitude of the correlation depends on how closely the constructs are related on a conceptual basis. Scales and items that measure similar constructs should be more highly correlated (i.e. greater than .40<sup>339</sup>) than with items and scales measuring different constructs. Similarly, items and scales should not be highly correlated with measures of different constructs. Scale scores should not be highly correlated with demographic data such as age, sex and social class or with other unrelated constructs.

*Known groups / hypothesis testing (analyses against external criteria).* Construct validity can also be evaluated by testing hypotheses of differences between groups known to differ according to an external criterion. For example, one would expect patients with more symptoms, measured by a clinical rating scale, to report poorer health outcomes on a disease-specific instrument than those with fewer symptoms. In the case of CHD, one would expect patients with greater disease severity, as measured by the CCS or the NYHA classifications of angina and dyspnoea, to report poorer health outcomes on a disease-specific questionnaire.

#### 2.1.6 *Responsiveness*

Responsiveness is an aspect of validity that has particular relevance in the measurement of health outcomes.<sup>377</sup> Responsiveness is the degree to which an instrument is able to detect clinically significant change over time. An instrument must be able to demonstrate that it can detect small but clinically important differences in outcome which clinicians and patients regard as important.<sup>379</sup> A clinically important change might be represented by an indication of a therapeutic

effect or through a meaningful reduction in symptoms from the patient's perspective. There are two types of responsiveness: internal and external.<sup>388</sup>

There are several ways of expressing the *internal responsiveness* of an instrument: *t-statistics*,<sup>379</sup> *effect sizes*,<sup>389</sup> <sup>390</sup> *standardised response means*,<sup>391</sup> and the *responsiveness statistic*.<sup>392</sup> The most common method of demonstrating responsiveness is through a comparison of scores before and after a treatment of known efficacy using paired *t*-tests.<sup>379</sup> Scales that demonstrate a significant difference between the two time points are judged to be responsive. There are several criticisms of this method: it is dependent on sample size and so needs to be supplemented with other measures of responsiveness;<sup>388</sup> it does not account for systematic changes in scores across the group (including apparently stable respondents) which could occur, for example, due to learning effects; and statistically significant change over time may not be synonymous with clinically important change.<sup>390</sup>

The *effect size* statistic relates change in mean scores over time to the standard deviation of baseline scores.<sup>389</sup> Effect sizes are used to translate before and after changes into a standard unit of measurement, rather than comparing raw score changes. Cohen defined effect sizes of 0.20 as small, 0.50 as moderate and 0.80 or greater as large.<sup>389</sup> The *standardised response mean* is a variant of the effect size. It is calculated as the mean change score divided by the standard deviation of the change score.<sup>391</sup> The *responsiveness statistic* measures change relative to variability for clinically stable respondents.<sup>392</sup> It is a variant of the *effect size* statistic, with a different denominator - the standard deviation of score changes among stable subjects. This statistic accounts for the non-specific score changes observed in patients who are apparently clinically unchanged. An instrument that has high variability in stable subjects in relation to typical change scores is considered to have poor responsiveness. The *responsiveness statistic* is inappropriate for studies that do not define clinically stable respondents.

*External responsiveness* reflects the extent to which changes in the measure relate to corresponding changes in a 'reference' measure (for example a validated HRQoL instrument) in a specified time frame.<sup>388</sup> The reference measure acts as an external standard against which comparisons are made. Change in the reference measure is regarded as an accepted indication of change. If the measure demonstrates changes seen in the reference measure, it can be used as a substitute outcome measure. Measures should be sensitive and specific; a measure should reflect both change and no change in the external standard.<sup>388</sup> There are several ways of expressing the *external responsiveness* of an instrument: receiver operating characteristic method, correlation, and regression models. The external responsiveness of an instrument is rarely evaluated.

### 2.1.7 *Interpretability*

Interpretability is defined as the degree to which qualitative meaning can be assigned to quantitative scores derived from an instrument.<sup>90</sup> Clinicians need to be able to make meaningful interpretations of results. Some leading health outcomes methodologists propose the use of clinical data to help calibrate HRQoL measures and facilitate interpretation.<sup>393 394</sup> There is some consensus that changes in a HRQoL instrument should be 'anchored' to other clinical changes or results i.e. to ideas that mean something to users.<sup>395</sup> In the case of generic instruments, data on the distribution of scores derived from a variety of patient populations and a representative sample of the general population facilitates interpretation across disease groups.<sup>87-89</sup> In the case of disease-specific instruments, comparisons can be made between changes in health status and changes in clinical measures. Descriptive statistics (means, standard deviations, floor and ceiling effects) should be provided alongside characteristics of the sample (socio-demographic characteristics, disease groups) to enable direct comparisons of samples.<sup>90 396</sup> The use of effect sizes, which have standardised units of measurement, should help interpretation across measures.<sup>390</sup> Leading health outcomes methodologists are currently investigating methods to help facilitate the interpretation of HRQoL scores.<sup>394 397 398</sup>

### **2.1.8 Cultural and language adaptations**

As the measurement of HRQoL is of international interest,<sup>399-403</sup> instruments have been developed in many different languages. In selecting an instrument it is essential to check whether the language version of interest has indeed been validated. Adaptations of an instrument for use in other cultures and languages must be evaluated in terms of conceptual and linguistic equivalence and the psychometric properties of the adapted instrument must be re-evaluated. For example, the psychometric properties of an instrument validated for use with Swedish patients must be re-evaluated for use with English patients, to confirm that the psychometric properties are retained when used in this group. Herdman *et al.*<sup>404</sup> propose six types of equivalence that should be evaluated when adapting HRQoL instruments: conceptual, item, semantic, operational, measurement, and functional equivalence. Guidelines have been proposed for the cross-cultural adaptation of HRQoL measures.<sup>402 403</sup> These include recommendations for obtaining semantic, idiomatic, experiential and conceptual equivalence in translation, by using back-translation techniques and committee review, pre-testing techniques and re-examining the weight of scores.<sup>402</sup>

## **2.2 Methodological issues related to scoring**

Methods of scoring the questionnaire should be evaluated to ensure that assumptions have not been violated. It is commonly accepted that the ordinal type of data used in questionnaires can be treated as interval level data,<sup>64</sup> although there has been considerable debate about this for some time.<sup>405-407</sup>

### **2.2.1 Summated-rating scaling assumptions**

The most common method for creating summary scale scores is to simply add the relevant items. This method is based on the assumption that all of the items in the scale are of equal importance. Some instrument developers have devised weights for each item relative to their contribution to the total score. However, it is generally accepted that the differential weighting of items is rarely worthwhile.<sup>64</sup> The following criteria are widely used to test the assumption that items can be summed to form scales without standardisation or weights: symmetry of item-

response distributions, equivalence of item means and standard deviations, and roughly equivalent item-total correlations.<sup>408</sup> Each item in a scale should show the same pattern of endorsement frequencies across response categories. Means and standard deviations should be 'roughly equivalent' for all items in a scale. Ware *et al.*<sup>374</sup> suggest that standard deviations should be around 1.0 for items with 5-point response scales. 'Roughly equal' item-total correlations indicate that all the items are contributing equally to the underlying construct and that equal weights can be applied to all items in the scale.<sup>369</sup>

Having tested the assumption that items can be summed to form scales without standardisation or weights, items in a scale which are measured on the same number of response categories (e.g. all items measured on a 5-point Likert scale) can be summed to create a summary score. Many instrument developers recommend transforming the scores to a 0-100 scale using the following formula:<sup>87</sup>

$$\text{Transformed scale} = \frac{(\text{actual raw score} - \text{lowest possible raw score range})}{\text{possible raw score range}} \times 100$$

### 2.2.2 *Items with a varying number of response categories*

For scales in which items are measured on response scales with a varying number of response categories (e.g. 5-point and 6-point Likert scales) it is not appropriate to simply sum the items to form a scale, as items with more response categories would be contributing more to the overall score. One option is to re-calibrate the items to the same response format before summing the items. This is an acceptable method where only a small amount of re-calibration is necessary, such as within a subscale. However, if a large amount of re-calibration is required, for example in the calculation of a total score, this method is less acceptable. Rather the scores need to be transformed (e.g. to percentiles, standardised scores, or normalised scores) before summing.<sup>64</sup>

The most commonly used method in psychometrics for standardising items is to transform items to z-score equivalents using the following formula.<sup>64 371 372</sup>

$$\text{Z score} = \frac{X - \bar{X}}{\text{SD}}$$

Because transforming raw scores to z-scores generates negative scores which are not easily interpretable, z-scores are frequently transformed to *T*-scores for reporting purposes.<sup>64 371 372</sup> *T*-scores are usually based on a mean of 50 and a standard deviation of 10 to give an easily understood range of scores ( $T = 50 + 10z$ ). In order to minimise the effect of missing data, mean z-scores rather than total z-scores are often used.<sup>371 372</sup> This is based on the sum of the z-score transformations of each item divided by the number of items in the scale.

### **2.3 Practical aspects**

This section discusses practical aspects that should be considered when selecting or evaluating a patient-based questionnaire: feasibility, appropriateness, and methods of instrument development.

#### **2.3.1 Feasibility**

The feasibility of the mode of administration of an instrument should be evaluated. For example, poor response rates for an instrument administered by postal survey might indicate that this method is inappropriate for gathering the information and that a different method should be used to gain the information. However, if the mode of administration is changed from its original use, e.g. from interview-administered to self-administered postal survey, the psychometric properties of the instrument need to be re-evaluated. Ideally an instrument should be easy to administer and should cause minimal burden on both respondents and staff. Respondent burden includes the time required to complete the questionnaire and any psychological stress experienced by respondents.<sup>409</sup> Heavy respondent burden may affect both the willingness of individuals to participate in the study and the quality of the data (including the amount of missing data).<sup>93</sup> Administrative burden is defined as the demands associated with administering, scoring and interpreting the instrument. Some instruments developed for research purposes are quite lengthy and as such may be impractical for routine use.

### 2.3.2 *Appropriateness*

In selecting a measure for use in a specific study, several issues related to appropriateness of use should be considered. Conceptual relevance is an issue of central importance. The content of the questionnaire should be appropriate to the aims of the study. The questionnaire should include all domains of interest and all the questions should be relevant to the patient group under study. Questionnaires are validated for use in specific patient groups, for example a particular disease or age group. The patient group under study should be similar to that in which the questionnaire was originally developed. If a disease-specific measure is used with a different patient group from that in which it was developed, the instrument needs to be re-evaluated in the new patient group to confirm its psychometric properties. Similarly, the choice of assessment point should be considered. Established psychometric properties of an instrument for use in one point in time, such as 3 months after surgery, cannot be assumed to be transferable to another point in time, such as 1 year after surgery. Factors that are important to patients in the short-term may be different from the long-term.

### 2.3.3 *Methods for instrument development*

Several stages of instrument development are necessary to ensure that the final version of the questionnaire is acceptable to patients and contains only items with the strongest measurement properties. When evaluating an instrument, it is important that the following assessments have been performed.

#### 2.3.3.1 Pre-testing

The first draft of an instrument should be pre-tested by face-to-face interview with a small number (approximately 15-35) of individuals for whom the questionnaire is intended.<sup>410</sup> The purpose is to evaluate content validity, clarity of wording and appropriateness of phrasing, typographical errors, faulty instructions, inadequate arrangements for recordings answers, and completion time.<sup>410</sup> Pre-testing is performed to identify any necessary revisions before field testing the questionnaire in large samples.

### 2.3.3.2 Preliminary field test (item reduction)

There should be two stages in a full psychometric evaluation, a preliminary and a final field test. The objective of the preliminary field test is to determine response rate and patient acceptability and to obtain psychometric data to select items for the final version of the questionnaire (item reduction). In an attempt to include all appropriate items, the preliminary field test version of a questionnaire is generally much longer than the questionnaire that is intended for final use. The preliminary field test is carried out to determine which items have the strongest measurement properties and to select items on the basis of quantitative (psychometric)<sup>64 366 411</sup> and qualitative (clinimetric)<sup>65 74</sup> criteria.

Another purpose of the preliminary field test is to perform scaling analyses. Scales can be created on the basis of both *a priori* conceptualisations of which items would be expected to be grouped together (e.g. separate scales for symptoms, physical and psychological functioning) and empirical criteria (e.g. factor analysis, Cronbach's alpha). Standard tests of scaling assumptions,<sup>64 369 383 411</sup> can then be conducted to confirm that the items are correctly grouped together, that items in the same scale measure the same construct, that items in different scales measure different aspects of outcome, and that items can be summed to produce scale scores. Preliminary tests of reliability, validity and responsiveness are then performed to confirm that the remaining item pool contains items with the strongest measurement properties. The item reduction phase in instrument development is often omitted. However, it is an essential step in identifying the most robust items and reducing the length of a questionnaire.

### 2.3.3.3 Final field test (psychometric evaluation)

The objective of the final field test is to confirm that the scales identified in the preliminary field test meet scaling assumptions and to evaluate the psychometric properties (reliability, validity, responsiveness) of the item-reduced version of the instrument in an independent sample. The item-reduced questionnaire should be administered with other validated measures of HRQoL and related outcomes to enable extensive tests of construct validity to be performed.

## **2.4 Summary**

This chapter discussed key psychometric properties and standard criteria, as well as practical aspects of evaluating patient-based questionnaires. These guidelines and criteria are used in subsequent chapters to evaluate the psychometric properties of existing cardiac-specific questionnaires (Chapter 3), and to evaluate the CROQ (Chapter 5).

## CHAPTER 3

### CRITICAL REVIEW OF CARDIAC-SPECIFIC PATIENT-BASED QUESTIONNAIRES

This chapter describes the methods and results of a literature review to identify existing cardiac-specific, patient-based questionnaires for patients with CHD. This is followed by a critical review of selected measures. The purpose of the literature review was to determine if there was an existing questionnaire suitable for measuring HRQoL and health outcomes in coronary revascularisation, which met practical and scientific criteria, and if not, to identify items for possible inclusion in a new questionnaire.

#### **3.1 Methods**

##### **3.1.1 Search strategy**

The main strategy was to identify articles describing the measurement of HRQoL in CHD, with the purpose of identifying all cardiac-specific, patient-based questionnaires that address aspects of CHD patients' experience of health and the consequences of illness or treatment. A comprehensive literature review was undertaken. A series of consecutive searches were carried out during the period 1997-2000 using computerised bibliographic databases. These were supplemented by reference follow-up, hand searching of key journals, consultation with experts, and website searches to identify other articles not detected in the computerised bibliographic searches.

Three computerised bibliographic databases were comprehensively searched to identify articles for inclusion in the literature review: Medline (searched from 1960-2000), Health Star (searched from 1974-2000), and PsychLit (searched from 1980-2000). Table 3.1 summarises the search strategy for a series of consecutive searches carried out over the period 1997-2000. As can be seen in this table, several thesaurus terms (key words) were combined with a list of "free text" words. Where possible, search terms were exploded to include all associated terms. The

searches were limited to abstracts published in English. The abstract of each article identified in the bibliographic searches was reviewed to determine whether the article was relevant to this study. All articles reporting the use of a cardiac-specific, patient-based questionnaire to measure HRQoL or satisfaction with treatment in CHD patients were obtained. This included questionnaires developed specifically for patients with CHD, as well as questionnaires that were validated in cardiac patients in general, including some patients with CHD. Abstracts that did not describe the direct measurement of HRQoL in CHD were discarded. Abstracts that reported only the use of a generic HRQoL instrument in CHD were also excluded, as the purpose was to identify cardiac-specific measures. Articles published in English about questionnaires developed in other languages were included. Reference follow-up of the articles obtained was then used to identify other articles not detected in the computerised bibliographic searches.

Hand searches of eight major cardiac journals (*American Heart Journal, American Journal of Cardiology, Heart, European Heart Journal, Heart and Lung, Coronary Artery Disease, Coronary Health Care, Circulation*) and three general journals (*Medical Care, Quality of Life Research, Journal of Clinical Epidemiology*) were also carried out to identify additional articles. Published conference abstracts in *Quality of Life Research* were reviewed between 1997-2000 to identify questionnaires still under development and relevant authors were contacted in writing.

Experts in cardiac surgery, health measurement and health services research were consulted to identify additional studies and questionnaires that may not have been identified or published. Relevant Internet Websites were searched for international research in this field that may not have been published: the UK Clearing House for Health Outcomes, European Research Group on Health Outcomes, Mapi Research, and Quality of Life in Medicine.

### 3.1.2 *Selection of measures for critical review*

The aim of the critical review was to: i) determine if any of the identified cardiac-specific measures were appropriate for comprehensive measurement of HRQoL and health outcomes in coronary revascularisation; and ii) if not, to identify validated questionnaires which could provide items for a new instrument for coronary revascularisation.

Questionnaires identified from the searches were reviewed and further articles rejected based on the following exclusion criteria. Only questionnaires developed for completion by the patient (self- or interview-administered) were included. Non patient-based measures, such as clinician or observer-ratings (including interviews), were excluded. Instruments developed for use with patients with heart failure were included, as ischaemia is a common cause of heart failure, but questionnaires developed specifically for hypertension were excluded, as this is a risk factor for CHD. Instruments that measured mediators of outcome, such as personality, were excluded as the purpose of the review was to identify patient-based questionnaires developed for CHD patients to measure outcomes.

The psychometric properties and general characteristics of all identified cardiac-specific questionnaires were reviewed to determine their appropriateness as a comprehensive outcome measure for coronary revascularisation. Evidence of each instrument's reliability (internal consistency, test-retest), validity (content, criterion, construct) and responsiveness was collated and summarised. The following descriptive information about general characteristics was also collected to help guide decisions of appropriateness: number of items, type of response format, methods of scaling and scoring, use of item reduction techniques, patient group, method of administration, assessment points used in the study, age of sample, and information about validated language versions.

Questionnaires that met minimum reliability criteria (i.e. Cronbach's alpha or test-retest correlations  $>.70$ ) and that provided at least minimum evidence of validity

(i.e. expected convergent or discriminant correlations with external criteria) were selected for further review.

## **3.2. Results**

### **3.2.1 Results of searches**

A very large number of articles (approximately 2000 including duplicates) were identified from the consecutive searches across the three computerised bibliographic databases. A large number of articles were subsequently discarded after reviewing the abstract, as they did not describe the measurement of HRQoL in CHD. The large majority of articles that were excluded were indexed as HRQoL articles, but actually involved proxy not direct measurement of HRQoL. For example, many articles indexed as HRQoL in fact reported on the proportion of patients able to return to work or able to perform well on exercise testing. A large number of articles that reported only the use of generic HRQoL instruments with patients with CHD were also excluded. All articles that described the measurement of HRQoL in CHD using a cardiac-specific, patient-based questionnaire were obtained.

Although the exact number of articles and questionnaires identified from the various searches was not recorded, the majority of questionnaires (approximately 90%) were identified through Medline searches. PsychLit did not identify any questionnaires included in the critical review that were not identified by other methods. Hand searching of conference abstracts in *Quality of Life Research* resulted in the identification of two questionnaires still under development, one of which has recently been published in a peer-reviewed journal. The remaining questionnaires were identified through reference follow-up and hand searching of key journals. Reference follow-up proved useful in identifying the source paper that described the development of the questionnaires. Hand searching of key journals identified further relevant articles for review, particularly articles which had only recently been published and had not yet been indexed on the computerised bibliographic databases.

### 3.2.2 Measures for critical review

Using the methods described above, 60 cardiac-specific, patient-based questionnaires developed for use with patients with CHD (or heart failure) were identified. Table 3.2 summarises the psychometric properties of these 60 patient-based questionnaires. Information about reliability (internal consistency, test-retest, inter-rater), validity (content, criterion, construct), and responsiveness is summarised in Table 3.2 to facilitate the comparison of measures. The table is sub-divided into five sections: measures for coronary revascularisation, angina, myocardial infarction, heart failure, and general (non-specific) cardiac measures developed for a range of conditions. Within subsections, questionnaires are presented in alphabetical order for ease of reference. For some measures, various psychometric properties have been evaluated in different studies rather than in a single study; where possible this information has been combined in Table 3.2. Actual values for statistical tests have been used where possible, but in some cases this information had to be summarised.

Of the 60 questionnaires identified, only a minority has actually been comprehensively evaluated for psychometric properties. Of the psychometric properties that have been evaluated, reliability has been most frequently assessed. Only 28 (47%) of the 60 questionnaires identified met minimum reliability criteria (Cronbach's alpha or test-retest correlations  $>.70$ ) and provided at least minimum evidence of validity. These questionnaires are identified with asterisks (\*\*) in Table 3.2, and are reviewed in more detail later in this chapter. The majority of instruments have not been adequately validated and many of their psychometric properties are unknown. Many were developed *ad hoc* for a specific research study with no attempt to evaluate psychometric properties. Consequently, they do not meet the required criterion of showing evidence of psychometric robustness.

General characteristics of the 60 questionnaires were also reviewed (see Appendix 3.1 for a summary). As can be seen in Appendix 3.1, the instruments varied considerably in length. Although the majority of measures used Likert response scales, several used dichotomous items or visual analogue scales. The majority of

measures are scored by summing items, although a few used weighting formulae. Only a few questionnaires were developed using item reduction techniques, and where these techniques were employed, few details are provided about how and which items were eliminated from the original instrument. Most questionnaires were developed for self-administration, although a few were developed for interview administration. Questionnaires have been validated for use at a range of assessment points, but all questionnaires were validated for use at a single point in time. For example, questionnaires were validated for use at baseline before treatment, but no attempt was made to validate the instrument again after treatment. The majority of questionnaires were developed for patients undergoing medical rather than surgical treatment; 17 for general cardiac samples including patients with a range of conditions, 15 were developed specifically for coronary revascularisation, 11 for angina, 11 for heart failure, and 6 for myocardial infarction. The majority of cardiac-specific questionnaires have been validated for patients under 75 years of age, and women have been largely underrepresented or excluded. Whilst 41 (68%) of the 60 questionnaires have been developed with or validated in English-speaking patients, only 10 have been validated in the UK. This reflects the strong interest in HRQoL assessment in North America. Of the ten measures developed or validated in the UK, only three met minimum reliability and validity criteria.

Table 3.3 summarises the subset of 28 of the 60 measures which met minimum reliability criteria (Cronbach's alpha or test-retest correlations  $>.70$ ) and which provided at least minimum evidence of validity. As can be seen in this table, only 18 of the 28 questionnaires have an English-language version, 16 have been evaluated for responsiveness, and 15 included item reduction techniques in the instrument development phase. These 28 questionnaires are critiqued in more detail later in this chapter.

In selecting a patient-based measure of outcome, it is essential that careful consideration be given to issues of conceptual relevance. Table 3.4 presents the content domains that have been evaluated in the subset of 28 reliable and valid

measures to clarify their conceptual relevance to patients undergoing coronary revascularisation. Chapter 1 described the content domains that should be measured in evaluating HRQoL and treatment outcomes in coronary revascularisation: disease-specific symptoms, limitations in daily activities, psychological/ cognitive/ social functioning, and post-procedural outcomes (adverse effects and satisfaction with treatment). As can be seen in Table 3.4, the majority of instruments cover the core domains of disease-specific symptoms, physical/ psychological/ and social functioning, but few cover procedure-related outcomes such as satisfaction with treatment. None of the reliable and valid cardiac-specific patient-based questionnaires include items on adverse effects such as readmission to hospital or complications (Table 3.4).

### **3.3 Critical review of selected cardiac-specific patient-based questionnaires**

This section presents a critical review of the subset of 28 of the 60 questionnaires, which met minimum psychometric criteria. Instruments listed in Table 3.2 that did not demonstrate minimal evidence of reliability and validity are not critically reviewed. The review of questionnaires has been divided into five sections: coronary revascularisation, angina, myocardial infarction, heart failure and general cardiac (non-specific) measures.

#### **3.3.1 Coronary revascularisation**

Of the 28 questionnaires, only 3 were developed specifically for coronary revascularisation: Cleary *et al.*'s battery,<sup>289</sup> Perception of the Waiting Period Questionnaire,<sup>331</sup> and Quality of Life Index-Novi Sad(QOLI-NS).<sup>333 412</sup> These three measures were critically reviewed to evaluate the strength of their psychometric properties, to determine whether they were suitable for the comprehensive measurement of HRQoL and health outcomes in coronary revascularisation, and to identify items for inclusion in a new questionnaire for coronary revascularisation.

As part of a clinical trial, Cleary *et al.*<sup>289</sup> developed and validated a battery of ten generic and disease-specific scales to measure HRQoL after PTCA. This battery,

administered via telephone interview, proved to be reliable (Cronbach's alpha  $>.80$  for all scales), valid (moderate inter-scale correlations and tests of scaling assumptions) and responsive (detected significant change between pre- and 1-month post-revascularisation). The content of the battery was derived from a review of the most sensitive dimensions in clinical trials that measured HRQoL in cardiovascular disease. It covers a number of important domains including symptoms, physical well-being, perceived health, emotional well-being, home management, work, recreation, and social and sexual functioning.

Although the Cleary *et al.* battery shows good psychometric properties, it is not appropriate for the purpose of this study for several reasons. The scales are largely taken from generic questionnaires and so do not focus on the experience of coronary revascularisation or CHD. The only disease-specific component is the inclusion of the London School of Hygiene Dyspnoea and Cardiovascular Questionnaires<sup>343</sup> and the Specific Activity Scale<sup>264</sup> to measure cardiac symptoms on exertion. The generic items do not enquire whether any limitations are the direct result of the patient's heart condition, as opposed to other factors or illnesses, and are less responsive than the disease-specific scales. Cleary *et al.*'s battery does not assess the impact of PTCA; it does not include some important domains such as adverse events (e.g. physical and psychological complications and readmission to hospital). These complications are bothersome for many patients in the early stages of recovery. There is no assessment of satisfaction, for example with the outcome of treatment, or with the information given about the procedure or recovery period. Satisfaction is an important aspect of outcome that can influence HRQoL. There are no items concerning cognitive functioning or the sense of uncertainty about restenosis that many PTCA patients report. Cleary *et al.*'s battery is further limited for the purpose of this study by not having been validated for use as a self-administered questionnaire or for use with CABG patients. As the items in this battery are largely generic, they are not the optimal choice for inclusion in a new coronary revascularisation specific questionnaire.

The Perception of the Waiting Period Questionnaire<sup>331</sup> is a 23-item instrument developed in the US to evaluate the perceived effect of waiting for CABG. This questionnaire, developed for use in a single study, has demonstrated only minimum reliability and validity in a very small sample of patients. Limited evidence of its psychometric properties, together with its narrow focus on the experience of waiting for surgery, precludes this questionnaire for the purposes of our study; it does not provide a comprehensive assessment of HRQoL in coronary revascularisation. However, the questionnaire was reviewed to determine whether it could provide items for inclusion in a new questionnaire for coronary revascularisation.

An 18-item reliable and valid cardiac surgery questionnaire for patients undergoing CABG and heart valve replacement has been developed in Yugoslavia: the Quality of Life Index - Novi Sad (QOLi-NS).<sup>333 412</sup> It includes questions on physical and mental health status, social interaction and self-perception of health and is scored as an index measure (0 to 1). Whilst the QOLi-NS contains some items of relevance to this study, it does not include any items specific to the experience of coronary revascularisation. It has been translated into English, but the standard procedures for forward-backward translation<sup>399 402</sup> have not been followed and the translation does not read well. The authors do not plan to psychometrically evaluate the English version (D Jakovljevic and Z Potic, personal communication, 6 April, 1998). Whilst the QOLi-NS satisfies the minimum criteria for reliability and validity, outlined in Section 3.1.2, evidence in support of its psychometric properties is not strong. Test-retest reliability has been confirmed, but evidence of internal consistency is lacking. Similarly, there is only weak support for validity. It is highly correlated with pre-operative risk scores calculated using Parsonnet's algorithm, but there is no further evidence of construct validity. It has not demonstrated the ability to detect groups known to differ and there is no evidence to support its scaling structure. Although it may be possible to translate the QOLi-NS into English using the appropriate methods and re-evaluate its psychometric properties, the fact of its limited psychometric properties and narrow conceptual focus precludes this option. It was also not considered appropriate to borrow items from

the QOLI-NS for inclusion in a new instrument as the translation into English is of poor quality.

As there is no single validated questionnaire specific to coronary revascularisation, which provides a comprehensive assessment of all content domains of interest, the remaining reliable and valid cardiac-specific questionnaires were critically reviewed. The purpose was to determine their appropriateness for measuring outcomes in coronary revascularisation and to determine whether they were a possible source of items for incorporation into a new questionnaire for coronary revascularisation. These 25 measures have been subdivided into measures specifically for angina, myocardial infarction, heart failure and finally general (non-specific) cardiac questionnaires.

### 3.3.2 *Angina*

Five questionnaires developed to measure the severity and impact of angina met minimum criteria for reliability and validity. These include: Seattle Angina Questionnaire,<sup>325</sup> Summary Index for Quality of Life in Angina<sup>337</sup> the Angina Pectoris Quality of Life Questionnaire,<sup>338 339 341</sup> the Quality of Life Questionnaire for Angina,<sup>341</sup> and the Angina-Related Limitations at Work Questionnaire.<sup>340</sup> Of these, only two (Seattle Angina Questionnaire and Angina-Related Limitations at Work Questionnaire) have a validated English language version.

Of the five questionnaires, the Seattle Angina Questionnaire (SAQ)<sup>325</sup> has demonstrated the strongest psychometric properties (reliability, validity and responsiveness). The SAQ is a widely-used, 19-item instrument developed in the US to measure functional status in CHD. It has been adapted cross-culturally for use in 13 countries, including the UK, and is recommended by the Medical Outcomes Trust. The Summary Index for Quality of Life in Angina (SI)<sup>337 413</sup> also appears to be a reliable, valid and responsive instrument. It has been validated in Finnish only and is not widely used, but has demonstrated some convincing preliminary evidence in support of its psychometric properties; results need to be confirmed in further studies. The remaining three of these five instruments (Angina

Pectoris Quality of Life Questionnaire (APQLQ),<sup>338 339 341</sup> Quality of Life Questionnaire for Angina Pectoris,<sup>341</sup> and Angina-Related Limitations at Work Questionnaire<sup>340</sup>) have demonstrated minimum evidence of reliability and validity. Further testing of their psychometric properties is required, particularly of test-retest reliability and responsiveness.

Whilst the primary clinical reason for coronary revascularisation is to relieve angina in order to improve functional capacity and HRQoL, angina relief is only one outcome of interest in evaluating outcomes in CABG and PTCA. These five angina-specific instruments focus exclusively on the experience and relief of angina. They are, therefore, too narrow in focus to measure outcome comprehensively after coronary revascularisation. However, some of these instruments were identified as sources of items for inclusion in a new coronary revascularisation questionnaire.

### 3.3.3 *Myocardial infarction*

Four questionnaires developed specifically for myocardial infarction patients met minimum criteria for reliability and validity: the Heart Patients Psychological Questionnaire,<sup>345 414</sup> Quality of Life after Acute Myocardial Infarction (QLMI),<sup>346</sup> Modified Quality of Life after Acute Myocardial Infarction (QLMI-1),<sup>347</sup> and Modified Quality of Life after Acute Myocardial Infarction (QLMI-2).<sup>348</sup> All instruments, except the Heart Patients Psychological Questionnaire, have been validated in English, but none have been widely used.

The oldest of these instruments, the Heart Patients Psychological Questionnaire,<sup>345 414</sup> is a 40-item instrument developed in The Netherlands and validated for use only in Dutch. Whilst it met the minimum criteria for reliability and validity, its psychometric properties have been poorly documented in English. The Quality of Life after Acute Myocardial Infarction questionnaire was originally developed as an interview-administered instrument (QLMI). It has since been revised twice to form two different versions of the same instrument, the QLMI-1 and QLMI-2.<sup>347 348</sup> Whilst the first two versions of the instrument have demonstrated some evidence

of reliability and validity, the third version (QLMI-2) has generally surpassed the earlier versions. The QLMI-2 is a 27-item self-administered instrument that covers emotional, physical and social functioning. It has demonstrated excellent internal consistency (Cronbach's alpha greater than .90 for all three scales). The test-retest reliability of this version of the instrument has not been evaluated, but the original version (QLMI) was shown to be reproducible. Evidence in support of its construct validity and responsiveness to detect clinical change is not strong; future studies should evaluate these properties. The QLMI-2 is currently being translated into German, Italian and Spanish.

Whilst there is considerable overlap of HRQoL and symptoms in MI patients and CABG/PTCA patients, the specific outcomes pertinent to coronary revascularisation, such as adverse effects and satisfaction with outcome, are not measured by these questionnaires. The QLMI-2 was identified as a source of appropriate items for inclusion in a new questionnaire for coronary revascularisation.

#### 3.3.4 *Heart failure*

Five questionnaires developed specifically for patients with heart failure met the minimum criteria for reliability and validity: Chronic Heart Failure Questionnaire (CHQ),<sup>415 416</sup> Kansas City Cardiomyopathy Questionnaire (KCCQ),<sup>417</sup> Left Ventricular Dysfunction Questionnaire (LVD-36),<sup>418</sup> Minnesota Living with Heart Failure Questionnaire (LihFE),<sup>419 420</sup> and Self Assessment of Quality of Life in Severe Heart Failure Questionnaire (QLQ-SHF).<sup>421</sup> These questionnaires have all been validated in English, with the exception of the QLQ-SHF, a Swedish instrument.

The most widely used measure of outcome in heart failure is the Minnesota Living with Heart Failure Questionnaire (LihFE). The LihFE is a 21-item instrument covering symptoms, physical, emotional and social functioning, which has been validated for use in 12 different languages. The LihFE has been shown to be reliable, valid and responsive to medications known to benefit patients with heart

failure and to be insensitive to the effects of placebo.<sup>420 422</sup> However, it does not clearly discriminate between patients with heart failure of differing severity.<sup>270</sup> The Chronic Heart Failure Questionnaire (CHQ)<sup>415 416</sup> is also widely used and has strong psychometric properties (reliability, validity and responsiveness) but has only been developed for interview-administration. It has been suggested that it compares favourably with the LhFE but takes longer to complete.<sup>270</sup>

A new instrument, the Kansas City Cardiomyopathy Questionnaire (KCCQ),<sup>417</sup> has recently been developed and has proven to be reliable, valid and responsive. This 23-item instrument should prove to be a useful tool for future studies of HRQoL in heart failure as the instrument developers report it to be more sensitive to important clinical change than the LhFE. The Left Ventricular Dysfunction Questionnaire (LVD-36)<sup>418</sup> is a 36-item questionnaire developed specifically to measure HRQoL in patients with left ventricular dysfunction that has demonstrated preliminary evidence of reliability, validity and responsiveness. This instrument needs to be further evaluated before being recommended for widespread use. The Self Assessment of Quality of Life in Severe Heart Failure Questionnaire (QLQ-SHF)<sup>421</sup> has been used in a few drug trials in Sweden. There are conflicting results about its ability to discriminate between active treatment and placebo, but it has demonstrated moderate sensitivity to small changes in HRQoL. This questionnaire has not been translated into English and is not widely used.

These five questionnaires have been included in this critical review because heart failure is commonly the consequence of ischaemia. However, heart failure is not always caused by ischaemia, and some of the measures reviewed have been developed for heart failure of varying causes. As such, they may not be relevant to measuring outcomes in patients with CHD. However, there is some overlap of HRQoL and symptoms in patients with heart failure and patients undergoing coronary revascularisation. These questionnaires contain some items that could be included in a new coronary revascularisation questionnaire.

### 3.3.5 *General cardiac (non-specific)*

Eleven questionnaires developed for cardiac patients in general met the minimum criteria for reliability and validity. Five of these are profile instruments measuring a range of dimensions: Ferrans and Powers Quality of Life Index (QLI-Cardiac Version III),<sup>255 355 423</sup> Cardiac Health Profile (CHP),<sup>353</sup> Multidimensional Index of Life Quality (MILQ),<sup>358</sup> Cardiac Quality of Life Index (CQLI)<sup>359</sup> and the Utility Based Quality of Life-Heart Questionnaire.<sup>363</sup> The remaining six questionnaires have a single focus i.e. physical or psychological functioning: Duke Activity Status Index,<sup>266</sup> Reduced Duke Activity Status Index,<sup>267</sup> Cardiac Denial of Impact Scale (CDIS),<sup>351</sup> Global Mood Scale (GMS),<sup>356</sup> Health Complaints Scale (HCS),<sup>357</sup> and Cardiac Depression Scale.<sup>352</sup>

The most widely used profile instrument is the Ferrans and Powers Quality of Life Index (QLI-Cardiac Version III),<sup>255 355 423</sup> which includes items on physical health and functioning, social and economic aspects, psychological and emotional functioning, and relationships with family members. However, as it is conceptually weak in the area of emotional functioning, the developers recommend the concurrent use of the Profile of Mood States.<sup>284</sup> In another study, the authors supplemented the QLI with questions on cardiac symptoms, physical activity and lifestyle.<sup>290</sup> Although Faris and Stotts<sup>255</sup> validated the QLI in 20 PTCA patients and report it to be reliable and sensitive to improvements in health, such a small sample is generally considered insufficient for a definitive psychometric evaluation. Papadantonaki<sup>284</sup> evaluated the QLI in 44 CABG and 32 PTCA patients and reported it to be reliable, but did not evaluate any other psychometric properties. Therefore, it would be inappropriate to describe this measure as having been validated for use with coronary revascularisation patients. Dougherty and colleagues<sup>282</sup> found the QLI to be insensitive to changes in clinical status measured by the Canadian Cardiovascular Society Classification of angina on exertion (CCS).

The remaining four profile questionnaires have not been widely used and require more extensive psychometric testing. The Cardiac Health Profile (CHP)<sup>353</sup> is a

psychometrically sound Swedish questionnaire developed to measure HRQoL in CHD. The CHP has been translated into English, but the standard procedures for forward-backward translation<sup>399 402</sup> have not been followed, and the English version has not yet been psychometrically evaluated (P Wahrborg, personal communication, 5 June, 1998). The CHP includes items on emotional and social functioning, general health status, severity of angina and satisfaction with treatment. It is currently undergoing expansion and is now available for use with patients with heart failure and arrhythmias (P Wahrborg, personal communication, 5 June, 1998). All items in the CHP are phrased in a generic fashion, with the exception of two questions on chest pain.

The Multidimensional Index of Life Quality (MILQ)<sup>358</sup> is a reliable and valid questionnaire developed in the US in 348 cardiovascular disease patients with a wide range of disease conditions, including hypertension, heart failure, stable angina, and post-revascularisation patients. The MILQ covers nine life domains: mental health, physical/ cognitive/ social functioning, physical health, intimacy, productivity, financial status, and relationship with health professionals. None of the MILQ items are cardiac-specific and the authors claim that the domains and items are relevant to most chronic diseases. As such, it is limited in its capacity as a sensitive outcome measure for coronary revascularisation.

The Cardiac Quality of Life Index<sup>359</sup> was derived from Padilla and Grant's Quality of Life Index for cancer patients and modified to measure the outcome of cardiac rehabilitation programmes. It has demonstrated preliminary evidence of reliability and validity in a sample of 222 patients, but further testing of its psychometric properties in independent samples is required. The responsiveness of this instrument has not been evaluated.

Recently, a new measure has been developed and validated for patients with cardiovascular disease: the Utility Based Quality of Life-Heart Questionnaire (UBQ-H).<sup>363</sup> The UBQ-H can be used to estimate a summary utility index for overall HRQoL and has proven to be reliable, valid and responsive in a sample of 322

cardiovascular outpatients, largely consisting of patients with severe heart failure. It includes items to assess psychological distress, self-care, social activities, physical ability, and overall quality of life. The UBQ-H represents an important new development as it will facilitate the calculation of quality adjusted survival time in studies of cardiovascular patients. The UBQ-H was published in 1999 after this study had been started.

Six reliable and valid instruments were identified which specifically measure a single aspect, i.e. psychological or physical aspects of CHD: Cardiac Denial of Impact Scale (CDIS),<sup>351</sup> Cardiac Depression Scale (CDS),<sup>352</sup> Global Mood Scale (GMS),<sup>356</sup> Health Complaints Scale (HCS),<sup>357</sup> Duke Activity Status Index<sup>266</sup> and the Reduced Duke Activity Status Index.<sup>267</sup> Although these questionnaires are narrow in focus, they were included in the review as a possible source of items for the development of a new questionnaire for coronary revascularisation.

These eleven general cardiac measures were considered conceptually and methodologically inadequate for the comprehensive measurement of HRQoL and health outcomes in coronary revascularisation as they failed to capture the full impact of CHD and coronary revascularisation on outcome. Some of the questionnaires reviewed required further psychometric testing and some were narrow in focus. The questionnaires were considered as possible sources of items for inclusion in a new questionnaire for coronary revascularisation.

### **3.4 Summary**

The purpose of this review was to determine whether there was an existing psychometrically sound, patient-based questionnaire appropriate for comprehensive measurement of HRQoL and health outcomes in coronary revascularisation. A total of 60 cardiac-specific patient-based questionnaires were identified. Many of these questionnaires were developed for specific heart conditions such as angina, myocardial infarction and heart failure, and so focus on issues relevant to patients receiving medical therapy, rather than all outcomes relevant to coronary revascularisation. Many of these questionnaires only address

a partial aspect of HRQoL or have been developed on an *ad hoc* basis and have not been fully tested for reliability, validity and responsiveness. Since undertaking this critical review, Dempster and Donnelly<sup>424</sup> have published a short review of HRQoL instruments used to evaluate outcomes in CHD. They came to similar conclusions: few of the existing disease-specific measures are psychometrically sound and amongst the best are the QLMI-2 and the SAQ.

A coronary revascularisation outcome questionnaire must be conceptually relevant and psychometrically sound. Questionnaires need to be carefully selected to ensure that they are sensitive to change, and that they contain items that are relevant to the impact of the coronary revascularisation. Of the 60 cardiac-specific questionnaires identified, only 28 met minimum criteria for reliability and validity. Of these, three were developed specifically for patients undergoing coronary revascularisation and none provided a comprehensive assessment of HRQoL and health outcomes. Existing coronary revascularisation questionnaires do not assess all the domains of interest; significant areas of importance to patients' experience of coronary revascularisation are not covered. None measure procedure-related outcomes, such as readmission to hospital, physical and psychological complications, satisfaction with results and information given about the procedure. Rather, most measures focus on the same core elements that are included in disease-specific questionnaires (symptoms, physical, psychological and social functioning).

As there was no single psychometrically sound questionnaire appropriate for comprehensive measurement of HRQoL and health outcomes in coronary revascularisation, other reliable and valid cardiac-specific questionnaires were critically reviewed to identify items for possible inclusion in a new questionnaire for coronary revascularisation. Whilst these instruments, largely developed for patients maintained on medical treatment, were not appropriate for measuring outcomes after coronary revascularisation *per se*, several included items of relevance to CABG and PTCA.

Subsequent chapters describe the development and psychometric validation of a new instrument, the Coronary Revascularisation Outcome Questionnaire (CROQ), to measure patient-based outcomes for patients undergoing CABG and PTCA. Where possible, items from existing questionnaires reviewed in this chapter were considered for inclusion in the CROQ.

## CHAPTER 4

### QUESTIONNAIRE DEVELOPMENT: METHODS & RESULTS

This chapter describes the development of the CROQ. The chapter begins with a description of the qualitative methods used to refine the conceptual model. Subsequent sections describe the development and pre-testing of the questionnaire.

#### **4.1 Refining the conceptual model and generating items**

The conceptual model for the CROQ was developed from four sources: review of the literature, review of existing instruments, qualitative interviews with patients, and expert opinion and consultation with health care professionals and researchers. Full details of the review of the literature and of existing questionnaires are presented in Chapters 1 and 3.

##### *4.1.1 Qualitative interviews with patients*

The use of qualitative interviews to guide the development phase of questionnaires is a necessary step to ensure that the patient's perspective is incorporated. Qualitative, in-depth interviews were conducted with CABG and PTCA patients to help develop the conceptual model and generate items. The purpose was to determine the "critical components" to be included as items, and to identify the words used by patients to ensure that the CROQ content was developed in a meaningful way.<sup>425</sup>

##### **4.1.1.1 Recruitment**

In August 1998, a total of 20 English-speaking patients at the Royal Brompton Hospital including 18 who had undergone CABG or PTCA in the previous 18 months, and 2 who were about to undergo CABG, were invited to participate. Patients were identified during visits to Outpatient clinics or from computerised patient lists at the Royal Brompton Hospital. An opportunistic sampling strategy was used to identify patients from Outpatient clinics. A more systematic sampling

strategy was used to identify patients from computerised lists, with every fifth name being selected until the required sample size was achieved.

Patients were recruited in two ways. The 11 patients identified during Outpatient clinic visits were invited by their Consultant to meet with the researcher, who then took patients to a private room to explain the purpose of the interview. The nine patients recruited from computerised patient lists were sent a letter from the researcher describing the study and inviting them to be interviewed (Appendix 4.1). These patients were telephoned a few days later to enquire whether they wanted to take part and, if so, to arrange a time for a home interview. All patients were asked to read and sign a patient consent form (Appendix 4.2). They were told the interview would involve questions about their personal experience of having CHD and the impact of CABG/PTCA on their day-to-day lives. Patients were assured that the interview was strictly confidential, that the researcher was not involved in their care, and that the information was for research purposes only.

All 20 patients (10 CABG, 10 PTCA) who were invited to participate agreed. The sample included 15 men and 5 women ranging in age from 41 to 76 (mean = 62) years.

#### 4.1.1.2 Interview techniques

Interviews in both settings followed the same two-phase format. The first phase used an unstructured approach to determine areas of importance to seven patients. The interviewer asked "*Tell me about your experience of heart disease and the impact your heart operation has had on your day-to-day life? Please describe anything that you feel is relevant because I want to understand what it is like to have heart disease and heart operations.*" The interviewer was deliberately vague about the purpose of the interview as spontaneous responses were desired.<sup>425</sup> No prompts were given as the purpose was to hear their "stories" and to generate ideas rather than impose a structure. Patients were interviewed until they indicated that there was no more to say.

The second phase of the interviews, carried out with 13 patients, used a general topic list (Table 4.1) generated from the findings of the first phase. This allowed issues identified in the first phase of interviews to be explored in this phase. The interviewer asked patients the same general question as in the first phase, but also used prompts to elicit patients' views about specific areas in the topic list if these areas were not spontaneously covered. These topics were covered in a different order depending on how the interview progressed. Patients were engaged in conversation until no new themes emerged or until they indicated that there was no more to say.

The interviewer made effort to keep eye contact with the patient, especially when sensitive issues were being discussed, to encourage them to speak freely, and to reassure them that they were being listened to. All patients were informed that the interview was confidential and that the care they received at the hospital would not be influenced by their taking part in the interview. The decision was made not to use a tape-recorder as it was felt that patients might feel inhibited to speak freely. Field notes were taken during all interviews and then supplemented with more detail immediately after. The researcher transcribed all field notes later the same day. The material generated from the interviews was then categorised into content domains. For each domain, the specific comments made by patients were listed (see Table 4.2 for selected excerpts from the patient interviews grouped by content domain) and the frequency of comments tabulated (see Appendix 4.3). This information was used to generate items for the CROQ.

#### 4.1.1.3 Main findings

The qualitative interviews confirmed the conceptual model described in Chapter 1. Several key content domains were identified for inclusion in the new questionnaire: cardiac symptoms, limitations in daily activities, psychological functioning (worry / anxiety, fear of death and pain, depressed mood, uncertainty, self-efficacy, frustration, irritation, avoidance of activities), cognitive functioning (memory, concentration, attention, decision making, completing activities), social functioning (impact on family and friends, independence, feeling a burden), adverse effects

(cardiac-related readmissions to hospital, physical and psychological complications) and satisfaction with treatment (information received and expectations about the impact of the operation).

Although the general topic list used in the second phase helped to ensure that all topics were covered, patients tended to discuss these areas of their own accord, just as they had in the unstructured interviews in the first phase, suggesting that both methods produce similar results. There did not appear to be any qualitative difference in the content generated from interviews carried out in a private room in the hospital clinic and those conducted at home. There was no difference between patients interviewed in hospital after an appointment and those interviewed at home in the emphasis placed on symptoms relative to other aspects of HRQoL. In all interviews, patients began by describing their symptoms without being prompted to do so. The majority of patients began with a history of their heart disease, which typically began when they first became aware of their symptoms. The qualitative interviews largely confirmed the findings from the literature review. However, some notable exceptions are described below.

Patients described a range of complications and the length of time they persisted after CABG (e.g. pain, infection, oozing, tenderness, numbness and tingling in and around the wounds in the chest and leg; bruising on the chest and leg; new painful sensations in the chest and neck area; swollen feet and ankles; weakness and lethargy; nausea, loss of appetite and general eating problems). Some CABG patients also expressed concern over the appearance of surgical scars. The interviews indicated that many of these complications continued to be a problem for some patients for up to 12 months. In contrast, complications from PTCA were less common and did not persist over a long period. This is not surprising as PTCA is less invasive and the required recovery time is shorter. A number of patients reported some complications in the first few weeks after PTCA (e.g. pain, infection, oozing, tenderness, numbness in the groin wound and surrounding area; bruising in the groin and thigh; discomfort in the chest due to the operation; swollen feet and ankles; problems in the groin where the catheter was inserted). Some

patients were bothered by the appearance of bruising in the groin and thigh area. Several qualitative studies of patients' perceptions and experiences of the post-procedural period for coronary revascularisation were identified in the literature review.<sup>172 173 175 178 426</sup> However, patients attached far more importance to these complications than has been documented previously. Little previous research has routinely monitored or quantified the impact of complications from the patient's perspective.

Patients also described new fears and concerns that arose after coronary revascularisation. Several patients reported being afraid of their symptoms returning and worried that they might need further heart operations in the future. Some explained that these fears were always in their mind and never went away. PTCA patients were especially concerned about their symptoms returning. Restenosis is an accepted complication of PTCA, yet few studies assess the impact of this uncertainty on the patient. Findings from one study suggest that patients' concerns about re-occlusion can contribute to poorer psychological functioning.<sup>205</sup> Many patients had been told that there was a significant chance that their angina would return, and in some cases they believed it had and that the PTCA had failed.

Several patients made a distinction between "chest pain", "chest tightness" and "chest discomfort" when describing their angina. Clinicians frequently ask patients about chest pain, but findings from these interviews suggest that some patients clearly experience discomfort as opposed to pain, and are not inclined to use the term pain, whilst others describe it as "a definite pain". These findings influenced the choice and phrasing of items in the CROQ. Patients' descriptions of severe radiating pain to other parts of the body including arms, shoulders, hands, neck, throat, jaw and back, not always accompanied by chest pain, also influenced the choice and phrasing of items in the CROQ.

#### **4.1.2**     *Expert opinion and consultation*

Expert opinion was sought from key health care professionals involved in cardiac patient care before, during and after coronary revascularisation. Experts, including cardiac surgeons, cardiologists, Cardiac Specialist Nurses, a Pain Control Nurse, and a Cardiac Liaison Nurse were asked to describe the impact of CABG / PTCA on patients' daily lives. They were asked to describe changes patients might notice in the short- and long-term in relation to symptoms, general and emotional functioning, and any complications. They were also asked to identify domains that they thought should be covered in the CROQ. In addition, researchers with experience in evaluating patient-based outcomes were consulted regarding methodological aspects of questionnaire development.

The content domains identified through expert opinion and consultation were similar to those identified by the literature review. However, the nursing staff provided further support for the findings from the patient interviews concerning the extent of complications after CABG. The Royal Brompton Hospital runs a telephone helpline service that provides advice to patients about any problems after discharge from hospital. This service is used frequently by CABG patients, with all calls documented in a ward diary. These diaries were reviewed to identify commonly reported problems and concerns. The diaries covered the same problems described in the patient interviews, literature, and consultations with nursing staff. Clinicians, whilst recognising the importance of psychosocial issues, tended to focus on pre-revascularisation symptoms and adverse events after revascularisation, such as stroke and myocardial infarction.

#### **4.2**     **CROQ conceptual model (pre-test version)**

Results of the qualitative work described above and the literature review formed the basis for the development of the conceptual model for the pre-test version of the CROQ (see Figure 4.1). Most importantly, findings clarified the need for two separate versions of the CROQ, one to evaluate outcomes before revascularisation and another similar but slightly different version to evaluate outcomes after revascularisation. Core content domains identified for inclusion in

the pre- and post-revascularisation versions included: cardiac symptoms, limitations in daily activities (including work), psychological functioning (worry / anxiety, fear of death and pain, depressed mood, uncertainty, self-efficacy, frustration, irritation, avoidance of activities), cognitive functioning (reasoning, memory, attention, concentration, decision making, speed of reaction, completing activities), and social functioning (impact on family and friends, independence, interference with social activities). Additional post-revascularisation domains identified for inclusion in only the post-revascularisation version included: adverse effects (e.g. cardiac related readmissions to hospital, physical and psychological complications) and satisfaction (with treatment including information received and expectations about the impact of the operation).

Qualitative interviews with patients confirmed the findings of the literature review and provided clear examples within each content domain. In addition, patient interviews revealed the importance of measuring both physical and psychological complications that can have a significant impact on HRQoL. The CROQ conceptual model is also based on existing conceptual models in heart disease, particularly Wenger *et al.*'s<sup>24</sup> (see Chapter 1). Wenger *et al.* distinguish symptoms induced by treatment from symptoms of the disease, and also incorporate expectations, both of which are supported by the findings from the patient interviews.

The CROQ conceptual model does not include two dimensions which were identified in existing models: economic circumstance / income and sexual functioning. Economic circumstance / income was excluded as this is generally believed to be part of "quality of life" in the general sense of the term, as opposed to HRQoL. Questions about sexual activity were excluded from the CROQ for several reasons. Firstly, as the topic did not arise in the patient interviews and was not mentioned as a missing domain during pre-testing, it was not considered to be an important problem for all patients. Secondly, the CROQ was developed with the aim of appropriateness for use with all patients, including the elderly, some of whom no longer have partners and some of whom might have stopped sexual

activities; only items applicable to all respondents should be included in a questionnaire.<sup>427</sup> Further justification for the exclusion of questions on sexual activity comes from the examination of responses to the open-ended question (*"Is there anything else that you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire?"*). During preliminary and final field testing, participants made no voluntary references to sexual functioning.

### **4.3 Development of the pre-test version of the CROQ**

Two versions of the CROQ were developed for each procedure: a pre- and a post-revascularisation version. The pre-revascularisation CROQ covers the same five core content domains (symptoms, limitations in daily activities, psychological, cognitive, and social functioning) in both the CABG and PTCA versions. The post-revascularisation version covers the same five core domains, but includes two additional domains (adverse effects and satisfaction), see Figure 4.1. The post-revascularisation CROQ-CABG and CROQ-PTCA are identical with the one exception; the items addressing complications in the adverse effects domain are different for the two procedures. Domains included in both the pre- and post-revascularisation versions of the CROQ are referred to as the core pre- / post-revascularisation domains. Domains included only in post-revascularisation versions are referred to as the post-revascularisation domains.

Items were generated for each content domain. Items were either borrowed from existing instruments after obtaining permission from the developers, or newly created. The CROQ includes two types of items: evaluative and descriptive. Evaluative items are scored, whereas descriptive items are not scored and are used for descriptive purposes only. Demographic questions were also included, but these are not formally a part of the CROQ. The 78-item pre-test version of the CROQ-CABG (Appendix 4.4) includes 76 evaluative and 2 descriptive items. The 72-item pre-test version of the CROQ-PTCA (Appendix 4.5) includes 70 evaluative and 2 descriptive items. Appendix 4.6 presents the source of each of the CROQ items, the original phrasing of borrowed items and their re-phrasing in the pre-test version of the CROQ.

#### 4.3.1 *Borrowed items*

Where possible, items were borrowed from existing validated cardiac-specific questionnaires (see Appendix 4.6). For each content domain in the CROQ, relevant items were identified for inclusion. For some domains, such as symptoms (particularly angina) there were several alternative items available to choose from. The item that was phrased in the simplest language and which most closely matched the "language" used by patients in the qualitative interviews was selected. However, some of the other content domains, such as cognitive functioning and satisfaction with treatment, were not well covered by existing cardiac-specific questionnaires. The wider literature of HRQoL questionnaires in other diseases was therefore consulted to identify items for possible inclusion after modification. A total of 33 items borrowed from existing psychometrically sound questionnaires were incorporated into the CROQ.

Nine cardiac-specific items were identified for inclusion in the CROQ. Three items were borrowed from the Seattle Angina Questionnaire<sup>325</sup> (medication frequency, fear of having a heart attack or dying suddenly, and the degree to which anginal symptoms interfered with the enjoyment of life), five items from the Quality of Life after Acute Myocardial Infarction - QLMi2<sup>348</sup> (lack of confidence, frustration, feeling excluded from social activities, family being overprotective feeling a burden) and one item from the Angina Impact Questionnaire<sup>337</sup> (difficulty completing activities). Minor changes in wording were made to these items to make them appropriate to the question stems (see Appendix 4.6).

Three multi-item scales from generic health status questionnaires were incorporated into the CROQ: the SF-36 Physical Functioning (10 items) and Role-Physical (4 items) scales<sup>87</sup> and the MOS Cognitive Functioning scale (6 items).<sup>428</sup> Minor changes in wording were made to the question stems to make these questions specific to heart disease (see Appendix 4.6). A single item (restricted in social activities) was also borrowed from the SF-36.

Three items from non-cardiac disease-specific questionnaires were borrowed and modified to make them specific to heart disease: two items from the Menorrhagia Outcomes Questionnaire – MOQ<sup>372</sup> (global change after surgery and expected speed of recovery) and one item from the Prostate Outcomes Questionnaire – POQ<sup>371</sup> (expectation of results).

#### 4.3.2 *New items*

New items were constructed for content domains that were not adequately covered by existing questionnaires. The pre-test versions of the CROQ-CABG and CROQ-PTCA included 45 and 39 new items, respectively.

Effort was made to write simple and specific questions. Unfamiliar and ambiguous terms<sup>429</sup> and double-barrelled questions<sup>64</sup> were avoided. The words and phrases used by patients to describe, for example a symptom such as chest tightness, were used in the questionnaire as language use can influence response by how closely it represents a patient's personal experience.<sup>430</sup> Items were kept as short as possible, as longer items have poorer validity.<sup>431</sup> Items were grouped in a logical order in sections of similar content, based on the conceptual model, as the interpretation of the intended meaning of items can be influenced by the content of adjacent items.<sup>429</sup> Only items applicable to all respondents were included as questions not applicable to some patients can result in missing responses.<sup>27</sup>

General health status measures tend to use 4 weeks as the time of reference.<sup>3</sup> This reference point was used throughout the CROQ as changing times of reference can be difficult for patients to follow. Underlining and the use of bold font were used to emphasise the most salient parts of each question.<sup>427</sup> The time of reference was underlined in each question stem and wherever possible, the terms "heart condition" or "heart operation" were included in bold font. This was done to help the patient focus on the specific problem and the impact of their heart condition / operation on their day-to-day life.

Dichotomous and Likert-type scales were used for all evaluative items. Response categories were chosen so as not to have more than seven options.<sup>64</sup> Wherever possible the response categories were modelled on existing measures: SF-36,<sup>87</sup> Seattle Angina Questionnaire,<sup>325</sup> Prostate Outcomes Questionnaire,<sup>371</sup> and MOS Cognitive Functioning scale.<sup>428</sup> Dichotomous response categories were used where a Yes / No answer was required. Pre-testing was used to check that response categories were mutually exclusive and exhaustive.<sup>427</sup>

#### 4.3.3 *Descriptive and demographic questions*

Two descriptive items are included in the CROQ. One item asks about the level of exertion that induces chest pain, chest tightness or angina. As this item is not scored on a Likert response scale, it is not treated as an evaluative item and is not included in any of the scales of the CROQ. It provides descriptive information of interest to clinicians. The second descriptive item asks about cardiac-related re-admissions to hospital. As the use of self-reported information about re-admissions to hospital has not been validated against hospital records, it was decided that this item should be used for descriptive information only and that it should not be scored in the scales of the CROQ, until further testing could confirm its validity.

A series of demographic questions are also included for descriptive and validation purposes only. Included are sociodemographic questions about: gender, age, date of completion of questionnaire, ethnicity, other long-standing illnesses,<sup>432</sup> current work situation, occupational class (e.g. job title and occupation, partner's job title and occupation<sup>433</sup>), time to return to work, living situation, date of CHD diagnosis, and the need for help to complete the questionnaire. Where possible, questions were borrowed from large surveys.<sup>432-434</sup> The final item in the CROQ asks "*Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire?*" This open-ended question was included as another means of evaluating the content validity of the questionnaires and to allow patients to include other relevant information.

#### **4.3.4 Questionnaire format and instructions**

Attention was given to the layout and appearance of the questionnaire as this can affect response rate and the accuracy of responses.<sup>425 427</sup> The CROQ was printed in an A3 size booklet to make it easy to read and turn pages.<sup>427</sup> The aim of the questionnaire design was to produce a very simple "uncluttered" format with sufficient space between items.<sup>427</sup> Each question was framed in a box to make a clear distinction between items. All coding details were excluded from the CROQ as there is evidence that changing the numbers used to code response categories can influence responses.<sup>435</sup> Response categories for each item were listed in the same order of magnitude, scoring from high to low, to avoid confusing the patient.

Simple instructions were included on the front page. As recommended,<sup>427</sup> a statement at the outset of the questionnaire informed patients that the information provided would be completely confidential. A unique patient identifier was written at the top of each questionnaire and no names were used.

#### **4.4 Questionnaire pre-testing**

As described in Chapter 2, there are several necessary steps in instrument development and the refining of a questionnaire. The first draft of an instrument (pre-test version) should be pre-tested with a small sample of patients to evaluate overall acceptability. Modifications should then be made before undertaking a preliminary field test in a large sample of patients (using the preliminary field test version). Item reduction analysis should then be performed to develop a shorter item-reduced questionnaire containing items with the strongest measurement properties (final field test version) which should then be further evaluated in the final field test. This section describes the methods and results of the first stage of questionnaire refinement (pre-testing). The methods and results of the preliminary and final field tests are reported in subsequent chapters.

##### **4.4.1 Methods**

All pre-testing was done on the post-revascularisation versions of the questionnaires as they contain every item of the CROQ. The purpose of the pre-

testing was to evaluate the content validity, readability, clarity of wording, appropriateness of phrasing, exhaustiveness of response categories, item sequence, questionnaire format and instructions, before use in the postal survey.

Preliminary versions of the post-revascularisation CROQ-CABG and CROQ-PTCA questionnaires were pre-tested by face-to-face interview, between December 1998 and January 1999, with patients 6 weeks to 4 months after revascularisation. Patients were invited to take part whilst waiting in the Outpatient clinics at the Royal Brompton and Harefield Hospitals. Patients were informed that they were helping to test a new questionnaire and that they should tell the researcher of any difficulties in answering the questions. Patients were observed whilst completing the questionnaires so that the researcher could see if the patient expressed difficulty answering an item by spending a longer time answering it.<sup>410</sup> Following completion of the questionnaire, all patients were interviewed as recommended<sup>427</sup> to address the following points:

- Does each question measure what it is intended to measure?
- Are all the words understood?
- Are the questions interpreted similarly by all respondents?
- Does each closed-ended question have an answer that applies to each respondent?
- Does the questionnaire create a positive impression that motivates people to reply?
- Are questions answered correctly?
- Are any questions missed out?
- Do any questions elicit uninterpretable answers?

Fowler<sup>410</sup> suggests that changes should be made when an item is problematic for 20-40% of the sample. In addition to pre-testing with patients, the questionnaires were peer reviewed by a panel of health services researchers and experts in health measurement. Revisions were made to the questionnaires on the basis of the results from the pre-testing. Preliminary field test versions of the CROQ were then developed.

#### 4.4.2 Results

All 19 patients (11 CABG, 8 PTCA) who were invited to take part in pre-testing agreed to participate. Some patients talked through their response options and explained their personal understanding of the meaning of each item as they completed the questionnaire, as well as being interviewed after completing the questionnaire. This exposed the researcher to the "conversational processes"<sup>429</sup> involved in answering each item and ensured that the items did not have unintended interpretations.<sup>410 425</sup>

Minor changes were made to the pre-test versions of the CROQ-CABG and CROQ-PTCA to develop the preliminary field test versions. Table 4.3 presents the phrasing of each of the CROQ items in the three stages of questionnaire development – pre-test, preliminary and final field test versions. Several CABG patients needed clarification of the meaning of four items (*chest pain, chest tightness, discomfort in the chest, and radiating pain*). Patients were confused as to whether the questions were referring to angina pain or to current pain sensations that were the result of the operation. For this reason "due to angina" was added to each of these items to make it clear that the question was asking about angina pain, not pain associated with the CABG operation which appear later in the questionnaire.

The pre-test version of the cognitive functioning domain asked about the frequency of cognitive problems, but did not ask whether these problems were a result of the patient's heart condition. Several patients answered this question in the "general sense" and stated that they experienced these problems because of age. For this reason the transition statement "*The next questions ask about problems related to your heart condition*" was added.

Minor changes were made to the items addressing complications. Two CROQ-CABG items were subdivided into six items as they combined several symptoms, which were not necessarily related, in a single item. The order of items in the CROQ-CABG was changed slightly to group all chest-related items together. The

wording of two CROQ-CABG items was slightly changed to make them more specific to the problem. One item in the CROQ-PTCA about infection, oozing or tenderness in the groin wound was split into three separate items, as these were considered too different to be grouped together. The CROQ-PTCA item about concern over the appearance of the scar was considered inappropriate and eliminated, as patients do not tend to scar after PTCA. This item was replaced with a new item (*problems in the groin where the catheter was inserted*) which covered the problems described in the patient interviews concerning lumps and problems in the groin wound.

All patients except one indicated that the questionnaires covered the relevant domains and that there was "nothing missing". An additional item was added to the psychological functioning domain about difficulty in planning ahead (e.g. vacations and social events), which one patient described had been a significant problem for him and his wife.

Some of the long questions in the pre-test versions of the CROQ were split over two pages. This caused difficulties for some patients when completing the questionnaires as they felt important issues had been missed out of these sections. Some felt frustrated when they discovered that the question continued over the page and changed their earlier responses in the light of the content of the next page. This was a particular problem for the items addressing complications in the CROQ-CABG. To resolve these problems, the question order was changed slightly for the CROQ to avoid splitting questions between pages.<sup>427</sup>

Minor changes were made to the pre-test questionnaire format. The grid lines were removed from the questions to make them clearer and replaced by light shading of alternate items to help the patients focus on the correct line and related response category.

The health services researchers who reviewed the questionnaires felt that the questionnaire would accomplish the study objectives.<sup>427</sup> A few minor grammatical

changes were made to the items. The experts in health measurement were satisfied by the format and style of the questionnaire, item sequence, questionnaire content and instructions. The CROQ was deemed ready for field testing in large samples.

The preliminary field test versions of the post-revascularisation CROQ-CABG (Appendix 4.7) and CROQ-PTCA (Appendix 4.8) contain 83 and 75 items, respectively. The 53-item pre-revascularisation preliminary field test versions of the CROQ-CABG (Appendix 4.9) and CROQ-PTCA (Appendix 4.10) are identical in item content.

#### **4.5 Summary**

This chapter described the development and pre-testing of the CROQ-CABG and CROQ-PTCA questionnaires. Subsequent chapters describe the methods and results of the preliminary and final field tests undertaken to evaluate the psychometric properties of the CROQ in large samples of patients.

## CHAPTER 5

### PSYCHOMETRIC EVALUATION OF THE CROQ: METHODS

The psychometric evaluation of the CROQ was carried out in three stages in two independent field tests: item reduction and preliminary psychometric evaluation (preliminary field test) and final psychometric evaluation (final field test). This chapter describes: i) data collection and management; ii) methods used for item reduction; and iii) methods used to evaluate the psychometric properties of the CROQ.

#### **5.1 Data collection and management**

This section describes the methods of data collection and management, including sampling frame and recruitment, inclusion and exclusion criteria, and questionnaire administration used in both the preliminary and final field tests.

##### *5.1.1 Sampling frame and recruitment*

Patients were recruited from three hospitals in the UK, the Royal Brompton and Harefield Trust Hospitals in London and the Wythenshawe Hospital in Manchester. All three hospitals perform a high number of CABG and PTCA procedures annually.

All patients who were expected to undergo coronary revascularisation in the study period were eligible to participate in the study. Patients were concurrently recruited from the three sites after they were given a date for CABG or PTCA, or from CABG waiting lists, where available. Patients were recruited between February 1999 and May 1999 for the preliminary field test and between November 1999 and May 2000 in the final field test. In order to identify patients scheduled for CABG and PTCA, waiting list administrators, Cardiology Facilitators, and Consultants' secretaries were contacted twice-weekly. In addition, ward and catheterisation laboratory diaries were checked where possible.

In all three hospitals, patients are given very short notice of the date for revascularisation. In many cases, patients are telephoned just a few days prior to admission as soon as a slot becomes available. Operations are frequently cancelled and rescheduled. Elective patients can be assigned a theatre slot a few days in advance, but if emergency cases are admitted, the elective patient moves down the list.

To avoid sending questionnaires to patients at a time so close to major surgery, CABG waiting lists were used to recruit patients where possible. Patients at the Royal Brompton Hospital were recruited if they had been on the central waiting list for over 40 weeks, or if they had been assigned a high urgency score category. The aim was to recruit patients on the waiting list who were most likely to undergo CABG in the following 2 to 3 months. This waiting list is clearly categorised and updated on a weekly basis. The Harefield Hospital does not routinely use urgency ratings and the central waiting list is not managed on a weekly basis. Consultants' secretaries at the Harefield were telephoned on a twice-weekly basis for patient details. It was not necessary to use the Wythenshawe Hospital waiting list, as a Waiting List Co-ordinator was able to provide information on a weekly basis. Surgeons and cardiologists at the Wythenshawe Hospital confirm CABG and PTCA lists toward the end of the week preceding the surgery date. The proposed theatre schedules were faxed to the Project Co-ordinator on a weekly basis, generally on a Friday morning. In an attempt to increase sample size, patients scheduled for CABG/PTCA on a Monday were sent the questionnaire as late as the previous Friday morning. This may have reduced the overall response rate, as some patients may not have received the pre-revascularisation questionnaire before they were admitted for revascularisation. Recruitment at all three sites continued until at least 100 CABG and 100 PTCA baseline questionnaires, from patients who had actually undergone the procedure, had been returned.

Procedure lists were produced at each hospital, confirming which patients had undergone CABG and PTCA and the date. All patients who underwent CABG or PTCA during the recruitment period were sent a 3-month post-revascularisation

questionnaire, even if they had not been sent a baseline questionnaire before revascularisation. This was done to maximise the sample size for the psychometric analyses of post-revascularisation data, and to ensure that the samples used for the psychometric analyses were representative samples of all patients undergoing CABG and PTCA at the three hospitals.

Patients who returned both the pre- and post-revascularisation versions of the CROQ comprised the responsiveness subsample. A random sample of CABG and PTCA patients in the 3-month post-revascularisation sample formed the test-retest subsample. Patients in this sample were sent two copies of the 3-month post-revascularisation CROQ and were asked to complete and return the second questionnaire 2 weeks after completing the first.

#### 5.1.1.1 Inclusion and exclusion criteria

No age limits were applied as coronary revascularisation is increasingly being offered to elderly patients with CHD. Patients who had coronary stents implanted during PTCA were also included to ensure a representative sample of patients who had undergone routine coronary revascularisation.

The following patients were excluded from the study: private patients, non-UK residents, patients participating in another trial involving completion of questionnaires, and patients undergoing CABG combined with another procedure, such as valve replacement. In addition, patients were excluded from the pre-revascularisation sample if the Project Co-ordinator was not informed that they were scheduled for surgery at least 2 days before the procedure date.

#### 5.1.2 *Questionnaire administration*

Both preliminary and final field tests were conducted by postal survey to patients' home addresses. All patients who met the inclusion criteria were invited to participate. Patients completed the preliminary field test version of the CROQ at two assessment points: pre-revascularisation and at 3-months post-revascularisation. Patients completed the final field test version of the CROQ at

three assessment points: pre-revascularisation, and at 3- and 9-months post-revascularisation.

Prior to revascularisation, patients were sent a package that included a letter of invitation from their Consultant (Appendix 5.1 or 5.2), a patient information sheet describing the study and introducing the research team (Appendix 5.3 or 5.4), a consent form (Appendix 5.5), a stamped addressed envelope and the pre-revascularisation version of the CROQ-CABG (Appendix 4.9 or 5.6) or CROQ-PTCA (Appendix 4.10 or 5.7).

A few days before the target assessment point of 3- and 9-months post-revascularisation, patients who had undergone revascularisation were sent the post-revascularisation package which contained a cover letter from the Project Co-ordinator (Appendix 5.8, 5.9 or 5.10), the post-revascularisation CROQ-CABG (Appendix 4.7 or 5.11) or CROQ-PTCA (Appendix 4.8 or 5.12), a patient information sheet (Appendix 5.13, 5.14 or 5.15), and a stamped addressed envelope. The 3-month post-revascularisation package sent to patients who had not completed the pre-revascularisation version of the CROQ contained a letter of invitation from their Consultant (Appendix 5.16), a patient information sheet (Appendix 5.17), a consent form (Appendix 5.18) and the post-revascularisation CROQ-CABG (Appendix 4.7 or 5.11) or CROQ-PTCA (Appendix 4.8 or 5.12). To avoid unnecessarily upsetting family members if a patient had died, the Project Co-ordinator confirmed whether the patient was still alive immediately before sending out all post-revascularisation questionnaires. This was done by either checking the hospital's Patient Administration System or by telephoning the patient's GP surgery.

All patients in the final field test (except patients in the test-retest subsample) were sent a booklet containing the CROQ and one of the following questionnaires: the Short-Form 36 (SF-36),<sup>87</sup> the Seattle Angina Questionnaire (SAQ),<sup>325</sup> the Quality of Life After Myocardial Infarction Questionnaire (QLMI-2)<sup>348</sup> or the Minnesota Living with Heart Failure Questionnaire (LHFE).<sup>419</sup> The purpose of administering two

questionnaires to each patient at each time point was to gather data to evaluate the external construct validity of the CROQ and to assess the comparative responsiveness of the different HRQoL instruments. The SF-36 was selected as it is the most commonly used generic HRQoL questionnaire and is well validated. The SAQ, QLMI-2 and LIhFE were selected as they are the most psychometrically sound cardiac-specific questionnaires and include some similar content domains.

Standard techniques<sup>425 436</sup> were used to ensure a high response rate, including personalised letters, standardised instructions, follow-up reminder letters and stamped addressed return envelopes. The cover letter inviting patients to take part in the study included the purpose of the study, what was required of participants and a statement informing patients about confidentiality.<sup>427</sup> In the post-revascularisation sample, reminder letters were sent at 3 and 5 weeks after the original mailing date to patients who did not return a completed questionnaire. The 3-week reminder contained a cover letter (Appendix 5.19) and another copy of the CROQ, whereas the 5-week reminder consisted only of the cover letter (Appendix 5.20). Patients who did not return the questionnaire after two reminders were considered non-responders. Reminders were not sent to patients in the pre-revascularisation sample, as the interval between notification and the date of the procedure was too short.

## **5.2 Item reduction**

The purpose of the preliminary field test was to select items to be retained for use in the final field test versions of the questionnaires (item reduction) and to carry out a preliminary psychometric evaluation of the item-reduced CROQ. This section describes the methods of analyses for item reduction of the CROQ.

### **5.2.1 *Item reduction strategy***

A detailed analysis plan, with three main phases of item reduction, was drawn up to incorporate the pre- and post-revascularisation assessment points. The item reduction analysis plan was based on earlier research incorporating a variety of methods,<sup>371 372</sup> but was modified for use with a pre- / post-intervention design.

The pre-revascularisation CROQ data were used as the starting point of the analyses due to the nature of the questionnaire. Common criteria for item reduction analysis include analyses of maximum and aggregate adjacent endorsement frequencies. However, one would expect ceiling effects in the post-revascularisation data as the procedures are known to be effective at alleviating problems associated with CHD, such as symptoms and accompanying limitations in physical and mental functioning. If the post-revascularisation data were used as the starting point and maximum endorsement frequency criteria applied, important items might have been eliminated. Analyses were, therefore, based on pre-revascularisation data and further tested in the post-revascularisation samples to confirm findings.

*Phase One:* Item reduction analyses were firstly carried out on the 52 items in the core domains that were common to both the pre- and post-revascularisation versions of the CROQ-CABG and CROQ-PTCA (Symptoms, Physical/ Psychological/ Social/ and Cognitive/ Functioning). As all patients about to undergo both CABG and PTCA have CHD, pre-revascularisation data for both procedures were pooled to increase the sample size enabling rigorous tests of scaling assumptions. Preliminary scales identified from analysis of the pooled pre-revascularisation data were then tested in the independent pre- and post-revascularisation samples (CABG only and PTCA only) to evaluate their robustness.

*Phase Two:* Item reduction analyses were then conducted on the set of 10 common items included in the post-revascularisation versions of both the CROQ-CABG and CROQ-PTCA. Data obtained from the CABG and PTCA post-revascularisation samples were pooled and used for these analyses. These analyses were then repeated in each of the post-revascularisation samples independently (CABG only and PTCA only) to check that similar items would have been eliminated if the questionnaires had been item-reduced independently without pooling the data.

*Phase Three:* Item reduction analyses were finally performed on the 19 CABG and 11 PTCA post-revascularisation complication items in each of the post-revascularisation samples independently (CABG only and PTCA only). This was done because the complication items differ in content for the CROQ-CABG and CROQ-PTCA.

The purpose of item reduction analyses is to determine the subset of items that are the most robust when evaluated rigorously using standard psychometric methods. Items with the weakest measurement properties that failed specified criteria were eliminated from the CROQ initial item pool (item elimination). The item-reduced questionnaire was then scaled and the scale properties evaluated (tests of scaling assumptions). Additional items were eliminated on the basis of further psychometric tests until all pre-specified criteria were satisfied.

### 5.2.2 *Item elimination*

Items were eliminated from the CROQ mainly on the basis of quantitative (psychometric)<sup>64 90 366 369 411 437</sup> criteria, but qualitative (clinimetric)<sup>65 74</sup> criteria were also considered for a few items. Item reduction involves many of the same tests described in Chapter 2, but these tests are applied at the item rather than scale level. Table 5.1 presents the psychometric criteria used to evaluate the CROQ at both the item and scale level. For some tests, the criteria for items are more stringent than for scales.

Standard psychometric methods for item reduction were applied including: item-total correlations, item redundancy, missing data, maximum and aggregate adjacent endorsement frequencies, item responsiveness, and item test-retest reliability. Criteria applied during item reduction that differed from those described in Chapter 2 are described below. In order to ensure that items of clinical significance were retained, qualitative criteria took precedence over psychometric criteria only for a very small number of items for which it was agreed that the item should be retained for clinical or conceptual reasons.

*Item-total correlations:* The criterion used to eliminate items in the CROQ was an item-total correlation less than .30.<sup>366</sup> Criteria cited in the literature range from strict (.40) to liberal (.20). With no consensus as to which criterion to use, the value in the middle of the range (.30) was chosen.

*Item redundancy:* Values of greater than .70<sup>438</sup> and .75<sup>439</sup> have been suggested as criteria for item redundancy. The criterion used to eliminate items in the CROQ was an inter-item correlation greater than or equal to .75. The item in the pair with the poorest psychometric properties as judged by other criteria (e.g. missing data, maximum endorsement frequencies and aggregate adjacent endorsement frequencies) was eliminated. In the case where two items were psychometrically equivalent, a decision was made by consensus with another psychometrician, based on other characteristics of the item (e.g. relevance, clarity, item length). If one or both items was considered clinically important, the item was retained. Highly correlated items of similar content were considered for combining into one item, and highly correlated items that appeared to measure distinct aspects were considered for retention.

*Missing data:* A more stringent criterion (greater than 5%) than applied at the scale level was used to eliminate items in the CROQ.

*Maximum endorsement frequencies:* Values for item floor/ceiling effects of greater than 90%,<sup>440</sup> 85%,<sup>26</sup> 80%,<sup>441</sup> and 70%<sup>439</sup>,<sup>440</sup> have been applied in the literature. The criterion used to eliminate items in the CROQ was maximum endorsement frequency (MEF) greater than or equal to 75%. This value was chosen for two reasons: it was within the range of values reported in the literature and, empirically did not lead to excessive item elimination. No criteria are specified in the literature for minimum endorsement frequencies so this was not used to eliminate items from the CROQ. The MEF criterion was applied with caution, as there are no guidelines for evaluating both pre- and post-intervention versions of a scale. In the case of coronary revascularisation, one would expect high endorsement frequencies for response alternatives that reflect poor health before surgery and improvement after

surgery. Furthermore, in some cases a symmetrical distribution of responses should not be expected,<sup>374</sup> as for example with items related to uncommon states such as severe depression. Items were, therefore, not eliminated on the basis of endorsement frequencies from the post-revascularisation CROQ.

*Aggregate adjacent endorsement frequencies:* An additional criterion is to eliminate items in which the aggregate endorsement frequency for two or more adjacent response categories is less than or equal to 10%.<sup>437</sup> This criterion was also applied in the analysis of the pre-revascularisation version of the CROQ, in which items are expected to be better distributed across response categories, but not in the post-revascularisation version, where data are expected to be skewed towards better outcomes.

*Item responsiveness:* Responsiveness is generally assessed for scales rather than for items. However, in order to retain only the most robust items, responsiveness was also assessed at the item level in the item reduction stage. Items which did not show significant change ( $p < .05$ ) between the pre-revascularisation and 3-month post-revascularisation assessments were considered unresponsive and eliminated. This criterion was used in the item reduction stage of the core domains of the pre- and post-revascularisation versions of the CROQ (Symptoms, Physical/, Psychosocial/, and Cognitive Functioning).

*Item test-retest reliability:* Test-retest reliability is also generally assessed for scales rather than for items, but was also assessed at the item level in order to retain only the most robust items. As there is no established criterion for item test-retest, a value of greater than .40 was used as this is well below the scale test-retest criterion of greater than or equal to .70.<sup>90</sup> Items with a test-retest correlation less than .40 were eliminated. As test-retest was only evaluated at 3-months post-revascularisation, this criterion was used only for item elimination in the post-revascularisation version of the CROQ.

### 5.2.3 Tests of scaling assumptions

After initial item elimination, preliminary subscales were created on the basis of both *a priori* conceptualisations of which items would be expected to be grouped together (i.e. separate scales for Symptoms, Physical/ Psychological/ Social/ and Cognitive Functioning, Satisfaction, and Complications) and empirical criteria (factor analysis and Cronbach's alpha). Scales were summed to create summary scores and the psychometric properties evaluated. Standard tests of scaling assumptions<sup>64 369 374 383 411</sup> were performed to confirm that items were correctly grouped together, that items in the same scale measured the same construct, and that items in different scales measured different aspects of outcome. Tests of scaling assumptions were carried out through exploratory factor analysis, internal consistency, and an examination of item convergent and discriminant correlations (multi-trait scaling techniques<sup>369 374</sup>).

Factor analysis was used to empirically derive scales after item elimination; it was used only as an exploratory technique to generate hypotheses about the structure of the data.<sup>385</sup> No items were eliminated based on factor analyses but "rogue" items that failed to load on a factor were identified. Unrotated Principal Components factor analysis was used as the starting point to check that all items loaded on the first factor (criterion: greater than or equal to .30) and that all items were measuring the same underlying construct. Cronbach's alpha and item-total correlations were used to confirm the internal consistency of scales. Item convergent and discriminant validity correlations were used to evaluate each item in relation to its hypothesised scale as well as in relation to other scales. Ware *et al.*'s<sup>374</sup> definitions of scaling successes and failures were used (see Chapter 2), but the more stringent criterion of only allowing definite scaling successes (SS) was applied in the initial stages of item elimination to ensure that only items with the most robust measurement properties were retained. Qualitative (clinimetric) criteria took precedence over psychometric criteria only if it was agreed that the item should be retained on clinical grounds. Further items were eliminated as they failed psychometric criteria and analyses were repeated until all criteria were satisfied.

### **5.3 Preliminary and final field tests**

After tests of scaling assumptions were carried out to confirm the psychometric adequacy of the item-reduced scales, the acceptability, reliability, validity and responsiveness of the scales were evaluated using standard psychometric techniques (see Chapter 2).<sup>64 366 411 442</sup> The psychometric evaluation was carried out in two stages: the *preliminary psychometric evaluation* was carried out using data from the preliminary field test and the *final psychometric evaluation* was carried out using data from the final field test. Analyses were conducted separately for both the pre- and post-revascularisation versions of the CROQ-CABG and CROQ-PTCA, using data obtained from the pre- and post-revascularisation patient samples.

The purpose of the final field test was to evaluate the psychometric properties of the item-reduced questionnaires in independent samples. It was necessary to confirm that the psychometric properties were maintained in an independent sample of patients who completed only the item-reduced versions of the CROQ. The methods for the preliminary and final psychometric evaluations were identical, but the final evaluation involved more extensive testing of external construct validity and responsiveness. The methods of the preliminary and final psychometric evaluations are described below; the criteria applied are described in Chapter 2.

#### **5.3.1 Acceptability**

Response rates in the pre- and post-revascularisation samples were calculated to establish overall acceptability to patients. Acceptability was also assessed on the basis of percentage of missing data for items and scales, floor and ceiling effects, and skewness of score distributions.

#### **5.3.2 Internal consistency and test-retest reliability**

Cronbach's alpha was calculated to assess internal consistency. Intraclass correlation coefficients were calculated between the two administrations of the post-revascularisation versions of the CROQ to determine test-retest reliability.

### 5.3.3 Calculation of summary scores

To test the assumption that items could be summed to form scales without standardisation or weights, several criteria were evaluated: symmetry of item-response distributions, equivalence of item means and standard deviations, and roughly equivalent item-total correlations<sup>408</sup> (see Chapter 2).

For subscales in which all items were measured on the same response scale (i.e. Physical/ Cognitive/ Psychosocial/ Functioning and Complications), items were summed to create a total score and then transformed to a 0-100 scale,<sup>87</sup> with 100 representing the best possible outcome. For subscales in which items were measured on response scales with a different number of categories (i.e. Symptoms and Satisfaction), items were re-calibrated to the response format held by the majority of items as follows:

<b>Scale (item)</b>	<b>Recoding for re-calibration</b>
Symptoms (Q2)	(1=1) (2=1.66) (3=2.50) (4=3.33) (5=4.16) (6=5)
Satisfaction (Q12)	(1=1) (2=1.75) (3=2.50) (4=3.25) (5=4)
Satisfaction (Q13)	(4=missing) (1=1) (2=2.5) (3=4)
Satisfaction (Q14)	(1=1) (2=2.5) (3=4)

One item (Q2) in the Symptoms scale is scored on a 6-point scale and the remaining six items on a 5-point scale. This item was re-calibrated to a 5-point scale. Three of the six items in the Satisfaction scale are measured on a 4-point scale (Q11a-c), two on a 3-point scale (Q13, Q14), and one on a 5-point scale (Q12). Items in the Satisfaction scale were re-calibrated to a 4-point scale. After re-calibration, items were summed to create a total score and then transformed to a 0-100 scale consistent with the other scales. Appendix 5.21 summarises these scoring procedures.

Missing data were imputed according to the algorithm recommended for scoring the SF-36.<sup>87 88</sup> If at least 50% of items in a scale were completed, a person-specific

estimate (mean of the non-missing items) was substituted for the missing items. A missing scale score was assigned if over 50% of the items in a scale were missing.

To calculate a total score (Core Total) for the core pre- / post-revascularisation domains (Symptoms, Physical/, Psychosocial/ and Cognitive/ Functioning) which are measured on response scales with a varying number of categories, it was necessary to standardise the scores rather than re-calibrate. Raw scores were transformed to z-score equivalents<sup>64 371 372</sup> before being summed to form total scores. In order to minimise the effect of missing data, mean z-scores rather than total z-scores were used. This is based on the sum of the z-score transformations of each item divided by the number of items in the scale. The program for calculating summary scale scores, based on the mean of the z-scores for items in the summary scale, allows inclusion of a questionnaire with 50% or less of missing data. Z-scores were transformed to T-scores based on a mean of 50 and a standard deviation of 10 for reporting purposes.<sup>64 371 372</sup> To calculate a total score (Total Outcome) for the post-revascularisation domains (Adverse effects and Satisfaction) the same scoring procedure was followed.

#### 5.3.4 *Tests of scaling assumptions*

Item convergent and discriminant correlations were calculated for each scale to test scaling assumptions. Correlations between each item to its own scale and to each of the other scales were examined. Scaling assumptions were tested by examining item convergent and discriminant correlations.<sup>374</sup>

#### 5.3.5 *Validity*

##### 5.3.5.1 Content validity

Content validity was evaluated in two different ways: firstly, during development of the CROQ through expert clinical opinion, a comprehensive literature review, and comparison with existing measures; and secondly, responses to an open-ended question asking the patient "*Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire?*" were examined to identify additional content not covered.

### 5.3.5.2 Construct validity: within-scale analyses

Four types of analyses were undertaken to evaluate the internal construct validity of the CROQ: internal consistency, intercorrelations between scales, factor analysis, and known group differences / hypothesis testing.

5.3.5.2.1 Internal consistency. Cronbach's alpha was calculated to measure internal consistency, the degree of support for the construct validity of the scales.

5.3.5.2.2 Intercorrelations between scales. Intercorrelations between scales were calculated to determine the extent to which the scales measure separate but related constructs; the objective was to evaluate unique reliable variance. The Symptoms and Physical Functioning scales were expected to be moderately to highly correlated, as cardiac symptoms tend to be induced on exertion. Scales measuring physical health (Symptoms and Physical Functioning) were expected to be correlated more highly with each other than with scales measuring mental aspects of health (Psychosocial and Cognitive Functioning). Similarly, scales measuring mental health (Psychosocial and Cognitive Functioning) were expected to be moderately correlated with each other and to be correlated more highly with each other than with scales measuring physical aspects of health (Symptoms and Physical Functioning). Low correlations were expected between Complications and all other scales, as this measures a different aspect of HRQoL.

5.3.5.2.3 Factor analysis. Factor analysis was performed on the pre- and post-revascularisation items in both pre- and post-revascularisation samples to confirm the assignment of items to the scales identified from item reduction analyses. It was also performed on the post-revascularisation items in both the CABG and PTCA post-revascularisation samples. Principal Axis Factoring with Varimax rotation, modelling the number of factors to be extracted based on the scales identified from the item reduction analyses, was performed. For the analysis of the 32 core pre- / post-revascularisation items, four factors were extracted to evaluate support for the four core scales identified from the item reduction analyses (Symptoms, Physical/, Psychosocial/, and Cognitive Functioning). For the

analyses of the post-revascularisation items, a two-factor solution was modelled to evaluate support for the assignment of items into the two procedural-specific outcome scales (Satisfaction and Complications). The number of cross loadings (items loading on more than one factor greater than or equal to .35) was examined.

5.3.5.2.4 Known groups / hypothesis testing (within scale analyses). T-tests were used to test a series of hypotheses about expected differences between known groups:

- Patients who report global improvement after revascularisation will show significantly higher CROQ scores (better health outcomes) than those who report their condition as being the same or worse. Mean CROQ scores for patients categorised as improved (scored 4 “a little better”, or 5 “much better” on Q12) and unimproved (scored 1 “much worse”, 2 “a little worse”, or 3 “about the same” on Q12), were compared.
- Patients who report being bothered by chest pain due to angina after revascularisation will show significantly lower CROQ scores (poorer health outcomes) than those who report they are not bothered. Mean CROQ scores for patients categorised as bothered (scored 1 “a lot”, 2 “quite a bit”, 3 “moderately”, or 4 “a little” on Q1a) and not bothered (scored 5 “not at all” on Q1a) by chest pain, were compared.

#### 5.3.5.3 Construct validity: comparison with external criteria

The external construct validity of the CROQ was not evaluated in the preliminary field test, which was primarily undertaken for purposes of item reduction analyses. In the final field test, the CROQ was compared against existing generic and disease-specific HRQoL questionnaires (SF-36, SAQ, QLMI-2, LIhFE), demographic and clinical variables.

5.3.5.3.1 Convergent and discriminant validity. Convergent and discriminant correlations between the CROQ and scales of other HRQoL questionnaires were examined to test hypothesised relationships. For example, the CROQ Physical

Functioning scale was expected to be more highly correlated with the Physical Component Score (PCS) than to the Mental Component Summary Score (MCS) of the SF-36. To further evaluate discriminant validity, CROQ scales were correlated with demographic variables (age, sex and social class); hypothesised low correlations with these variables demonstrate that scores on the CROQ are not biased by these demographic factors.

For CABG, some clinical variables are routinely collected in hospitals for purposes of clinical audit. Where possible this information was obtained. Clinical pre-revascularisation data available for a subsample of CABG patients included: Canadian Cardiovascular Society Classifications of angina (CCS<sup>76</sup>), New York Heart Association classifications of dyspnoea (NYHA<sup>75</sup>), and ejection fractions. Correlations between pre-revascularisation CCS and NYHA classifications and the CROQ-CABG Symptoms scale and symptom items (*chest pain, chest discomfort, radiating pain, and nitro frequency*) were examined. As few data are routinely collected for PTCA, the CROQ-PTCA could not be evaluated against clinical data.

5.3.5.3.2 Known groups / hypothesis testing (analyses against external criteria). One-way ANOVA was used to test differences in mean pre-revascularisation CROQ-CABG symptom scores for patients who differed in the severity of angina as measured by the CCS, dyspnoea as measured by the NYHA, and heart function as measured by ejection fraction. It was hypothesised that CROQ-CABG symptom scores would decrease with increasing severity of angina, dyspnoea and heart function. Ejection fraction was defined as either good (>50%), fair (30-50%) or poor (<30%).<sup>171</sup>

### 5.3.6 Responsiveness

T-statistics, effect sizes<sup>389 390</sup> and standardised response means<sup>391</sup> were calculated for all CROQ (and SF-36, SAQ, QLMI-2, LIhFE in the final field test) scales across time (pre- and 3-months post-revascularisation). In the final field test, these statistics were also calculated between pre- and 9-month post-revascularisation. The ability of scales to detect continuing change over time (longitudinal change)

was also evaluated between the 3- and 9-month post-revascularisation time periods.

#### **5.4 Summary**

This chapter presented the methods of analyses for the three stages of psychometric evaluation of the CROQ questionnaires: item reduction, preliminary psychometric evaluation and final psychometric evaluation. Chapter 6 presents the results of these analyses.

## CHAPTER 6

### PSYCHOMETRIC EVALUATION OF THE CROQ: RESULTS

The psychometric properties of the CROQ were evaluated in two field tests: the preliminary and final field tests. This chapter presents the results from these two field tests. The preliminary field test was undertaken for the purpose of item reduction and to perform a preliminary psychometric evaluation. The final field test was undertaken to perform a full psychometric evaluation of the CROQ in an independent sample, using the same methodology as the preliminary psychometric evaluation, but with more extensive testing of external construct validity and responsiveness. As the results of analyses in the preliminary psychometric evaluation are very similar to those of the final psychometric evaluation, this chapter reports only results for the final psychometric evaluation, results of the preliminary psychometric evaluation are presented in Appendices 6.1 to 6.18.

#### **6.1 Preliminary field test**

##### *6.1.1 Respondent characteristics*

Respondents in the pre-revascularisation CABG sample (N=146) ranged in age from 34 to 82 (mean age  $63.3 \pm 8.7$ ) years, with 22% of the sample 70 years of age or over and 74% male (Table 6.1a). Respondents in the post-revascularisation CABG sample (N=289) ranged in age from 35 to 82 (mean age  $63.7 \pm 9.0$ ) years, with 24% of the sample 70 years of age or over and 75% male. Respondents in the responsiveness subsample (N=128) had similar demographic characteristics to those in the pre- and post-revascularisation samples. The majority of patients in each CABG sample were white, retired, males, living with their partner. In each sample, patients were recruited from all three hospitals. A large proportion of patients reported that they got angina on exertion or at rest at pre-revascularisation and these figures fell at 3-months post-revascularisation. 20% of patients reported that they had been re-admitted to hospital for reasons to do with their heart condition.

Respondents in the pre-revascularisation PTCA sample (N=128) ranged in age from 36 to 88 (mean age  $62.1 \pm 9.7$ ) years, with 21% of the sample 70 years of age or over and 67% male (Table 6.1b). Respondents in the post-revascularisation PTCA sample (N=280) ranged in age from 35 to 88 (mean age  $62.3 \pm 9.8$ ) years, with 23% of the sample 70 years of age or over and 69% male. Respondents in the responsiveness subsample (N=114) had similar demographic characteristics to those in the pre- and post-revascularisation samples. The majority of patients in each PTCA sample were white, retired, males, living with their partner. In each sample, patients were recruited from all three hospitals. A large proportion of patients reported that they got angina on exertion or at rest at pre-revascularisation and these figures fell at 3-months post-revascularisation. 19% of patients reported that they had been re-admitted to hospital for reasons to do with their heart condition.

#### 6.1.2 *Response rates*

Questionnaires were considered ineligible if the patient reported that the procedure had not been carried out. A few patients reported that their PTCA had been started, but not completed due to the nature of the blockage in the arteries. These patients were scheduled for PTCA and consequently appear on the procedure lists. The validity of these patient reports were not confirmed by checking the patients' medical records.

##### 6.1.2.1 Pre-revascularisation samples

A total of 257 questionnaires were posted to patients awaiting CABG (Table 6.2). Of these, 192 (75%) were returned. Of the 257 questionnaires sent, 186 were considered eligible for inclusion; 71 did not actually undergo CABG in the study period and so were not considered eligible. Of the 186 eligible patients, 146 completed and returned questionnaires. The response rate for the CABG pre-revascularisation sample was thus 78% (146/186).

A total of 272 questionnaires were posted to patients awaiting PTCA (Table 6.2). Of these, 186 (68%) were returned. Of the 272 questionnaires sent, 183 were

considered eligible for inclusion; 89 did not actually undergo PTCA in the study period and so were not considered eligible. Of the 183 eligible patients, 128 completed and returned questionnaires. The response rate for the PTCA pre-revascularisation sample was thus 70% (128/183).

#### 6.1.2.2 Post-revascularisation samples

A total of 358 3-months post-revascularisation questionnaires were sent to patients who had undergone CABG (Table 6.3). Of these, 289 (81%) were returned. Included in this sample of 289 patients were 103 patients who were only sent the 3-month post-revascularisation CROQ-CABG, 58 patients in the test-retest subsample, and 128 patients in the responsiveness sample (see below).

A total of 341 3-months post-revascularisation questionnaires were sent to patients who had undergone PTCA (Table 6.3). Three of these patients were later considered ineligible for this study (procedure abandoned due to nature of blockage). Of the 338 eligible patients sent a questionnaire, 280 (83%) returned it. Included in this sample of 280 patients were 109 patients who were only sent the 3-month post-revascularisation CROQ-PTCA, 57 patients in the test-retest subsample, and 114 patients in the responsiveness sample (see below).

*Post-revascularisation only subsamples:* A subsample of 122 CABG patients were sent a questionnaire only at 3-months post-revascularisation. Of these 122 patients, 103 (84%) returned the questionnaire. A subsample of 123 PTCA patients were sent a questionnaire only at 3-months post-revascularisation. Of these 123 patients, 109 (89%) returned the questionnaire.

*Test-retest subsamples:* A subsample of 90 CABG and 90 PTCA patients were sent two questionnaires at 3-months post-revascularisation to complete within a 2-week interval to provide data for test-retest analyses. Of the 90 CABG patients, 58 (64%) returned both questionnaires. Of the 90 PTCA patients, 57 (63%) returned both questionnaires.

*Responsiveness samples:* Patients who completed both the pre- and post-revascularisation versions of the CROQ are referred to as the responsiveness sample. The 146 CABG patients who completed the pre-revascularisation questionnaire were sent a 3-month post-revascularisation questionnaire. Of the 146 patients, 128 (88%) returned it (Table 6.3). This sample of 128 patients is referred to as the CABG *responsiveness sample*. Five of the 146 patients had died and three were too sick to complete the questionnaire according to relatives.

The 128 PTCA patients who completed the pre-revascularisation questionnaire were sent a 3-month post-revascularisation questionnaire. Three of these patients were later considered ineligible as they notified the Project Co-ordinator that the operation had been started but abandoned due to the nature of the blockage in the arteries. (Table 6.3) Of the 125 eligible patients in the sample, 114 (91%) returned the 3-months post-revascularisation questionnaire and are referred to as the PTCA *responsiveness sample*.

### 6.1.3 *Item reduction*

During the item reduction analyses, the pre-revascularisation CROQ was reduced from 52 to 32 evaluative items, the post-revascularisation CROQ-CABG from 81 to 50 evaluative items, and the CROQ-PTCA from 73 to 45 evaluative items. Table 6.4 summarises the results of the item reduction analyses, showing items that were eliminated at each stage of the analysis.

#### 6.1.3.1 Phase one: item reduction of core pre- / post-revascularisation items

A total of 20 items were eliminated from the 52 core pre- / post-revascularisation evaluative items, leaving a total of 32 evaluative items covering four domains (Symptoms – 7 items, Physical Functioning – 8 items, Psychosocial Functioning – 14 items, Cognitive Functioning – 3 items) and one descriptive item (*symptoms on exertion*). Sixteen items were eliminated for failing the following criteria: inter-item correlations <.75 (9 items), missing data <5% (1 item), maximum endorsement frequencies <75% (4 items), and aggregate adjacent endorsement frequencies >10% (2 items). This left a reduced item pool of 36 items. A further four items

were eliminated in the two stages of tests of scaling assumptions, leaving a final item pool of 32 core pre- / post-revascularisation evaluative items and one descriptive item in the CROQ.

#### 6.1.3.2 Phase two: item reduction of common post-revascularisation only items

Three of the ten common evaluative items included in both post-revascularisation versions of the CROQ were eliminated for failing the following criteria: item-total correlations  $\geq .30$  (1 item), and inter-item correlations  $< .75$  (2 items). This left a reduced item pool of seven evaluative items (six items in the Satisfaction domain and one item about *fear of symptoms returning*) and one descriptive item (*re-admission to hospital*). The item about *fear of symptoms returning* failed the tests of scaling assumptions and so was excluded from the scale. However, this item was retained in the CROQ as it was considered important based on the findings of the patient interviews.

#### 6.1.3.3 Phase three: item reduction of procedure-specific complication items

A total of 8 items were eliminated from the 19 CROQ-CABG complication items. Three of the 19 complication items were eliminated for failing the inter-item correlations criterion of  $< .75$ , leaving a reduced item pool of 16 items. A further five items were eliminated when scaling assumptions were tested, leaving an 11-item Complications scale in the CROQ-CABG.

Five items were eliminated from the 11 CROQ-PTCA complication items, leaving a 6-item Complications scale. Three of the 11 complication items were eliminated for failing the following criteria: inter-item correlations  $< .75$  (1 item), and item test-retest  $> .40$  (2 items), leaving a reduced item pool of 8 items. Two items *bruised thigh* and *bruised groin area* were inter-correlated  $.75$ , just failing the inter-item correlation criterion of  $< .75$ . *Bruised thigh* was eliminated from further analyses, but it was decided on clinimetric grounds to combine the two items in the final field test version. In the qualitative interviews, patients reported the content of both items to be problems, and both items had similar psychometric properties with neither appearing to be 'better' than the other. A further two items were eliminated

when scaling assumptions were tested, leaving a final item pool of six complication items in the CROQ-PTCA.

#### 6.1.4 CROQ (final version)

Figure 6.1 presents the conceptual model for the final version of the CROQ. As a result of item reduction analyses the final version of the CROQ includes four core pre- / post-revascularisation scales (Symptoms, Physical Functioning, Psychosocial Functioning, Cognitive Functioning) and two post-revascularisation scales (Complications, Satisfaction). Analyses did not support the division of items into separate scales for psychological and social functioning; empirical evidence supported a single scale, Psychosocial Functioning for these items. The evaluative item addressing *fear of symptoms returning* which did not 'fit' in the subscales was retained in the CROQ and included in the Total Outcome score. The descriptive item addressing *symptoms on exertion* was retained in the Symptoms domain, but not scored in the Symptoms scale. The descriptive item addressing *readmission to hospital* was retained in the Adverse effects content domain, but not scored.

#### 6.1.5 Preliminary psychometric evaluation

The results of the preliminary psychometric evaluation are similar to those of the final psychometric evaluation so results are presented in Appendices 6.1 to 6.18.

## 6.2 Final field test

As there were no major differences in the findings of the preliminary and final psychometric evaluations, only the results of the final field test are presented. Where minor differences did occur between the findings of the preliminary and final psychometric evaluations, these differences are noted. Response frequencies for each question on the CROQ-CABG and CROQ-PTCA at pre-, 3-, and 9-months post-revascularisation are presented in Appendices 6.19a to 6.21b. Values are the percent endorsed and not valid percent so not all numbers add up to exactly 100% due to missing data and rounding error.

### 6.2.1 *Respondent characteristics*

Respondents in the pre-revascularisation CABG sample (N=281) ranged in age from 35 to 85 (mean age  $63.6 \pm 9.2$ ) years, with 26% of the sample 70 years of age or over and 85% male (Table 6.5a). Respondents in the post-revascularisation CABG sample (N=415) ranged in age from 37 to 94 (mean age  $65.0 \pm 8.9$ ) years, with 33% of the sample 70 years of age or over and 83% male. Respondents in the responsiveness subsample (N=198) had similar demographic characteristics to those in the pre- and 3-month post-revascularisation samples. The majority of patients in each CABG sample were white, retired, males, living with their partner. In each sample, patients were recruited from all three hospitals. The majority of patients completed the SF-36 or SAQ as the second questionnaire, with fewer completing the QLMI-2 or the LIhFE. Based on occupation, each social class was represented in all CABG samples. A large proportion of patients reported that they got angina only on exertion or at rest and on exertion at pre-revascularisation and these figures fell at 3-months post-revascularisation. 16% of patients reported that they had been re-admitted to hospital for reasons to do with their heart condition.

Respondents in the pre-revascularisation PTCA sample (N=159) ranged in age from 38 to 89 (mean age  $60.6 \pm 9.7$ ) years, with 18% of the sample 70 years of age or over and 75% male (Table 6.5b). Respondents in the post-revascularisation PTCA sample (N=345) ranged in age from 36 to 84 (mean age  $62.3 \pm 10.2$ ) years, with 25% of the sample 70 years of age or over and 73% male. Respondents in the responsiveness subsample (N=107) had similar demographic characteristics to those in the pre- and 3-month post-revascularisation samples. The majority of patients in each CABG sample were white, retired, males, living with their partner. In each sample, patients were recruited from all three hospitals. The majority of patients completed the SF-36 or SAQ as the second questionnaire, with fewer completing the QLMI-2 or the LIhFE. Based on occupation, all social classes except social class V were represented in all PTCA samples. A large proportion of patients reported that they got angina only on exertion or at rest and on exertion at pre-revascularisation and these figures fell at 3-months post-revascularisation.

17% of patients reported that they had been re-admitted to hospital for reasons to do with their heart condition.

## 6.2.2 *Acceptability*

### 6.2.2.1 Response rates

6.2.2.1.1 Pre-revascularisation samples. A total of 408 questionnaires were posted to patients awaiting CABG (Table 6.6). Of the 408 questionnaires sent, 407 were considered eligible for inclusion; one patient reported that they had already undergone CABG in another hospital and so were not considered eligible. Of the 407 eligible patients, 281 completed and returned the questionnaire. The response rate for the CABG pre-revascularisation sample was thus 69% (281/407).

A total of 274 questionnaires were posted to patients awaiting PTCA (Table 6.6). Of the 274 questionnaires sent, 270 were considered eligible for inclusion; four patients reported that they were only undergoing investigation, not PTCA, and later did not appear on the PTCA procedure lists for the date their 'operation' had been scheduled. Of the 270 eligible patients, 159 completed and returned the questionnaire. The response rate for the PTCA pre-revascularisation sample was thus 59% (159/270).

6.2.2.1.2 Post-revascularisation samples. A total of 509 3-months post-revascularisation questionnaires were sent to patients who had undergone CABG (Table 6.7). Of these, 415 (82%) were returned. Included in this sample of 415 patients were 167 patients who were only sent the 3-months post-revascularisation CROQ-CABG, 50 patients in the test-retest subsample, and 198 patients in the responsiveness sample (see below).

A total of 468 3-months post-revascularisation questionnaires were sent to patients who had undergone PTCA (Table 6.7). Four of these patients were later considered ineligible for this study (procedure abandoned due to nature of blockage). Of the 464 eligible patients sent a questionnaire, 345 (74%) returned it. Included in this sample of 345 patients were 190 patients who were only sent the

3-months post-revascularisation questionnaire, 48 patients in the test-retest subsample, and 107 patients in the responsiveness sample (see below).

*Post-revascularisation only subsamples:* A subsample of 223 CABG patients were sent a questionnaire only at 3-months post-revascularisation. Of these 223 CABG patients, 167 (75%) returned the questionnaire. A subsample of 279 PTCA patients were sent a questionnaire only at 3-months post-revascularisation. Four of these 279 PTCA patients were subsequently considered ineligible as they reported that the procedure had not been completed due the nature of the blockage in the arteries. Of the 275 eligible patients, 190 (69%) returned the questionnaire.

*Test-retest subsamples:* A subsample of 70 CABG and 70 PTCA patients were sent two questionnaires at 3-months post-revascularisation to complete within a 2-week interval to provide data for test-retest analyses. Of the 70 CABG patients, 50 (78%) returned both questionnaires. Of the 70 PTCA patients, 48 (69%) returned both questionnaires.

*Responsiveness samples:* 216 of the 281 patients who completed and returned the pre-revascularisation version of the CROQ underwent CABG in the study period and were sent a 3-months post-revascularisation questionnaire. Of the 216 patients, 198 (92%) returned the questionnaire (Table 6.7). This sample of 198 patients is referred to as the *CABG responsiveness sample*. Two of the 281 patients had died and one was too sick to complete the questionnaire according to relatives.

119 of the 159 patients who completed and returned the pre-revascularisation version of the CROQ underwent PTCA in the study period were sent a 3-months post-revascularisation questionnaire. Of the 119 patients, 107 (90%) returned the questionnaire (Table 6.7). This sample of 107 patients is referred to as the *PTCA responsiveness sample*.

#### 6.2.2.2 Item and scale non-response

As shown in Tables 6.8a-6.9b, the proportion of missing data for each item is low, ranging from 0 – 7.1% in the pre- and post-revascularisation versions of the CROQ. In the preliminary field test, the proportion of missing data was less than 5% for all items. Scale non-response was also low in both pre- and post-revascularisation samples (Table 6.10 and 6.11); scale scores could be calculated for 95-100% of patients.

#### 6.2.2.3 Item floor and ceiling effects

Analysis of item endorsement frequencies for the pre- and post-revascularisation versions of the CROQ (Table 6.8a to 6.9b) show responses to be well distributed across response categories, with all response categories used. There were no marked floor or ceiling effects in the pre-revascularisation samples. However, as expected, there were noticeable ceiling effects in the post-revascularisation sample, i.e. higher endorsement frequencies for the response categories representing more favourable health states.

#### 6.2.2.4 Scale floor and ceiling effects

Table 6.10 presents descriptive statistics for CROQ pre-revascularisation scale scores. The full range of the score distribution was observed for all scales in the CABG and PTCA samples. All scale scores showed substantial variability suggesting that they cover all important levels of the constructs they measure. There were no large scale floor or ceiling effects, as only a small percentage of respondents endorsed the bottom (zero) and top (100) of the scale score ranges. The only exception was the Cognitive Functioning scale where the top of the scale was endorsed by 18% of CABG patients and 21% of PTCA patients. This result was consistent with that of the preliminary field test and is not surprising, as not all patients report cognitive problems. Pre-revascularisation scale scores were not heavily skewed, with all skew values falling in the range +1 to -1.

Table 6.11 presents descriptive statistics for the CROQ post-revascularisation scale scores. The full range of the score distribution was observed for two of the

six scales of the CROQ-CABG (Physical/ and Cognitive Functioning) and for five of the six CROQ-PTCA scales (Symptoms, Physical/ and Cognitive/ Functioning, Satisfaction and Complications). All scale scores showed substantial variability suggesting that they cover all the important levels of the constructs they measure. There were no scale floor effects in either of the post-revascularisation samples. No criteria were set for scale ceiling effects in the post-revascularisation samples as ceiling effects were expected after revascularisation. There were moderate scale ceiling effects for the Symptoms (21% and 13%), Physical Functioning (28% and 24%), Cognitive Functioning (5% and 30%) and Satisfaction (1% and 21%) scales in the CROQ-CABG and CROQ-PTCA respectively, reflecting good outcomes in these domains at 3-months post-revascularisation. There was a very large ceiling effect for the Complications scale in the PTCA sample (62%). This ceiling effect was expected at 3-months after PTCA, as complications are short-lasting in comparison to those of CABG where there was a very small ceiling effect (4%). These results are consistent with the findings in the preliminary field test.

Table 6.11 also shows that all the scales were heavily negatively skewed in the CABG sample indicating more respondents scoring more favourable outcomes after coronary revascularisation. In the PTCA sample, the scale scores were less heavily skewed with the exception of the Complications scale. For both the CABG and PTCA samples, mean post-revascularisation scores for the four core pre- / post-revascularisation scales (Symptoms, Physical/, Psychosocial/, and Cognitive Functioning) were higher than they were at pre-revascularisation (Tables 6.10 and 6.11), suggesting improvement in these domains after treatment for both procedures.

### 6.2.3 *Reliability*

#### 6.2.3.1 Internal consistency

Cronbach's alpha coefficients for all pre- and post-revascularisation scales of the CROQ exceeded the criterion of  $>.70$  (Tables 6.12 and 6.13). All coefficients are  $>.80$  in all samples indicating excellent internal consistency.

The homogeneity of the CROQ was evaluated on the basis of item-total correlations. Item-total correlations within each scale of the CROQ were similar (Tables 6.8 and 6.9), indicating that each item was contributing equally to the scale construct. Tables 6.12 and 6.13 present the range and mean of the item-total correlations within each scale of the pre- and post-revascularisation versions of the CROQ. The range of item-total correlations within each scale is small and the mean item-total correlations are moderate to high. All item-total correlations are above the criterion of  $\geq .30$ , except *infection in the chest wound*. The item-total correlation for this item was .25 in the CROQ-CABG Complications scale and .19 in the Total Outcome score. One possible reason for this is that only a few patients reported that they were bothered by infection in the chest wound, whereas reports of the other complications were more common. This item passed the criterion of  $\geq .30$  in the preliminary field test. The item was retained on grounds of clinical importance.

Tables 6.12 and 6.13 also present the range and mean inter-item correlations for each scale in the pre- and post-revascularisation samples. In the pre-revascularisation samples, mean inter-item correlations for the scales range from .39 to .78 for the CROQ-CABG .47 to .79 for the CROQ-PTCA. In the post-revascularisation samples, mean inter-item correlations for the scales range from .28 to .73 for the CROQ-CABG .33 to .80 for the CROQ-PTCA.

#### 6.2.3.2 Test-retest reliability

Intraclass correlation coefficients were greater than the criterion of  $>.70$  for all scales of the CROQ, indicating excellent test-retest reliability (Table 6.13). The CROQ-CABG Complications scale just failed the criterion of  $>.70$  in the preliminary psychometric evaluation (ICC=.68), but demonstrated excellent reproducibility in the final field test (ICC=.83). It is possible that some CABG patients in the preliminary field test sample were still experiencing change in the bothersomeness of complications at 3-months after CABG.

#### 6.2.4 Tests of assumptions for summated-rating

The item-response distributions for all items within each scale in the pre- and post-revascularisation samples are presented in Tables 6.8a-6.9b. Item response distributions are similar for all items within each scale for each of the pre- and post-revascularisation samples. Item means and standard deviations within each scale were similar; for example means range between 1.54 to 2.52 for the Physical Functioning scale in the CABG pre-revascularisation sample (Table 6.8a). For the great majority of items, the values of the standard deviations fell within two tenths of a unit with only a few discrepancies. Tables 6.8a-6.9b also present item-total correlations for each of the scales. With the exception of the Symptoms and Complications scales, the item-total correlations within each scale were "roughly equal" indicating that they are all contributing to the underlying construct and that equal weights can be applied to all items within the scale when scoring. These data support the assumption that items can be summed to form scales without standardisation or weights. Item-total correlations in the Symptoms and Complications scales demonstrated a slightly wider range of values.

Six scales were calculated (Symptoms, Physical/, Psychosocial/, and Cognitive Functioning, Satisfaction and Complications). Two total scores were also calculated: the Core Total which is comprised of the 32 core pre- / post-revascularisation items, and the Total Outcome score which is comprised of the post-revascularisation Satisfaction and Complication items plus one additional item which is not included in the subscales (*symptoms return*).

#### 6.2.5 Tests of scaling assumptions

Tables 6.14a – 6.15b present item convergent and discriminant correlations for the CROQ in the pre- and post-revascularisation samples. These data were used to test scaling assumptions and to confirm the robustness of the scales identified from item reduction analyses. In all samples, the great majority of items were definite scaling successes, a few were probable scaling successes and very few were probable scaling failures; none of the items were definite scaling failures. A consistent finding across most samples was that *shortness of breath* was more

highly correlated with the Physical Functioning scale than to the Symptoms scale. This is probably because shortness of breath is induced on physical exertion. It was decided to retain this item in the Symptoms scale for clinimetric reasons.

In general, there were slightly more definite scaling successes in each of the samples in the preliminary field test. In the CABG pre-revascularisation samples, 28 and 22 items were definite scaling successes in the preliminary and final field tests, respectively. In the PTCA pre-revascularisation samples, 24 and 19 items were definite scaling successes in the preliminary and final field tests, respectively. In the CABG post-revascularisation samples, 44 and 40 items were definite scaling successes in the preliminary and final field tests, respectively. In the PTCA post-revascularisation samples, 39 and 40 items were definite scaling successes in the preliminary and final field tests, respectively.

#### 6.2.5.1 Pre-revascularisation

Table 6.14a presents the item convergent and discriminant correlations for the 32 core evaluative items in the pre-revascularisation CABG sample. 21 of the 32 items were definite scaling successes, 10 were probable scaling successes, and 1 was a probable scaling failure (*shortness of breath*). The Cognitive Functioning scale achieved a scaling success rate of 100%. *Shortness of breath* was also a probable scaling failure in the preliminary field test.

Table 6.14b presents the item convergent and discriminant correlations for the 32 core evaluative items in the pre-revascularisation PTCA sample. 19 of the 32 items were definite scaling successes, 11 were probable scaling successes and 2 were probable scaling failures (*shortness of breath* and *palpitations*). It is possible that the small sample size (N=159) contributed to this pattern. *Palpitations* and *shortness of breath* were retained in the Symptoms scale for clinimetric reasons; these two items were probable scaling successes in the preliminary field test. The Cognitive Functioning scale achieved a scaling success rate of 100%.

### 6.2.5.2 Post-revascularisation

Table 6.15a presents item convergent and discriminant correlations for all CROQ-CABG evaluative items in the post-revascularisation sample. 40 of the 49 items were definite scaling successes, 8 were probable scaling successes and 1 was a probable scaling failure (*shortness of breath*). The Physical Functioning scale achieved a scaling success rate of 100%. In the preliminary field test *shortness of breath* was a probable scaling success and *overall* was a probable scaling failure. The item, *overall*, is a global item, which one would expect to be correlated with other domains.

Table 6.15b presents item convergent and discriminant correlations for all CROQ-PTCA evaluative items in the post-revascularisation sample. 40 of the 44 items were definite scaling successes, 3 were probable scaling successes and 1 was a probable scaling failure (*shortness of breath*). The Physical Functioning, Cognitive Functioning and Complications scales achieved a scaling success rate of 100%. In the preliminary field test *shortness of breath* was a probable scaling success.

## 6.2.6 *Validity*

### 6.2.6.1 Content validity

The content validity of the CROQ was confirmed during the development of the questionnaires through expert opinion from clinicians, interviews with patients, a comprehensive literature review, and comparison with existing measures.

Inspection of the responses made to the open-ended question in the preliminary field test, (*"Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire?"*) confirmed that no important issues had been excluded. The most common responses concerned the long wait prior to revascularisation and the associated anxiety, details of medication and medical history, and appreciation for care received. None of these issues addressed missing content from the questionnaires indicating that the content validity of the CROQ is acceptable from the patient's perspective.

No comments were made about the impact of CHD or CABG/PTCA on sexual functioning thus confirming the decision to exclude this domain from the CROQ.

#### 6.2.6.2 Construct validity: within scale analyses

6.2.6.2.1 Internal consistency. Evidence of excellent internal consistency for all scales supports the construct validity of the CROQ. Moderately high item-total correlations and high Cronbach's alpha coefficients (Tables 6.12 and 6.13) indicate that a single construct is being measured and that the items can be combined into scales.

6.2.6.2.2 Intercorrelations between scales. Tables 6.16 and 6.17 present intercorrelations between CROQ scales and total scores for the pre- and post-revascularisation samples, respectively.

*Pre-revascularisation:* In both pre-revascularisation samples, each of the four CROQ core scales were moderately to highly correlated with the Core Total score (Table 6.16). The Cognitive Functioning scale was least highly correlated with the Core Total score; this was expected as this scale has only 3 items. In both samples, the correlations between the scales and the Core Total score were higher than the inter-scale correlations, supporting the convergent validity of all the scales.

Table 6.16 shows moderate correlations between each of the scales in the pre-revascularisation samples (ranging from .41 to .71 and .51 to .74 in the CROQ-CABG and CROQ-PTCA, respectively). These values indicate that the scales are measuring different, but related constructs. There was also evidence of unique reliable variance indicated by reliability coefficients for each scale being greater than each of the inter-scale correlations. In both pre-revascularisation samples, the highest inter-scale correlation was between Physical Functioning and Symptoms (.71 and .74 for the CROQ-CABG and CROQ-PTCA, respectively) and the lowest inter-scale correlation was between Symptoms and Cognitive Functioning (.41 and .51 for the CROQ-CABG and CROQ-PTCA, respectively). These results support

the division of items into scales as one would expect scales measuring related health constructs to be moderately correlated and scales measuring different constructs to be less highly correlated.

*Post-revascularisation:* In the post-revascularisation samples, each of the four CROQ core scales was highly correlated with the Core Total score, and each of the post-revascularisation only scales (Satisfaction and Complications) was highly correlated with the Total Outcome score (Table 6.17). Each scale was more highly correlated with its own total score than to the other scales, supporting the convergent validity of the scales.

Table 6.17 shows moderate correlations between each of the scales in the post-revascularisation samples (ranging from .28 to .69 and .23 to .71 in the CROQ-CABG and CROQ-PTCA, respectively). These scales are clearly measuring different, but related constructs. There was also evidence of unique reliable variance indicated by reliability coefficients for each scale being greater than each of the inter-scale correlations.

In the CABG post-revascularisation sample, the highest inter-scale correlations were between Cognitive Functioning and Psychosocial Functioning (.69), Physical Functioning and Symptoms (.63) and Psychosocial Functioning and Physical Functioning (.63). The lowest inter-scale correlations were between Cognitive Functioning and Satisfaction (.28), Complications and Satisfaction (.43), and Cognitive Functioning and Complications (.44). In the PTCA post-revascularisation sample, the highest inter-scale correlations were between Physical Functioning and Symptoms (.71), Psychosocial Functioning and Physical Functioning (.67), and Psychosocial Functioning and Cognitive Functioning (.64). The lowest inter-scale correlations were between, Complications and Physical Functioning (.23), Complications and Satisfaction (.28), Complications and Symptoms (.31), and Cognitive Functioning and Satisfaction (.31). These correlations followed the expected pattern with the exception of the moderately high correlation between Physical Functioning and Psychosocial Functioning (.63 and .67 in the CROQ-

CABG and CROQ-PTCA, respectively). This finding was consistent with the findings in the preliminary psychometric evaluation of the post-revascularisation CROQ-PTCA.

6.2.6.2.3 Factor analysis. Principal axis factor analysis with Varimax rotation was performed on the 32 core pre- / post-revascularisation evaluative items of the CROQ, both at pre- and post-revascularisation in the CABG and PTCA samples (Tables 6.18a to 6.19b). Separate factor analyses were carried out on the post-revascularisation only items (Tables 6.20a and b). The principal axis factoring was modelled on four factors for the core 32-item pool and modelled on two factors for the post-revascularisation only items (18-item CABG pool and 13-item PTCA pool). Findings supported the CROQ's scale structure. A consistent finding throughout the factor analyses was that Psychological/ and Social Functioning were not separate constructs as originally proposed; items in these two domains loaded on to just one factor, the Psychosocial Functioning factor.

*Pre-revascularisation:* The principal axis factor analysis of the 32 core items in the CABG pre-revascularisation sample produced four clear factors: Symptoms, Physical Functioning, Cognitive Functioning, and Psychosocial Functioning (Table 6.18a). Tests of sampling adequacy (Kaiser-Meyer-Olkin =.95) and sphericity (Bartlett's test of sphericity =.000) were acceptable. The four-factor solution accounted for 59% of the variance. Six items crossloaded onto another factor with a difference <.20, but five of these loaded higher on their 'hypothesised factor'. *Shortness of breath* loaded higher on the Physical Functioning factor than Symptoms, as it did in the preliminary field test.

The principal axis factor analysis of the 32 core items in the PTCA pre-revascularisation sample also produced four clear factors: Symptoms, Physical Functioning, Cognitive Functioning, and Psychosocial Functioning (Table 6.18b). Tests of sampling adequacy (Kaiser-Meyer-Olkin =.94) and sphericity (Bartlett's test of sphericity =.000) were acceptable. The four-factor solution accounted for 61% of the variance. Six items crossloaded onto another factor with a difference

<.20, but five of these were more highly correlated with their 'hypothesised' factor. *Shortness of breath* loaded higher on the Physical Functioning factor than Symptoms; this did not occur in the preliminary field test.

*Post-revascularisation:* The principal axis factor analysis of the 32 core items in the CABG post-revascularisation sample produced four clear factors: Symptoms, Physical Functioning, Cognitive Functioning, and Psychosocial Functioning (Table 6.19a). Tests of sampling adequacy (Kaiser-Meyer-Olkin =.95) and sphericity (Bartlett's test of sphericity =.000) were acceptable. The four-factor solution accounted for 58% of the variance. Four items crossloaded onto another factor with a difference <.20, three items loaded higher on the 'wrong' factor (*shortness of breath, trouble, restricted*), and *overprotective* did not load on a factor >.35. The factor solution in the final field test was considerably clearer than in the preliminary field test. In the preliminary field test, only two clear factors were identified (Symptoms and Physical Functioning) with some overlap between the Cognitive Functioning and Psychosocial Functioning items (Appendix 6.12a). This finding questioned the construct validity of the Psychosocial Functioning and Cognitive Functioning scales, but evidence from further psychometric testing provided evidence that these scales do measure separate constructs.

The principal axis factor analysis of the 32 core items in the PTCA post-revascularisation sample produced four clear factors: Symptoms, Physical Functioning, Cognitive Functioning, and Psychosocial Functioning (Table 6.19b). Tests of sampling adequacy (Kaiser-Meyer-Olkin =.96) and sphericity (Bartlett's test of sphericity =.000) were acceptable. The four-factor solution accounted for 65% of the variance. Four items crossloaded onto another factor with a difference <.20, but three of these were more highly correlated with their 'hypothesised' factor. *Shortness of breath* loaded higher on the Physical Functioning factor than Symptoms. In the preliminary field test, *palpitations* did not load on a factor >.35, but was retained in the Symptoms scale for clinimetric reasons; in the final field test *palpitations* did load on the Symptoms factor.

The principal axis factor analysis of the 18 CABG post-revascularisation only items produced two clear factors (Satisfaction and Complications) with no items cross loading (Table 6.20a). Tests of sampling adequacy (Kaiser-Meyer-Olkin =.85) and sphericity (Bartlett's test of sphericity =.000) were acceptable. The two-factor solution accounted for 36% of the variance. *Infection in the chest wound* did not load on a factor >.35 in the final field test, but did in the preliminary field test. As previously described, few patients reported bothersomeness from this complication.

The principal axis factor analysis of the 13 PTCA post-revascularisation items produced two clear factors (Satisfaction and Complications) with no items cross loading on more than one factor (Table 6.20b). Tests of sampling adequacy (Kaiser-Meyer-Olkin =.82) and sphericity (Bartlett's test of sphericity =.000) were acceptable. The two-factor solution accounted for 47% of the variance. In the preliminary field test, *concern over bruises* did not load on a factor >.35, but was retained in the Complications scale; in the final field test it loaded .61 on the Complications factor.

The item *symptoms return* inconsistently loaded on either the Complications scale, the Satisfaction scale, or both across all the samples and was therefore excluded from the subscales, but it was included in the Total Outcome score as it was considered an important item.

6.2.6.2.4 Known group differences / hypothesis testing (within scale analyses). Evidence in support of the construct validity of the CROQ was demonstrated through tests of hypotheses for known groups.

Table 6.21 presents mean scores for patients who reported global improvement in their heart condition at 3-months post-revascularisation compared with those who reported no improvement. As hypothesised, those who reported global improvement scored higher (better health outcomes) on all CROQ scales than those who reported no improvement. These scores were significantly higher

( $p < .05$ ) for all except the Cognitive Functioning ( $p = .251$ ) and Complications ( $p = .057$ ) scales in the CROQ-CABG, and for all scales in the CROQ-PTCA. These findings were supported in the preliminary field test; all scales (except the CROQ-CABG Complications scale,  $p = .338$ ) demonstrated significant differences between these two groups for the CABG and PTCA samples.

Table 6.22 presents mean post-revascularisation scores for patients who reported being bothered by chest pain due to angina at 3-months post-revascularisation, versus those not at all bothered. As hypothesised, all CROQ scores were significantly lower ( $p < .05$ ) for patients who reported that they were bothered by chest pain at 3-months post-revascularisation.

#### 6.2.6.3 Construct validity: comparison with external criteria

Tables 6.23 to 6.31 present the comparison of the CROQ against external criteria: HRQoL questionnaires (SF-36, SAQ, QLMI-2, LIhFE), demographics (age, sex, social class), and clinical variables (CCS, NYHA, and ejection fraction).

6.2.6.3.1 Convergent and discriminant validity (pre-revascularisation). Tables 6.23 and 6.24 present convergent and discriminant correlations between the CROQ and the SF-36, SAQ, QLMI-2 and the LIhFE in the CABG and PTCA pre-revascularisation samples. The CROQ demonstrated the expected relationship with the SF-36 Summary Component Scores at pre-revascularisation (Table 6.23). The convergent and discriminant validity of the CROQ were demonstrated by Symptoms (.71 and .66) and Physical Functioning (.75 and .81) being more highly correlated than Psychosocial Functioning (.38 and .53) and Cognitive Functioning (.29 and .35) with the SF-36 Physical Component Summary Score (PCS) in both the CABG and PTCA pre-revascularisation samples, respectively. Similarly, Psychosocial Functioning (.70 and .60) and Cognitive Functioning (.58 and .57) were more highly correlated than Symptoms (.34 and .31) and Physical Functioning (.22 and .31) with the SF-36 Mental Component Summary Score (MCS) in both the CABG and PTCA pre-revascularisation samples, respectively. The CROQ Core Total score was moderately correlated with the PCS and MCS in

both the CABG and PTCA samples, reflecting its physical and mental health components. Correlations between the CROQ and the SF-36 Summary Component Scores are moderate as one would expect between generic and disease-specific questionnaires.

Table 6.24 presents correlations between the CROQ and each of the eight SF-36 dimension scores. This table presents additional data in support of the construct validity of the CROQ at pre-revascularisation. The Symptoms and Physical Functioning scales of the CROQ were more highly correlated with the SF-36 dimension scores measuring physical aspects of health (convergent validity) than to the dimensions measuring mental aspects of health (discriminant validity). Similarly, the Psychosocial Functioning and Cognitive Functioning scales were more highly correlated with the SF-36 dimension scores measuring mental rather than physical aspects of health.

Table 6.23 presents further evidence supporting the construct validity of the CROQ at pre-revascularisation through its relationship with other disease-specific questionnaires. The Physical Functioning scale of the CROQ-CABG and CROQ-PTCA was highly correlated with the SAQ Exertional Capacity scale (.90) supporting the construct validity of this scale. These scales are similar in content so one would expect them to be highly correlated. The CROQ Symptoms scale was moderately to highly correlated with the SAQ Anginal Frequency scale (.78) supporting the construct validity of this scale. As these scales have slightly different content (frequency of chest pain and bothersomeness of cardiac symptoms), they were not expected to be too highly correlated. The Core Total score of the CROQ-CABG and CROQ-PTCA was very highly correlated with the QLMI-2 Global (.82 and .90) and LIhFE Total (-.94 and -.93) scores, suggesting that the CROQ is measuring the overall impact of heart disease including both mental and physical components. As some of the items in the CROQ were derived from the QLMI-2, high correlations were expected.

Table 6.25 presents correlations between the CROQ and age, sex and social class in the pre-revascularisation samples. All coefficients were low (less than the criterion of .40) indicating good discriminant validity. Responses to the CROQ were not strongly influenced by age, sex or social class at pre-revascularisation.

Table 6.26 presents further evidence of the convergent validity of the CROQ-CABG at pre-revascularisation through correlations between pre-revascularisation CROQ-CABG item and scale scores and the CCS and NYHA classifications of angina and dyspnoea. CROQ-CABG item and scale scores were only moderately correlated with these clinical classifications of disease severity (<.40). Correlations of this magnitude between clinician and patient reports of symptom severity are common.

6.2.6.3.2 Convergent and discriminant validity (post-revascularisation). Tables 6.27 and 6.28 present convergent and discriminant correlations between the CROQ and the SF-36, SAQ, QLMI-2 and LIhFE in the CABG and PTCA post-revascularisation samples. The CROQ demonstrated the expected relationship with the SF-36 Summary Component Scores at post-revascularisation (Table 6.27). The convergent and discriminant validity of the CROQ were demonstrated by Symptoms (.60 and .68) and Physical Functioning (.75 and .75) being more highly correlated than Psychosocial Functioning (.59 and .49) and Cognitive Functioning (.46 and .49) with the SF-36 PCS in both the CABG and PTCA pre-revascularisation samples, respectively. Similarly, Psychosocial Functioning (.64 and .73) and Cognitive Functioning (.46 and .49) were more highly correlated than Symptoms (.36 and .32) and Physical Functioning (.36 and .37) with the SF-36 MCS in both the CABG and PTCA pre-revascularisation samples, respectively. The CROQ Core Total score was moderately correlated with the PCS and MCS in both the CABG and PTCA samples, reflecting its physical and mental health components. Again, correlations between the CROQ and the SF-36 Summary Component Scores were moderate as expected.

Table 6.28 presents correlations between the CROQ and each of the eight SF-36 dimension scores at post-revascularisation and provides additional data in support

of the construct validity of the CROQ. As in the pre-revascularisation samples, the Symptoms and Physical Functioning scales of the CROQ were more highly correlated with the SF-36 dimension scores measuring physical aspects of health (convergent validity) than with the dimensions measuring mental aspects of health (discriminant validity). Similarly, the Psychosocial Functioning and Cognitive Functioning scales were more highly correlated with the SF-36 dimension scores measuring mental rather than physical aspects of health.

Table 6.27 presents further evidence supporting the construct validity of the CROQ at post-revascularisation through its relationship with other disease-specific questionnaires. The Physical Functioning scale of the CROQ-PTCA was highly correlated with the SAQ Exertional Capacity scale (.90) supporting the construct validity of this scale. The correlation was noticeably smaller with the CROQ-CABG (.67), a relationship which was not observed at pre-revascularisation. The CROQ Symptoms scale was moderately to highly correlated with the SAQ Anginal Frequency scale supporting the construct validity of this scale (.74 and .86 for the CABG and PTCA samples, respectively). The CROQ's Satisfaction scale was moderately to highly correlated with the SAQ's Treatment Satisfaction scale (.65 and .72) in the CABG and PTCA samples, respectively. High correlations between these scales were not expected as the CROQ measures satisfaction with the outcome of revascularisation and information received and the SAQ measures satisfaction with care and treatment. The Core Total score of the CROQ-CABG and CROQ-PTCA was highly correlated with the QLMI-2 Global (.92 and .89) and LIhFE Total (-.87 and -.74) scores, once again suggesting that the CROQ is measuring the overall impact of heart disease including both mental and physical components.

Tables 6.29 presents correlations between the CROQ and age, sex and social class in the post-revascularisation samples. All coefficients were low (less than the criterion of .40) indicating good discriminant validity. Responses to the CROQ were not strongly influenced by age, sex or social class at post-revascularisation.

6.2.6.3.3 Known groups / hypothesis testing (analyses against external criteria). Table 6.30 presents mean pre-revascularisation CROQ-CABG symptom scores for each grade of angina (CCS), dyspnoea (NYHA), and ejection fraction. As hypothesised, mean CROQ-CABG symptom scores were significantly lower (reflecting poor health outcomes) for patients with more severe angina ( $p < .005$ ) and dyspnoea ( $p < .033$ ). Although, CROQ-CABG symptom scores were lower for patients with poor ejection fraction, this difference was not significant.

### 6.2.7 *Responsiveness*

Effect sizes and standardised response means are presented for all responsiveness analyses, but to summarise the results, this section focuses on the effect sizes and describes any noticeable differences when standardised response means are used. Table 6.31 presents mean pre- and 3-months post-revascularisation scores for the CROQ. All CROQ scales showed significant change between pre- and 3-months post-revascularisation ( $p < .05$ ). Large effect sizes were observed for CROQ-CABG Symptoms (2.83), Physical Functioning (1.47) and Psychosocial Functioning (1.53), but only a moderate effect size for Cognitive Functioning (0.67). A large effect size was observed for CROQ-PTCA Symptoms (0.99), moderate effect sizes for Physical Functioning (0.66) and Psychosocial Functioning (0.67), and a small effect size for Cognitive Functioning (0.24). The standardised response means showed a similar pattern in both samples. Figures 6.2 and 6.3 are graphical presentations of pre- and post-revascularisation CROQ-CABG and CROQ-PTCA scores for the responsiveness subsamples.

Effect sizes reflect both the responsiveness of the CROQ and the effectiveness of treatment i.e. CABG or PTCA. As some patients did not report global improvement and coronary revascularisation is not always successful in alleviating symptoms and problems associated with CHD, the responsiveness analyses were repeated on a subsample of patients who reported global improvement to determine the responsiveness of the CROQ (Table 6.32). As expected, effect sizes for the CROQ-PTCA increased after excluding 22% of the sample who did not report

global improvement after PTCA; large effect sizes were observed for three of the four core scales. However, the expected pattern was not observed for the CROQ-CABG when just 8% of the sample who did not report global improvement were excluded. Effect sizes for the CROQ-CABG were lower for this subsample than for the whole responsiveness CABG sample, but were of the same magnitude, i.e. moderate or large. There is no obvious reason for these unexpected results. Standardised response means did however increase in value (but not magnitude) when those who did not report global improvement were excluded (i.e. followed the expected pattern). In the preliminary field test, all effect sizes and standardised response means increased in value when performed on the CABG and PTCA subsamples who reported global improvement.

Table 6.33 presents mean pre- and 9-months post-revascularisation scores for the CROQ. All CROQ scales showed significant change between pre and 9-months post-revascularisation ( $p < .05$ ). Large effect sizes were observed for all CROQ-CABG scales: Symptoms (1.87), Physical Functioning (1.61), Psychosocial Functioning (1.43), and Cognitive Functioning (0.81). A similar pattern was observed for the standardised response means, but Cognitive Functioning demonstrated only a moderate effect (0.66). Large effect sizes were observed for CROQ-PTCA Symptoms (0.95), moderate for Physical Functioning (0.63) and Psychosocial Functioning (0.64), and small for Cognitive Functioning (0.33). Standardised response means were of the same magnitude. Effect sizes and standardised response means between pre- and 9-months post-revascularisation are of the same magnitude as observed at 3-months post-revascularisation for each scale, except Cognitive Functioning in the CROQ-CABG. Cognitive Functioning demonstrated a large effect size (0.81) at 9-months post-revascularisation and only a moderate effect size (0.67) at 3-months post-revascularisation, in the CABG sample indicating that cognitive functioning improved between 3- and 9-months post-revascularisation. There was a noticeably smaller effect size for CROQ-CABG Symptoms between pre- and 9-months post-revascularisation (1.87) than between pre- and 3-months post-

revascularisation (2.83), but this difference is less dramatic using the standardised response means (1.39 and 1.56).

Table 6.34 presents mean CROQ change scores for patients who reported global improvement in their heart condition after revascularisation compared with those who did not report improvement. As expected, CROQ mean change scores were significantly higher ( $p < .05$ ) for those who reported that their heart condition was better overall 3-months post-revascularisation than for those who did not report improvement for the CABG and PTCA samples. The same pattern was observed at 9-months post-revascularisation. Some caution should be paid in interpreting these results as sample sizes are small for the unimproved groups.

Table 6.35 presents longitudinal change in CROQ scores over time between 3- and 9-months post-revascularisation. Only very small effect sizes were observed for all CROQ scales between 3- and 9-months post-revascularisation, except for CROQ-CABG Complications. This indicates that there was little change (improvement or deterioration) in these domains between 3- and 9-months post-revascularisation. However, CROQ-CABG Complications demonstrated significant change ( $p < .05$ ) reflected in a moderate effect size (0.53); CABG patients continued to be bothered by complications between 3- and 9-months post-revascularisation reflecting the length of time these problems can persist. Satisfaction scores remained stable over this period, with almost no differences between scores at these two time points.

#### 6.2.7.1 Relative responsiveness

Tables 6.37 to 6.39 present the relative responsiveness of the CROQ, SF-36, and SAQ. This section describes differences in effect sizes for the CROQ, SF-36 and SAQ for scales measuring similar constructs. Table 6.36 shows larger effect sizes for the Symptoms (2.50 and 0.97) and Physical Functioning (1.19 and 0.73) scales of the CROQ than for the SF-36 PCS (0.85 and 0.56) in the CABG and PTCA samples, respectively. The standardised response means showed a similar pattern with the exception of the CROQ-PTCA Physical Functioning scale (0.70)

which is of similar magnitude to the SF-36 PCS (0.75). Similarly, a larger effect size and standardised response mean was demonstrated for the Psychosocial Functioning scale of the CROQ (1.52 and 0.64) than for the SF-36 MCS (0.67 and 0.07), in the CABG and PTCA samples, respectively. These data demonstrate the superior responsiveness of the disease-specific CROQ compared with the generic SF-36 in the CABG (n=72) and PTCA (n=38) samples, who completed both questionnaires at pre- and 3-months post-revascularisation.

Table 6.37 presents effect sizes and standardised response means for each of the eight SF-36 dimension scores. Large effect sizes were observed in the CABG sample for the Physical Functioning (1.14), Vitality (0.89), and Social Functioning (0.83) scales, but in the PTCA sample these scales only demonstrated small to moderate effect sizes (0.42, 0.56, 0.27, respectively). Very small effect sizes were observed for the Role-Emotional (0.14) and Mental Health (0.13) dimensions in the PTCA sample, contrasting greatly with the effect size of 0.64 observed for the CROQ Psychosocial Functioning scale in the PTCA sample.

Table 6.38 presents the relative responsiveness of the CROQ and the SAQ. Large effect sizes and standardised response means of similar magnitude were observed for both the CROQ Physical Functioning scale (1.74) and the SAQ Exertional Capacity scale (1.56) in the CABG sample. However, the SAQ Exertional Capacity scale (0.84) demonstrated greater responsiveness than the CROQ Physical Functioning scale (0.67), in the PTCA sample. Large effect sizes of similar magnitude were observed for the CROQ Symptoms scale (2.74 and 1.09) and the SAQ Anginal Frequency (2.59 and 0.80) and Anginal Stability (2.57 and 0.91) scales in the CABG and PTCA samples, respectively. The CROQ appears to be as responsive as the SAQ.

## **CHAPTER 7**

### **DISCUSSION**

This chapter begins with a brief summary of results. Subsequent sections include a discussion of study strengths and limitations, and of methodological and practical issues. Implications of the study findings and areas for future research are then discussed.

#### **7.1 Summary of results**

This study reports on the development and rigorous psychometric evaluation of the CROQ. Results demonstrate that it is possible to develop an acceptable, reliable, valid and responsive disease-specific questionnaire to evaluate patient-based outcomes before and after two types of coronary revascularisation, CABG and PTCA.

Evidence from two independent field tests demonstrated that the CROQ is acceptable, reliable, valid and responsive. The acceptability of the CROQ was indicated by high response rates, a low proportion of missing data, well distributed endorsement frequencies (in the pre-revascularisation versions) and acceptable floor and ceiling effects. Good internal consistency and reproducibility provided strong evidence for the reliability of the CROQ. Tests of scaling assumptions and factor analysis confirmed the grouping of items into scales. The content validity of the CROQ was confirmed during development of the questionnaires. Support for the construct validity of all versions of the CROQ was demonstrated by high correlations between scale and total scores, moderate correlations between scales, and convergent and discriminant correlations with other HRQoL instruments (SF-36, SAQ, QLMI-2, and LIhFE). The CROQ was also able to detect differences between groups of patients who reported varying levels of global improvement, and between patients with different levels of disease severity as measured by the CCS and the NYHA. The CROQ demonstrated responsiveness through its ability to detect significant improvements after CABG and PTCA. A

comparison of relative responsiveness demonstrated that the CROQ was more responsive to change than the generic SF-36, and at least as responsive as the disease-specific SAQ in both the CABG and PTCA samples.

As the CROQ has been validated against rigorous scientific criteria and on large samples of patients from three different clinical sites, the psychometric evidence is robust. The CROQ far exceeded the criterion set for each psychometric test. The psychometric properties of the CROQ are strong and were replicated in two studies with few differences between the two. The CROQ is now ready for use in other studies where further tests of its validity can be evaluated. In terms of Erickson's<sup>396</sup> life cycle model of a health status instrument, the CROQ has passed stage one (concept formation, draft instrument, pilot testing), stage two (test of measurement properties, use by developers) and is now ready for stage three (use by others for the same purpose of study) and stage four (widespread use including different types of studies and different populations).

## **7.2 Study strengths**

This study used state-of-the-art methods for instrument development and validation, including the involvement of patients in instrument development, extensive two-stage field testing in large samples, item reduction analyses using explicit criteria and responsiveness analyses. As elderly people and women have been largely underrepresented in the development of existing cardiac-specific questionnaires, the inclusion of these groups in this study is an important feature of study design.

### **7.2.1 *Patient involvement in instrument development***

Patient involvement in instrument development is a necessary step to ensure that the core "critical components" are included<sup>425</sup> and that the questionnaire is acceptable to patients. However, it is often overlooked and instruments are often developed without interviewing patients about their experience of living with a condition or undergoing a specific treatment.<sup>44</sup> There is currently a paucity of research exploring patients' perspectives of cardiac conditions.<sup>426</sup> Incorporating

patients' views in health care evaluation helps to ensure that factors which may influence health outcomes are known and understood. The CROQ was developed using content identified from 20 patient interviews, expert opinion, the literature and existing instruments. Where possible the "language" patients used was incorporated into the items. These steps are important as familiar language and relevant issues should increase response rate and the accuracy of responses.<sup>430</sup>

It was the interviews with patients that revealed the importance of measuring physical and psychological complications after coronary revascularisation. Patients described a range of treatment-specific complications that persisted for some time after coronary revascularisation, such as post-procedural pain, wound healing problems, bruising and swelling. Whilst these problems associated with treatment have been described in the literature, they tend to be viewed as relatively minor problems. However, the interviews with patients revealed the impact that these complications have on patients' day-to-day lives, sometimes for many months after revascularisation. There have been no attempts to routinely quantify and monitor these complications using a validated instrument. The CROQ is the first validated instrument to assess these complications; results show that these questions form a reliable and valid scale that is sensitive to change over time. The findings of the qualitative interviews were confirmed by the data collected using the CROQ; many patients reported that they were bothered by complications at least 3 months after revascularisation, and some still reported bothersomeness at 9 months after revascularisation.

In addition to involving patients in helping to generate the content of the CROQ, patients also participated in pre-testing the instrument. Although pre-testing is of crucial importance in instrument development to determine the acceptability of the questionnaire in terms of content and phrasing, many instrument developers do not include this stage or do not report their findings. Instrument developers for the majority of cardiac-specific measures do not report results from pre-testing. Excluding this stage of instrument development could result in questionnaires with unintended meaning. Pre-testing of the CROQ with CABG patients revealed the

necessity of very clear definitions between chest pain *due to angina* and chest pain *due to the operation*. Careless use of existing measures in post-CABG samples might result in patients reporting chest pain (from angina) when in fact it is post-operative pain that they are experiencing. This could lead to an interpretation of reduced effectiveness of the procedure.

### 7.2.2 *Extensive two-stage field testing*

The CROQ was subjected to a rigorous two-stage validation process: a preliminary field test for item reduction and preliminary psychometric evaluation, and a final field test for extended psychometric validation of the item-reduced questionnaires in independent samples. The majority of patient-based, CHD-specific questionnaires have not undergone this two-stage psychometric validation, a methodological weakness that is not limited to instrument development in CHD. Whilst some cardiac-specific instrument developers have performed item reduction analyses, it is less common for the item-reduced questionnaire to be further tested in an independent sample before publication, as was done in the evaluation of the CROQ. For scientific integrity, when items are removed from an instrument the psychometric properties of the new item-reduced instrument must be tested again in an independent sample. All changes made to an instrument need to be validated to ensure that the instrument retains its psychometric properties.

By conducting extensive two-stage field testing in independent samples, important additional information about the generalisability of the results and the robustness of the psychometric properties is generated. As instrument developers tend to be over optimistic about a measure's validity,<sup>368</sup> there is the danger that other researchers take these properties as established and use the measure without confirming the psychometric properties in their own sample. Whilst publication is an important method of disseminating information on newly available instruments, journal editors and peer reviewers need to be encouraged to be more familiar with the necessary steps in instrument development and evaluation before accepting papers for publication. In this way, the publication of measures in their infancy will be avoided. The problem is confounded by authors frequently failing to report

details about instrument format, such as mode of administration and modification to the original instrument.<sup>396</sup> Results generated from modified instruments are not directly comparable to results generated from the source instrument.<sup>367 396</sup> With more attention to these apparently minor details, greater confidence can be placed in the results from studies using these instruments and further data can be accumulated in support of the validity of the instrument.

### 7.2.3 *Large samples*

The CROQ was field tested in large samples of patients to increase the generalisability of results. It is not uncommon for disease-specific instruments to be developed and validated on small samples of patients, and cardiac-specific measures are no exception. Appendix 3.1 describes the samples in which existing cardiac-specific measures were developed. Many of these measures were originally validated in small samples, but some have since undergone psychometric testing in independent samples in other studies. However, it is interesting to note that the majority of these questionnaires were published before being tested on large samples. Instruments developed on small samples, which are not tested further in other samples, have only preliminary evidence of scientific credibility. As guidelines for sample sizes are poorly defined for psychometric testing, guidance is needed on the size of sample needed for the testing of each psychometric property (reliability, validity and responsiveness). However, the smaller the sample, the less confidence can be placed in the results. Juniper *et al.*<sup>443</sup> recommend a sample of at least 100 subjects for item reduction analyses, and Ware *et al.*<sup>374</sup> recommend at least 300 for tests of item convergent and discriminant validity. As the CROQ was developed using large numbers of patients in excess of 300, it is very likely that the results are generalisable and that they can be replicated in further studies using independent samples. However, this assumption needs to be tested.

### 7.2.4 *Tests of scaling assumptions*

Large sample sizes in this study also permitted tests of scaling assumptions to be performed using item convergent and discriminant correlations. Only one<sup>289</sup> of the

reliable and valid cardiac-specific measures identified in Chapter 3 applied tests of scaling assumptions in the validation phase. Scaling tests helped to confirm the construct validity of the CROQ and were essential for item reduction. The CROQ demonstrated excellent construct validity when scaling assumptions were tested using strict criteria, with some scales achieving a scaling success rate of 100%. Tests of scaling assumptions should be performed for existing cardiac-specific questionnaires to further evaluate their construct validity. The QLMI-2, for example, has several items that are scored in more than one scale, suggesting that these questions might have poor item discriminant validity.

#### 7.2.5 *Item reduction analyses using explicit criteria*

The item reduction phase in instrument development is often omitted, or poorly documented. For example, only a small proportion of existing cardiac-specific questionnaires included an item reduction stage in instrument development (see Appendix 3.1). The methods and results of these analyses are also poorly documented. This study used explicit and clearly defined criteria in item reduction analyses and reported which individual items were eliminated. There is a need for more research into the consequences of taking different approaches,<sup>444</sup> as different methods and criteria can produce scales with different content.<sup>65 445 446</sup> Some criteria for item reduction, such as item floor and ceiling effects are very poorly reported in the health measurement literature; instrument developers need to specify all criteria used. In this study, methods and criteria for item reduction used by other researchers were reviewed and then combined into a single item reduction strategy for the CROQ with explicit criteria. This strategy was then tested in the pre- and post-revascularisation CABG and PTCA samples to ensure that only the strongest items were retained.

During item reduction, items were eliminated from the CROQ primarily on the basis of explicit psychometric criteria.<sup>64 90 366 369 411 437</sup> However, qualitative (clinimetric) criteria<sup>65 74</sup> were also considered for some items; the balance between these two approaches is rarely described. Items were eliminated if they did not meet explicit psychometric criteria, but representative coverage of *a priori* content domains and

the retention of items of clinical significance were also ensured. Qualitative criteria took precedence over psychometric criteria on the rare occasion when it was agreed that the item could be retained on clinical grounds or for conceptual reasons, as in the case of global items. However, these items were only retained if the psychometric properties of the scale were not weakened by their inclusion. For example, the item *shortness of breath* repeatedly failed the tests of scaling assumptions and did not load highest on its hypothesised factor during factor analysis. Elimination of this item, which is an important symptom of CHD, might have limited the clinical usefulness of the scale and the CROQ might be viewed as having poor content validity. This item was retained in the Symptoms scale, as retaining it did not weaken the already strong psychometric properties of this scale. A similar situation occurred with *palpitations*. Excessive adherence to strictly psychometric criteria could result in scales with poor content validity; instrument developers need to give specific reasons for retaining or discarding items from a scale.

#### 7.2.6 *Responsiveness analyses*

Many instrument developers do not evaluate the responsiveness of their instrument. Only about half of the existing reliable and valid cardiac-specific questionnaires reviewed in Chapter 3 have demonstrated the ability to detect change over time. It is essential for evaluative instruments used in clinical trials to have demonstrated the ability to measure change. Highly responsive scales are preferred because they allow clinical trials to be performed with smaller samples.<sup>97</sup> The CROQ demonstrated the ability to detect change over time between pre-revascularisation and 3- / 9-months post-revascularisation; some very large effect sizes and standardised response means were demonstrated. The Complications scale of the CROQ-CABG also demonstrated evidence of the ability to detect long-term change over time between 3- and 9-months post-revascularisation.

Further research into the relationship between different methods of evaluating responsiveness is needed.<sup>382 396 447</sup> Wright and Young<sup>97</sup> compared the responsiveness of a series of instruments using different indices of

responsiveness. They found that the rank order of responsiveness of the instruments changed when different indices were used. In this study, the magnitude of responsiveness (i.e. small, moderate or large) was only slightly different when the standardised response means<sup>391</sup> were used instead of the standard effect size.<sup>389 390</sup> Husted *et al.*,<sup>388</sup> in their review of methods of assessing responsiveness, concluded that if there are different aspects of responsiveness that are of interest, more than one statistic can be reported.

### 7.2.7 *Inclusion of specific patient groups*

A feature of this study is the inclusion of women and the elderly, both of whom have been largely underrepresented in the development of many of the existing cardiac-specific questionnaires.

#### 7.2.7.1 Women

Women have been largely under-represented in HRQoL studies in cardiac populations.<sup>260 448</sup> With an increasing number of women undergoing CABG and PTCA in the UK each year, the measurement of health outcomes in this group is becoming increasingly pertinent. As described in Chapter 3, the majority of cardiac-specific measures have been developed exclusively with male populations. The CROQ is different in that it was developed and validated on samples of patients including both men and women. Further validation in larger samples of women, or in a purely female sample, is recommended before promoting the use of this measure for women. However, as women were included in the patient interviews used to generate the CROQ and in the samples used for psychometric evaluation, there is preliminary evidence that the CROQ is appropriate for measuring disease-specific outcomes in both men and women undergoing CABG and PTCA.

There is currently a paucity of research into gender comparisons of HRQoL following coronary revascularisation.<sup>260</sup> The availability of a questionnaire appropriate for use with women might encourage more extensive gender comparison studies in the future. Gender comparisons are all the more important

with recent studies suggesting that women with CHD may experience a different pattern of symptoms to men, with women reporting more pain in the neck, back and jaw.<sup>136-139 449</sup> The CROQ is the first validated CHD-specific questionnaire to include an item about radiating pain to other parts of the body (e.g. arms, shoulders, hands, neck, throat, jaw, back). Future studies using the CROQ will be able to compare symptom patterns for men and women. As existing CHD-specific measures have included definitions of angina that were developed when CHD was considered to be a male disease, they may not be sensitive enough to detect different patterns of cardiac symptoms experienced by women. Women have reported worse HRQoL after CABG and PTCA than men,<sup>450 451</sup> but it is possible that the use of a more appropriate outcome measure, such as the CROQ, will produce different findings after adjustment for age and disease severity. There is also evidence that women have different problems from men during recovery;<sup>452</sup> more research is needed to determine whether men and women report different patterns of concerns and experiences.<sup>178</sup>

#### 7.2.7.2 Elderly people

Many existing cardiac-specific questionnaires have been developed with patients under 75 years of age. The CROQ-CABG was validated in a sample of patients ranging in age from 36 to 94 years, with 33% of the sample aged 70 years of age or over. The CROQ-PTCA was validated in a sample of patients ranging in age from 36 to 84 years, with 25% 70 years of age or over. As the CROQ was developed on patients with a wide age range and with no age exclusions, it should be appropriate for measuring disease-specific outcomes in all age groups. However, the CROQ needs to be further evaluated in a sample of purely elderly and very elderly patients to check that its strong measurement properties are maintained in these subsamples. This is planned as a future research project.

As health care resources are scarce and coronary revascularisation expensive, providers of health care may have to prioritise patients for surgery. Decisions should be based on need, but need is a very vague and imprecise concept. The best definition of need is the 'ability to benefit'. Whilst different mechanisms for

prioritising patients are used, the underlying theory is that patients who can 'benefit' most in terms of extended life expectancy or improvement in HRQoL should be prioritised for treatment. In an equitable system there would be equal access for equal need, but other factors such as age may be factored into the decision process; higher rates of intervention occur among younger people than among older people, despite the considerably higher prevalence of CHD in older people.<sup>453</sup> Some patients may be being denied treatment due to their increasing age. The use of age as a criterion for rationing is defended on the grounds that older people have had their "fair innings" and that younger people can benefit more.<sup>454</sup> One counter argument is that age as a criterion *per se* should be rejected on the basis that risk should be individually assessed based on physiological condition and the ability to benefit.<sup>455</sup> Justification for performing coronary revascularisation in the elderly has been a contentious issue due to the high costs involved.<sup>456</sup> However, whilst a higher proportion of older patients have complications leading to death and disability after coronary revascularisation compared with younger patients, it is proving to be effective in terms of both survival and improvement in HRQoL in this group.<sup>322 365 456-460</sup> With coronary revascularisation being offered increasingly to elderly patients, it is important to have an instrument to measure health outcomes and HRQoL in this group. A sensitive disease-specific instrument, appropriate for use with elderly people, offers the optimal method for detecting actual improvements in HRQoL and should provide important information relevant to decisions on treatment prioritisation.

### **7.3 Study limitations**

Results of this study should be interpreted in the light of limitations in both the qualitative and quantitative stages of the study. These limitations are described in terms of two general classes of systematic error: selection bias and observation (information) bias.<sup>461</sup> Selection bias refers to error due to systematic differences in characteristics between those who are selected for study and those who are not.<sup>462</sup>  
<sup>463</sup> Observation bias includes any systematic error in the measurement of information on outcome.<sup>461</sup>

### 7.3.1 *Selection bias*

A possible limitation in the qualitative and quantitative stages of the study is the degree to which findings are biased as a result of the sampling strategy and sampling frame. In the qualitative stage, patients were selected for interview in Outpatient clinics using an opportunistic rather than random sampling strategy. This method of sampling limits the generalisability of findings to the group studied, as the experiences of patients excluded by the sampling strategy are not known. The patients who were not interviewed might have had different experiences and characteristics than those who were interviewed. This method of sampling was adopted as it gave the researcher immediate access to patients. To overcome the possible effects of this bias, a more systematic sampling strategy was used to identify patients to be invited for interview in their own homes.

A potential for selection bias in the quantitative stage of the study occurred due to difficulties in recruiting consecutive patients prior to revascularisation; not all patients scheduled for CABG and PTCA could be included in the pre-revascularisation samples. This problem was a direct result of the system of providing patients with a date for revascularisation with very short notice. This prevented the researcher from sending questionnaires to all elective patients scheduled for surgery. In addition, due to the use of a postal survey to patients' homes, it was not possible to include patients admitted as emergency cases or as transfers from other hospitals. The pre-revascularisation samples may not be entirely representative of all patients who undergo these procedures at these hospitals. To minimise the problem, the researcher kept in close contact with Consultants' secretaries, waiting list administrators, and Cardiology Facilitators to take note of any changes in theatre schedules. Some patients were also recruited from the waiting list.

To minimise the potential for selection bias in the post-revascularisation samples, consecutive patients who had undergone coronary revascularisation at the three study hospitals (in the same time period that patients were recruited in the pre-revascularisation sample) were invited to take part in the study. Hence, all patients

who were not invited to participate at pre-revascularisation (emergency cases and those given short notice of the procedure) were invited to take part at 3-months post-revascularisation. This consecutive recruitment of patients removed the possibility of selection bias due to selective recruiting.

*Non-response bias* is another possible study limitation. The sample may not be representative of the larger population as non-respondents may differ from respondents in some important and/or systematic way.<sup>464</sup> It is possible that patients who did not respond by completing the CROQ were different in some way to those who did respond. For example, they might have been less satisfied with treatment or may have been sicker or have been re-hospitalised. To overcome the potential problem of non-response bias, steps were taken to increase the response rate to the survey through the use of personalised letters, emphasis on confidentiality, stamped addressed return envelopes and postal reminders.<sup>436</sup> The high response rates achieved in this study suggest that a high degree of confidence can be placed in the results. Response rates in each part of the study (with the exception of the 59% response rate for the pre-revascularisation CROQ-PTCA in the final field test) were in excess of the figure of 68% cited by Asch *et al.*<sup>370</sup> as the mean response rate to postal surveys published in medical journals. The high response rates will have partly offset the potential for non-response bias. Ideally, non-respondents should be compared with respondents in terms of demographic and disease-severity variables, but this is not always possible. In future studies using the CROQ, effort should be made to determine reasons for non-response, and non-responders should be compared with responders in terms of characteristics such as disease severity, age, sex, and social class.<sup>465</sup>

*Withdrawal bias* arises when patients who withdraw from a study differ systematically from those who remain.<sup>462</sup> It is unlikely that withdrawal bias was a significant limitation in this study as very few patients who completed the baseline (pre-revascularisation) questionnaire failed to return the follow-up post-revascularisation questionnaire. However, it is possible that the few patients who

withdrew were less satisfied or had poorer health outcomes than those who responded.

### 7.3.2 *Observation (information) bias*

Further limitations of this study are described below in terms of observation (information) bias. This type of bias results from systematic differences in the way outcome data are obtained.<sup>461</sup>

*Interviewer bias* refers to systematic differences in soliciting, recording, or interpreting information from subjects.<sup>461</sup> Interviewer bias was a potential source of bias in the qualitative stage of development of the CROQ. It is possible that the personal characteristics of the interviewer, such as gender and age, influenced patients' willingness to disclose information.<sup>466</sup> To minimise the effect of interviewer bias, the researcher tried to develop a rapport with participants to make them feel more relaxed and able to speak freely. Chapter 4 describes the interview techniques used to gather information in an unbiased manner. To avoid *inter-interviewer bias*, one researcher conducted all interviews. It is possible that field notes might have been unintentionally recorded in a biased manner. As the researcher can never be totally free from preconceptions, *expectation bias*, i.e. the systematic error of measuring and recording observations so that they concur with prior expectations,<sup>461</sup> may have occurred. The interviewer tried to keep an open, reflective mind whilst gathering the data and recorded patients' stories as they were reported. The purpose of the interviews was to gather information about the experiences of patients who have undergone coronary revascularisation; the researcher took a non-directive approach in order to generate spontaneous responses,<sup>425</sup> and tried not to be judgmental.

Another potential source of information bias in the quantitative stage of the study was the timing of questionnaire administration in the pre-revascularisation samples. Before coronary revascularisation, patients may be anxious about the procedure they are about to undergo.<sup>160 168</sup> Ideally, the pre-revascularisation questionnaire should be administered before pre-operative emotional responses

confound patients' responses.<sup>260</sup> However, due to the short notice given to patients about when the procedure would take place, some patients completed the CROQ very close to their operation date. Whilst all responses to the pre-revascularisation CROQ might be confounded by emotional state, this problem may have been more salient for those patients who completed the CROQ very close to their operation date. To counterbalance this potential problem, some patients in the pre-revascularisation samples were recruited from the waiting lists.

Two further types of information bias, *social desirability bias* and *'faking good'*, might have influenced the study findings in both the qualitative and quantitative stages of the study. Social desirability bias concerns the unintentional tendency to report positive answers, and 'faking good' concerns the intentional creation of a false positive impression.<sup>64</sup> During the qualitative stage of instrument development, it is possible that patients (intentionally or unintentionally) focused on the positive aspects of the care as they were grateful for the life-saving treatment they had received. Several patients were 'full of praise' for the treatment they had received. To minimise the potential effect of this bias, attempts were made by the researcher to encourage patients to talk freely and confidentially about their experiences. A few patients did criticise some aspects of the care they received, for example inadequate follow-up after hospital discharge, hospital food and the long wait for their operation. The fact that patients were negative about some aspects of care suggests that social desirability bias and faking good had only a limited impact on the content of the interviews. All patients invited to participate in the interviews agreed. It could be argued that some patients agreed to take part in the interviews as they did not want to appear ungrateful for their treatment in the presence of their doctor. However, the enthusiasm and complete acceptance of those invited to be interviewed at home by an unknown researcher cannot be dismissed. The researcher was welcomed into each of the patients' homes, and several patients even organised their working day around the visit. Patients' sincerity in wanting to help with the research project was also reflected in their comments to the open-ended item in the CROQ; many patients offered to be of

more help and provided contact telephone numbers. The willingness to participate suggests that information provided was of good quality and not intentionally biased.

Social desirability bias and faking good are also possible sources of bias in the quantitative stage of the study. To minimise the potential for this bias, the questionnaire was phrased carefully to avoid biased and / or leading questions.<sup>427</sup>  
<sup>429</sup> In order to encourage honest responses, effort was also made to inform patients that the study was confidential and would not affect the care they received at the hospital. A standard method for measuring the extent to which an instrument is effected by social desirability is the simultaneous administration of a scale such as the Crowne-Marlowe scale of social desirability.<sup>467</sup> Social desirability bias was not formally evaluated in this study due to the already large number of questionnaires administered, but this was identified as an important area for future research.

### 7.3.3 *Generalisability*

This section discusses the extent to which patients recruited in this study are representative of patients undergoing coronary revascularisation in the UK, and consequently the extent to which results are generalisable. Where available, the demographics (i.e. age, gender, ethnicity and social class) of patients in this study are compared with national figures<sup>171</sup> and data from three large UK clinical trials (BARI,<sup>468</sup> CABRI,<sup>242</sup> RITA<sup>244</sup>) to evaluate the effectiveness of coronary revascularisation (see Table 7.1).

Patients in this study were recruited from three hospitals in the UK. The extent to which patients treated at these hospitals are representative of all patients undergoing CABG and PTCA in the UK needs to be addressed. Two of the hospitals in this study (Royal Brompton and Harefield Trust Hospitals) are tertiary referral centres and are generally considered to be national centres of excellence. It is possible that they treat patients with a different case-mix severity than other hospitals, and hence the patients treated might not be representative of patients treated elsewhere. To overcome this potential bias, a third hospital (the

Wythenshawe, a District General hospital in Manchester) was selected to complement these two centres by providing patients with a potentially different case-mix. The purpose of this study was to develop a questionnaire appropriate for use with patients with all levels of disease-severity. It was, therefore, necessary to include patients with severe disease to gather the spectrum of problems.

The average age of patients undergoing CABG in the UK has risen steadily from 60.5 years in 1993 to 62.7 years in 1998.<sup>171</sup> The mean age of CABG patients in the pre-revascularisation sample of this study is similar to the average age of all patients undergoing CABG in the UK, although the post-revascularisation sample was on average 2.3 years older (see Table 7.1). National figures for PTCA were not available. In comparison to the age composition of patients recruited in three large clinical trials conducted in the UK,<sup>242 244 468</sup> the PTCA samples in the CROQ validation study are representative of patients undergoing coronary revascularisation in the UK. Again, the CABG post-revascularisation sample was approximately 4 years older.

In terms of gender composition, the proportion of women in the PTCA samples in this study, was generally similar to the other studies reported in Table 7.1. There was a 7-9% smaller proportion of women in this study compared with the UK CABG national figures.

South Asians (Indians, Bangladeshis, and Sri Lankans) living in the UK have particularly high rates of CHD,<sup>124</sup> but this group was largely underrepresented in this study, as in other UK studies (see Table 7.1). About 7-12% of patients in this study were from ethnic minorities. This might in part be due to the geographical catchment areas for these hospitals. The ethnicity composition of samples undergoing coronary revascularisation in the UK is poorly documented in the literature. Only one of the clinical trials (BARI) presented in Table 7.1 presented the proportion of patients who were white.<sup>468</sup> The proportion of white patients in the CROQ validation study was similar to that reported in the BARI study.

In this study, approximately half of the patients in the samples were from manual and half from non-manual social classes. Two of the hospitals in this study are based in the greater London area with catchment areas largely covering the south of England. The south of England is generally considered to be more affluent than the north.<sup>469</sup> It is therefore possible that the Brompton and Harefield hospitals treat patients with a different social class composition than hospitals in other areas of the UK, and are hence unrepresentative of the UK as a whole. The Wythenshawe Hospital was included in this study to minimise the potential for this bias by increasing the catchment area of this study to include areas in the north west of England. CHD is more prevalent in manual than non-manual workers in the UK.<sup>124</sup>  
<sup>126 128</sup> In this study, patients from each social class were represented. None of the large studies reporting outcomes in CABG and PTCA have described social class distributions of their sample, thus precluding comparisons with this study. By using patients treated at all three hospitals in the quantitative stages of the study, bias as a result of hospital geographical location and social class should have been reduced.

#### 7.3.3.1 Comparison with other studies using the SF-36

The extent of the generalisability of the findings of this study to the wider population can be assessed by comparison with results of other studies using the SF-36. Tables 7.2 and 7.3 show SF-36 scores CABG and PTCA patients in this study, compared with three sets of US norms and with CABG and PTCA patients in other studies reported in the literature. . Independent t-tests were used to test differences between SF-36 PCS/MCS summary scores for CABG and PTCA patients in this study, compared with normative data and with scores for CABG and PTCA patients in other studies. Some studies reported in Tables 7.2 and 7.3 did not report PCS and MCS scores and these studies are included in the tables for information purposes only.

7.3.3.1.1 Pre-revascularisation. As expected, SF-36 PCS/MCS scores for CABG patients in this study are significantly lower than US norms for the general population ( $p=.000$  /  $p=.000$ ), for people in the general population with angina

( $p=.015$  /  $p=.002$ ) and for MOS participants with angina ( $p=.000$  /  $p=.000$ ), but similar ( $p=.913$  /  $p=.325$ ) to scores reported in another study of CABG patients.<sup>470</sup> Results are similar for PTCA. SF-36 PCS/MCS scores for PTCA patients in this study are significantly lower than US norms for the general population ( $p=.000$  /  $p=.006$ ) and for MOS participants with angina ( $p=.000$  /  $p=.004$ ), but not significantly lower compared with people in the general population with angina ( $p=.055$  /  $p=.329$ ). It was not possible to test the differences between scores in this study and those reported by Nash *et al.*<sup>302</sup> and Seto *et al.*<sup>305</sup> as mean scores and standard deviations were not available for these studies.

#### 7.3.3.1.2 Post-revascularisation.

SF-36 PCS scores for CABG patients at 3-months post-revascularisation in this study are significantly lower than US norms for the general population ( $p=.000$ ), but are significantly higher than the norms for people in the general population with angina ( $p=.000$ ) and for MOS participants with angina ( $p=.007$ ). However, MCS scores at 3-months post-CABG are not significantly different from the US norms for the general population ( $p=.588$ ), for people in the general population with angina ( $p=.092$ ) and for MOS participants with angina ( $p=.926$ ). The same pattern in PCS and MCS scores is found at 9-months post-CABG.

SF-36 PCS scores for PTCA patients at 3-months post-revascularisation in this study are significantly lower than US norms for the general population ( $p=.000$ ), but not significantly different from the norms for people in the general population with angina ( $p=.058$ ) and MOS participants with angina ( $p=.429$ ). SF-36 MCS scores for PTCA patients at 3-months post-revascularisation in this study are significantly lower than US norms for the general population ( $p=.005$ ), and the norms for MOS participants with angina ( $p=.006$ ), but not significantly different from the norms for people in the general population with angina ( $p=.528$ ).

SF-36 PCS scores for PTCA patients at 9-months post-revascularisation in this study are significantly lower than US norms for the general population ( $p=.000$ ), but not significantly different from the norms for people in the general population with

angina ( $p=.375$ ) and MOS participants with angina ( $p=.999$ ). SF-36 MCS scores for PTCA patients at 9-months post-revascularisation in this study are not significantly different from the US norms for the general population ( $p=.544$ ), the norms for people in the general population with angina ( $p=.723$ ) and for MOS participants with angina ( $p=.433$ ).

## **7.4 Methodological issues**

This study presented some challenging methodological issues: scoring questionnaires with varying numbers of response categories, the appropriateness of treating ordinal-level data as interval, and what item reduction strategy to adopt in developing a questionnaire to be used both pre- and post-intervention.

### **7.4.1 *Scoring questionnaires with varying numbers of response categories***

This study raised important methodological questions about combining items to form scales. In questionnaires with items that are all measured on the same response scale, i.e. scales with the same number of response categories, items can be summed to form scale scores. Although many HRQoL and other outcome questionnaires do indeed contain items that are all measured on the same scale, it is not always possible or appropriate to use the same response scale for all items. For example, it might be most appropriate to use dichotomous items to indicate the presence or absence of symptoms and graded Likert-type scales to measure the frequency or severity of emotional responses, all in the same questionnaire. Sometimes it is difficult to put all items on the same response scale without appearing to force the items to fit. In this study, where items were borrowed from several different questionnaires, it was not possible to force all items to the same metric. This raised the issue of how to scale and score the CROQ items.

There is relatively little guidance in the HRQoL literature about strategies for constructing summated rating scales and the relative advantages and disadvantages of the different methods.<sup>407</sup> This is because most scales are based on items with the same number of response categories. However, after a review of established instruments and methods of combining items to form scales, several

methods were identified. The SF-36 Bodily Pain scale contains two items measured on different response scales; one item is measured on a 6-point scale and the other on a 5-point scale. One assumption of summated rating is that items should have equal variance. Recognising that items measured on different response scales do not satisfy this criterion, Ware *et al.*<sup>87</sup> developed a scoring algorithm to recalibrate the 5-point item to the same 6-point response scale of the other item (1=6.0) (2=4.75) (3=3.5) (4=2.25) (5=1.0). After recalibration, items are summed before being transformed to a 0-100 point scale with scores between zero and 100 representing the percentage of the total possible score achieved. This same method of recalibrating items and transforming scales to 0-100 scores was followed for scoring the subscales of the CROQ.

However, whilst this method of scoring has been adopted frequently in the literature, it is not strictly the most psychometrically appropriate method.<sup>64 371 372 407</sup> To facilitate interpretation between scores on different scales and instruments, it is common practice in many of the most frequently used psychological measures to standardise scores before summing items to form scales, (i.e. raw scores are transformed to z-score equivalents<sup>64</sup> before being summed to form total scores). Because transforming raw scores to z-scores generates negative scores which are not easily interpretable, z-scores are often transformed to *T*-scores for reporting purposes.<sup>64</sup> *T*-scores are based on a mean of 50 and a standard deviation of 10 to give an easily understood range of scores. One advantage of using standardised scores such as z- and *T*-scores is that similar to percentiles, they enable comparisons about where one respondent stands in relation to all other respondents.<sup>64</sup> Whilst these scoring methods are common in psychometrics, they are generally unfamiliar to developers and users of health outcome instruments. One criticism of *T*-scores is that they may be difficult to understand, which is why 0-100 point scales are so popular in HRQoL measurement.<sup>87</sup>

As items in the CROQ are measured on scales with a varying number of response categories, it is difficult to compare scores on one scale with scores on another. *T*-scores were, therefore, considered as a possible solution. *T*-scores were used to

create CROQ total scores (Total Core and Total Outcome), but not for any of the subscale scores. This is because all subscales except two (Symptoms and Satisfaction) are measured on the same response scale. For the Symptoms and Satisfaction subscales, items were re-calibrated to the same response scale and then summed and transformed to a 0-100 scale using the method of the SF-36. The decision to alter the scores through re-calibration was weighed up against the strong advantage of not having to use standardised *T*-scores for individual subscales. Whilst *T*-scores may not be familiar to some users of the CROQ, failure to standardise the items in the total scores before summing would have been methodologically unacceptable.

One limitation of *T*-scores is that as they are sample dependent, the interpretation of scores is limited to comparisons within the sample from which *T*-scores were derived. To make cross-sample comparisons, it is necessary to undertake normative studies with large numbers of subjects to generate population *T*-scores and norms. Population norms provide a standard against which scores from other studies can be compared and are essential for the interpretation of a scale's scores in a particular study. The use of a normative sample allows a population rather than sample mean and standard deviation to be used to evaluate *T*-scores. In this way, *T*-scores are no longer sample dependent.

It is interesting that recent improvements in the SF-36<sup>89</sup> have taken into account the methodological superiority of scoring using standardised scores (*z*- and *T*-scores) over the earlier approach<sup>87</sup> of transforming scores to a 0-100 point scale. That is, whereas in version 1 of the SF-36 the eight dimension scores were calculated using the 0-100 point transformation (although PCS and MCS scores use the *T*-score method), version 2 has adopted the *T*-score method for the scoring of the eight dimension scores. This method is viewed as preferable as the general population norm is built into the scoring algorithm, thus all scores above or below 50 can be interpreted as above or below the general population norm. By developing this scoring method for all the scales, comparisons in scores can be made across the scales and PCS and MCS summary scores directly.

#### 7.4.2 *Treating ordinal-level data as interval*

Related to methodological issues about scoring is the debate about the appropriateness of applying interval-level statistics to ordinal-level data. For some years<sup>407</sup> there has been considerable debate as to whether it is acceptable to treat ordinal data generated from Likert scales as interval-level data.<sup>405 406</sup> Stevens<sup>471</sup> proposed that the level of measurement dictates the choice of statistical method, i.e. parametric statistics for interval data and non-parametric statistics for ordinal data. His view has been ferociously challenged for many years,<sup>405 472</sup> but not without rejoinder.<sup>406</sup> As recent as 1997, there was a resurgence of the old debate with an entire issue of the *British Journal of Psychology* dedicated to this debate.<sup>473-479</sup> It is now generally accepted by many methodologists that data from rating scales can be analysed as if they were interval without introducing severe bias if the distribution of scores is not severely skewed.<sup>64 87 366</sup> The treatment of ordinal data as interval does not lead to a great loss in accuracy and the advantage is that the results from parametric tests are more easily interpreted.

In this study, as the CROQ items were not severely skewed, it was appropriate to treat the data as interval. The assumption that items could be summed to form scales without standardisation or weights was evaluated using several criteria: symmetry of item-response distributions, equivalence of item means and standard deviations, and 'roughly equivalent' item-total correlations.<sup>369 408</sup>

#### 7.4.3 *Item reduction strategy for a pre- and post-intervention instrument*

Whilst item reduction techniques are now quite widely used in developing health measurement questionnaires, methods and techniques of item reduction analyses are poorly documented in the HRQoL literature.<sup>444</sup> In measuring outcomes before and after an intervention such as coronary revascularisation, the same instrument is usually administered at both assessment points. However, the CROQ is slightly different in that it has a core set of 33 items that are administered both before and after coronary revascularisation, as well as some additional items in the post-revascularisation version that are specific to the procedure and are therefore only asked after the procedure. The pre- and post-revascularisation versions of the

CROQ are thus very similar, but different. During item reduction analyses, the question arose as to whether to treat these two different versions as entirely different questionnaires and to validate them separately, or to item-reduce one version and then model it on the second to verify the item reduction strategy. It was clearly not appropriate to consider the questionnaires as entirely separate and to item reduce each one separately, as doing two separate item reductions could result in different content for the two versions without a common core. The lack of a common core would make comparisons of before and after revascularisation difficult. There were no precedents in the literature to resolve this issue.

A decision had to be made, therefore, about which questionnaire version (pre-revascularisation or post-revascularisation) to use for item reduction analyses. The pre-revascularisation version was selected for initial item reduction analyses as standard item reduction techniques include an analysis of item endorsement frequencies, which one would expect to be skewed after coronary revascularisation reflecting significant health improvements. If the post-revascularisation version had been used as the starting point, some items of key importance at pre-revascularisation might have been eliminated. The elimination of items from item pools at one point in time based on inter-item correlations (item redundancy) can be risky as their relationship at another point in time might be different.<sup>443</sup> For this reason, reduced item pools developed from the pre-revascularisation version of the questionnaire were modelled in each post-revascularisation sample to test the robustness of the scales identified at pre-revascularisation and to verify the core set of items in the pre-revascularisation version. The clear presentation of the methods and criteria used to eliminate items from the CROQ both at pre- and post-revascularisation should help guide other methodologists who need to develop both pre- and post-intervention versions of an outcome instrument.

As dramatic changes in health status and HRQoL are observed after coronary revascularisation, it is important to ensure that an instrument used before treatment retains its psychometric properties when used to assess outcome after revascularisation. Domains of interest can vary with the stage or severity of illness;

issues that are pertinent to CHD patients before revascularisation might not remain relevant after treatment and this could alter the psychometric properties of an instrument.

## **7.5 Practical issues in developing the CROQ**

A number of practical challenges were encountered in implementing a systematic sampling strategy, verifying that patients are alive, and being a researcher in the clinical context.

### **7.5.1 *Implementing a systematic sampling strategy***

The implementation of a systematic recruitment strategy before revascularisation proved to be impossible, as the identification of patients scheduled for coronary revascularisation was surprisingly difficult. The ideal of recruiting consecutive patients as they were given a date for revascularisation seemed feasible in hospitals with central waiting lists and a system of informing patients of their date for CABG or PTCA by letter. However, the vast majority of cases were actually given very short notice of the date for revascularisation. Some patients, for whom there was insufficient time to send a letter, were telephoned by the Consultant's secretary or Cardiology Facilitator and asked to come to the hospital within the next couple of days. Within each hospital, each Consultant had a different system for scheduling patients in theatre slots. It took some time to determine how these systems actually worked in practice.

Several of the cardiac surgeons did not have a regular system for deciding which patients would be called in for CABG for the next week, whilst others did. Sometimes theatre schedules were decided on a Friday afternoon, including the slot for the following Monday's procedures. This gave the researcher very short notice to try to recruit the patient into the study, with the result that not all eligible patients could be recruited; several patients reported that they had received the questionnaire too late. Whilst one hospital had a detailed central waiting list specifying the urgency of cases for CABG using a 3-point scoring system, scheduling appeared to go on at a series of different levels. Some Consultants'

secretaries held files of patients categorised as 'urgent', 'previous cancellations', and 'long waiters' who were priority cases. These files were inspected on a regular basis by the researcher in an attempt to identify those most likely to be admitted for CABG over the coming weeks. All secretaries were visited or telephoned on a twice-weekly basis to request information on patients scheduled or likely to be scheduled for CABG. It soon became obvious that a multi-level approach needed to be taken in each hospital to gather the necessary information. Hospital ward admission diaries were inspected in one nearby hospital on a twice-weekly basis to identify patients who had been missed by the other methods. Sole reliance on busy medical secretaries for information about which patients were scheduled for surgery proved to be unfeasible. The Wythenshawe Hospital appeared to have the optimal system; each Friday, the Waiting List Administrator provided the researcher with a list of patients scheduled for surgery for the following week.

Recruitment of patients prior to PTCA also proved to be difficult. In all three hospitals, patients were scheduled for PTCA by a Cardiology Facilitator. However, these records were sometimes inaccurate. In one hospital, the name of patients scheduled for PTCA were entered in a catheter laboratory diary held by the Cardiology Facilitator, but were identified only by name (not hospital number). The researcher took note of patients' names and the date they were scheduled for PTCA, then proceeded to identify addresses and hospital numbers from the computerised patient administration system (PAS). As hospital numbers are the unique identifier for patients, this information was essential to correctly identify patients. On entering the names into the PAS, difficulties were encountered, particularly with patients with common surnames who could not be easily identified out of a large bank of possible patients. Some patients' names had been spelt incorrectly in the diary and were consequently difficult to identify on the PAS. These problems aside, on several occasions, patients returned blank CROQ questionnaires to the Project Co-ordinator with a note saying that they were not due to have PTCA as they had already had it done elsewhere or had already had it done in this same hospital. The researcher was later informed that one Consultant in particular might schedule a patient for investigation only (i.e. not for intervention),

but then on discovering that the patient needed PTCA, would perform it at the same time rather than scheduling the patient at a later date. This caused problems in the scheduling of procedures as the Cardiology Facilitator was not always informed that the patient had undergone PTCA.

It was easier to implement a systematic sampling strategy for the post-revascularisation sample as patients were easily identified according to procedure lists generated by Information Departments. However, some problems were also encountered at this stage. A few patients notified the Project Co-ordinator that they had not undergone PTCA, despite being on the procedure list indicating that they had undergone the procedure. These patients reported they had only undergone invasive investigation (not intervention), as the cardiologist had found that the PTCA was anatomically impossible to perform. As these patients should not strictly have been on the PTCA list, they were considered ineligible for purposes of this study.

Response rates were lower in the pre-revascularisation than post-revascularisation samples. This might partly be explained by the fact that patients were frequently sent the pre-revascularisation CROQ too close to the date of their operation to permit completion before the procedure. Some patients who felt unwell or anxious prior to their operation and did not want to complete the questionnaire might also explain the lower response rate. Another reason might be the inability to send patients reminders due to the short time period between the date of the notification of revascularisation and the actual date of the procedure. These problems with recruitment at pre-revascularisation are common to other surgical procedures where short notice is given for procedure dates, and are difficult to overcome. Researchers should be aware of the potential difficulties in recruiting patients prior to surgery using a postal survey and allow sufficient time and resources to recruit the necessary sample.

### **7.5.2**      *Verifying that patients are alive*

To avoid unnecessarily upsetting families and friends by sending a deceased person a questionnaire, the local ethics committees advised that hospital records were checked before sending out post-revascularisation questionnaires. However, hospital records are notoriously out of date for registering deceased patients. Hospitals are often not informed that a patient has died after leaving the hospital, as they are reliant on GPs and relatives to contact them with this information. In this study, despite routinely checking hospital records, several patients who were deceased were unknowingly sent questionnaires. This caused unnecessary upset for families and friends. The hospital records were subsequently amended to avoid upsetting the families again. The use of the national system of data flagging was considered as a method of gaining more reliable data, but these records are several months out of date and current information was essential. As the Project Co-ordinator was unable for practical reasons to check all three hospitals' computerised hospital records, the GP practice at which the patient was registered was telephoned to obtain this information. This proved to be a more reliable method of gathering this sensitive information. However, as this information is confidential, receptionists should not, according to a Data Protection Act, divulge this information without a formal request in writing, a process that can take some time. The majority of practices contacted did verify whether the patient was alive over the telephone, but this was in fact a breach of patient confidentiality.

### **7.5.3**      *Being a researcher in a clinical context*

This study highlighted some of the problems of being a researcher in a clinical context, for example dealing with sensitive issues, requests for clinical advice and "cries for help".

During the qualitative interviews with patients, some sensitive issues were raised. Several patients recounted very distressing stories about their experiences of having a chronic disease and of life-threatening events. Repeated references were made to death and fear of dying and experiences were discussed which some patients might have wanted to forget. It is essential that researchers interviewing

patients with chronic diseases have experience in dealing with sensitive issues and that they show compassion to patients rather than treating them as a source of information for their study. Before interviewing patients with chronic diseases for research purposes, it is advisable to have a list of relevant specialist contacts within the hospital to whom patients can be referred. Where several interviewers are involved in data collection, ground rules should be established before interviewing, e.g. agreeing follow-up mechanisms such as informing liaison or community nurses with the patient's permission, informing patients of self-help groups, not leaving distressed interviewees alone after the interview where possible, etc. Interviewers should also debrief with colleagues after interviewing so that they are not burdened by the problems described in the interviews. During the patient interviews in this study, several patients requested technical information and advice about their clinical condition. The researcher referred these patients to qualified health care professionals who were able to answer these questions accurately.

Inspection of responses to the open-ended item in the CROQ also revealed some "cries for help". On several occasions patients attached letters describing their current concerns, medication problems, or lack of follow-up from the hospital and several patients wrote questions in the hope of getting a response. Once again, this raises the question of how researchers should deal with these 'real' problems. The ethics of research practice dictates that the information obtained in a research study should be kept confidential; contacting hospital staff without the consent of the patient is considered to be a breach of patient confidentiality. However, at times it can appear to be equally unethical to ignore a "cry for help". The most appropriate method is to ask the patient if they would like you to put them in touch with someone who can help. Unfortunately, in this study it was only on entering the data that these comments were read in detail and in most occasions this was too late as it was several weeks after the data was collected. Researchers gathering this type of information should read all comments made by respondents immediately on receiving the questionnaires in case there are any cries for help which need urgent attention.

## 7.6 Study implications

This section discusses the potential contribution of the CROQ to research and clinical audit / quality improvement.

### 7.6.1 Research

In order to evaluate the effectiveness of treatments, the choice of outcome measure is of paramount importance. For some time the lack of an appropriate disease-specific instrument for coronary revascularisation has been noted.<sup>260 262 287 480</sup> Researchers have had to choose from a range of disease-specific measures which are either conceptually inappropriate or which have unknown psychometric properties when used with coronary revascularisation patients. Alternately, researchers have used a battery of measures in an attempt to cover all of the important content domains. The CROQ is the only psychometrically sound disease-specific questionnaire that is conceptually appropriate for the comprehensive assessment of HRQoL and health outcomes both before and after coronary revascularisation. Its potential uses are therefore numerous.

In clinical studies of effectiveness, researchers are often trying to detect small and sensitive treatment effects, which sometimes cannot be measured by clinical measures alone. HRQoL questionnaires are now frequently used in many areas of medicine and surgery to detect these sometimes subtle changes. As a validated instrument tested against rigorous scientific standards, the CROQ can be used with confidence in research. Generic measures such as the NHP<sup>225 241</sup> and SF-36<sup>226</sup> have mainly been used in cardiovascular clinical trials, possibly because there is more evidence of their robustness to measure patient-based outcomes in a variety of patient groups and the ability to compare results across trials. The CROQ has demonstrated evidence of responsiveness that exceeds that of the generic SF-36.

In recent years, a few clinical trials have used disease-specific questionnaires, for example the international trial of PTCA with stenting versus CABG, the Stent or Surgery (SOS) trial.<sup>481</sup> However, instruments such as these, originally developed

for patients maintained on medical therapy, need to be further validated for use with CABG and PTCA patients. As the CROQ has been validated scientifically for use in CHD patients before and after CABG and PTCA, confidence can be placed in its measurement properties. The inappropriate use of HRQoL instruments that have not been validated in the target population can lead to confusing or inconsistent results. All modifications to an instrument need to be validated, including its use in different patient groups from those in whom it was initially validated. It is not just psychometric equivalence that can change but also conceptual relevance. These rules and violations have not been made clear to potential users of HRQoL questionnaires and need to be made more accessible.

Recognising the need to measure a diverse range of outcomes after CABG and PTCA, some clinical trial investigators have administered a battery of HRQoL measures (with each instrument measuring one or two domains). In the SOS trial,<sup>481</sup> for example, patients complete a combination of five generic and disease-specific questionnaires (Seattle Angina Questionnaire, Cardiac Health Profile, SF-36, EuroQol, and the Zung Self-Rating Depression Scale). The result is that patients have a number of lengthy questionnaires to complete. The CROQ has several advantages over this battery approach. As a single comprehensive measure covering all the important domains, it avoids the need for using more than one instrument. This reduces the burden placed on the patient in terms of the reduced time taken to complete the CROQ compared with a battery of measures. The use of a single measure also avoids the situation where the patient perceives a great deal of repetition across the different questionnaires.

Another advantage of the CROQ over the battery approach is its simple scoring system. By using a battery of measures, researchers have to score each instrument separately, some of which have complex scoring mechanisms, thus creating a greater burden. The use of a battery also creates a number of dependent variables, making analysis and interpretation more cumbersome. The CROQ has a further advantage in that the four core pre- / post-revascularisation scales (Symptoms, Physical Functioning, Psychosocial Functioning and Cognitive

Functioning) can be summed to create an overall core functioning scale (Core Total). Although it is not valid to simply form a summated total score from a battery of individual measures,<sup>83</sup> factor analysis can be used to derive a composite score for use in analysis. The availability of a reliable and valid summary score will enable researchers to measure the impact of several key domains in a single score. This will make it easier to compare health outcomes between groups of patients as it measures overall impact as opposed to individual components. It is sometimes difficult to determine whether one procedure should be described as more effective than another if one results, for example, in improvement in symptoms and another results in improvement in psychosocial functioning. The reliability and validity of the Core Total score has been demonstrated and it can be used with confidence with patients both before and after CABG and PTCA.

#### *7.6.2 Clinical audit / quality improvement*

The CROQ is a potentially useful tool for clinical audit and quality improvement at both the national and local level. The National Service Framework (NSF) that has recently been published for CHD<sup>11</sup> to define standards for service provision in an attempt to tackle unacceptable variations in quality across the country, includes suggestions of indicators and clinical audit criteria that can be used to assess the quality of treatment. These criteria are currently based on clinical parameters, such as risk-adjusted number and percent of patients dying after CABG before discharge from hospital, by surgeon and centre. It is feasible that the CROQ could be used to provide information on health outcomes and service quality that is not measured by these clinical outcomes and that scores could be compared across Trusts after adjusting for case-mix severity. The CROQ could also be used to measure the impact on the patient of policy changes described in the NSF e.g. reduced waiting times for CABG and PTCA patients.

The CROQ could also be used by hospitals as a local indicator of quality. It could be used as a quality improvement tool to provide information about the impact of care from the patient's perspective; gaps in care could be identified and local standards could be set. If, for example, a large percentage of patients reported that

they were not satisfied with the information they received about their heart operation, action could be taken to improve the quality of information provided to patients whilst in hospital. Improvements in patient education and information dissemination might result in improved outcomes.<sup>172</sup> Information generated from the open-ended item in the CROQ could also be used to identify areas for improvement in care. These areas could then be further explored through other methods such as qualitative interviews to further understand the nature of the problems and ways to overcome them.

Findings from this study suggest that the CROQ can be successfully implemented as an audit tool. Successful implementation was demonstrated by the support the study received at the three hospitals by surgeons and cardiologists, the ease with which the CROQ was administered and the high response rates from patients in each of the three hospitals. Surgeons and cardiologists at participating hospitals were enthusiastic and supportive in providing the researcher with access to patient information. Once details of patients scheduled for surgery are known, the CROQ can be administered easily, as demonstrated by one researcher's ability to recruit large numbers of patients simultaneously from three different clinical sites across the UK. On-site clinical audit assistants should be able to administer the CROQ more easily, as they have access to the relevant information and can regularly check for scheduled procedures. A scoring manual and scoring programme are soon to be developed for the CROQ, which will help users score their data. The CROQ could be implemented in other UK hospitals and become a nationally recognised audit tool.

The CROQ provides information about a range of procedure-specific adverse effects. As these adverse effects can negatively affect HRQoL, they need to be monitored.<sup>175</sup> Little previous research has attempted to quantify the impact of adverse effects from the patient's perspective after CABG and PTCA. Studies which have evaluated these outcomes have either been qualitative studies<sup>172 173 332 482</sup> or have used instruments with unknown psychometric properties.<sup>176 482</sup> There have been no attempts to routinely monitor these important aspects of outcome

from the patient's perspective using a validated instrument. Providers of care generally do not know the proportion of patients who experience these adverse effects following CABG and PTCA. The CROQ will be a useful tool for health care providers for routine monitoring of the bothersomeness and persistence of these outcomes.

Information generated through use of the CROQ could also potentially help improve health outcomes. Studies suggest that patient expectations can influence outcome;<sup>118</sup> beliefs and expectations have been shown to play a role in recovery from CABG.<sup>483</sup> Data generated from the CROQ could be used to provide health care professionals with more information about the changes patients should expect when they have CABG or PTCA, enabling them to provide patients with more accurate information about how other patients have felt at specific points in time after CABG and PTCA. The provision of information to patients about what they should expect when undergoing procedures and recovery might lead to improved health outcomes.<sup>482</sup> If patients expect specific problems after revascularisation, they might experience less anxiety and improved outcome. Better provision of information about the course of recovery before revascularisation and before leaving hospital might help patients be more realistic about expected recovery time.

The potential for the use of the CROQ in clinical audit is illustrated in the next section. The data collected as part of this psychometric study will feed directly into the clinical audit departments at the Royal Brompton, Harefield and Wythenshawe Hospitals. A full report for clinical audit is currently being prepared; the following section illustrates the type of descriptive information about outcome that can be fed into the audit process.

#### 7.6.2.1 Patient-based outcomes in coronary revascularisation as measured by the CROQ

This section reports on some of the descriptive findings and changes that occurred between pre- and post-revascularisation for CABG and PTCA patients in this study,

as measured by the CROQ. It provides descriptive information about the experience of CABG and PTCA from the patient's perspective. It does not address the comparative effectiveness of CABG and PTCA procedures as it is a psychometric study that was not designed to evaluate effectiveness. However, it does consider, at a strictly exploratory level, some of the descriptive findings in CABG versus PTCA. Appendices 6.19a-6.21b present frequencies of responses to each item in the pre- and post-revascularisation versions of the CROQ-CABG and CROQ-PTCA in the final field test.

Consistent with the findings of numerous other studies, this study demonstrated that patients report dramatic improvements in several dimensions of HRQoL after both CABG and PTCA. Previous research using generic HRQoL questionnaires has shown that CABG and PTCA generally result in improvements in symptoms, functional capacity, emotional and social functioning.<sup>162 176 179 181 271 300 310 320 325 326</sup> This study also demonstrated statistically significant changes in symptoms, physical/, psychosocial/ and cognitive functioning for CABG and PTCA patients between pre- and 3- / 9-months post-revascularisation, as measured by the CROQ.

In terms of symptom relief, CABG patients reported a dramatic improvement in symptoms. At pre-revascularisation, only 12% of patients reported that they were "not at all" bothered by chest pain, 12% by discomfort in the chest, 15% by shortness of breath, 25% by radiating pain and 41% by palpitations. At 3-months post-revascularisation these figures increased dramatically, with 82% of patients reporting that they were "not at all" bothered by chest pain, 78% by discomfort in the chest, 34% by shortness of breath, 75% by radiating pain, and 58% by palpitations. At 9-months post-revascularisation, scores remained high, but some values were lower than at 3-months post-revascularisation. Before CABG, 20% of the sample reported that they had taken no nitroglycerin over the past 4 weeks and 8% reported that their heart condition had caused them no trouble. At 3-months post-revascularisation, these figures rose to 89% and 57%, respectively. There was little change in these figures between 3- and 9-months post-revascularisation.

PTCA patients also reported a dramatic improvement in symptoms. At pre-revascularisation, only 16% of patients reported that they were "not at all" bothered by chest pain, 8% by discomfort in the chest, 11% by shortness of breath, 23% by radiating pain and 35% by palpitations. At 3-months post-revascularisation these figures increased dramatically, with 52% of patients reporting that they were "not at all" bothered by chest pain, 42% by discomfort in the chest, 26% by shortness of breath, 54% by radiating pain, and 57% by palpitations. However, by 9-months post-revascularisation, all of these figures had fallen; improvement reported at 3-months post-PTCA was not maintained at 9-months post-PTCA, suggesting that some patients experienced recurrent angina. Before PTCA, 26% of the sample reported that they had taken no nitroglycerin over the past 4 weeks and 6% reported that their heart condition had caused them no trouble over the past 4 weeks. At 3-months post-revascularisation, these figures rose to 55% and 39%, respectively. There was little change in these figures between 3- and 9-months post-revascularisation.

At pre-revascularisation, CABG and PTCA patients reported similar levels of the bothersomeness of symptoms, but at post-revascularisation there was a very different pattern, with PTCA patients showing less symptom improvement than CABG patients. On average, CABG and PTCA patients in the responsiveness subsample reported 39- and 23-point score improvements on the Symptoms scale between pre- and 3-months post-revascularisation, respectively. Symptom relief was accompanied by dramatic improvements in physical functioning for CABG and PTCA patients between pre- and 3-months post-revascularisation. On average, CABG and PTCA patients in the responsiveness subsamples reported 32- and 18-point score improvements on the Physical Functioning scale between pre- and 3-months post-revascularisation, respectively. CABG patients reported continued improvement in physical functioning between 3- and 9-months post-revascularisation, but PTCA patients did not.

CABG and PTCA patients reported improvements in social functioning between pre- and 3-months post-revascularisation and continued improvement between 3-

and 9-months post-revascularisation, but these changes were less dramatic than improvements in psychological functioning. CABG and PTCA patients reported improvement in all items measuring psychological functioning between pre- and post-revascularisation and most, but not all, items demonstrated continued improvement between 3- and 9-months post-revascularisation. A surprising finding was that CABG and PTCA patients reported similar levels of feeling depressed at pre- and 3-months post-revascularisation, with approximately 30% reporting depression "none of the time" at both assessment points. However, at 9-months post-revascularisation 64% of CABG and 53% of PTCA patients reported feeling depressed "none of the time", suggesting that 36-47% of patients continue to feel depressed for some time after revascularisation. On average, CABG and PTCA patients in the responsiveness subsamples reported 30- and 17-point score improvements on the Psychosocial Functioning scale between pre- and 3-months post-revascularisation, respectively.

Little change was observed in cognitive functioning between pre- and post-revascularisation for CABG and PTCA patients. On average, CABG and PTCA patients in the responsiveness subsamples reported 15- and 7-point score improvements on the Cognitive Functioning scale between pre- and 3-months post-revascularisation, respectively. At 9-months post-revascularisation many CABG and PTCA patients still reported problems with cognitive functioning (reasoning, memory and concentration). There were no obvious differences between CABG and PTCA patients.

At 3-months post-revascularisation, 16% of CABG and 17% of PTCA patients reported that they had been re-admitted to hospital since revascularisation for an overnight stay for reasons to do with their heart condition or heart operation. At 9-months post-revascularisation, these figures rose to 21% for CABG and 28% for PTCA patients. Few studies in the literature have evaluated complications after coronary revascularisation from the patient's perspective. However, studies that have described these complications report very similar results to this study, in terms of the type of problems and the length of time these problems can persist.<sup>176</sup>

206 482 The most bothersome complications 3 months after CABG in this study were tenderness around the chest wound, numbness in the leg or arm as a result of having the vein removed for use as grafts, numbness around the chest wound, and swollen feet or ankles. Skaggs and Yates reported swollen ankles as the most common complication reported by patients 3 months after CABG.<sup>482</sup>

Many patients reported that they were bothered by complications at 3-months post-CABG and a number still reported bother from complications at 9-months post-CABG. At 3-months post-CABG, many patients reported that they were at least "moderately" bothered by chest wound pain (23%), tenderness around the chest wound (30%), numbness or tingling around the chest wound (28%), pain in the leg or arm wound (23%), numbness or tingling in the leg or arm due to the operation (34%) and swollen feet or ankles (29%). At 9-months post-CABG these figures had fallen, but continued to be at least "moderately" bothersome for some patients; the CROQ was able to detect long-term changes in these complications. Longer-term follow-up might have determined the point in time at which these complications disappear for the subgroup of patients still reporting them at 9-months post-CABG. Other studies have reported that these types of problems can persist for as long as 12 months after CABG.<sup>175 176</sup> Caine *et al.*<sup>176</sup> found that 28% and 26% of patients continued to report chest or leg pain at 3- and 12-months post-CABG, respectively. Caine *et al.*'s findings are consistent with the findings in this study at 3-months post-CABG, but higher than the values reported at 9-months post-CABG. One possible reason for this difference is that the CROQ asks about bothersomeness of the problem rather than simply whether it exists.

There is very little discussion about minor complications with PTCA in the literature. However, patients interviewed in developing the content of the CROQ-PTCA did identify some complications that they had experienced, some of which caused them considerable bother in the first few weeks of recovery. Due to the relatively less invasive nature of PTCA over CABG, researchers have paid little attention to these complications which are often short-lived. Skaggs and Yates<sup>482</sup> did, however, report that the most common complication post-PTCA in their study

was bleeding or haematoma at the catheter insertion site. In the interviews for this study, problems at the catheter insertion site were also reported to be bothersome by patients. However, bruising around the groin wound or thigh was the most commonly reported complication in the CROQ-PTCA.

Whilst studies in the literature do not report minor complications post-PTCA, this study found that a small proportion of PTCA patients do report bother from complications for as long as 3-months after PTCA. For example, patients reported that they were at least "moderately" bothered by pain in the groin wound (6%), tenderness around the groin wound (7%), numbness or tingling in the groin area (4%), and bruising around the groin wound or thigh (10%). At 9-months post-PTCA, patients continued to report that they were bothered by some of these complications. It is likely that patients might report more bothersomeness of the complication items in the CROQ-PTCA if the assessment point was closer to the date of PTCA, e.g. 1-month post-PTCA, as the problems are usually short-lasting. However, the 3-month assessment point was selected as it is generally considered to be a time when patients have recovered from coronary revascularisation or are showing signs of recurring angina.<sup>482</sup>

A more serious and common problem after PTCA is recurrent angina,<sup>204</sup> but insufficient research has been carried out to examine the psychosocial impact of recurring angina in patients who have undergone PTCA. White and Frasure-Smith<sup>206</sup> reported that 1- and 3-months post-revascularisation, PTCA patients were more uncertain about their illness than patients who had undergone CABG. They proposed that this increased uncertainty is the result of being informed about high rates of restenosis. Similarly, in this study, PTCA patients were more worried that their symptoms might return than CABG patients; at 3-months post-revascularisation, 36% of CABG and 58% of PTCA patients reported that they were worried at least "a little of the time" that their symptoms might return. At 9-months post-revascularisation, these figures rose for CABG (53%) and PTCA (76%) patients; patients were more concerned that their symptoms might return at 9-months than at 3-months post-revascularisation.

CABG and PTCA patients reported being very satisfied with the results of their operation and care received, although CABG patients generally reported more favourable outcomes. A total of 81% of CABG and 64% of PTCA patients reported that they were "much better" overall compared with before their operation and almost half of both samples reported that the results from their operation were "better than expected". A total of 83% of CABG and 65% of PTCA patients reported that they were very satisfied with the results of their operation. More CABG patients (70%) reported to be very satisfied with the information they received about how they might feel while recovering from their operation than PTCA patients (57%). Little change in satisfaction was reported between 3- and 9-months post-revascularisation by CABG or PTCA patients.

## **7.7 Future research**

Several areas for future research are discussed in this section, including: further validation in different samples and specific patient groups; the development of norms; the measurement of long-term outcomes; the prediction of health outcomes; the development of methods for the interpretation of scores; the use of self-report to evaluate adverse effects; and the development of language adaptations.

### **7.7.1 Further validation of the CROQ**

In terms of Erickson's<sup>396</sup> life cycle model of a health status instrument, the CROQ is ready for stage three (use by others for the same purpose of study) to further evaluate its validity, before stage four (widespread use including different types of studies and different populations). The most important proposal for future research is for further studies to confirm the validity of the CROQ.

Whilst this study demonstrated that the CROQ has excellent psychometric properties, further studies are needed to investigate the measurement properties of the CROQ in different samples to help further confirm its validity as an outcome measure. The CROQ has currently only been used in limited samples; findings need to be replicated in other samples, with patients from different hospitals in

different geographical locations, possibly with a different gender, ethnic and social class composition, to ensure greater generalisability. These studies will help accumulate important confirmatory evidence that is necessary before the CROQ can be fully recommended as a reliable, valid and responsive tool for all patients undergoing CABG and PTCA in the UK. Further confirmation of its psychometric properties in independent samples will lend weight to its suitability as a national audit tool.

Whilst the CROQ was tested in representative samples of coronary revascularisation patients, it is possible that some groups were less well represented than others. For example, whilst the CROQ was validated in samples that included elderly patients and women, further studies are required in these specific groups. As previously discussed in Section 7.2.7.2, the CROQ should be validated in samples of patients comprised only of elderly and only of women to further confirm the validity in these specific groups. Future research with the CROQ should also focus on the inclusion of ethnic minority groups. For example, South East Asians who comprise a significant proportion of patients with CHD in the UK.<sup>124</sup> were poorly represented in this and most national studies.

Further research should evaluate the appropriateness of the CROQ as an outcome measure for different types of treatment for CHD, such as for minimally invasive bypass surgery and for the evaluation of cardiac rehabilitation programmes. Recent technical advances in coronary revascularisation have resulted in the development of some novel procedures, including surgery directly on the beating heart and minimally invasive CABG surgery. The effectiveness of these procedures is currently being evaluated. It is possible that the CROQ could be a useful tool in evaluating these procedures from the patient's perspective. Future research needs to be directed at assessing the appropriateness of using the CROQ to evaluate outcomes for each new procedure. The CROQ is currently being used in a randomised controlled trial of coronary revascularisation with or without cardiopulmonary bypass (B Reeves, personal communication, 20 February, 2001). It is also currently being used to evaluate patient-based outcomes in a

clinical trial (AMIST) of coronary angioplasty with stenting versus minimally invasive CABG for patients with single vessel disease of the left anterior descending coronary artery.<sup>484</sup> Both these clinical trials are in progress and results are not yet available. The psychometric properties of the CROQ will need to be evaluated in the minimally invasive surgery sample to establish its acceptability, reliability, validity and responsiveness in this group, as it was not originally intended for use with these patients. It is possible that some items might not be appropriate for patients treated with minimally invasive surgery; some items may need to be eliminated and new ones created to address the different complications associated with treatment. A new Complications scale could be developed; the psychometric properties of the 'new' instrument would then need to be fully validated.

Further research should evaluate the appropriateness of the CROQ as an outcome measure for CABG and PTCA patients undergoing cardiac rehabilitation programmes. The aim of cardiac rehabilitation programmes is to improve health outcomes and HRQoL for patients who have experienced a cardiac event such as myocardial infarction, CABG or PTCA. McGee *et al.*<sup>281</sup> undertook a systematic review of psychosocial outcome assessment in cardiac rehabilitation and reported that there is widespread use of instruments with poor psychometric justification for their use. They found that there is currently not a single instrument that is user-friendly, reliable, valid and responsive. The reliability, validity and responsiveness of the CROQ have been demonstrated in this study for use with patients before and 3-months after revascularisation. The CROQ proved to be very responsive to treatment changes after CABG and PTCA in this study and it is possible that it is responsive enough to detect smaller changes in health status that occur as a result of cardiac rehabilitation.

### 7.7.2 *Developing norms*

The development of population norms for the CROQ has been identified as an important area for future research. Population norms provide expected and typical scores, i.e. they provide a standard against which results from other studies can be compared. To enable accurate comparisons, normative data can be reported for

different age and gender distributions. As the collection of data to create norms involves very large samples, most published HRQoL instruments are initially validated in the study sample and in many cases the instrument is further tested in several other studies. However, with the exception of some of the gold-standard generic measures such as the SF-36, few measures get to the point of generating normative data. In psychological measurement, a gold-standard instrument is considered completed only when normative data for the instrument has been generated. For example, most measures of intelligence and personality provide normative data for comparative purposes. This can be a time-consuming and expensive process. To encourage widespread use of the CROQ, the development of normative data should become a priority. The availability of population normative data for the CROQ will enable users to compare their scores with expected values from a larger reference population i.e., it would resolve the current problem of the sample dependency of *T*-scores. Norms could be developed for different age, gender and disease-severity groups at different assessment points, such as before revascularisation, 3, 6, 9 months and 1, 3 and 5 years after revascularisation. Researchers and health care providers could then identify differences in scores and investigate the reasons for these differences.

### *7.7.3 Long-term outcomes*

This study measured health outcomes at 3- and 9-months after CABG and PTCA. Small differences in outcome were observed between 3 and 9 months post-revascularisation, suggesting that longer-term follow-up to at least 1-year post-revascularisation is needed to provide information on the pattern of responses over time. Future studies using the CROQ should measure outcomes additionally at 1 and 5 years after CABG and PTCA. It is not uncommon for researchers using HRQoL instruments to measure only short- and medium-term outcomes in cardiac populations. However, in order to compare lasting differences between treatments, longer-term follow up is essential. The measurement of long-term outcomes would also provide additional data to assess the responsiveness of the CROQ.

#### 7.7.4 *Prediction of health outcomes*

As discussed in Chapter 1, psychosocial factors have been shown to predict clinical outcomes and survival in CHD. Future research should evaluate the ability of the CROQ to predict patients at high risk of adverse events after coronary revascularisation (such as recurrent angina, repeat revascularisation, MI and death). Rumsfeld *et al.*<sup>470</sup> propose that self-report may be a valuable tool for risk stratification before CABG, as they found that pre-revascularisation SF-36 PCS scores independently predicted mortality at 6 months after adjusting for known clinical risk factors. Herlitz *et al.*<sup>485</sup> reported that pre-operative HRQoL (measured by the NHP, PGWB and PAS) was a strong independent predictor for impaired HRQoL 5 years after CABG. The collection of clinical data for individual patients in conjunction with CROQ data will provide information to test the ability of the CROQ to detect adverse events after revascularisation. After adjusting for clinical and sociodemographic variables, the ability of the CROQ to independently predict long-term HRQoL could also be evaluated.

#### 7.7.5 *Developing methods for the interpretation of scores*

One problem faced by all HRQoL instrument developers is that whilst scores on an instrument may be useful in research, their meaning in the clinical setting is less obvious. Interpretability is defined as the degree to which one can assign qualitative meaning to the quantitative scores of an instrument.<sup>90</sup> Many instrument developers inadequately explore this attribute. Many instruments have demonstrated the ability to detect change, but the clinical meaningfulness of these changes is rarely established - statistical significance does not imply clinical significance.<sup>27</sup> It is only with increased use and familiarity with specific instruments that we can begin to appreciate clinically meaningful differences.<sup>395 397</sup> The understanding of the clinical significance of objective measures has been based on experience with a large number of patients over time; the same is true of HRQoL measurement.<sup>486</sup>

A variety of methods have been proposed to interpret scores.<sup>395 397 398 487 488</sup> A recent expert panel symposium organised by the Agency for Healthcare Research

and Quality (AHRQ) to address advances in the measurement of health status and HRQoL focused on methods to facilitate the interpretation of HRQoL scores.<sup>447</sup> Some leading health outcomes methodologists propose the use of clinical data to help calibrate HRQoL instruments and facilitate interpretation.<sup>393 394</sup> There is some consensus that changes in HRQoL should be “anchored” to other clinical changes or results.<sup>395</sup> For example, a 10-point change in a HRQoL instrument might be shown to demonstrate a change in functional ability from grade 4 to grade 3 as measured by the CCS.<sup>76</sup> It is also important to note that minimal important differences<sup>487</sup> can have different meanings for different users. For the patient this might be the increment in health status that is “noticeable” as improvement or worsening, whereas for the clinician this might be the amount of change in HRQoL that would warrant a change in treatment plan.<sup>393</sup> Methods of score interpretation are attracting increasing attention in the HRQoL literature as it is of crucial importance for widespread adoption of these instruments into clinical practice.<sup>89 397</sup>

447

Although the CROQ has demonstrated the ability to detect change, the clinical meaningfulness of these changes is yet to be established. The collection of CROQ data alongside clinical variables will facilitate the interpretation of the meaning of scores. Methods could be developed to calibrate the meaning of changes in the CROQ in relation to other clinical parameters to provide meaningful information to clinicians, and consequently to patients. This important area for future research needs to be investigated using methods proposed by the leading experts who recognise that clinical significance of scores will evolve over time, as is the case for biochemical and other clinical measures.<sup>395 486</sup> The collection of CROQ data alongside other HRQoL instruments will provide information to help evaluate the external responsiveness of the CROQ.<sup>388</sup> The extent to which CROQ scores relate to corresponding changes in a ‘reference’ instrument should help interpretation of the meaning of scores. This was not evaluated in this study, but was identified as an area for future research. It is not uncommon for instrument developers to exclude this type of analysis from the initial validation study. With increased use of the CROQ in several studies, data will be generated to permit these analyses.

The issue of clinical interpretation is even more pertinent with the application of measures into clinical practice for use at the individual-patient level. There is increasing interest in using HRQoL instruments for individual assessment and treatment monitoring. As is the case with the majority of health outcome instruments, the CROQ was developed as a tool for group-level application, not for individual clinical assessment. Measures that are used to make treatment decisions for individual patients need to be evaluated using different criteria to those used in this study. It is possible that the CROQ could be used for individual-patient level assessments, but research needs to be conducted to assess whether it meets the appropriate measurement standards.<sup>26</sup>

#### *7.7.6 Using self-report to evaluate adverse effects*

After a patient has been discharged from hospital it is notoriously difficult to gather information about adverse effects, such as re-admissions to other hospitals and complications. One method of gathering this information is to ask the patient about subsequent events after leaving hospital. However, it is essential that such self-reported information be validated.

In this study, information about adverse effects including re-admission to hospital was collected through patient self-report. The CROQ includes an item about re-admissions to hospital for cardiac-related problems since revascularisation. Whilst this question appears to have been answered 'well', its reliability and validity are unknown, and hence it is not scored with the evaluative items in the questionnaire. This single descriptive item may be useful to hospitals performing CABG and PTCA, as after discharge patients do not necessarily return for follow-up, making it difficult to assess the proportion who experience problems during recovery (such as recurrent chest pain, wound infections, arrhythmias, stroke, repeat revascularisation). To place confidence in the information reported by patients in the CROQ, medical case notes at various hospitals (or GP records) would need to be inspected for evidence to support or refute the information given by patients. This was not done as part of this study due to time and resource constraints. It is,

however, a necessary step that patients' self-reports of reasons for re-admissions to hospital be validated against clinical data.

Whilst this study has demonstrated that it is possible to develop a reliable, valid and responsive Complications scale for coronary revascularisation, the validity of the information at the item level needs to be further evaluated. We currently do not know, for example, whether patients' descriptions of wound 'infections' reflect actual infections as described by health professionals. Further research is needed to validate patient self-report and clinical evidence of infections. Health professionals sometimes use a telephone follow-up service to collect information about complications after discharge from hospital. Gathering this type of information by telephone can be time consuming and expensive. This study is the first to have developed a standardised method for collecting information about complications after coronary revascularisation.

#### *7.7.7 Cultural and language adaptations*

An important area of future research is the development and validation of different language and cultural adaptations of the CROQ, using standardised scientific methods for translating and evaluating instruments for use in different cultural and language groups.<sup>399-404</sup>

CHD affects large numbers of ethnic minorities living in the UK who do not speak English. For example, South East Asians living in the U.K are at particularly high risk of developing CHD<sup>124</sup> and not all are able to speak or read English. The inclusion of patients from ethnic minority communities who do not speak English can cause some practical problems in HRQoL research as interpreters and trained interviewers are needed. However, it is feasible to develop and validate patient-based measures of outcome for patients from minority ethnic groups.<sup>399 489 490</sup>

The measurement of HRQoL before and after coronary revascularisation has attracted great international interest. With an increasing number of international clinical trials to evaluate the effectiveness of coronary revascularisation, there is an

increasing need for a patient-based instrument that can be administered in various languages. Future research should be directed at developing different language versions of the CROQ to facilitate comparison of disease-specific HRQoL and health outcomes between different countries. All cultural and language adaptations of the CROQ should be carried out using accepted methods to ensure conceptual and linguistic equivalence.<sup>399-403</sup> A full psychometric evaluation of the properties of each cultural and or language adaptation should be undertaken.<sup>404</sup>

Work is currently in progress to develop and validate an Italian version of the CROQ.<sup>491</sup> The CROQ has been translated into Italian using standard methods of forward-backward translation.<sup>402 403</sup> Firstly, two expert bilingual translators independently translated the CROQ from English to Italian. Two different expert translators, blind to the original version, then independently back-translated the Italian version into English. The Italian questionnaires have been pre-tested with a focus group of Italian patients to evaluate the clarity of wording and appropriateness of phrasing. The questionnaires are currently undergoing field testing with 100 CABG and 100 PTCA patients before and 3-months post-revascularisation. This field study will provide data for the preliminary psychometric evaluation of the Italian version of the CROQ. The Italian version will be evaluated according to the same psychometric criteria as those described for this study.

## **7.8 Conclusions**

The measurement of HRQoL after coronary revascularisation has attracted considerable research. Measures of morbidity and mortality provide a limited evaluation of the impact of coronary revascularisation, as CABG and PTCA are usually directed toward improving HRQoL and symptom relief rather than cure. Numerous disease-specific HRQoL questionnaires have been developed for CHD, but most have not been developed and validated against rigorous scientific standards. Those with established psychometric properties have largely been developed for use with medically not surgically treated patients, and are conceptually inappropriate for the comprehensive measurement of the impact of

coronary revascularisation. Due to the lack of an available validated and conceptually appropriate patient-based measure of outcome for coronary revascularisation, a new instrument was developed. The Coronary Revascularisation Outcome Questionnaire is an acceptable, reliable, valid and responsive measure of patient-based outcomes in CABG and PTCA. The CROQ has many potential uses, including research on the appropriateness and effectiveness of coronary revascularisation in different patient groups and use as a routine clinical audit tool for providers of CABG and PTCA in the UK.

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## **TABLES**

**TABLE 1.1 Mortality Rates for Coronary Heart Disease in England and Wales by Age (1999)**

	Mortality rate per 1,000,000 <sup>1</sup>	
	Males	Females
All ages England & Wales	2,297	1,880
5-14 years	1	1
15-24 years	1	2
25-34 years	24	7
35-44 years	208	46
45-54 years	927	194
55-64 years	3,046	883
65-74 years	8,780	3,725
75-84 years	20,311	11,371
85 years and over	37,256	26,252

<sup>1</sup> The 'All ages England & Wales' rates are age-standardised. The rates for the other rows are not age-standardised i.e. they are age-specific only.

Source: National Statistics. Mortality statistics cause. Review of the Registrar General on deaths by cause, sex and age, in England and Wales, 1999. London: The Stationery Office, 2000.

**TABLE 1.2 Mortality Rates for Coronary Heart Disease in the UK by Country, Region, and Sex (1991-97)**

	Overall	Mortality rates per 100,000 <sup>1</sup>		
		15-44yrs	45-64 yrs	65+ yrs
<b>Males</b>				
United Kingdom	268	10	260	1,805
England	~261	10	~248	~1,765
North East	*315	*13	*323	*2,079
North West	*302	*13	*305	*2,000
Yorkshire and the Humber	*287	11	*280	*1,932
East Midlands	~262	10	~248	~1,776
West Midlands	*276	11	*269	*1,854
East	~232	~8	~202	~1,620
London	~246	10	~243	~1,647
South East	~226	~8	~198	~1,568
South West	~238	~8	~210	~1,655
Wales	*285	11	*281	*1,907
Scotland	*321	*13	*342	*2,093
Northern Ireland	*303	10	*308	*2,016
<b>Females</b>				
United Kingdom	127	2	72	984
England	~123	2	~67	~955
North East	*159	*3	*101	*1,203
North West	*147	*3	*90	*1,122
Yorkshire and the Humber	*138	2	*80	*1,068
East Midlands	~124	2	70	~963
West Midlands	*130	2	74	*1,002
East	~108	~1	~49	~866
London	~112	~2	~64	~868
South East	~103	~1	~47	~828
South West	~106	~2	~50	~844
Wales	*134	2	*80	*1,024
Scotland	*161	*3	*108	*1,205
Northern Ireland	*149	2	*93	*1,135

<sup>1</sup> Mortality rates are age-standardised.

\* Significantly higher than the United Kingdom rate.

~ Significantly lower than the United Kingdom rate

Source: National Statistics. Geographic variations in health. London: The Stationery Office, 2001.

**TABLE 1.3a Prevalence Rates of Treated Coronary Heart Disease in England and Wales by Age and Sex (1994-98)<sup>1</sup>**

	All ages <sup>2</sup>	0-34 yrs	35-44 yrs	45-54 yrs	Rates per 1,000 patients				Number of cases (all ages) <sup>3</sup>
					55-64 yrs	65-74 yrs	75-84 yrs	85 yrs and over	
<b>Males</b>									
England	35.5	0.1	5.0	28.8	92.1	173.3	215.7	203.6	101,019
Wales	41.8	0.1	5.3	32.3	116.5	206.0	236.5	233.5	6,758
<b>Females</b>									
England	21.1	0.1	1.8	12.4	47.6	107.6	160.7	171.4	81,918
Wales	24.2	0.0	1.4	16.0	61.3	117.9	176.0	176.7	5,371

<sup>1</sup> Data are aggregated over the 5 calendar years. Cases in each calendar year were defined as patients who had a diagnosis of CHD ever-recorded and treatment with aspirin, or drugs in BNF chapter 2, during that year.

<sup>2</sup> Age-standardised to the European population.

<sup>3</sup> Number of cases derived from a sample of 211 general practices, with 1,388,000 patients, 684,000 males and 704,000 females.

Source: National Statistics. United Kingdom Health Statistics. London: The Stationery Office, 2001.

**TABLE 1.3b Prevalence Rates of Treated Coronary Heart Disease in Scotland by Age and Sex (1998)**

	All ages <sup>1</sup>	0-34 yrs	35-44 yrs	45-54 yrs	Rates per 1,000 patients				Number of cases (all ages) <sup>3</sup>
					55-64 yrs	65-74 yrs	75-84 yrs	85 yrs and over	
<b>Males</b>									
Scotland <sup>3</sup>	24.3	0.4	4.9	26.2	79.0	102.4	104.0	78.9	2,795
<b>Females</b>									
Scotland <sup>3</sup>	14.3	0.2	2.8	14.1	43.7	63.5	68.2	55.5	2,090

<sup>1</sup> Age standardised to the European population.

<sup>2</sup> Number of cases derived from 40 general practices with a combined practice population of 110,729 males and 114,007 females.

<sup>3</sup> Cases were defined as patients who had a CHD diagnosis recorded during 1998.

Source: National Statistics. United Kingdom Health Statistics. London: The Stationery Office, 2001.

**TABLE 1.4 UK Trends in Coronary Artery Bypass Graft Surgery**

<b>Isolated CABGs</b>	
<b>Year</b>	<b>n</b>
1977	2,297
1978	2,653
1979	2,918
1980	4,057
1981	5,130
1982	6,008
1983	8,332
1984	9,433
1985	10,667
1986	10,767
1987	11,521
1988	11,113
1989	12,648
1990	14,431
1991	15,659
1992	19,241
1993	21,031
1994	22,056
1995	22,475
1996/7	22,160
1997/8	25,639

Source: Society of Cardiothoracic Surgeons' National Adult Cardiac Surgical Database Report, 1998.

**TABLE 1.5 UK Percutaneous Coronary Intervention Procedures**

<b>Year</b>	<b>Number of intervention centres</b>	<b>Total angioplasty and other coronary intervention procedures <sup>1</sup></b>	<b>Rate per million</b>	<b>Increase (%)</b>
1991	52	9,933	174	-
1992	52	11,575	203	16.5
1993	53	12,937	227	11.8
1994	54	14,624	256	13.0
1995	54	17,344	304	18.6
1996	53	20,511	359	18.1
1997	58	22,902	402	11.7
1998	61	24,899	437	8.7
1999	63	28,133	494	13.0

Source: British Cardiovascular Intervention Society (1999) (<http://www.bcis.org.uk/audit>).

<sup>1</sup> Including PTCA, atherectomy, excimer laser, rotator and stents.

**TABLE 1.6 Content Domains Included In Conceptual Models of HRQoL in Coronary Revascularisation**

Study	Target group	Physical functioning	Psychological functioning	Social functioning	Neuro-psychological functioning	Symptom relief	Mood / general well-being	Socio-economic / return to work	Satisfaction / expectations
Jenkins & Stanton, 1984 <sup>286</sup>	CABG & Valve	•	•	•	•	•		•	
Working Group for CABG, 1984 <sup>287</sup>	CABG	•	•	•	•	•	•	•	•
Mayou & Bryant, 1987 <sup>179</sup>	CABG	•	•	•		•			•
Cleary <i>et al.</i> , 1991 <sup>289</sup>	PTCA	•	•	•		•	•	•	
Walter, 1992 <sup>285</sup>	Cardiac surgery	•	•	•	•				•
Bliley & Ferrans, 1993 <sup>290</sup>	PTCA	•	•	•				•	
Papadantonaki <i>et al.</i> , 1994 <sup>284</sup>	CABG & PTCA	•	•	•			•	•	
Cornell <i>et al.</i> , 1996 <sup>260</sup>	CABG & PTCA	•	•	•	•	•		•	

**TABLE 1.7 Selected Examples of Change in HRQoL After Coronary Revascularisation**

Instrument and study	Procedure	Assessment point	Results
<b>Generic measures of HRQoL</b>			
<b>Short Form 36 (SF-36)</b> <sup>87</sup>			
MacDonald et al. (1998) <sup>301</sup>	CABG	Pre and 3-months post	Improvement in all 8 dimensions 3m post-revascularisation, but improvements not statistically significant in General Health Perceptions, Mental Health, and Role-Emotional. Largest improvements observed in Role-Physical and Physical Functioning.
Barnason et al. (2000) <sup>303</sup>	CABG	Pre and 3, 6, & 12 months post	Baseline scores on 7 of the 8 dimensions were significantly lower than at 3, 6, and 12 m after CABG. Role-Emotional baseline scores were not significantly lower than at 3m post CABG, but were significantly lower than 6 and 12m post CABG scores. 3m dimension scores were also significantly lower than 6 and 12m scores except for Social Functioning and General Health Perceptions.
Lindsay et al. (2000) <sup>304</sup>	CABG	Pre and 12 months post	Significant improvement in all 8 dimensions at 12m post. Pts with lower pre-operative SF-36 scores were less likely to gain improvement in SF-36 scores post CABG.
Krumholz et al. (1996) <sup>271</sup>	PTCA	Pre and 6-months post	Before PTCA, many pts reported substantial disability. Pre-operative scores for all dimensions (except General Health Perceptions) were well below values for the US norm. There were significant changes in all dimensions 6m post PTCA except for General Health Perceptions. 6m post-operative scores were very close to values for the US norm. Role-Physical was most responsive to changes after PTCA followed by Physical Functioning.
Seto et al. (2000) <sup>305</sup>	PTCA	Pre and 6-months, 1yr post	Pre-revascularisation, both elderly and non-elderly pts had substantial impairments in PCS and modest impairments in MCS compared to the normative data for the US population. At 6m post PTCA, PCS and MCS improved substantially in both groups and these improvements were sustained at 1yr post PTCA.
Nash et al. (1999) <sup>302</sup>	PTCA	Pre- and 6-months post	Mean PCS increased significantly from 36.6 before PTCA to 43.4 at 6m post PTCA. Mean MCS increased significantly from 48.5 before PTCA to 50.5 at 6m post PTCA.

Instrument and study	Procedure	Assessment point	Results
<b>Nottingham Health Profile (NHP) <sup>306</sup></b>			
Caine et al. (1991) <sup>176</sup> Caine et al. (1999) <sup>307</sup>	CABG	Pre, and 3-months, 1yr and 5yrs post	Significant improvement in NHP scores between pre and 3m post CABG indicating an appreciable improvement in general health state. At 1yr scores compared favourably with those from a normal male population. Between 1 and 5yrs post CABG, slight improvements were seen in NHP dimensions of pain, sleep, social isolation, and emotional reactions, whereas signs of deterioration were noted in the physical mobility and energy scores.
Pocock et al. (1996) <sup>225</sup>	CABG & PTCA	Pre, 1m, 6m and 12m post	CABG & PTCA produced marked improvement in all dimensions (energy, pain, emotional reactions, sleep, social isolation, and mobility) and seven aspects of daily living (Part 2 of NHP). Pts with angina at 2 yrs scored lower than angina-free pts, whose perceived health was similar to population norms. PTCA pts reported slightly greater impairment on NHP compared with CABG pts post-revascularisation.
Wahrborg for CABRI (1999) <sup>308</sup>	CABG & PTCA	Pre and 1yr post	Marked improvements in QOL total score and 6 dimensions of the NHP Part 1 for both CABG & PTCA compared to baseline. The change in score was not significant for the sleep dimension in the PTCA group or for social isolation for the CABG group. Marked improvement in QOL in NHP Part 2. The improvement concerning family, social ad sexual life was not significant in either group. For both groups, scores at 1yr were similar to NHP scores in a normal age-matched group.
<b>General Health Questionnaire (GHQ) <sup>309</sup></b>			
McKenna et al. (1992) <sup>310</sup>	PTCA	Pre, 2- and 10-months post	Highly significant changes on GHQ between pre- and 2m post PTCA. No further significant changes occurred between 2 and 10m indicating that the initial improvement was sustained over this period.
<b>Measurements of components of HRQoL</b>			
<b>Functional Status Questionnaire (FSQ)</b>			
Allen et al. (1990) <sup>205</sup>	CABG & PTCA	1, 6 and 12 months post	CABG pts: significant improvements of functional status on every subscale (physical activity, social activity, work performance, mental health, quality of interaction) over the 1yr follow-up. PTCA pts: significant improvements in all dimensions except for the quality of interaction at 1yr compared with baseline.

Instrument and study	Procedure	Assessment point	Results
<b>Psychosocial Adjustment to Illness Scale (PAIS)</b>			
Langeluddecke et al. (1989) <sup>159</sup>	CABG	Pre, 6 and 12 months post	Psychological morbidity prior to surgery was high, with one-third having clinically significant levels of depression and/or anxiety symptoms. Scores on the PAIS indicated a generally high level of psychosocial impairment pre-operatively, with vocational and domestic functioning being most severely affected, social and sexual functioning being less impaired, and extended family relationships being largely unaffected. In general, there was a significant reduction in psychological morbidity and an improvement in psychosocial functioning at 6m, which remained at 12m. Vocational and domestic functioning showed the greatest improvement. Sexual and social functioning showed modest improvements overall, with significant numbers reporting residual impairment due to their heart disease.
Folks et al. (1986) <sup>315</sup>	CABG	Pre and 6-months post	Significant improvement on 4 of the 7 subscales (sexual function, vocational status, domestic environment, social activities). No significant changes were observed in patient relationships to their extended families or with psychologic distress displayed by the patient population as a whole. The only significant decline with respect to post-operative psychosocial adjustment was observed on the subscale examining health concerns.
Raft et al. (1985) <sup>314</sup>	CABG & PTCA	6 and 15 months post	Overall PAIS scores were significantly better for pts who had undergone PTCA than the scores for those who had undergone CABG after 6m, and this superior functioning continued after 15m. After 6m pts who had undergone PTCA functioned significantly better at work, in sexual performance and with their families. The significant improvement in work functioning continued at 15m, but the differences in sexual and family domains became non-significant.
<b>Profile of Moods State (POMS) <sup>316</sup></b>			
Papadantonaki et al. (1994) <sup>284</sup>	CABG & PTCA	Pre and 3 weeks post	No difference in overall POMS or individual subscales between CABG and PTCA pts before revascularisation. Overall mood state improved for pts in both CABG and PTCA groups after the procedure compared with their scores before the procedure. However, there was a significantly greater improvement in mood for the PTCA than the CABG group. Improved mood for both groups was significant for all subscales except vigor.

Instrument and study	Procedure	Assessment point	Results
<b>Spielberger's State-Trait Anxiety Inventory (STAI) 317</b>			
Pinna Pintor et al. (1992) 166	CABG	Pre and post-op	No change in trait anxiety, but improvement in state anxiety after CABG. Pts who experienced cardiac events were characterised by significantly higher levels of state anxiety at the pre and post-operative evaluations than those who did not experience cardiac events.
Faris & Stotts (1990) 255	PTCA	Pre and 6 weeks post	No change in trait anxiety scores, but significant decrease in state anxiety scores after PTCA
<b>Zung Depression Scale 318</b>			
Pinna Pintor et al. (1992) 166	CABG	Pre and post-op	Depression scores were significantly worse than before surgery
<b>Psychological General Well-being Index (PGWB) 311</b>			
Herlitz et al. (2000) 312	CABG	Pre and 5yrs post	Significant improvement in all six dimensions (anxiety, depression, well-being, self-control, health, vitality)
<b>Social Activities Questionnaire</b>			
Lindsay et al. (2000) 304	CABG	Pre and 12 months post	A higher social network score and higher pre-operative health status were associated with improved health status. High levels of social support were associated with improved health status post operatively.

**Key:**

Pts: Patients

PCS: Physical Component Summary Score of the SF-36

MCS: Mental Component Summary Score of the SF-36

**TABLE 3.1 Search Strategy for Computerised Bibliographic Databases**

<b>Medline / Health Star</b>	<b>PsychLit</b>
<b>Thesaurus terms</b>	
Heart disease/ all subheadings Myocardial ischaemia/ all subheadings Coronary artery bypass/ all subheadings Angioplasty-transluminal percutaneous coronary/ all subheadings	
<b>Text words</b>	
Quality of life Questionnaire* Interview* Health status Disease-specific* Disease specific* Outcome measure Outcome assessment Patient-based Self-assessment Self-administered Self-report Psychometric Patient satisfaction Expectation* Well-being	Heart disease Heart surgery Cardiac Quality of life Questionnaire Psychometric

\* indicates that the text word can be followed by any letter, for example questionnaire\* is used to identify articles containing the words questionnaire and questionnaires.

**TABLE 3.2 Cardiac-Specific Patient-Based Questionnaires: Psychometric Properties**

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>Coronary revascularisation</b>											
<b>** Cleary <i>et al.</i>'s Battery:</b> Cleary <i>et al.</i> (1991)	≥ 0.84 for all scales	-	-	Based on existing measures	-	-	Moderate inter-scale correlations. Large battery of existing scales	Tested scaling assumptions	-	YES	All scales showed significant change after 1 month. Most responsive: dyspnoea, angina, emotional
<b>Coronary Health Profile:</b> Karlsson (1999)	-	-	-	-	-	-	-	-	-	-	-
<b>Experience of waiting for CABG:</b> Jonsdottir & Baldursdottir (1998)	-	-	-	Confirmed by clinicians, nurses & pts	-	-	-	-	-	-	-
<b>Global post-operative questionnaire:</b> Pinna Pintor <i>et al.</i> (1992)	-	-	-	-	-	-	-	-	-	-	-
<b>Modified Physical Functioning Questionnaire:</b> Faris & Stotts (1990) & Papadantonaki (1994)	Total (0.82): [Papadantonaki]	-	-	Based on existing measures	-	-	-	-	-	-	Scores showed improvement over time for CABG & PTCA

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Perception of the Waiting Period Questionnaire:</b> <i>Pieper et al. (1985)</i>	Life effect (0.70), Life rating (0.70), Relationship effect (0.87), Relationship rating (0.57)	-	-	Confirmed by nurses	-	-	Total life-effect score correlated significantly with the tension-anxiety, depression-dejection, fatigue-inertia scales of POMS	-	The greater the concern about surgery, the greater was the perceived effect of waiting on life & relationship with partner	-	-
<b>Problems of cardiac patients in early recovery questionnaire:</b> <i>Jaarsma et al. (1995)</i>	-	-	-	Confirmed by panel of experts	-	-	-	-	-	-	-
<b>Prospective study of QOL before &amp; after CABG:</b> <i>Caine et al. (1991)</i>	-	-	-	-	-	-	-	-	-	-	-
<b>Quality of Life during rehabilitation after CABG:</b> <i>Engbolm et al. (1992)</i>	-	-	-	-	-	-	-	-	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC) [2-3 wk interval]	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Quality of Life Index - Novi Sad (QOLI-NS): Potic <i>et al.</i> (1999)</b>	-	(0.74)	Total variance explained 99.1%	Confirmed by clinicians, pts, literature review, & existing measures	-	-	Highly correlated to Parsonnet pre-operative risk scores (0.99)	-	-	-	Sensitive to change between pre-surgery and 6, 12 and 24 month follow-up
<b>Self-report of recovery questionnaire: Gortner <i>et al.</i> (1994)</b>	-	-	-	-	-	-	-	-	-	-	-
<b>Symptoms of Illness Factor Score: Jenkins <i>et al.</i> (1994)</b>	Total (0.84)	-	-	Based on existing measures	-	-	-	Not correlated with neuropsychological function, personal relps, or economic variables	-	YES	-
<b>Waiting List Impact Questionnaire (WLIQ): Teo <i>et al.</i> (1998)</b>	-	-	-	Confirmed by pts	-	-	-	-	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>Wythenshawe Hospital Cardiothoracic Outcomes Study :</b> <i>Bridgewater et al.</i> (unpublished)	Problematic due to high % of missing data	-	-	Confirmed by clinicians	-	-	-	-	-	YES	-
<b>Zyzanski's Behavioural Change Scales:</b> <i>Zyzanski et al.</i> (1981)	Mean item-total correlations range between 0.50-0.79 for the 4 scales	-	-	-	-	-	-	-	-	-	-
<b>Angina</b>											
<b>Angina Impact Questionnaire (AIQ):</b> <i>Wilson et al.</i> (1991)	Total (0.85)	-	-	Confirmed by clinicians & literature review	-	-	-	-	-	-	-
<b>Angina Pectoris Quality of Life Questionnaire (APQLQ):</b> <i>Wiklund et al.</i> (1991) Swedish Version <sup>1</sup>	-	-	-	-	-	-	Total exercise time related to physical dimension	-	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** French version Angina Pectoris Quality of Life Questionnaire (APQLQ): Marquis et al. (1995)</b>	Global (0.95), Physical (0.82), Symptoms (0.87), Emotional (0.90), Life Satisfaction (0.87)	-	-	-	-	-	High level inter-scale correlations (>0.60) suggests one global concept. Expected correlations with SF-36, eg physical activity scale & SF-36 Physical Functioning (0.76)	Item convergent & discriminant validity (84-91% success rate)	Asymptomatic pts had better QOL. QOL reduced with increasing angina pain. Discriminated betw symptomatic & asymptomatic pts (except Emotional)	YES	Physical activity scale responsive after CABG
<b>** Angina-Related Limitations at Work Questionnaire: Lerner et al. (1998)</b>	Total (0.97)	-	-	Confirmed by patient focus group	-	-	Degree of work limitation correlated significantly with SF-36 & with self reports of angina symptoms	Not correlated with gender, age, education or income	-	-	-
<b>Angina TyPE Specification Form: Health Outcomes Institute Database (1997)</b>	-	-	-	-	-	-	-	-	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Quality of Life Questionnaire for Angina Pectoris: Marquis (1995)</b>	SF-36 (0.80-0.95), APQLQ (0.95), 3 single item scales. Patient's complaint module not evaluated	-	-	Confirmed by clinicians, pts, literature review. Composed of SF-36, APQLQ 3 new items & 9-item patient's complaints module	-	-	-	-	Asymptomatic pts had better QOL. Pts with lowest number of attacks reported best QOL. QOL decreased with increasing chest pain	-	-
<b>RAND Chest Pain (Angina) Battery: Berman <i>et al.</i> (1981)</b>	-	-	-	Based on Rose Questionnaire	-	-	-	-	Distinguished subjects who had angina	-	-
<b>Rose Questionnaire (London School of Hygiene Chest Pain / Cardiovascular Questionnaire): Rose <i>et al.</i> (1977)</b>	-	-	-	-	-	Predict or of CHD mortality, ECG abnormality	Validated against clinician diagnosis of angina	-	-	-	-
<b>Rose (London School of Hygiene Dyspnoea) Questionnaire: Rose <i>et al.</i> (1982)</b>	-	-	-	-	-	-	-	-	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
** Seattle Angina Questionnaire (SAQ): Spertus et al. (1995)	Physical (0.89), Anginal Frequency (0.87), Treatment Satisfaction (0.77), Disease Perception (0.66) [Dougherty et al. 1998]	Physical (0.83), Anginal Stability (0.24), Anginal Frequency (0.76), Treatment Satisfaction (0.81), Disease Perception (0.78). Analyses performed in stable pts baseline and 3m later	-	Confirmed by clinicians	-	-	All 5 scales correlated significantly with other measures of diagnosis and patient function. E.g. Physical & treadmill performance, Disease Perception & SF-36 GHP scale (0.60), treatment Satisfaction & external measure (0.67)	-	No signif changes amongst stable pts after 3m. Unstable pts scored lower on Anginal Stability. Signif. Difference in scores between CCS grades	-	4 of the 5 SAQ scales responsive 3m after PTCA. More responsive than SF-36

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Summary Index (SI) for the assessment of quality of life in angina pectoris:</b> <i>Wilson et al.</i> (1991)	Total (0.94), Impact (0.95), Physical (0.96), Vitality (0.98), Alertness (0.98), Self-control (0.98), Emotional (0.91)	Total (0.84), Impact (0.77), Physical (0.84), Vitality (0.76), Alertness (0.69), Self-control (0.77), Emotional (0.83) [4 wk interval]	-	Confirmed by clinicians & literature review	-	-	Overall index correlated with symptom scores & negatively correlated to frequency of attacks. Majority of inter-scale correlations were moderate	-	-	YES	Detected more change at 3m than 6 wks. All categories showed >3% improvement. More responsive than PGWB. But pts had been on treatment before they entered the study
<b>Myocardial Infarction</b>											
<b>CAST Quality of Life Questionnaire:</b> <i>Wiklund et al.</i> (1992)	Symptoms (0.77), Mental (0.85), Physical (0.78), Social functioning (0.60), Social integration (0.10), Life Events (0.44)	-	-	Based on existing measures	-	-	-	Inter-scale correlations generally moderate to low (<0.50)	Symptomatic pts had worse HRQoL	-	-
<b>** Heart Patients Psychological Questionnaire:</b> <i>Erdman</i> (1982)	-	Well-being (0.73), Disability (0.85), Displeasure (0.80), Social (0.77)	-	-	-	-	Low to moderate intercorrelations. Moderate correlations with external criteria	Low correlations with age, sex	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Quality of Life after acute MI (QLMI):</b> Oldridge et al (1991), Hillers et al. (1994)	Symptoms (0.59), Restrictions (0.73), Confidence (0.50), Self-esteem (0.78), Emotion (0.83)	Symptoms (0.83), Restrictions (0.75), Confidence (0.87), Self-esteem (0.85), Emotion (0.86) & Total (0.86). [8-12m interval]	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	Highly correlated to emotional function. Moderately correlated to utility measures. QWB, BDI, POMS, Katz instrument of social function	-	Distinguished between treatment & control groups	YES	Responsive over 12 months. Emotional dimension more responsive than existing measures. 12 month effect sizes: Total (1.22), Restrictions (1.34), Confidence (1.43)
<b>** Modified Quality of Life after acute MI (QLMI-1):</b> Lim et al. (1993)	Emotional (0.94), Physical (0.89), Social (0.84)	No values, but based on QLMI which is reproducible	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	No details, but claim "good construct validity"	-	Previous MI & rehospitalised pts scored lower, as expected	YES	Responsive to differences between treatment groups
<b>** Modified Quality of Life after acute MI (QLMI-2):</b> Valenti et al. (1996)	Emotional (0.95), Physical (0.93), Social (0.95)	-	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	Similar scores as previous study of QLMI-1	-	QOL higher for pts with no previous MI and no hospital readmittance	YES	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>WHO Rehabilitation Questionnaire:</b> Fridlund (1991)	-	-	-	-	-	-	-	-	-	-	Sensitive to improvement at 6 & 12 months
<b>Heart Failure</b>											
<b>** Chronic Heart Failure Questionnaire (CHQ):</b> Guyatt <i>et al.</i> (1989)	-	Reproducible with 25 pts	-	Confirmed by clinicians, pts, & literature review	-	-	Six min walking test (0.60), NYHA (0.42). Moderate correlations with pts' global ratings of dyspnoea, fatigue, & emotional functioning change scores (0.34-0.65)	-	-	-	Distinguished pts who improved & those who didn't. Correlations between CHQ & pts global ratings of change in dyspnoea, change in walking test score & change in heart failure classification (0.42-0.65)
<b>Disease Specific Questionnaire for Severe Heart Failure:</b> Cowley <i>et al.</i> (1994)	-	-	-	-	-	-	-	-	Discriminated between treatment and placebo groups	-	Sensitive to change in treatment group vs placebo group
<b>Heart Failure Functional Status Inventory:</b> Dracup <i>et al.</i> (1992) Walden <i>et al.</i> (1989, 1994)	-	-	YES	Based on existing measures	-	-	PAIS Total score (0.31). Ejection fraction & 6 min walk results & self-reported activity level are correlated	Not correlated with age, sex, marital status	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Kansas City Heart Failure Questionnaire (KCHFQ): Green et al. (2000)</b>	Physical limitation (0.90), Symptoms (0.88), Quality of life (0.78), Social limitation (.86), Self-efficacy (0.62), KCCQ functional status (0.93), KCCQ clinical summary (0.95)	No significant change in scores for clinically stable pts between baseline and 3 months	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	Physical limitations with NYHA (0.65), SF-36 Physical limitations (0.84), QOL domain and SF-36 GHP (0.45), LihFE (0.62), Social domain and SF-36 Social (0.62), Functional status and NYHA (0.55), clinical summary score and NYHA (.55)	-	Statistical difference between mean symptom scores and mean Functional status scores for NYHA classes	-	Very sensitive to changes in cardiomyopathy status (3 months apart). Responsiveness statistics range between 0.62 – 3.19. More responsive than the SF-36 and the LihFE
<b>** Left Ventricular Dysfunction Questionnaire (LVD-36): O'Leary &amp; Jones (2000)</b>	Kuder-Richardson's coefficient (0.95)	0.95 [1-3 wks interval]	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	More correlated to physical health of SF-36 than psychological. Weak correlation between LVD-36 & ECG, but signif. correlation with exercise test	Not correlated to age, gender or aetiology	-	YES	Responsive between baseline & 6 months. Change in LVD-36 was strongly related to a transition question measuring global change

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Kansas City Heart Failure Questionnaire (KCHFQ):</b> Green <i>et al.</i> (2000)	Physical limitation (0.90), Symptoms (0.88), Quality of life (0.78), Social limitation (.86), Self-efficacy (0.62), KCCQ functional status (0.93), KCCQ clinical summary (0.95)	No significant change in scores for clinically stable pts between baseline and 3 months	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	Physical limitations with NYHA (0.65), SF-36 Physical limitations (0.84), QOL domain and SF-36 GHP (0.45), LihFE (0.62), Social domain and SF-36 Social (0.62), Functional status and NYHA (0.55), clinical summary score and NYHA (.55)	-	Statistical difference between mean symptom scores and mean Functional status scores for NYHA classes	-	Very sensitive to changes in cardiomyopathy status (3 months apart). Responsiveness statistics range between 0.62 – 3.19. More responsive than the SF-36 and the LihFE
<b>** Left Ventricular Dysfunction Questionnaire (LVD-36):</b> O'Leary & Jones (2000)	Kuder-Richardson's coefficient (0.95)	0.95 [1-3 wks interval]	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	More correlated to physical health of SF-36 than psychological. Weak correlation between LVD-36 & ECG, but signif. correlation with exercise test	Not correlated to age, gender or aetiology	-	YES	Responsive between baseline & 6 months. Change in LVD-36 was strongly related to a transition question measuring global change

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Self Assessment of quality of life in severe heart failure (QLQ-SHF):</b> Wiklund <i>et al.</i> (1987)	Total (0.88)	Total (0.82), Somatic (0.82), Life Satisfaction (0.75), Psychological (0.79), Physical (0.85)	-	Based on authors judgement & patient complaints	-	-	Somatic with physical (0.33). Correlations with SIP, Mood Adjective Checklist NYHA (0.42-0.72)	Psychological with physical (0.36)	Conflicting results of its ability to discriminate between active treatments and placebo	YES	Moderately sensitive to small changes in HRQoL
<b>Self-Management of Heart Failure:</b> Riegel <i>et al.</i> (2000)	Alpha ranged between 0.79 and 0.92 for all 6 subscales	-	-	Confirmed by experts, pts, & literature review	-	-	-	-	-	-	-
<b>Cardiac non-specific</b>											
<b>Cardiac Adjustment Scale:</b> Rumbaugh (1965)	-	-	-	Confirmed by pts	-	-	-	-	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Cardiac Denial of Impact Scale:</b> Fowers (1992)	Total (0.72)	(0.71) [3 wk interval]	-	Based on existing measures	-	-	Supported by its pattern of correlations with Multidimensional Health Locus of Control Scale & Marlowe Crowne Scale. Negatively related to measures of both physical & psychological distress (various instruments)	Not correlated with age, ethnicity, gender, number of cardiac events	-	-	-
<b>** Cardiac Depression Scale:</b> Hare & Davis (1995)	Total (0.90)	-	-	Confirmed by health professionals	Beck Depression Scale (0.73) & clinical ratings of depression (0.67)	-	-	Not correlated with age	-	YES	-
<b>** Cardiac Health Profile (CHP):</b> Wahrborg & Emanuelsson (1996)	Total (0.89)	Results 4 weeks prior to angiography compared with before catheterisation (0.93)	-	Confirmed by clinicians & pts	-	-	CHP outcome score & global NHP score (0.75)	-	Significant difference between mean scores for angina pts (35.7) & control (22.5) pts	YES	Compared before angiography (29.1) & after CABG (23.2) scores. No PTCA scores reported

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Duke Activity Status Index (DASI): Hlatky, et al. (1989)</b>	-	-	-	Confirmed by clinicians	-	-	Peak O <sub>2</sub> uptake (0.58)	-	-	-	-
<b>Expectations and Satisfaction Questionnaire: Staniszewska &amp; Ahmed (2000)</b>	-	-	-	Confirmed by pts	-	-	-	-	-	-	-
<b>** Ferrans &amp; Powers Quality of Life Index: (QLI-Cardiac Version III): Ferrans &amp; Powers (1985) [Faris &amp; Stotts, 1990] (Papadantonaki, 1994)</b>	Overall (0.98), Functioning (0.90), Socio-economic (0.89), Psychological (0.90), Family (0.79) [Papadantonaki, 1994]	(0.87) [2 wk interval] [Faris & Stotts, 1990]	-	Based on Ferrans & Powers' generic QLI measure	-	-	Correlations between Total score and subscales 0.77 - 0.90 [Faris & Stotts, 1990]	Moderate correlations with external measures	No signif. differences in QLI scores between CCS grades [Dougherty et al. 1998]	-	Only overall QOL & Functioning scale improved in both gps over time. Psychological scale not as sensitive as POMS [Papadantonaki, 1994]
<b>** Global Moods Scale (GMS): Denollet (1993)</b>	Negative Affect (0.66) Positive Affect (0.57)	(0.55) [3m interval]	-	Devised to reflect two-dimensional model of mood	-	-	A series of hypothesised correlations with the subscales of the POMS & STAI	Consistent pattern of convergent & discriminant validity	-	YES	Rehab pts reported signif. increase in positive affect & decrease in negative affect after 3m

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Health Complaints Scale (HCS): Denollet (1994)</b>	All scales $\geq 0.89$	All scales $\geq 0.69$ [3m interval]	-	Based on existing measures	-	-	Correlated to STAI, Symptom Checklist-90 & Heart Patients Psychological Questionnaire	Not correlated to measures of self-deception & social inhibition	-	YES	Rehab subjects but not controls reported signif. decrease in somatic & cognitive health complaints after 3m
<b>** Multidimensional Index of Life Quality (MLIQ): Avis <i>et al.</i> (1996)</b>	All above 0.76 except Social Functioning (0.62)	(0.62 to 0.84) [10-21 day interval]	-	Confirmed by clinicians, pts, literature review, & existing measures	-	-	Physical Health & Physical Functioning (0.68). Correlations with criterion measures ranged 0.51 to 0.78 (exceeded 0.70 for 4 domains). Used several QOL measures	Physical & Mental Health scales correlated 0.57	-	-	-
<b>** Cardiac Quality of Life Index (CQLI): Rukholm <i>et al.</i> (1998)</b>	Total (0.87)	Total (0.81)	-	Based on Padilla & Grant's Quality of Life Index & expert opinion	-	-	Positively correlated to Spitzer's global measure of QOL (0.67)	-	Discriminated healthy pts from those with cardiac illness	YES	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Reduced Duke Activity Status Index:</b> Alonso <i>et al.</i> (1997)	Ranged between 0.81-0.89	46 stable pts [2 wk interval]	-	Confirmed by clinicians	CCS (-0.51), exercise test (0.45)	-	-	-	Stable pts scored higher than those undergoing PTCA	-	Effect size after PTCA = 0.75, for stable pts =0.22
<b>Soderlind et al's Quality of Life Questionnaire:</b> Soderlind <i>et al.</i> (1997)	-	-	-	-	-	-	-	-	-	-	-
<b>Specific Activity Questionnaire:</b> Rankin <i>et al.</i> (1996)	-	-	-	-	-	-	Significantly correlated to measured peak VO <sub>2</sub> (0.57)	-	-	-	-
<b>Symptom Scale:</b> Keresztes <i>et al.</i> (1993)	Total (0.92), Angina (0.87), Shortness of Breath (0.86), Fatigue (0.85)	-	-	Confirmed by clinicians & literature review	-	-	Stable correlations in the expected direction between all instruments with the MET level achieved on the treadmill	-	-	-	-

Questionnaire	Reliability			Content validity	Criterion-related validity		Construct validity				Responsiveness
	Internal consistency ( $\alpha$ )	Test-retest (r/ICC)	Inter-rater (k)		Concurrent	Predictive	Convergent (r)	Discriminant (r)	Known groups	Factor analysis	
<b>** Utility Based Quality of Life-Heart Questionnaire:</b> Martin <i>et al.</i> (1999)	Psychological distress (0.91), Self-care (0.79), Social activities (0.85), Physical ability (0.80)	Psychological distress (0.81), Self-care (0.65), Social activities (0.71), Physical ability (0.76)	-	-	-	-	Correlations with other QOL questionnaires (GHQ & Life Satisfaction A) followed the expected pattern	-	Pts with signif. angina/dyspnoea scored signif. worse than other pts	-	Detected changes in clinical status for who experienced adverse event
<b>Veterans Specific Activity Questionnaire:</b> Myers <i>et al.</i> (1994)	-	-	-	-	-	-	-	-	-	-	-

**KEY**

- Details not found. Instruments with testing ongoing are included in table, but assigned "-" where the results are not yet given
- \*\* Questionnaire met minimum reliability and validity criteria.
- Pts Patients.
- YES Authors claim the measure satisfies criteria, but values not given in instrument development paper, or too much information to summarise
- ICC Intra class correlation coefficient.
- MET Metabolic equivalents.
- PGC-MAI Philadelphia Geriatric Centre Multilevel Assessment Instrument.
- PGWB Psychological General Well-Being Index.

<sup>1</sup> The paper describing the psychometric properties of this questionnaire is published in Swedish restricting the critique of the psychometric properties.

**TABLE 3.3 Selected Reliable and Valid Cardiac-Specific Patient-Based Questionnaires: Item Reduction, Responsiveness and Validated Language Versions**

Questionnaires	Patient group	Included item reduction	Responsiveness evaluated	Validated language versions (country)
<b>Coronary revascularisation</b>				
Cleary et al's Battery	CHD: PTCA only	-	✓	English (USA)
Perception of the Waiting Period Questionnaire	CHD: Pre-CABG only	-	-	English (USA)
Quality of Life Index - Novi Sad (QOLi-NS)	CHD: CABG only	✓	✓	Serbo-Croatian (Yugoslavia)
<b>Angina</b>				
Angina Pectoris Quality of Life Questionnaire (APQLQ): French version	CHD: Angina only	-	-	French (France)
Angina-Related Limitations at Work Questionnaire	CHD: Angina only	-	-	English (USA)
Quality of Life Questionnaire for Angina Pectoris	CHD: Angina only	-	-	French (France)
Seattle Angina Questionnaire (SAQ)	CHD: Angina only	-	✓	English (UK, USA, Australia, New Zealand & Canada), Italian (Italy), Spanish (Spain), Norwegian (Norway), Dutch (Belgium & The Netherlands), Danish (Denmark), German (Germany), Swedish (Sweden), French (France, Belgium & Canada)
Summary Index for QOL in angina (SI)	CHD: Angina only	✓	✓	Finnish (Finland)

Questionnaires	Patient group	Included item reduction	Responsiveness evaluated	Validated language versions (country)
<b>Myocardial infarction</b>				
Heart Patients Psychological Questionnaire	CHD: MI only	-	-	Dutch (The Netherlands)
Quality of life after Acute MI (QLMI)	CHD: MI only	✓	✓	English (Canada)
Quality of Life after Acute MI (QLMI-1)	CHD: MI only	✓	✓	English (Australia)
Quality of Life after Acute MI (QLMI-2)	CHD: MI only	✓	✓	English (Australia) [German, Italian & Spanish translations underway]
<b>Heart failure</b>				
Chronic Heart Failure Questionnaire (CHQ)	Heart failure	✓	✓	English (Canada)
Kansas City Cardiomyopathy Questionnaire (KCCQ)	Heart failure	-	✓	English (USA)
Left Ventricular Dysfunction Questionnaire (LVD-36)	Heart failure	✓	✓	English (UK)
Minnesota Living with Heart Failure Questionnaire (LHFE)	Heart failure	-	✓	English (USA, Canada & UK, Australia), French (France, Canada, Switzerland & Belgium), Portuguese (Portugal, Brazil), German (Germany), Norwegian (Norway), Swedish (Sweden), Dutch (The Netherlands & Belgium), Hebrew (Israel), Polish (Poland), Italian (Italy), Danish (Denmark), Finnish (Finland)
Self Assessment of Quality of Life in severe Heart Failure Questionnaire (QLQ-SHF)	Heart failure	✓	-	Swedish (Sweden)

Table 3.14 Content Domains Included in Related and Valid Cardiac-Specific Patient-Based Questionnaires

Questionnaires	Patient group	Included item reduction	Responsiveness evaluated	Validated language versions (country)
<b>Cardiac non-specific</b>				
Cardiac Denial of Impact Scale (CDIS)	Cardiac: General	✓	-	English (USA)
Cardiac Depression Scale	Cardiac: General	✓	-	English (Australia)
Cardiac Health Profile (CHP)	CHD: General	✓	✓	Swedish (Sweden)
Duke Activity Status Index (DASI)	Cardiac: General	-	-	English (USA)
Ferrans & Powers Quality of Life Index: (QLI-Cardiac Version III)	CHD: General	-	-	English (USA), Spanish (Spain), Norwegian (Norway)
Global Moods Scale (GMS)	CHD: General	✓	✓	Dutch (Belgium)
Health Complaints Scale (HCS)	CHD: General	✓	✓	Dutch (Belgium)
Multidimensional Index of Life Quality (MLIQ)	Cardiac: General	✓	-	English (USA)
Cardiac Quality of Life Index (CQLI)	Cardiac: General	-	-	English (Canada)
Reduced Duke Activity Status Index	CHD: General	✓	✓	Spanish (Spain)
Utility Based Quality of Life-Heart Questionnaire (UBQ-H)	Cardiac: General	-	✓	English (Australia)

**TABLE 3.4 Content Domains Included in Reliable and Valid Cardiac-Specific Patient-Based Questionnaires**

Questionnaires	Cardiac symptoms	Physical	Psychological	Social	General well-being	Adverse effects	Satisfaction with treatment	Expectations
<b>Coronary revascularisation</b>								
Cleary et al's Battery	•	•	•	•	•			
Perception of the Waiting Period Questionnaire			•	•	•			•
Quality of Life Index - Novi Sad (QOLI-NS)	•	•	•	•	•		•	•
<b>Angina</b>								
Angina Pectoris Quality of Life Questionnaire (APQLQ): French version	•	•	•					
Angina-Related Limitations at Work Questionnaire	•	•	•					
Quality of Life Questionnaire for Angina Pectoris	•	•	•	•	•			
Seattle Angina Questionnaire (SAQ)	•	•	•				•	•
Summary Index for QOL in angina (SI)	•	•	•	•	•			
<b>Myocardial infarction</b>								
Heart Patients Psychological Questionnaire								
Quality of life after Acute MI (QLMI)	•	•	•	•				
Modified Quality of Life after Acute MI (QLMI-1)	•	•	•	•	•			

Questionnaires	Cardiac symptoms	Physical	Psychological	Social	General well-being	Adverse effects	Satisfaction with treatment	Expectations
Modified Quality of Life after Acute MI (QLMI-2)	•	•	•	•	•			
<b>Heart failure</b>								
Chronic Heart Failure Questionnaire (CHQ)	•	•	•					
Kansas City Heart Failure Questionnaire (KCHFQ)	•	•	•	•	•		•	•
Left Ventricular Dysfunction Questionnaire (LVD-36)	•	•	•	•			•	
Minnesota Living with Heart Failure Questionnaire (LHFE)	•	•	•	•				
Self Assessment of Quality of Life in severe Heart Failure (QLQ-SH)	•	•	•		•			
<b>Cardiac non-specific</b>								
Cardiac Denial of Impact Scale (CDIS)			•					
Cardiac Depression Scale	•		•	•	•			
Cardiac Health Profile (CHP)	•	•	•	•	•		•	
Duke Activity Status Index (DASI)		•						
Ferrans & Powers Quality of Life Index: (QLI-Cardiac Version III)	•	•	•	•	•			
Global Moods Scale (GMS)			•					

Questionnaires	Cardiac symptoms	Physical	Psychological	Social	General well-being	Adverse effects	Satisfaction with treatment	Expectations
Health Complaints Scale (HCS)	•		•					
Multidimensional Index of Life Quality (MLIQ)		•	•	•			•	
Cardiac Quality of Life Index (CQLI)	•		•	•	•			
Reduced Duke Activity Status Index		•						
Utility Based Quality of Life-Heart Questionnaire	•	•	•	•				

**TABLE 4.1 Qualitative Interview Topic List**

<b>Content domain</b>	<b>Topics</b>
<b>Symptoms</b> (pre- and post-revascularisation)	Type of symptoms Severity / intensity of symptoms / bothersomeness Which activities / situations induce the symptoms
<b>Medication</b> (pre- and post-revascularisation)	Frequency & bothersomeness of taking medication
<b>Limitations in daily activities</b> (pre- and post-revascularisation)	Interference with employment Interference with activities which are physically demanding (shopping / housework / gardening) Disturbance of other activities (lifting light objects, walking, stairs) Disturbance of self-care (dressing, bathing) Interference with recreational activities Interference with social activities Disturbance of sleep (restless, early wakening, discomfort, anxiety)
<b>Psychological functioning</b> (pre- and post-revascularisation)	Feelings about coronary heart disease (anxiety, depression, frustration) Feelings / fears about CABG / PTCA Fear of death / heart attacks Coping
<b>Cognitive functioning</b> (pre- and post-revascularisation)	Trouble keeping attention and concentrating Memory problems Difficulties reasoning / making decisions Speed of reactions Any changes from pre- to post-revascularisation
<b>Social functioning</b> (pre- and post-revascularisation)	Impact on friends and family before and after operation (anxiety) Too much / not enough attention and worry Impact on personal relationships Social support Independence / feeling a burden on family & friends

Content domain	Topics
Complications (physical and psychological)	Re-admission to hospital – reason? Repeat revascularisation? Complications Wound infection – where, when? New feelings of pain / numbness– where, when? Weakness / lethargy Eating problems / loss of appetite / nausea Concern over appearance of scars / bruising
Psychological functioning (post-revascularisation)	Feelings immediately post-surgery Unresolved anxiety & concerns post-operatively Feelings whilst recovering – progress made, frustration Need for reassurance about heart condition / progress Post surgery depression / mood Attitude towards surgery Fear of symptoms returning Concern about needing another heart operation in the future
Satisfaction (post-revascularisation)	Impact of surgery on day-to-day life Satisfaction with outcome of surgery Satisfied with progress made (immediate and long term) Satisfaction with care received How can care be improved?
Information (post-revascularisation)	Knowledge of own condition and operation About recovering from operation Quality of information given Quantity of information given Timing of information given
Pre- / post-surgical perceptions	What did you hope would be different after surgery? What were your concerns about the surgery? Reflections about speed of recovery

**TABLE 4.2 Selected Excerpts From Patient Interviews Grouped by Content Domain**

Content domain	Sample statements from patient interviews [procedure]
Pre-revascularisation symptoms	"Sometimes it was like a lancing pain, others just pain". She would not describe this as a discomfort but "just pain really". [CABG]
	He described one of his attacks of chest pain: "I held my head in my hands on the steering wheel and experienced <u>excruciating</u> pain", "it was so bad I just wanted to die there and then". "It is like a paralysing weakness and sort of went down my arm". [PTCA]
	"I got a feeling, ... not pain,... sort of a discomfort, a soreness in my chest when walking up hill, or doing DIY like sawing or gardening" [CABG]
	She described her angina as "a pain..... not tightness!". I had "awful arm pain (she grabbed her arm).... A constant pain like having a blood pressure band tightened around the arm". It was very painful and she was "frightened". [CABG]
	"I started to notice a pain in my arms which was quite minute at the time I suppose"... "it was a tightness across the chest". [PTCA]
Limitations in daily activities	"I get sick if I walk too far". "I have good days and bad days, but if I do too much like walk to the shops (under half a mile) I feel terrible... I don't like to go too far from home". She has been like this for a "good couple of months now". Her husband drives her everywhere so that she doesn't have to walk. She said she couldn't survive without him - he does so much. She says she is fine as long as she sits doing nothing but that is boring and she gets frustrated and "it isn't a life really". "I can't go out as the chest pain comes on.... I can't remember the last time I went out socially!" [CABG]
	"I cant lift heavy things which is annoying" [CABG]
	"I got short of breath when walking up hills,..... on the staircase,.... and walking the dog" [CABG]
Psychological functioning	He "packed up the business" (owned his own). He "feared that it would all happen again" and "found it hard to live with". It "protruded all my thoughts". "There is always the doubt in the back of your mind that it can all go wrong again.... The family all live in fear that it will happen again. It is hard to be positive". [PTCA]
	"I was afraid of doing too much, but I pushed myself on". [PTCA]
	His wife described him as becoming very selfish after the operation. She had to put up with the situation too. She used to worry a lot. He would go off on cycle rides and she wouldn't know where he was going or when he would be back. He would be adamant that there was nothing wrong with him and just say: "I'm doing it for me!.... There is nothing wrong with me!" [PTCA]
	"I get very frustrated because I am not used to being inactive". [PTCA]
	Her husband said that "she has no quality of life - there is no fun in it, feeling like this".

Content domain	Sample statements from patient interviews [procedure]
Social functioning	Didn't tell his wife about the chest pains and heart attacks he was having even when she was there when they happened. "I used to pretend it was something else". He usually felt better fairly quickly and didn't want to worry his wife. [PTCA]
	"I spent 2 weeks with my son in the country, but I felt a burden.... I found it depressing and embarrassing.... I wanted to go home to my own bed,... own privacy". "I wanted my independence". [CABG]
	"I don't have the confidence to go too far which is annoying". [CABG]
Cognitive functioning	"Memory problems are frustrating". My memory was immediately affected and still is. "I used to do six crosswords a day, but I find them difficult even now,... the words just don't come to me any longer, and I forget names". On several occasions he forgot the word he wanted to use such as "stemum" and got frustrated, but is obviously used to it. [3 months post CABG- believed these problems were related to the operation]
Complications	I have a "tight pain" across my chest like I am "strapped in and need to be released". "It feels like something needs to be taken out or taken off"... "it is horrible". It causes her a lot of worry and she doesn't know what it is or why it happens. This pain was there straight after the operation and 3 months later it has not gone. [CABG]
	"The muscular pains are fading gradually" .... "I am still sore from where they opened the chest" (4 months post CABG)
	She has a swollen leg which causes her to worry a lot. She doesn't understand why it hurts so much. "It is a burning pain".....It hurts a lot when I sit still for a long time or stand on it for a long time". [CABG]
	"For the first 4-6 weeks my leg wound hurt.... the area between the thigh to the knee hurt most".... "My lower leg still feels numb (3 months post CABG), but this will get better in time"...."It was only really the leg pain that bothered me".... "the wound dragged me down a bit". [CABG]
	"My leg is numb and it hurts when you touch it"... "I have been very worried about it" .... "I don't know whether it is normal?" [3 months post CABG]
	"I felt nauseous about eating immediately after surgery and this still affects me a bit (4 months post surgery)...it's a horrible experience". [CABG]
	"I had a weepy leg and chest wound". [CABG]
	He has a chest wound infection ("hospital acquired infection") which he regards as a "nuisance" even though it has been "seeping for weeks" and he has to have his dressing changed twice a week. [4 months post CABG]
	"My sternum used to click from where they sewed me up". [CABG]
He noticed that he had a "strong heart beat.... A real thump, not rapid though". He described how you do not usually feel your heart beat, but he "could certainly feel this one!" [CABG]	

Content domain	Sample statements from patient interviews [procedure]
Satisfaction	"Six months he said,.....if it hadn't been for the Brompton I would be dead" [CABG]
	"I would have died if I hadn't had the operation" [CABG]
	"Very satisfied with the surgery as long as it has worked this time!" [PTCA]
	"Can't complain about anything really" [CABG]
	"It completely changed my life - it is wonderful!.... "Absolutely 100% satisfied" [PTCA]
	"Not impressed"... (by PTCA)... "it has failed 3 times and I don't want another!"
	"I got better much faster than I thought I would! [PTCA]
	"I can only say nice things about the experience"...."I can't criticise anything in any way" [PTCA] She thought that all her heart disease symptoms would go - that she would no longer have pain etc. She never imagined that she would have "a different sort of chest pain, which is as horrible as this". She never thought she would have leg pain. The doctors might have told her but it was all too much to take in and she was too worried. She said she was not scared of having the surgery she just wanted to have it done to get better. She said that she is "not happy now" as she feels so unwell and she "had hoped to be feeling much better". [CABG]

**TABLE 4.3 Phrasing of CROQ Items For The Three Phases of Questionnaire Development**

CROQ item	Phrasing of pre-test version of CROQ items	Phrasing of preliminary field test version of CROQ items	Phrasing of final field test version of CROQ items
<b>Evaluative items</b>			
	During the <u>past 4 weeks</u> , how much were you bothered by each of the following problems related to your <b>heart condition</b> ?		
Chest pain	Chest pain	Chest pain due to angina	Chest pain due to angina
Chest tightness	Chest tightness	Chest tightness due to angina	-
Chest discomfort	Discomfort in the chest	Discomfort in your chest due to angina	Discomfort in your chest due to angina
Short of breath	Shortness of breath	Shortness of breath	Shortness of breath
Radiating pain	Pain that radiates to other parts of your body (e.g. arms, shoulders, back, neck, throat, jaw, hands)	Angina pain that radiates to other parts of your body (e.g. arms, shoulders, hands, neck, throat, jaw, back)	Angina pain that radiates to other parts of your body (e.g. arms, shoulders, hands, neck, throat, jaw, back)
Palpitations	Palpitations (strong or irregular heart beat)	Palpitations (strong or irregular heart beat)	Palpitations (strong or irregular heart beat)
Disturbed sleep	Disturbed sleep	Disturbed sleep	-
Worn out	Feeling worn out or low in energy	Feeling worn out or low in energy	-
Nitroglycerin	During the <u>past 4 weeks</u> , on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your <b>chest pain, chest tightness or angina</b> ?	During the <u>past 4 weeks</u> , on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your <b>chest pain, chest tightness or angina</b> ?	During the <u>past 4 weeks</u> , on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your <b>chest pain, chest tightness or angina</b> ?
Trouble	During the <u>past 4 weeks</u> , how much trouble has your <b>heart condition</b> caused you?	During the <u>past 4 weeks</u> , how much trouble has your <b>heart condition</b> caused you?	During the <u>past 4 weeks</u> , how much trouble has your <b>heart condition</b> caused you?
	The following questions ask about activities which you might do during a typical day. During the <u>past 4 weeks</u> , has your <b>heart condition</b> limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below.		
Vigorous activities	<b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	<b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	-
Moderate activities	<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
Lifting & carrying	Lifting or carrying groceries	Lifting or carrying groceries	Lifting or carrying groceries
Climbing flights of stairs	Climbing <b>several</b> flights of stairs	Climbing <b>several</b> flights of stairs	Climbing <b>several</b> flights of stairs

CROQ item	Phrasing of pre-test version of CROQ items	Phrasing of preliminary field test version of CROQ items	Phrasing of final field test version of CROQ items
Climbing one flight of stairs	Climbing <b>one</b> flight of stairs	Climbing <b>one</b> flight of stairs	Climbing <b>one</b> flight of stairs
Bending, keeling, stooping	Bending, keeling, stooping	Bending, keeling, stooping	Bending, kneeling or stooping
Walk > 1 mile	Walking <b>more than a mile</b>	Walking <b>more than a mile</b>	-
Walk half a mile	Walking <b>half a mile</b>	Walking <b>half a mile</b>	Walking <b>half a mile</b>
Walk 100 yards	Walking <b>one hundred yards</b>	Walking <b>one hundred yards</b>	Walking <b>one hundred yards</b>
Bathing or dressing	Bathing or dressing yourself	Bathing or dressing yourself	Bathing or dressing yourself
	During the <b>past 4 weeks</b> , have you had any of the following problems with your work or other regular daily activities as a result of your <b>heart condition</b> ?		-
Time spent	Cut down the <b>amount of time</b> spent on work or other activities	Cut down the <b>amount of time</b> spent on work or other activities	-
Accomplish	<b>Accomplished less</b> than you would like	<b>Accomplished less</b> than you would like	-
Kind of work	Were limited in the <b>kind</b> of work or other activities	Were limited in the <b>kind</b> of work or other activities	-
Performing	Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	-
	The next questions ask about your feelings about your <b>heart condition</b> . During the <b>past 4 weeks</b> , how often have you felt:		
Worry heart condition	Worried about your heart condition?	Worried about your heart condition?	Worried about your heart condition?
Over-doing it	Worried about doing too much or over-doing it?	Worried about doing too much or over-doing it?	Worried about doing too much or over-doing it?
Heart attack	Worried that you might have a heart attack or die suddenly?	Worried that you might have a heart attack or die suddenly?	Worried that you might have a heart attack or die suddenly?
Symptoms return	Worried that your symptoms might return?	Worried that your symptoms might return?	Worried that your symptoms might return?
Another operation	Worried that you might need another heart operation in the future?	Worried that you might need another heart operation in the future?	-
Frightened by pain	Frightened by the pain or discomfort of your heart condition?	Frightened by the pain or discomfort of your heart condition?	Frightened by the pain or discomfort of your heart condition?
Out of control	Out of control of your life?	Out of control of your life?	-
Uncertain	Uncertain about the future?	Uncertain about the future?	Uncertain about the future?

CROQ item	Phrasing of pre-test version of CROQ items	Phrasing of preliminary field test version of CROQ items	Phrasing of final field test version of CROQ items
Unsure	Unsure of yourself or lacking in self-confidence?	Unsure of yourself or lacking in self-confidence?	-
Low morale	Low in morale?	Low in morale?	-
Depressed	Depressed?	Depressed?	Depressed?
Frustrated	Frustrated or impatient?	Frustrated or impatient?	Frustrated or impatient?
Irritated	Irritated?	Irritated?	-
Avoid activities	That you had to avoid certain activities because of your heart condition?	That you had to avoid certain activities because of your heart condition?	-
Interfered with enjoyment	That your heart condition interfered with your enjoyment of life?	That your heart condition interfered with your enjoyment of life?	That your heart condition interfered with your enjoyment of life?
Positive outlook	That it was difficult to keep a positive outlook about your health?	That it was difficult to keep a positive outlook about your health?	That it was difficult to keep a positive outlook about your health?
Difficult to plan	-	That it was difficult to plan ahead (eg vacations, social events, etc.)?	That it was difficult to plan ahead (eg vacations, social events, etc.)?
	During the <u>past 4 weeks</u> , how much of the time did you:	The next questions ask about problems related to your <b>heart condition</b> . During the <u>past 4 weeks</u> , how much of the time did you:	
Reason	Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?
Forget	Forget, for example things that happened recently, where you put things or appointments?	Forget, for example things that happened recently, where you put things or appointments?	Forget, for example things that happened recently, where you put things or appointments?
Attention	Have trouble keeping your attention on any activity for long?	Have trouble keeping your attention on any activity for long?	-
Concentration	Have difficulty doing activities involving concentration and thinking?	Have difficulty doing activities involving concentration and thinking?	Have difficulty doing activities involving concentration and thinking?
Confusion	Become confused and start several actions at a time?	Become confused and start several actions at a time?	-
React slowly	React slowly to things that were done or said?	React slowly to things that were done or said?	-

CROQ item	Phrasing of pre-test version of CROQ items	Phrasing of preliminary field test version of CROQ items	Phrasing of final field test version of CROQ items
Not complete	Not complete things or activities you started?	Not complete things or activities you started?	-
	This question is about the impact of your <b>heart condition</b> on your family and friends and the extent to which it has interfered with your social activities. During the <u>past 4 weeks</u> , how often have you experienced the following as a result of your <b>heart condition</b> :		
Personal relationships	Difficulties with your personal relationships?	Difficulties with your personal relationships?	-
Family overprotective	Family or friends being overprotective toward you?	Family or friends being overprotective toward you?	Family or friends being overprotective toward you?
Feeling a burden	Feeling like you are a burden on others?	Feeling like you are a burden on others?	Feeling like you are a burden on others?
Restricted in social activities	Feeling restricted in your social activities (like visiting with friends, relatives, etc)	Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	Feeling restricted in your social activities (like visiting with friends, relatives, etc)?
Feeling excluded	Feeling excluded from doing things with other people?	Feeling excluded from doing things with other people?	-
Too far from home	Feeling worried about going too far from home?	Feeling worried about going too far from home?	Feeling worried about going too far from home?
	The next question asks about how satisfied you are with your <b>heart operation</b> . How satisfied are you with the:	The next question asks about how satisfied you are with your <b>heart operation</b> . How satisfied are you with the:	The next question asks about how satisfied you are with your <b>heart operation</b> . How satisfied are you with the:
Satisfied with progress	Progress you have made since your heart operation?	Progress you have made since your heart operation?	-
Satisfied with results	Results of your heart operation?	Results of your heart operation?	Results of your heart operation?
Satisfied with info about op	Information you were given about your heart operation?	Information you were given about your heart operation?	Information you were given about your heart operation?
Satisfied with recovery info	Information you were given about how you might feel while recovering from your heart operation?	Information you were given about how you might feel while recovering from your heart operation?	Information you were given about how you might feel while recovering from your heart operation?
Info at the right time	Were you given the information about your <b>heart operation</b> at the right time?	Were you given the information about your <b>heart operation</b> at the time you needed it?	-
Overall compared to before op	Overall, how would you describe your <b>heart condition</b> <u>now compared to before</u> your heart operation?	Overall, how would you describe your <b>heart condition</b> <u>now compared to before</u> you had your heart operation?	Overall, how would you describe your <b>heart condition</b> <u>now compared to before</u> you had your heart operation?

<b>CROQ item</b>	<b>Phrasing of pre-test version of CROQ items</b>	<b>Phrasing of preliminary field test version of CROQ items</b>	<b>Phrasing of final field test version of CROQ items</b>
Speed of recovery	Has your recovery from your <b>heart operation</b> so far been:	Has your recovery from your <b>heart operation</b> so far been:	Has your recovery from your <b>heart operation</b> so far been:
Expectation of results	Are the results from your <b>heart operation</b> :	Are the results from your <b>heart operation</b>	Are the results from your <b>heart operation</b> :
<b>CROQ-CABG complication items</b>			
	The next section asks about problems you might have had <b>since your heart operation</b> . During the <u>past 4 weeks</u> , how much were you bothered by the following problems?		
Pain in chest wound	Pain in your <b>chest wound</b>	Pain in your <b>chest wound</b>	Pain in your <b>chest wound</b>
Pain in chest area	Any other pain in your <b>chest or neck</b> due to your operation	Any other pain in your <b>chest or neck</b> area due to your operation	-
Infection in chest wound	Infection, oozing or tenderness in your <b>chest wound</b>	Infection in your <b>chest wound</b>	Infection in your <b>chest wound</b>
Oozing chest wound	-	Oozing from your <b>chest wound</b>	-
Tender chest wound	-	Tenderness around your <b>chest wound</b>	Tenderness around your <b>chest wound</b>
Numb chest wound	Numbness or tingling in your <b>chest</b>	Numbness or tingling around your <b>chest wound</b>	Numbness or tingling around your <b>chest wound</b>
Pain leg wound	Pain in your <b>leg or arm wound</b>	Pain in your <b>leg or arm wound</b>	Pain in your <b>leg or arm wound</b>
Other pain in leg	Any other pain in your <b>leg or arm</b> due to your operation	Any other pain in your <b>leg or arm</b> due to your operation	Any other pain in your <b>leg or arm</b> due to your operation
Infection in leg wound	Infection, oozing or tenderness in your <b>leg or arm wound</b>	Infection in your <b>leg or arm wound</b>	Infection in your <b>leg or arm wound</b>
Oozing leg wound	-	Oozing from your <b>leg or arm wound</b>	-
Tender leg wound	-	Tenderness around your <b>leg or arm wound</b>	-
Numb leg	Numbness or tingling in your <b>leg or arm</b>	Numbness or tingling in your <b>leg or arm</b> due to your operation	Numbness or tingling in your <b>leg or arm</b> due to your operation
Bruising on chest	Bruising on your chest	Bruising on your <b>chest</b>	Bruising on your <b>chest</b>
Bruising on leg	Bruising on your leg or arm where a vein was removed	Bruising on your <b>leg or arm</b> where a vein was removed	Bruising on your <b>leg or arm</b> where a vein was removed
Swollen feet	Swollen feet or ankles	Swollen feet or ankles	Swollen feet or ankles
Weakness	Weakness or lethargy	Weakness or lethargy	-
Nausea	Nausea	Nausea	-
Loss of appetite	Loss of appetite	Loss of appetite	-

CROQ item	Phrasing of pre-test version of CROQ items	Phrasing of preliminary field test version of CROQ items	Phrasing of final field test version of CROQ items
Concern over scars	Concern over the appearance of your surgical scars	Concern over the appearance of your surgical scars	-
<b>CROQ-PTCA complication items</b>			
	The next section asks about problems you might have had <b>since your heart operation</b> . During the <u>past 4 weeks</u> , how much were you bothered by the following problems?		
Pain in groin wound	Pain in your groin wound	Pain in your groin wound	Pain in your groin wound
Infection in groin wound	Infection, oozing or tenderness in your groin wound	Infection in your groin wound	-
Oozing groin wound	-	Oozing from your groin wound	-
Tender groin wound	-	Tenderness around your groin wound	Tenderness around your groin wound
Numb groin	Numbness or tingling in your groin area	Numbness or tingling in your groin area	Numbness or tingling in your groin area
Bruised groin wound	Bruising around your groin wound	Bruising around your groin wound	Bruising around your groin wound or thigh
Bruised thigh	Bruising on your thigh	Bruising on your thigh	-
Chest discomfort from op	Discomfort in your chest due to your operation	Discomfort in your chest due to your operation	-
Swollen feet	Swollen feet or ankles	Swollen feet or ankles	-
Concern over scar	Concern over the appearance of your surgical scar	-	-
Problems from catheter	-	Problems in your groin where the catheter was inserted	Problems in your groin where the catheter was inserted
Concern over bruises	Concern over the appearance of your bruises	Concern over the appearance of your bruises	Concern over the appearance of your bruises
<b>Descriptive items</b>			
Symptoms on exertion	During the <u>past 4 weeks</u> , have you had <b>chest pain, chest tightness or angina</b> : <ul style="list-style-type: none"> <li>• At rest?</li> <li>• Only on exertion?</li> <li>• Not at all?</li> </ul>	During the <u>past 4 weeks</u> , have you had <b>chest pain, chest tightness or angina</b> : <ul style="list-style-type: none"> <li>• At rest?</li> <li>• Only on exertion?</li> <li>• Not at all?</li> </ul>	During the <u>past 4 weeks</u> , have you had <b>chest pain, chest tightness or angina</b> : <ul style="list-style-type: none"> <li>• At rest?</li> <li>• On exertion?</li> <li>• At rest and on exertion?</li> <li>• Not at all?</li> </ul>

<b>CROQ item</b>	<b>Phrasing of pre-test version of CROQ items</b>	<b>Phrasing of preliminary field test version of CROQ items</b>	<b>Phrasing of final field test version of CROQ items</b>
Readmission to hospital	<u>Since your heart operation</u> , have you been re-admitted to hospital (for an overnight stay) for any reason to do with your <b>heart condition or your heart operation</b> ? Please give as many details as you can below.	<u>Since your heart operation</u> , have you been re-admitted to hospital for an overnight stay for any reason to do with your <b>heart condition or heart operation</b> ? Please give as many details as you can below.	<u>Since your heart operation</u> , have you been re-admitted to hospital for an overnight stay for any reason to do with your <b>heart condition or heart operation</b> ? Please give as many details as you can below.

**TABLE 5.1 Criteria Used in the Psychometric Evaluation of the CROQ**

<b>Psychometric test</b>	<b>Criterion: item level analyses</b>	<b>Criterion: scale level analyses</b>
<b>Tests applied at the item and scale level</b>		
<b>Acceptability</b>		
Missing data	<5%	<10%
Floor/ceiling effects	NA	<75% <sup>a</sup>
Skewness	+1 to -1 <sup>a</sup>	+1 to -1
<b>Reliability</b>		
<i>Internal consistency</i>		
Cronbach's alpha	NA	.70
Item-total correlation	.30	.30
<i>Test-retest</i>		
Intraclass / Pearson correlation Coefficient	.40	.70
<b>Validity</b>		
<i>Construct</i>		
Internal consistency	NA	>.70
Inter-scale correlations	NA	Moderate
Convergent correlations	NA	>.40
Discriminant correlations	NA	<.40
Factor analysis	NA	Factor loadings ≥.35. Cross loadings <sup>b</sup> with a difference of at least .20
<b>Responsiveness</b>		
Effect size / standardised response mean	NA	Small (.20 ), moderate (.50), large (.80)
<b>Tests applied only in item level analyses</b>		
Item redundancy (correlation)	≥.75	NA
Maximum endorsement frequency	≥.75%	NA
Aggregate endorsement frequency	<10%	NA
Item responsiveness	p<.05 <sup>c</sup>	NA
Item convergent / discriminant correlations	Items must be SS or PSS <sup>d</sup>	NA

**Key:**

NA Not applicable.

<sup>a</sup> Pre-revascularisation version of the CROQ only.

<sup>b</sup> Items which cross load onto another factor should have a difference of at least .20.

<sup>c</sup> *T-tests* between pre- and 3-months post-revascularisation.

<sup>d</sup> SS = scaling success, PSS = probable scaling success.

**TABLE 6.1a Respondent Characteristics: CROQ-CABG (Preliminary Field Test)**

	Pre CABG (N=146) <sup>2</sup>	3m post CABG (N=289) <sup>3</sup>	CABG Responsiveness (N=128) <sup>4</sup>
<b>Gender</b>			
Male	108 (74) <sup>1</sup>	216 (75)	95 (74)
Female	38 (26)	73 (25)	33 (26)
<b>Age (years)</b>			
Mean (SD)	63.3 (8.7)	63.7 (9.0)	63.6 (8.4)
Range	34-82	35-82	34-82
≥ 70 years	32 (22)	69 (24)	25 (20)
<b>Clinical site</b>			
Brompton	65 (44)	88 (31)	52 (40)
Harefield	32 (22)	82 (28)	29 (23)
Wythenshawe	49 (34)	119 (41)	47 (37)
<b>Ethnicity</b>			
White	137 (94)	267 (92)	121 (94)
Black/Caribbean	1(1)	1(1)	1 (1)
Indian	3 (2)	9 (3)	2 (2)
Pakistani	0 (0)	2 (1)	0 (0)
Other	5 (3)	10 (3)	4 (3)
Missing	0 (0)	0 (0)	0 (0)
<b>Employment status</b>			
Employed full-time	31 (21)	47 (16)	28 (22)
Employed part-time	7 (5)	17 (6)	7 (5)
Voluntary work	1 (1)	2 (1)	1 (1)
Homemaker	7 (5)	5 (2)	4 (3)
Retired	81 (55)	165 (57)	72 (56)
Unable to work / disabled/ unemployed	16 (11)	50 (17)	13 (10)
Other	2 (1)	0 (0)	2 (2)
Missing	1 (1)	3 (1)	1 (1)

	Pre CABG (N=146) <sup>2</sup>	3m post CABG (N=289) <sup>3</sup>	CABG Responsiveness (N=128) <sup>4</sup>
<b>Living situation</b>			
Alone	24 (16)	44 (15)	22 (17)
Only with partner	72 (49)	137 (47)	66 (52)
With other family members	31 (22)	52 (18)	26 (20)
Other	0 (0)	1 (1)	0 (0)
Missing	19 (13)	55 (19)	14 (11)
<b>Symptoms on exertion?</b>			
At rest	(44)	(10)	-
Only on exertion	(47)	(30)	-
At rest and on exertion	-	-	-
Not at all	(8)	(60)	-
Missing	(1)	(0)	-
<b>Readmitted to hospital after CABG?</b>			
No	-	(80)	-
Yes	-	(20)	-
Missing	-	(0)	-

<sup>1</sup> Numbers in brackets are percents, unless specified otherwise.

<sup>2</sup> All patients who completed pre-revascularisation CROQ, and actually had CABG in study period.

<sup>3</sup> All patients who completed 3-month post-revascularisation CROQ, including those not sent a pre-revascularisation questionnaire and the Test-retest subsample.

<sup>4</sup> All patients who completed both the pre- and 3-month post-revascularisation CROQ-CABG.

**TABLE 6.1b Respondent Characteristics: CROQ-PTCA (Preliminary Field Test)**

	Pre PTCA (N=128) <sup>2</sup>	3m post PTCA (N=280) <sup>3</sup>	PTCA Responsiveness (N=114) <sup>4</sup>
<b>Gender</b>			
Male	86 (67) <sup>1</sup>	192 (69)	75 (66)
Female	42 (33)	88 (31)	39 (34)
<b>Age (years)</b>			
Mean (SD)	62.1 (9.7)	62.3 (9.8)	62.8 (9.7)
Range	36-88	35-88	35-88
≥ 70 years	27 (21)	64 (23)	29 (25)
<b>Clinical site</b>			
Brompton	48 (38)	88 (32)	43 (38)
Harefield	49 (38)	107 (38)	44 (39)
Wythenshawe	31 (24)	85 (30)	27 (23)
<b>Ethnicity</b>			
White	118 (92)	250 (89)	104 (91)
Black/Caribbean	1 (1)	1 (1)	1 (1)
Indian	5 (4)	13 (4)	5 (4)
Pakistani	2 (2)	7 (2)	2 (2)
Other	2 (1)	4 (2)	2 (2)
Missing	0 (0)	5 (2)	0 (0)
<b>Employment status</b>			
Employed full-time	34 (27)	61 (22)	29 (25)
Employed part-time	10 (8)	12 (4)	10 (9)
Voluntary work	0 (0)	3 (1)	0 (0)
Homemaker	5 (4)	10 (4)	4 (4)
Retired	58 (45)	136 (48)	53 (46)
Unable to work / disabled/ unemployed	20 (15)	55 (20)	17 (15)
Other	1 (1)	0 (0)	1 (1)
Missing	0 (0)	3 (1)	0 (0)

	Pre PTCA (N=128) <sup>2</sup>	3m post PTCA (N=280) <sup>3</sup>	PTCA Responsiveness (N=114) <sup>4</sup>
<b>Living situation</b>			
Alone	23 (18)	46 (16)	21 (18)
Only with partner	59 (46)	142 (51)	54 (47)
With other family members	26 (20)	57 (20)	21 (18)
Other	1 (1)	1 (1)	1 (1)
Missing	19 (15)	34 (12)	17 (14)
<b>Symptoms on exertion?</b>			
At rest	(41)	(24)	
Only on exertion	(49)	(38)	-
At rest and on exertion	-	-	
Not at all	(9)	(38)	
Missing	(1)	(0)	
<b>Readmitted to hospital after PTCA?</b>			
No		(80)	-
Yes	-	(19)	
Missing		(1)	

<sup>1</sup> Numbers in brackets are percents, unless specified otherwise.

<sup>2</sup> All patients who completed pre-revascularisation CROQ, and actually had PTCA in study period.

<sup>3</sup> All patients who completed 3-month post-revascularisation CROQ, including those not sent a pre-revascularisation questionnaire and the Test-retest subsample.

<sup>4</sup> All patients who completed both the pre- and 3-month post-revascularisation CROQ-PTCA.

**TABLE 6.2 Response Rates: CROQ Pre-Revascularisation (Preliminary Field Test)**

		<b>CROQ-CABG</b>	<b>CROQ-PTCA</b>
Total number questionnaires sent		257	272
Total number ineligible questionnaires		71	89
	Number did not have CABG/PTCA in study period	71	89
Total number eligible questionnaires sent		186	183
Total number eligible questionnaires received		146	186
Non-responders	Number returned blank – no reason given	0	0
	Number returned blank – received too late	0	0
	Number too sick to complete	0	0
<b>Response rate: number questionnaires completed / number eligible questionnaires</b>		<b>146 / 186 = 78%</b>	<b>128 / 183 = 70%</b>

**TABLE 6.3 Response Rates: CROQ Post-Revascularisation (Preliminary Field Test)**

	<b>CABG-CABG 3m</b>	<b>CROQ-PTCA 3m</b>
Total number questionnaires sent	358	341
Total number of ineligible patients <sup>1</sup>	0	3
Total number eligible questionnaires received	289	280
<b>Overall response rate</b>	<b>289 / 358 = 81%</b>	<b>280 / 338 = 83%</b>
<i>Responsiveness sample</i>		
Number sent	146	128
Number ineligible	0	3
Number eligible questionnaires received	128	114
Response rate	128 / 146 = 88%	114 / 125 = 91%
<i>Patients sent 3-month post questionnaire only</i>		
Number sent	122	123
Number ineligible	0	0
Number eligible questionnaires received	103	109
Response rate	103 / 122 = 84%	109 / 123 = 89%
<i>Test-retest sample</i>		
Number sent	90	90
Number ineligible	0	0
Number eligible questionnaires received	58	57
Response rate	58 / 90 = 64%	57 / 90 = 63%

<sup>1</sup> Questionnaires were considered ineligible if the patient reported that the procedure was not carried out, e.g. due to the nature of the blockage in the arteries.

**TABLE 6.4 Item Reduction Analyses**

Test (Criterion)	Result	Items eliminated
<b>Phase One: Item Reduction of Core Pre- / Post-Revascularisation Items Using Pooled Pre-Revascularisation Sample (N=274)</b>		
<b>52-item pool</b>		
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Inter-item correlations ( $< .75$ )	Inter-item correlations $\geq .75$ : <ul style="list-style-type: none"> <li>• <i>attention &amp; concentration</i> (.86)</li> <li>• <i>low morale &amp; depressed</i> (.83)</li> <li>• <i>frustrated &amp; irritated</i> (.83)</li> <li>• <i>avoid activities &amp; interfered with enjoyment</i> (.82)</li> <li>• <i>chest tightness &amp; chest discomfort</i> (.81)</li> <li>• <i>walk &gt; 1 mile &amp; walk half a mile</i> (.81)</li> <li>• <i>restricted in social activities &amp; feeling excluded</i> (.79)</li> <li>• <i>confusion &amp; react slowly</i> (.78)</li> <li>• <i>concentration &amp; react slowly</i> (.77)</li> <li>• <i>out of control &amp; uncertain</i> (.77)</li> <li>• <i>attention &amp; react slowly</i> (.75)</li> </ul>	9 items eliminated: <ul style="list-style-type: none"> <li>• <i>attention</i></li> <li>• <i>low morale</i></li> <li>• <i>irritated</i></li> <li>• <i>avoid activities</i></li> <li>• <i>chest tightness</i></li> <li>• <i>walk &gt; 1 mile</i></li> <li>• <i>feeling excluded</i></li> <li>• <i>react slowly</i></li> <li>• <i>out of control</i></li> </ul>
Missing data ( $< 5\%$ )	Missing data $\geq 5\%$ : <ul style="list-style-type: none"> <li>• <i>vigorous activities</i> (7%)</li> <li>• <i>walk &gt; 1 mile</i> (7%)</li> </ul>	1 item eliminated: <ul style="list-style-type: none"> <li>• <i>vigorous activities</i></li> </ul>
Maximum endorsement frequency ( $< 75\%$ )	Maximum endorsement frequencies $\geq 75\%$ : <ul style="list-style-type: none"> <li>• <i>accomplish</i> (85%)</li> <li>• <i>time spent</i> (75%)</li> <li>• <i>kind of work</i> (81%)</li> <li>• <i>performing</i> (78%)</li> </ul>	4 items eliminated: <ul style="list-style-type: none"> <li>• <i>accomplish</i></li> <li>• <i>time spent</i></li> <li>• <i>kind of work</i></li> <li>• <i>performing</i></li> </ul>
Aggregate adjacent endorsement frequency ( $> 10\%$ )	2 or more adjacent response categories endorsed $\leq 10\%$ : <ul style="list-style-type: none"> <li>• <i>confusion</i> (6.2%)</li> <li>• <i>attention</i> (7.6%)</li> <li>• <i>react slowly</i> (7.6%)</li> <li>• <i>not complete</i> (8.4%)</li> </ul>	2 items eliminated: <ul style="list-style-type: none"> <li>• <i>confusion</i></li> <li>• <i>not complete</i></li> </ul>
Item responsiveness (items must be responsive $p < .05$ between pre- and 3 months post-revascularisation)	All items responsive between pre- and 3 months post-revascularisation ( $p < .05$ )	None
		<b>16 items eliminated</b>

Test (Criterion)	Result	Items eliminated
<b>36-item pool</b>		
Factor analysis (principal components factoring) unrotated for 36 items (eigen values >1, factor loadings $\geq .30$ )	No items loaded on the first factor <.30 No "rogue" items identified	None
Factor analysis (principal axis factoring) with Varimax rotation for 36 items (eigen values >1, factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Produced 5 factors accounting for 58.9% variance, with all items loading on a factor. Some items crossloaded on more than one factor. Social Functioning did not form a separate scale as hypothesised, but loaded on same factor as Psychological Functioning	None
Factor analysis (principal axis factoring) with Varimax rotation for 36 items (modelling 4 factors: factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Factors conceptually measuring Psychosocial Functioning, Cognitive Functioning, Symptoms, & Physical Functioning	None
Factor analysis (principal axis factoring) with Varimax rotation for 36 items (modelling 6 factors: factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Too many factors and crossloading items	None
Cronbach's alpha using scales identified by factor analysis (alpha $\geq .70$ ; deletion of items should not 'substantially increase' value of alpha)	Cronbach's alpha: Symptoms (9 items) = .89 Physical (8 items) = .91 Psychosocial (16 items) = .95 Cognitive (3 items) = .88 Core Total = (36 items) .96 Alpha would not substantially increase if any items were deleted in any scale	None
Item-total correlations ( $\geq .30$ )	No item-total correlations <.30	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success). Probable scaling success (PSS) allowed only if item can be retained on clinical or conceptual grounds	All items were more highly correlated to their own scale than to other scales by at least 2 SEs except: <ul style="list-style-type: none"> <li>• <i>shortness of breath</i> (PSS): Retained for clinical reasons</li> <li>• <i>sleep</i> (PSS)</li> <li>• <i>low energy</i> (PSS)</li> <li>• <i>unsure</i> (PSS)</li> </ul>	3 items eliminated: <ul style="list-style-type: none"> <li>• <i>low energy</i></li> <li>• <i>sleep</i></li> <li>• <i>unsure</i></li> </ul>
		3 items eliminated

Test (Criterion)	Result	Items eliminated
<b>33-item pool</b>		
Factor analysis (principal axis factoring) with Varimax rotation for 33 items (eigen values >1, factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Produced 5 factors conceptually measuring Psychosocial Functioning, Cognitive Functioning, Symptoms, & Physical Functioning. Every item loaded on a factor, but too many factors. 3 cross loadings <.2 ( <i>shortness of breath, interfered with enjoyment, difficult to plan</i> ).	None
Factor analysis (principal axis factoring) with Varimax rotation for 33 items (modelling 4 factors, factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Factors identified: Psychosocial Functioning, Cognitive Functioning, Symptoms, & Physical Functioning. 3 items cross loaded <.2 difference ( <i>shortness of breath, trouble, feeling restricted</i> )	None
Cronbach's alpha using scales identified by factor analysis (alpha $\geq .70$ ; deletion of items should not 'substantially increase' value of alpha)	Cronbach's alpha: Symptoms (7 items) = .87 Physical (8 items) = .91 Psychosocial (15 items) = .94. Cognitive (3 items) = .88 Core Total (33 items) = .96 Alpha would not substantially increase if items were deleted in any scales	None
Item-total correlations ( $\geq .30$ )	No item-total correlations <.30	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success). Probable scaling success (PSS) allowed only if item can be retained on clinical or conceptual grounds	All items were more highly correlated to their own scale than to other scales by at least 2 SEs except: <ul style="list-style-type: none"> <li>• <i>shortness of breath</i> (PSS)</li> <li>• <i>palpitations</i> (PSS)</li> <li>• <i>personal relationships</i> (PSS)</li> </ul> <i>shortness of breath &amp; palpitations</i> were retained for clinical reasons	1 item eliminated: <ul style="list-style-type: none"> <li>• <i>personal relationships</i></li> </ul>
		1 item eliminated
<b>32-item pool</b>		
Factor analysis (principal axis factoring) with Varimax rotation for 32 items (eigen values >1, factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Produced 5 factors conceptually measuring Psychosocial Functioning, Cognitive Functioning, Symptoms, & Physical Functioning. Every item loaded on a factor, but too many factors. 2 items cross loaded <.2 difference ( <i>interfered with enjoyment, difficult to plan</i> )	None
Factor analysis (principal axis factoring) with Varimax rotation for 32 items (modeling 4 factors: factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Factors identified: Psychosocial Functioning, Cognitive Functioning, Symptoms & Physical Functioning. 1 item cross loaded with a difference <.2 ( <i>trouble</i> ). <i>Trouble</i> is a global item which one would expect to be correlated to several factors	None

Test (Criterion)	Result	Items eliminated
Cronbach's alpha using scales identified by factor analysis (alpha $\geq .70$ ; deletion of items should not 'substantially increase' value of alpha)	Cronbach's alpha: Symptoms (7 items) = .88 Physical (8 items) = .91 Psychosocial (14 items) = .94 Cognitive (3 items) = .88 Core Total (32 items) = .95 Alpha would not substantially increase if any items were deleted in any scale	None
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success). Probable scaling success (PSS) allowed only if item can be retained on clinical or conceptual grounds	All items were more highly correlated to their own scale than to the other scales by at least 2 SEs except: <ul style="list-style-type: none"> <li>• <i>shortness of breath</i> (PSS)</li> <li>• <i>palpitations</i> (PSS)</li> </ul> <i>shortness of breath &amp; palpitations</i> were retained for clinical reasons	None
<b>No items eliminated. Final item pool: 32 items</b>		
<b>Phase Two: Item Reduction of 10 Common Post-Revascularisation Only Items Using Pooled Post-Revascularisation Sample (N=569)</b>		
<b>10-item pool</b>		
Factor analysis (principal components factoring) unrotated for 10 items (eigen values $> 1$ , factor loadings $\geq .30$ )	All items loaded on first factor $> .30$ except: <ul style="list-style-type: none"> <li>• <i>timing of information</i></li> </ul> <i>timing of information</i> identified as "rogue" item	None
Item-total correlations ( $\geq .30$ )	Item-total correlations $< .30$ : <ul style="list-style-type: none"> <li>• <i>timing of Information</i> (.18)</li> </ul>	1 item eliminated: <ul style="list-style-type: none"> <li>• <i>timing of information</i></li> </ul>
Inter-item correlations ( $< .75$ )	Inter-item correlations $\geq .75$ : <ul style="list-style-type: none"> <li>• <i>satisfied with progress &amp; satisfied with results</i> (.83)</li> <li>• <i>symptoms return &amp; another operation</i> (.80)</li> </ul>	2 items eliminated: <ul style="list-style-type: none"> <li>• <i>satisfied with progress</i></li> <li>• <i>another operation</i></li> </ul>
Missing data ( $< 5\%$ )	No items with missing data $\geq 5\%$	None
Item test-retest ( $> .40$ )	No correlation coefficients $\leq .40$	None
<b>3 items eliminated</b>		
<b>7-item pool</b>		
Cronbach's alpha for 7-item common post scale ( $\geq .70$ , deletion of items should not 'substantially increase' value of alpha)	Cronbach's alpha = .83 (alpha would not substantially increase if any items were deleted from scale)	None

Test (Criterion)	Result	Items eliminated
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success). Probable scaling success (PSS) allowed only if item can be retained on clinical or conceptual grounds	All items were more highly correlated to their own scale by at least 2 SEs except: <ul style="list-style-type: none"> <li>• <i>overall</i> (PSF)</li> <li>• <i>symptoms return</i> (SF)</li> </ul> <i>Overall</i> was retained as it was correlated to scales that fit conceptually for a global item. <i>Symptoms return</i> was excluded from Satisfaction scale as it was a scaling failure, but was retained in the CROQ (in Total Outcomes scale)	None
<b>Final item pool: 7 items</b>		
<b>Phase Three: Item Reduction of Procedure-Specific Complication Items</b>		
<b>CROQ-CABG Complications (N=289)</b>		
<b>19-item pool</b>		
Factor analysis (principal components factoring) unrotated for 19 items (eigen values $>1$ , factor loadings $\geq .30$ )	No items loaded on the first factor $< .30$ . No "rogue" items identified	None
Factor analysis (principal axis factoring) with Varimax rotation for 19 items (eigen values $>1$ , factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Produced 5 factors, but too many factors and too many cross loading items. 2 items did not load on any of the factors ( <i>Appetite</i> and <i>Scar appearance</i> )	None
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Inter-item correlations ( $< .75$ )	Inter-item correlations $\geq .75$ : <ul style="list-style-type: none"> <li>• <i>infection leg/arm wound</i> &amp; <i>oozing leg/arm wound</i> (.90)</li> <li>• <i>oozing from chest wound</i> &amp; <i>infection chest wound</i> (.85)</li> <li>• <i>pain in leg/arm wound</i> &amp; <i>tenderness around leg/arm wound</i> (.78)</li> </ul>	3 items eliminated: <ul style="list-style-type: none"> <li>• <i>oozing from chest wound</i></li> <li>• <i>oozing leg/arm wound</i></li> <li>• <i>tenderness around leg/arm wound</i></li> </ul>
Missing data ( $< 5\%$ )	No items with missing data $\geq 5\%$	None
Item test-retest ( $\geq .40$ )	Item test-retest correlation coefficients $< .40$ : <ul style="list-style-type: none"> <li>• <i>oozing from chest wound</i> (.24)</li> <li>• <i>oozing leg/arm wound</i> (-.06)</li> </ul>	None - items already eliminated
		<b>3 items eliminated</b>

Test (Criterion)	Result	Items eliminated
<b>16-item pool</b>		
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success)	All items were more highly correlated to their own scale than to the other scales by at least 2 SEs except: <ul style="list-style-type: none"> <li>• <i>pain in the chest area</i> (PSS)</li> <li>• <i>weakness</i> (PSF)</li> <li>• <i>appetite</i> (PSS)</li> <li>• <i>scar appearance</i> (PSS)</li> </ul> All these items were also correlated to at least 2 other scales and were eliminated	4 items eliminated: <ul style="list-style-type: none"> <li>• <i>pain in the chest area</i></li> <li>• <i>weakness</i></li> <li>• <i>appetite</i></li> <li>• <i>scar appearance</i></li> </ul>
<b>12-item pool</b>		
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success)	All items were more highly correlated to their own scale than to other scales by at least 2 SEs except: <ul style="list-style-type: none"> <li>• <i>nausea</i> (PSS)</li> </ul> Nausea was also correlated to at least 2 other scales	1 item eliminated: <ul style="list-style-type: none"> <li>• <i>nausea</i></li> </ul>
<b>11-item pool</b>		
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success)	All items were more highly correlated to their own scale than to other scales by at least 2 Ses	None
<b>8 items eliminated. Final item pool: 11 items</b>		
<b>CROQ-PTCA Complications (N=280)</b>		
<b>11-item pool</b>		
Factor analysis (principal components factoring) unrotated for 11 items (eigen values $> 1$ , factor loadings $\geq .30$ )	No items loaded on the first factor $< .30$ . No "rogue" items identified	None
Factor analysis (principal axis factoring) with Varimax rotation for 11 items (eigen values $> 1$ , factor loadings $\geq .35$ , cross loadings $\geq .2$ difference)	Produced 3 factors, but too many factors and too many crossloading items No items loaded on a factor $< .35$	None
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None

Test (Criterion)	Result	Items eliminated
Inter-item correlations (<.75)	Inter-item correlations $\geq .75$ : <ul style="list-style-type: none"> <li><i>bruised groin wound &amp; bruised thigh (.75)</i></li> </ul>	1 item eliminated: <ul style="list-style-type: none"> <li><i>bruised thigh</i></li> </ul> but this item is joined with bruised groin wound in final field test version to create a new item ( <i>bruising around your groin wound or thigh</i> )
Missing data (<5%)	No items with missing data $\geq 5\%$	None
Item test-retest ( $\geq .40$ )	Item test-retest correlation coefficients $< .40$ : <ul style="list-style-type: none"> <li><i>infection in groin wound</i> (can't compute as "not at all" for all but one pt)</li> <li><i>oozing groin wound (-.19)</i></li> </ul>	2 items eliminated: <ul style="list-style-type: none"> <li><i>infection in groin wound</i></li> <li><i>oozing groin wound</i></li> </ul>
<b>3 items eliminated. Pool reduced to 8 items</b>		
<b>8-item pool</b>		
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success)	All items were more highly correlated to their own scale than to other scales by at least 2 SEs except: <ul style="list-style-type: none"> <li><i>discomfort in chest from op</i> (PSF)</li> <li><i>swollen feet</i> (PSF)</li> </ul>	2 items eliminated: <ul style="list-style-type: none"> <li><i>discomfort in chest from op</i></li> <li><i>swollen feet</i></li> </ul>
<b>6-item pool</b>		
Item-total correlations ( $\geq .30$ )	No item-total correlations $< .30$	None
Tests of scaling assumptions (item convergent and discriminant correlations). Items should be more highly correlated to their own scale by $\geq 2$ standard errors (scaling success)	All items were more highly correlated to their own scale than to other scales by at least 2 SEs	None
<b>5 items eliminated and 1 pair of items combined. Final item pool: 6 items</b>		

**Key:**

SE: Standard error. SS: Scaling success. PSS: Probable scaling success. PSF: Probable scaling failure. SF: Scaling failure.

**TABLE 6.5a Respondent Characteristics: CROQ-CABG (Final Field Test)**

	Pre CABG (N=281) <sup>2</sup>	3m Post CABG (N=415) <sup>3</sup>	CABG Responsiveness (N=198) <sup>4</sup>
<b>Gender</b>			
Male	238 (85) <sup>1</sup>	343 (83)	166 (84)
Female	43 (15)	72 (17)	32 (16)
<b>Age (years)</b>			
Mean (SD)	63.6 (9.2)	65.0 (8.9)	64.31 (8.8)
Range	35-85	37-94	36-84
≥ 70 years	72 (26)	139 (33)	59 (30)
<b>Clinical site</b>			
Brompton	101 (34)	131 (32)	53 (27)
Harefield	63 (22)	125 (30)	46 (23)
Wythenshawe	117 (42)	159 (38)	99 (50)
<b>Ethnicity</b>			
White	261 (93)	369 (89)	183 (92)
Indian	12 (4)	20 (5)	9 (5)
Pakistani	3 (1)	8 (2)	1 (1)
Other	5 (2)	12 (3)	5 (2)
Missing	-	6 (1)	-
<b>Employment status</b>			
Employed full-time	53 (19)	65 (16)	33 (17)
Employed part-time	9 (3)	19 (5)	7 (3)
Voluntary work	1 (1)	0 (0)	0 (0)
Homemaker	6 (2)	12 (3)	4 (2)
Retired	147 (52)	239 (58)	109 (55)
Unable to work / disabled/ unemployed	49 (17)	54 (12)	32 (16)
Other	15 (5)	23 (5)	12 (6)
Missing	1 (1)	3 (1)	1 (1)
<b>Living situation</b>			
Alone	39 (14)	66 (16)	23 (12)
Only with partner	188 (67)	272 (66)	142 (71)
With other family members	51 (18)	70 (17)	31 (16)
Other	3 (1)	4 (1)	2 (1)
Missing	-	3 (1)	0 (0)

	Pre CABG (N=281) <sup>2</sup>	3m Post CABG (N=415) <sup>3</sup>	CABG Responsiveness (N=198) <sup>4</sup>
<b>2<sup>nd</sup> Questionnaire</b>			
SF-36	101 (36)	123 (30)	73 (37)
SAQ	85 (30)	102 (25)	56 (28)
QLMI-2	48 (17)	71 (17)	35 (18)
LhFE	47 (17)	69 (17)	34 (17)
Test-Retest	-	50 (12)	-
<b>Social class<sup>5</sup></b>			
Class I	25 (9)	35 (8)	14 (7)
Class II	77 (27)	107 (26)	55 (27)
Class III N	30 (11)	43 (10)	19 (10)
Class III M	93 (33)	131 (32)	71 (36)
Class IV	29 (10)	48 (12)	22 (11)
Class V	13 (5)	20 (5)	11 (6)
Missing	14 (5)	31 (7)	5 (3)
<b>Symptoms on exertion?</b>			
At rest	(9)	(5)	-
Only on exertion	(39)	(11)	
At rest and on exertion	(40)	(15)	
Not at all	(11)	(66)	
Missing	(1)	(3)	
<b>Readmitted to hospital after CABG?</b>			
No	-	(82)	-
Yes		(16)	
Missing		(2)	

<sup>1</sup> Numbers in brackets are percents, unless specified otherwise.

<sup>2</sup> All patients who completed pre-revascularisation CROQ, and actually had CABG in study period.

<sup>3</sup> All patients who completed 3-month post-revascularisation CROQ, including those not sent a pre-revascularisation questionnaire and the Test-retest subsample.

<sup>4</sup> All patients who completed both the pre- and 3-month post-revascularisation CROQ-CABG.

<sup>5</sup> Coded according to occupation using the classifications described by the Office of Population Censuses and Surveys (Standard occupational classification vol 3: social classifications and coding methodology. London: HMSO, 1991). Categorized as: I) Professional, etc. occupations; II) Managerial and Technical occupations; IIIN); Skilled occupations (non-manual); IIIM) Skilled occupations (manual); IV) Partly skilled occupations; V) Unskilled occupations.

**TABLE 6.5b Respondent Characteristics: CROQ-PTCA (Final Field Test)**

	Pre PTCA (N=159) <sup>2</sup>	3m Post PTCA (N=345) <sup>3</sup>	PTCA Responsiveness (N=107) <sup>4</sup>
<b>Gender</b>			
Male	120 (75) <sup>1</sup>	251 (73)	80 (75)
Female	39 (25)	94 (27)	27 (25)
<b>Age (years)</b>			
Mean (SD)	60.6 (9.7)	62.3 (10.2)	60.92 (9.8)
Range	38-89	36-84	39-80
≥ 70 years	29 (18)	86 (25)	23 (21)
<b>Clinical site</b>			
Brompton	28 (18)	73 (21)	21 (20)
Harefield	40 (25)	92 (27)	20 (19)
Wythenshawe	91 (57)	180 (52)	66 (62)
<b>Ethnicity</b>			
White	144 (91)	303 (88)	96 (89)
Indian	4 (2)	14 (4)	3 (3)
Pakistani	1 (1)	8 (2)	1 (1)
Other	8 (5)	13 (4)	5 (5)
Missing	2 (1)	7 (2)	2 (2)
<b>Employment Status</b>			
Employed full-time	39 (25)	83 (24)	28 (26)
Employed part-time	11 (7)	15 (4)	8 (7)
Voluntary work	-	2 (1)	0 (0)
Homemaker	7 (4)	10 (3)	4 (4)
Retired	63 (40)	152 (44)	40 (37)
Unable to work / disabled/ unemployed	26 (16)	52 (15)	20 (19)
Other	13 (8)	24 (7)	7 (7)
Missing	-	7 (2)	0 (0)
<b>Living situation</b>			
Alone	21 (13)	54 (16)	17 (16)
Only with partner	98 (61)	191 (55)	65 (61)
With other family members	38 (24)	93 (27)	25 (23)
Other	1 (1)	2 (1)	0 (0)
Missing	1 (1)	5 (1)	0 (0)

	Pre PTCA (N=159) <sup>2</sup>	3m Post PTCA (N=345) <sup>3</sup>	PTCA Responsiveness (N=107) <sup>4</sup>
<b>2<sup>nd</sup> Questionnaire</b>			
SF-36	48 (30)	84 (24)	38 (35)
SAQ	53 (33)	90 (26)	34 (32)
QLMI-2	32 (20)	66 (19)	22 (21)
LihFE	26 (17)	57 (17)	13 (12)
Test-Retest	-	48 (14)	-
<b>Social class<sup>5</sup></b>			
Class I	7 (4)	19 (6)	5 (4)
Class II	42 (26)	97 (28)	31 (29)
Class III N	22 (14)	42 (12)	19 (19)
Class III M	52 (33)	109 (32)	32 (30)
Class IV	24 (15)	43 (12)	12 (11)
Class V	0 (0)	7 (2)	0 (0)
Missing	12 (8)	28 (8)	8 (7)
<b>Symptoms on exertion?</b>			
At rest	(13)	(7)	-
Only on exertion	(32)	(26)	
At rest and on exertion	(45)	(22)	
Not at all	(8)	(42)	
Missing	(12)	(3)	
<b>Readmitted to hospital after PTCA?</b>			
No		(80)	
Yes	-	(17)	-
Missing		(3)	

<sup>1</sup> Numbers in brackets are percents, unless specified otherwise.

<sup>2</sup> All patients who completed pre-revascularisation CROQ, and actually had PTCA in study period.

<sup>3</sup> All patients who completed 3-month post-revascularisation CROQ, including those not sent a pre-revascularisation questionnaire and the Test-retest subsample.

<sup>4</sup> All patients who completed both the pre- and 3-month post-revascularisation CROQ-PTCA.

<sup>5</sup> Coded according to occupation using the classifications described by the Office of Population Censuses and Surveys (Standard occupational classification vol 3: social classifications and coding methodology. London: HMSO, 1991). Categorized as: I) Professional, etc. occupations; II) Managerial and Technical occupations; IIIN); Skilled occupations (non-manual); IIIM) Skilled occupations (manual); IV) Partly skilled occupations; V) Unskilled occupations.

**TABLE 6.6 Response Rates: CROQ Pre-Revascularisation (Final Field Test)**

		<b>CROQ-CABG</b>	<b>CROQ-PTCA</b>
Total number questionnaires sent		408	274
Total number ineligible questionnaires		1	4
	Number not having operation or already had operation	1	4
Total number eligible questionnaires sent		407	270
Total number eligible questionnaires received		281	159
Non-responders	Number returned blank - no reason given	2	0
	Number returned blank - received too late	5	2
	Number too sick to complete	1	1
	Number not known at this address	1	0
Response rate: number questionnaires completed / number of eligible questionnaires		<b>281/407= 69%</b>	<b>159/270= 59%</b>

**TABLE 6.7 Response Rates: CROQ Post-Revascularisation (Final Field Test)**

	CROQ-CABG 3m	CROQ-PTCA 3m
Total number questionnaires sent	509	468
Total number of ineligible patients <sup>1</sup>	0	4
Total number eligible questionnaires received	415	345
<b>Overall response rate</b>	<b>415 / 509 = 82%</b>	<b>345 / 464 = 74%</b>
<i>Responsiveness sample</i>		
Number sent	216	119
Number ineligible	0	0
Number eligible questionnaires received	198	107
Response rate	198 / 216 = 92%	107 / 119 = 90%
<i>Patients sent 3-month post questionnaire only</i>		
Number sent	223	279
Number ineligible	0	4
Number eligible questionnaires received	167	190
Response rate	167 / 223 = 75%	190 / 275 = 69%
<i>Test-retest sample</i>		
Number sent	70	70
Number ineligible	0	0
Number eligible questionnaires received	50	48
Response rate	50 / 70 = 71%	48 / 70 = 69%

<sup>1</sup> Questionnaires were considered ineligible if the patient reported that the procedure was not carried out, e.g. due to the nature of the blockage in the arteries.

**TABLE 6.8a Item Descriptive Statistics: CROQ-CABG Pre-Revascularisation (Final Field Test)**

Item	% missing data	Endorsement frequencies by response category (%)						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Chest pain	2.5	14.9	23.8	23.8	22.8	12.1	-	2.93 (1.3)	279	.83
Chest discomfort	3.2	14.2	27.4	24.2	19.2	11.7	-	2.86 (1.2)	279	.82
Shortness of breath	0.7	17.4	25.6	20.3	21.4	14.6	-	2.90 (1.3)	279	.55
Radiating pain	1.1	14.6	21.4	18.1	19.9	24.9	-	3.19 (1.4)	279	.64
Palpitations	2.5	4.3	11.4	14.2	27.0	40.6	-	3.91 (1.2)	279	.46
Nitroglycerin Trouble	0.0	13.5	26.0	18.9	13.9	7.5	20.3	3.37 (1.7)	279	.63
	1.1	16.4	28.1	29.5	17.1	7.8	-	2.72 (1.2)	279	.77
Moderate activities	3.2	34.9	40.9	21.0	-	-	-	1.86 (.75)	275	.69
Lifting & carrying	2.8	30.6	45.2	21.4	-	-	-	1.90 (.73)	275	.69
Climbing flights of stairs	7.1	53.0	29.2	10.7	-	-	-	1.54 (.69)	275	.73
Climbing one flight of stairs	3.9	15.3	45.6	35.2	-	-	-	2.21 (.70)	275	.75
Bending, keeling, stooping	2.8	15.3	43.4	38.4	-	-	-	2.24 (.71)	275	.57
Walk half a mile	3.2	46.3	34.5	16.0	-	-	-	1.69 (.74)	275	.67
Walk 100 yards	2.8	15.7	43.1	38.4	-	-	-	2.23 (.71)	275	.68
Bathing or dressing	2.5	6.0	34.9	56.6	-	-	-	2.52 (.61)	275	.62
Reason	0.0	6.8	9.6	10.7	23.8	17.4	31.7	4.31 (1.6)	281	.81
Forget	0.4	6.8	11.7	12.1	24.9	17.8	26.3	4.15 (1.6)	281	.81
Concentration	0.0	6.4	10.7	11.4	20.6	19.6	31.3	4.30 (1.6)	281	.86
Worry heart condition	1.4	20.3	23.8	28.8	19.2	6.4	-	2.67 (1.2)	279	.81
Over-doing it	1.4	13.9	27.8	29.5	18.5	8.9	-	2.81 (1.2)	279	.78
Heart attack	1.1	12.8	11.7	25.3	24.6	24.6	-	3.37 (1.3)	279	.72
Frightened by pain	0.4	10.0	13.5	35.6	19.6	21.0	-	3.28 (1.2)	279	.78
Uncertain	1.4	19.2	16.7	25.3	24.9	12.5	-	2.95 (1.3)	279	.73
Depressed	1.1	8.9	8.9	26.7	24.9	29.5	-	3.58 (1.3)	279	.66
Frustrated	1.4	15.3	25.3	25.6	20.3	12.1	-	2.88 (1.3)	279	.71
Interfered with enjoyment	0.7	23.8	28.1	23.5	17.1	6.8	-	2.54 (1.2)	279	.78
Positive outlook	1.1	11.7	23.5	27.4	22.8	13.5	-	3.03 (1.2)	279	.76
Difficult to plan	0.7	34.2	29.5	15.3	13.5	6.8	-	2.29 (1.3)	279	.65
Family overprotective	1.1	12.5	20.3	21.0	22.8	12.5	-	3.03 (1.2)	279	.54
Feeling a burden	1.1	11.7	11.0	25.6	21.4	29.2	-	3.46 (1.3)	279	.70
Restricted in social activities	1.1	14.2	18.9	27.4	13.5	24.9	-	3.16 (1.4)	279	.75
Too far from home	0.7	16.7	19.2	20.3	14.9	28.1	-	3.19 (1.5)	279	.76

**TABLE 6.8b Item Descriptive Statistics: CROQ-PTCA Pre-Revascularisation (Final Field Test)**

Item	% missing data	Endorsement frequencies by response category (%)						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Chest pain	3.8	15.1	20.8	23.9	20.1	16.4	-	3.02 (1.3)	159	.79
Chest discomfort	1.9	17.0	28.3	21.4	23.3	8.2	-	2.77 (1.2)	159	.83
Shortness of breath	1.3	18.2	28.3	19.5	21.4	11.3	-	2.79 (1.3)	159	.54
Radiating pain	3.1	13.8	21.4	21.4	17.0	23.3	-	3.15 (1.4)	159	.74
Palpitations	4.4	4.4	13.2	17.6	25.2	35.2	-	3.77 (1.2)	159	.50
Nitroglycerin Trouble	0.0	7.5	19.5	24.5	11.3	10.7	26.4	3.77 (1.7)	159	.61
	1.3	14.5	25.8	35.8	16.4	6.3	-	2.50 (1.1)	159	.82
Moderate activities	2.5	37.1	35.8	24.5	-	-	-	2.74 (0.8)	156	.74
Lifting & carrying	5.0	30.8	40.9	23.3	-	-	-	1.87 (0.8)	156	.78
Climbing flights of stairs	3.8	55.3	30.2	10.7	-	-	-	1.92 (0.7)	156	.68
Climbing one flight of stairs	3.1	21.4	40.9	34.6	-	-	-	1.54 (0.8)	156	.75
Bending, keeling, stooping	3.1	17.6	37.7	41.5	-	-	-	2.14 (0.7)	156	.64
Walk half a mile	3.1	47.2	34.6	15.1	-	-	-	2.25 (0.7)	156	.72
Walk 100 yards	5.0	13.2	41.5	40.3	-	-	-	1.67 (0.7)	156	.69
Bathing or dressing	3.1	4.4	25.8	66.7	-	-	-	2.28 (0.6)	156	.63
Reason	1.9	8.2	11.9	10.7	11.3	18.2	37.7	4.35 (1.7)	159	.81
Forget	0.0	5.7	10.7	15.1	20.1	14.5	34.0	4.29 (1.6)	159	.81
Concentration	0.0	6.3	13.2	9.4	17.6	17.0	36.5	4.35 (1.7)	159	.87
Worry heart condition	1.9	18.9	22.0	28.9	20.1	8.2	-	2.76 (1.2)	157	.78
Over-doing it	0.6	18.9	23.9	30.8	16.4	9.4	-	2.73 (1.2)	157	.79
Heart attack	1.3	13.8	10.1	30.2	18.2	26.4	-	3.34 (1.4)	157	.68
Frightened by pain	1.3	14.5	17.0	27.7	19.5	20.1	-	3.14 (1.3)	157	.79
Uncertain	1.9	27.0	17.6	20.8	17.0	15.7	-	2.76 (1.4)	157	.78
Depressed	1.3	7.5	11.9	27.0	22.0	30.2	-	3.56 (1.3)	157	.72
Frustrated	1.3	14.5	22.0	31.4	20.1	10.7	-	2.90 (1.2)	157	.65
Interfered with enjoyment	1.3	28.9	20.8	22.6	16.4	10.1	-	2.57 (1.3)	157	.78
Positive outlook	1.3	18.9	12.6	28.9	17.6	20.8	-	3.09 (1.4)	157	.81
Difficult to plan	1.3	30.2	17.6	19.5	13.8	17.6	-	2.71 (1.5)	157	.78
Family overprotective	1.3	10.1	20.8	23.9	23.3	20.8	-	3.24 (1.3)	157	.62
Feeling a burden	2.5	8.8	10.7	23.3	18.2	36.5	-	3.65 (1.3)	157	.70
Restricted in social activities	0.6	17.0	15.7	23.3	14.5	28.9	-	3.23 (1.5)	157	.74
Too far from home	0.6	19.5	12.6	18.9	15.7	32.7	-	3.30 (1.5)	157	.78

**TABLE 6.9a Item Descriptive Statistics: CROQ-CABG Post-Revascularisation (Final Field Test)**

Item	% missing data	Endorsement frequencies by response category %						Item-total correlation		
		1	2	3	4	5	6	Mean (SD)	n	r
Chest pain	2.7	0.5	1.4	2.7	10.8	81.9	-	4.77 (0.6)	410	.69
Chest discomfort	2.4	0.5	2.9	3.4	13.0	77.8	-	4.69 (0.7)	410	.71
Shortness of breath	1.7	4.1	9.2	12.8	38.1	34.2	-	3.91 (1.1)	410	.53
Radiating pain	3.1	1.7	3.6	3.6	13.5	74.5	-	4.60 (0.9)	410	.67
Palpitations	2.7	1.4	3.9	9.2	24.8	58.1	-	4.38 (0.9)	410	.38
Nitroglycerin Trouble	1.0	1.0	1.4	0.7	1.4	5.1	89.4	5.79 (0.8)	410	.57
	1.7	1.9	3.4	6.5	29.9	56.6	-	4.38 (0.9)	410	.69
Moderate activities	3.1	10.4	33.0	53.5	-	-	-	2.45 (0.7)	406	.64
Lifting & carrying	4.3	10.1	37.1	48.4	-	-	-	2.40 (0.7)	406	.68
Climbing flights of stairs	6.7	11.3	35.4	46.5	-	-	-	2.38 (0.7)	406	.72
Climbing one flight of stairs	4.3	3.1	15.2	77.3	-	-	-	2.78 (0.5)	406	.76
Bending, keeling, stooping	3.4	7.0	27.5	62.2	-	-	-	2.57 (0.6)	406	.66
Walk half a mile	4.1	8.0	17.1	70.8	-	-	-	2.66 (0.6)	406	.72
Walk 100 yards	3.4	3.6	10.4	82.7	-	-	-	2.82 (0.5)	406	.64
Bathing or dressing	2.4	2.9	10.6	84.1	-	-	-	2.93 (0.5)	406	.64
Reason	0.7	1.9	4.1	6.0	14.2	24.1	48.9	5.03 (1.3)	413	.74
Forget	0.2	1.9	4.8	8.7	18.6	28.4	37.3	4.79 (1.3)	413	.78
Concentration	0.7	1.9	4.3	5.5	16.9	29.6	41.0	4.92 (1.2)	413	.83
Worry heart condition	1.7	2.9	5.5	14.5	31.5	44.1	-	4.10 (1.0)	410	.77
Over-doing it	1.4	3.1	7.7	18.6	42.2	27.0	-	3.93 (1.0)	410	.74
Heart attack	1.2	2.7	1.9	10.1	14.2	69.9	-	4.49 (1.0)	410	.70
Frightened by pain	1.7	2.9	3.1	9.9	18.1	64.3	-	4.40 (1.0)	410	.78
Uncertain	2.4	4.8	4.6	13.0	25.3	49.9	-	4.14 (1.1)	410	.77
Depressed	1.9	2.9	3.4	14.2	21.0	56.6	-	4.28 (1.0)	410	.71
Frustrated	2.9	2.9	9.2	21.2	29.9	34.0	-	3.85 (1.1)	410	.69
Interfered with enjoyment	1.4	5.5	7.0	13.5	27.7	44.8	-	4.01 (1.2)	410	.80
Positive outlook	1.7	2.7	7.7	9.4	25.3	53.3	-	4.21 (1.1)	410	.84
Difficult to plan	1.7	7.0	7.2	14.7	20.2	49.2	-	3.99 (1.3)	410	.81
Family overprotective	2.2	1.7	10.8	24.8	38.8	21.7	-	3.69 (1.0)	410	.49
Feeling a burden	2.2	3.4	5.5	13.7	17.1	58.1	-	4.24 (1.1)	410	.72
Restricted in social activities	1.9	4.1	5.3	11.8	14.7	62.2	-	4.28 (1.1)	410	.75
Too far from home	1.7	4.1	5.5	9.6	18.1	61.0	-	4.28 (1.1)	410	.74

Item	% missing data	Endorsement frequencies by response category %						Item-total correlation		
		1	2	3	4	5	6	Mean (SD)	n	r
Pain in chest wound	0.7	4.1	8.9	9.9	29.2	47.2	-	4.07 (1.1)	411	.60
Infection in chest wound	1.2	2.4	1.0	0.7	5.8	88.9	-	4.80 (0.7)	411	.25
Tender chest wound	1.9	5.5	8.9	15.4	43.6	24.6	-	3.74 (1.1)	411	.56
Numb chest wound	2.2	6.5	9.9	11.3	32.3	37.8	-	3.87 (1.2)	411	.47
Bruising on chest	2.7	1.4	1.0	5.5	8.0	81.4	-	4.72 (0.8)	411	.53
Pain leg wound	2.9	5.1	7.2	11.1	25.5	48.2	-	4.08 (1.2)	411	.71
Other pain in leg	3.6	4.3	6.0	6.0	12.8	67.2	-	4.38 (1.1)	411	.67
Infection in leg wound	2.9	3.9	4.1	1.7	7.2	80.2	-	4.61 (1.0)	411	.41
Numb leg	1.7	8.7	10.1	14.7	30.1	34.7	-	3.73 (1.3)	411	.58
Bruising on leg	2.9	2.7	3.4	5.3	14.7	71.1	-	4.53 (1.0)	411	.53
Swollen feet	1.0	8.9	8.9	11.1	26.7	43.4	-	3.88 (1.3)	411	.46
Satisfied with results	0.5	1.7	1.7	13.3	82.9	-	-	3.78 (0.6)	414	.60
Satisfied with info about op	0.7	1.7	4.3	15.4	77.8	-	-	3.71 (0.6)	414	.52
Satisfied with recovery info	0.5	2.2	7.7	19.5	70.1	-	-	3.58 (0.7)	414	.57
Overall compared to before op	0.5	0.7	1.4	5.1	11.1	81.2	-	4.71 (0.7)	414	.48
Speed of recovery	0.0	17.3	28.4	32.0	22.2	-	-	2.59 (1.0)	414	.60
Expectation of results	1.4	7.0	41.9	49.6	-	-	-	2.43 (0.6)	414	.60
Symptoms return	1.4	4.1	2.2	18.6	29.2	44.6	-	4.10 (1.1)	-	-

**TABLE 6.9b Item Descriptive Statistics: CROQ-PTCA Post-Revascularisation (Final Field Test)**

Item	% missing data	Endorsement frequencies by response category %						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Chest pain	4.1	3.2	7.2	9.3	24.3	51.9	-	4.19 (1.1)	340	.86
Chest discomfort	4.3	2.9	9.9	9.9	30.7	42.3	-	4.04 (1.1)	340	.84
Shortness of breath	2.9	7.2	12.2	16.5	35.1	26.1	-	3.62 (1.2)	340	.63
Radiating pain	4.1	3.2	7.0	10.1	21.4	54.2	-	4.21 (1.1)	340	.72
Palpitations	3.2	1.7	5.2	5.5	27.5	56.8	-	4.37 (0.9)	340	.51
Nitroglycerin Trouble	1.7	0.9	7.5	10.1	5.8	19.4	54.5	5.02 (1.4)	340	.74
Trouble	2.3	3.2	5.2	17.4	32.8	39.1	-	4.02 (1.0)	340	.82
Moderate activities	5.8	14.8	34.5	44.9	-	-	-	2.32 (0.7)	327	.80
Lifting & carrying	7.0	15.7	33.0	44.3	-	-	-	2.31 (0.7)	327	.77
Climbing flights of stairs	7.0	26.1	34.8	32.2	-	-	-	2.07 (0.8)	327	.78
Climbing one flight of stairs	6.4	6.7	29.0	58.0	-	-	-	2.55 (0.6)	327	.79
Bending, keeling, stooping	4.9	10.7	29.6	54.8	-	-	-	2.46 (0.7)	327	.68
Walk half a mile	5.2	18.6	28.7	47.5	-	-	-	2.31 (0.8)	327	.79
Walk 100 yards	6.7	7.8	18.6	67.0	-	-	-	2.63 (0.6)	327	.73
Bathing or dressing	4.6	3.2	18.8	73.3	-	-	-	2.74 (0.5)	327	.68
Reason	3.2	3.8	6.1	8.1	11.9	15.9	51.0	4.89 (1.5)	336	.81
Forget	2.3	4.9	6.1	9.6	13.9	24.3	38.8	4.67 (1.5)	336	.84
Concentration	2.3	4.6	5.5	8.1	13.6	18.3	47.5	4.82 (1.5)	336	.89
Worry heart condition	3.2	7.5	10.1	25.2	33.6	20.3	-	3.51 (1.2)	333	.81
Over-doing it	3.5	5.8	13.0	24.9	26.1	26.7	-	3.57 (1.2)	333	.78
Heart attack	3.5	6.4	7.2	22.6	19.1	41.2	-	3.84 (1.2)	333	.74
Frightened by pain	3.8	8.1	7.5	15.1	23.5	42.0	-	3.87 (1.3)	333	.81
Uncertain	3.2	11.9	12.5	17.4	27.0	28.1	-	3.49 (1.4)	333	.84
Depressed	3.5	4.6	6.1	18.3	22.3	45.2	-	4.01 (1.2)	333	.71
Frustrated	4.3	9.0	9.9	22.0	21.4	33.3	-	3.63 (1.3)	333	.77
Interfered with enjoyment	3.8	10.1	11.9	20.6	22.3	31.3	-	3.55 (1.3)	333	.83
Positive outlook	3.8	5.8	12.2	21.4	24.1	32.8	-	3.68 (1.2)	333	.83
Difficult to plan	2.9	8.7	16.2	13.6	19.1	39.4	-	3.66 (1.4)	333	.83
Family overprotective	4.1	5.8	8.1	26.1	27.2	28.7	-	3.68 (1.2)	333	.56
Feeling a burden	3.5	3.5	4.6	13.9	18.0	56.5	-	4.24 (1.1)	333	.68
Restricted in social activities	4.3	4.6	5.5	15.7	16.2	53.6	-	4.13 (1.2)	333	.78
Too far from home	3.5	7.2	8.7	12.2	22.9	45.5	-	3.94 (1.3)	333	.76

Item	% missing data	Endorsement frequencies by response category %						Item-total correlation		
		1	2	3	4	5	6	Mean (SD)	n	r
Pain in groin wound	3.5	1.2	1.7	3.5	10.4	79.7	-	4.72 (0.7)	330	.76
Tender groin wound	4.3	1.2	2.0	4.1	12.8	75.7	-	4.67 (0.8)	330	.78
Numb groin	4.6	2.0	0.9	1.2	6.1	85.2	-	4.80 (0.7)	330	.59
Bruised groin wound	4.9	2.9	2.9	4.3	11.0	73.9	-	4.58 (0.9)	330	.54
Problems from catheter	4.9	1.4	1.4	1.7	5.2	85.2	-	4.80 (0.7)	330	.71
Concern over bruises	3.8	1.2	0.6	0.3	3.8	90.4	-	4.89 (0.5)	330	.61
Satisfied with results	2.0	5.2	7.8	20.0	64.9		-	3.48 (0.9)	340	.70
Satisfied with info about op	2.9	2.3	7.8	14.2	72.8		-	3.62 (0.7)	340	.54
Satisfied with recovery info	2.6	4.9	12.5	22.6	57.4		-	3.36 (0.9)	340	.53
Overall compared to before op	2.0	2.9	4.1	12.5	14.8	63.8	-	4.35 (1.0)	340	.58
Speed of recovery	3.2	13.9	24.9	20.9	37.1	-	-	2.84 (1.1)	340	.62
Expectation of results	3.2	15.4	39.7	41.7	-	-	-	2.27 (0.7)	340	.62
Symptoms return	3.8	9.6	13.0	26.1	30.7	16.8	-	3.33 (1.2)	-	-

**TABLE 6.10 Scale Descriptive Statistics: CROQ Pre-Revascularisation (Final Field Test)**

CROQ scale	% missing	Range of scores		Mean	SD	Skewness	% floor	% ceiling
		Scale	Sample					
<b>CROQ-CABG (N=281)</b>								
Symptoms	1	0-100	0-100	51.14	24.6	.088	1	4
Physical Functioning	2	0-100	0-100	51.55	26.7	.133	3	5
Psychosocial Functioning	1	0-100	0-100	50.52	24.3	-.010	1	1
Cognitive Functioning	0	0-100	0-100	65.08	28.9	-.525	2	18
<i>Core Total</i>	1	-	35-65	50.00	6.6	-.008	1	1
<b>CROQ-PTCA (N=159)</b>								
Symptoms	0	0-100	0-100	51.34	24.7	.046	1	2
Physical Functioning	2	0-100	0-100	51.48	28.0	.075	3	7
Psychosocial Functioning	1	0-100	0-100	51.78	26.3	-.037	1	1
Cognitive Functioning	0	0-100	0-100	66.33	30.7	-.597	3	21
<i>Core Total</i>	1	-	37-63	49.92	7.0	-.025	1	1

**TABLE 6.11 Scale Descriptive Statistics: CROQ Post-Revascularisation (Final Field Test)**

CROQ Scale	% missing	Range of scores		Mean	SD	Skewness	% floor	% ceiling
		Scale	Sample					
<b>CROQ-CABG (N=415)</b>								
Symptoms	1	0-100	9-100	87.57	14.9	-2.16	0	21
Physical Functioning	2	0-100	0-100	80.27	22.7	-1.53	1	28
Psychosocial Functioning	1	0-100	1-100	78.14	21.0	-1.45	0	28
Cognitive Functioning	1	0-100	0-100	78.27	22.6	-1.23	1	5
<i>Core Total</i>	1	-	21-57	49.95	6.6	-1.63	1	29
Complications	1	0-100	4-100	80.36	16.9	-1.46	0	4
Satisfaction	1	0-100	11-100	83.12	18.0	-1.33	0	1
<i>Total Outcome</i>	1	-	25-57	49.98	5.5	-1.58	1	1
<b>CROQ-PTCA (N=345)</b>								
Symptoms	1	0-100	0-100	77.02	22.1	-1.17	1	13
Physical Functioning	5	0-100	0-100	71.22	28.1	-0.75	1	24
Psychosocial Functioning	4	0-100	1-100	69.24	24.9	-0.71	0	7
Cognitive Functioning	3	0-100	0-100	75.91	27.6	-1.18	2	30
<i>Core Total</i>	3	-	29-59	49.98	7.03	-0.83	1	1
Complications	4	0-100	0-100	93.54	14.08	-3.49	1	62
Satisfaction	1	0-100	0-100	76.77	21.99	-1.02	1	21
<i>Total Outcome</i>	2	-	13-56	49.97	5.92	-2.38	1	3

TABLE 6.12 Reliability: CROQ Pre-Revascularisation (Final Field Test)

TABLE 6.12 Reliability: CROQ Pre-Revascularisation (Final Field Test)

CROQ scale	Internal consistency			Cronbach's alpha
	Item-total correlation range (mean)	Inter-item correlation range (mean)	N	
<b>CROQ-CABG (N=281)</b>				
Symptoms (7 items)	.46-.82 (.67)	.29-.87 (.52)	279	.88
Physical Functioning (8 items)	.57-.75 (.68)	.31-.70 (.52)	275	.90
Psychosocial Functioning (14 items)	.54-.81 (.72)	.29-.77 (.56)	279	.95
Cognitive Functioning (3 items)	.81-.86 (.83)	.73-.80 (.78)	281	.91
<i>Core Total (32 items)</i>	.44-.75 (.61)	.10-.86 (.39)	232	.95
<b>CROQ-PTCA (N=159)</b>				
Symptoms (7 items)	.50-.83 (.69)	.22-.79 (.54)	159	.89
Physical Functioning (8 items)	.62-.78 (.70)	.38-.73 (.55)	156	.91
Psychosocial Functioning (14 items)	.62-.81 (.74)	.38-.76 (.58)	157	.95
Cognitive Functioning (3 items)	.81-.87 (.83)	.73-.81 (.79)	159	.92
<i>Core Total (32 items)</i>	.50-.77 (.67)	.13-.81 (.47)	130	.97

**TABLE 6.13 Reliability: CROQ Post-Revascularisation (Final Field Test)**

CROQ Scale	Internal consistency			Test-retest sample		
	Item-total correlation range (mean)	Inter-item correlation range (mean)	N	Cronbach's alpha	N	ICC <sup>1</sup>
<b>CROQ-CABG (N=415)</b>						
Symptoms (7 items)	.38-.71 (.61)	.19-.84 (.45)	410	.85	50	.90
Physical Functioning (8 items)	.64-.76 (.68)	.38-.70 (.53)	406	.90	49	.93
Psychosocial Functioning (14 items)	.49-.84 (.74)	.32-.79 (.57)	410	.95	49	.92
Cognitive Functioning (3 items)	.74-.83 (.78)	.67-.79 (.73)	413	.89	49	.80
Core Total (32 items)	.41-.78 (.63)	.13-.84 (.41)	333	.96	49	.95
Complications (11 items)	.25-.71 (.52)	.05-.75 (.33)	411	.84	50	.83
Satisfaction (6 items)	.48-.60 (.56)	.19-.69 (.41)	414	.81	50	.90
<i>Total Outcome (18 items)</i>	.19-.64 (.49)	.01-.75 (.28)	288	.88	50	.90
<b>CROQ-PTCA (N=345)</b>						
Symptoms (7 items)	.51-.86 (.73)	.36-.89 (.59)	340	.91	46	.84
Physical Functioning (8 items)	.68-.80 (.75)	.48-.74 (.62)	327	.93	42	.91
Psychosocial Functioning (14 items)	.56-.84 (.77)	.33-.80 (.61)	333	.96	44	.93
Cognitive Functioning (3 items)	.81-.89 (.84)	.74-.85 (.80)	336	.92	47	.86
<i>Core Total (32 items)</i>	.47-.81 (.69)	.22-.87 (.48)	260	.97	44	.93
Complications (6 items)	.54-.78 (.66)	.31-.80 (.52)	330	.87	46	.86
Satisfaction (6 items)	.53-.70 (.60)	.23-.73 (.45)	340	.83	47	.91
<i>Total Outcome (13 items)</i>	.36-.63 (.53)	.02-.76 (.33)	184	.86	46	.93

<sup>1</sup> ICC: Intraclass correlation coefficient.

**TABLE 6.14a Item Convergent and Discriminant Correlations: CROQ-CABG Pre-Revascularisation (Final Field Test)**

CROQ-CABG scale	CROQ-CABG item	CROQ-CABG scale			
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning
Symptoms	Chest pain	.83	.56	.48	.30
	Chest discomfort	.82	.59	.50	.33
	Shortness of breath	.55	<b>.59<sup>2</sup></b>	<b>.44</b>	.39
	Radiating pain	.64	<b>.54<sup>1</sup></b>	.47	.31
	Palpitations	.46	<b>.35</b>	<b>.41</b>	.29
	Nitroglycerin	.63	.47	.35	.17
	Trouble	.77	<b>.68</b>	.57	.39
Physical Functioning	Moderate activities	<b>.58</b>	.69	.54	.35
	Lifting & carrying	.57	.69	.47	.32
	Climbing flights of stairs	.56	.73	.46	.35
	Climbing one flight of stairs	.55	.75	.45	.33
	Bending, keeling, stooping	.43	.57	<b>.46</b>	.30
	Walk half a mile	<b>.58</b>	.67	.50	.36
	Walk 100 yards	.53	.68	.49	.31
	Bathing or dressing	<b>.54</b>	.62	.49	.35
Psychosocial Functioning	Worry heart condition	.48	.45	<b>.81</b>	.41
	Over-doing it	.50	.53	<b>.78</b>	.40
	Heart attack	.41	.35	<b>.72</b>	.38
	Frightened by pain	.57	.56	<b>.78</b>	.44
	Uncertain	.34	.32	<b>.73</b>	.45
	Depressed	.39	.33	<b>.66</b>	<b>.55</b>
	Frustrated	.46	.49	<b>.71</b>	.47
	Interfered with enjoyment	.51	.54	<b>.78</b>	.50
	Positive outlook	.42	.41	<b>.76</b>	.52
	Difficult to plan	.37	.42	<b>.65</b>	.44
	Family overprotective	<b>.43</b>	<b>.49</b>	<b>.54</b>	.39
	Feeling a burden	.50	<b>.60</b>	<b>.70</b>	.45
	Restricted in social activities	.54	.63	<b>.75</b>	.45
Too far from home	.52	.59	<b>.76</b>	.43	
Cognitive Functioning	Reason	.39	.42	.61	<b>.81</b>
	Forget	.40	.41	.49	<b>.81</b>
	Concentration	.34	.39	.53	<b>.86</b>

<sup>1</sup> Values in bold indicate probable scaling successes. <sup>2</sup> Values in bold and underlined indicate probable scaling failures.

**TABLE 6.14b Item Convergent and Discriminant Correlations: CROQ-PTCA Pre-Revascularisation (Final Field Test)**

CROQ-PTCA scale	CROQ-PTCA item	CROQ-PTCA scale			
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning
Symptoms	Chest pain	.79	.56	.51	.42
	Chest discomfort	.83	.60	.58	.45
	Shortness of breath	.54	<u>.62</u> <sup>2</sup>	.50	.36
	Radiating pain	.74	.59	.54	.45
	Palpitations	.50	<u>.48</u> <sup>1</sup>	<u>.51</u>	.40
	Nitroglycerin	.61	.48	.45	.30
	Trouble	.82	.72	.65	.41
Physical Functioning	Moderate activities	.63	.74	.62	.43
	Lifting & carrying	.62	.78	.65	.44
	Climbing flights of stairs	.64	.68	.55	.36
	Climbing one flight of stairs	.59	.75	.57	.47
	Bending, keeling, stooping	.44	.64	.48	.40
	Walk half a mile	.59	.72	.56	.38
	Walk 100 yards	.58	.69	.55	.40
	Bathing or dressing	.54	.63	.58	.39
Psychosocial Functioning	Worry heart condition	.54	.54	.78	.51
	Over-doing it	.58	.59	.79	.48
	Heart attack	.50	.46	.68	.44
	Frightened by pain	.66	.59	.79	.54
	Uncertain	.51	.52	.78	.49
	Depressed	.50	.55	.72	.57
	Frustrated	.45	.51	.65	.46
	Interfered with enjoyment	.54	.62	.78	.51
	Positive outlook	.52	.62	.81	.57
	Difficult to plan	.53	.61	.78	.57
	Family overprotective	.42	.46	.62	.37
	Feeling a burden	.56	.59	.70	.44
Restricted in social activities	.62	.71	.74	.48	
Too far from home	.59	.63	.78	.47	
Cognitive Functioning	Reason	.49	.47	.62	.81
	Forget	.46	.50	.54	.81
	Concentration	.47	.47	.58	.87

<sup>1</sup> Values in bold indicate probable scaling successes. <sup>2</sup> Values in bold and underlined indicate probable scaling failures.

**TABLE 6.15a Item Convergent and Discriminant Correlations: CROQ-CABG Post-Revascularisation (Final Field Test)**

CROQ-CABG scale	CROQ-CABG item	CROQ-CABG scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Symptoms	Chest pain	.69	.38	.42	.32	.36	.30
	Chest discomfort	.71	.42	.45	.35	.38	.33
	Shortness of breath	.53	.58 <sup>2</sup>	.47 <sup>1</sup>	.35	.41	.43
	Radiating pain	.67	.47	.44	.28	.38	.33
	Palpitations	.38	.30	.35	.24	.33	.29
	Nitroglycerin	.57	.38	.34	.28	.26	.26
	Trouble	.69	.60	.62	.38	.50	.54
Physical Functioning	Moderate activities	.51	.64	.54	.34	.41	.42
	Lifting & carrying	.45	.68	.50	.33	.35	.35
	Climbing flights of stairs	.51	.72	.48	.34	.39	.39
	Climbing one flight of stairs	.49	.76	.50	.37	.32	.30
	Bending, kneeling, stooping	.50	.66	.45	.37	.41	.37
	Walk half a mile	.51	.72	.50	.37	.43	.40
	Walk 100 yards	.44	.64	.42	.31	.36	.28
	Bathing or dressing	.46	.64	.46	.38	.37	.33
Psychosocial Functioning	Worry heart condition	.52	.45	.77	.50	.47	.43
	Over-doing it	.47	.47	.74	.52	.44	.37
	Heart attack	.45	.36	.70	.52	.40	.30
	Frightened by pain	.58	.49	.78	.51	.52	.47
	Uncertain	.42	.40	.77	.54	.42	.35
	Depressed	.39	.47	.71	.53	.45	.38
	Frustrated	.45	.45	.69	.54	.48	.44
	Interfered with enjoyment	.54	.53	.80	.56	.55	.51
	Positive outlook	.53	.48	.84	.60	.55	.46
	Difficult to plan	.51	.53	.81	.57	.54	.48
	Family overprotective	.28	.36	.49	.44	.33	.15
	Feeling a burden	.49	.55	.72	.54	.45	.38
Restricted in social activities	.55	.65	.75	.55	.50	.45	
Too far from home	.54	.64	.74	.52	.46	.39	
Cognitive Functioning	Reason	.42	.42	.66	.74	.37	.31
	Forget	.36	.39	.54	.78	.40	.18
	Concentration	.42	.45	.67	.83	.44	.28

CROQ-CABG scale	CROQ-CABG item	CROQ-CABG scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Complications	Pain in chest wound	.44	.37	<b>.53</b>	.36	<b>.58</b>	.34
	Infection in chest wound	<b>.21</b>	<b>.22</b>	<b>.22</b>	<b>.25</b>	.25	.10
	Tender chest wound	.41	.35	.49	.38	<b>.56</b>	.33
	Numb chest wound	.32	.23	<b>.38</b>	.29	<b>.47</b>	.17
	Bruising on chest	.37	.30	.40	.32	<b>.53</b>	.30
	Pain leg wound	.39	.42	.47	.32	<b>.71</b>	.34
	Other pain in leg	.39	.39	.48	.36	<b>.67</b>	.36
	Infection in leg wound	.22	.23	.21	.14	<b>.41</b>	.22
	Numb leg	.32	.37	.44	.28	<b>.58</b>	.30
	Bruising on leg	.31	.33	.32	.24	<b>.53</b>	.30
Swollen feet	.23	.25	.24	.16	<b>.56</b>	.21	
Satisfaction	Satisfied with results	.47	.42	.44	.21	.36	<b>.60</b>
	Satisfied with info about op	.21	.26	.33	.19	.27	<b>.52</b>
	Satisfied with recovery info	.21	.28	.34	.15	.25	<b>.57</b>
	Overall	<b>.46</b>	.34	.33	.19	.25	<b>.48</b>
	Speed of recovery	.40	.40	.41	.26	.37	<b>.60</b>
	Expectation of results	.42	.34	.36	.20	.31	<b>.60</b>

<sup>1</sup> Values in bold indicate probable scaling successes. <sup>2</sup> Values in bold and underlined indicate probable scaling failures.

**TABLE 6.15b Item Convergent and Discriminant Correlations: CROQ-PTCA Post-Revascularisation (Final Field Test)**

CROQ-PTCA scale	CROQ-PTCA item	CROQ-PTCA scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Symptoms	Chest pain	.86	.59	.56	.41	.25	.49
	Chest discomfort	.84	.55	.52	.36	.24	.52
	Shortness of breath	.63	.65 <sup>2</sup>	.48	.36	.25	.38
	Radiating pain	.72	.52	.51	.37	.29	.45
	Palpitations	.51	.41 <sup>1</sup>	.40	.26	.24	.28
	Nitroglycerin	.74	.54	.47	.33	.20	.40
	Trouble	.82	.68	.63	.43	.28	.57
Physical Functioning	Moderate activities	.64	.80	.62	.43	.18	.36
	Lifting & carrying	.61	.77	.61	.42	.20	.36
	Climbing flights of stairs	.55	.78	.55	.44	.15	.34
	Climbing one flight of stairs	.57	.79	.55	.39	.13	.30
	Bending, kneeling, stooping	.51	.68	.50	.42	.27	.33
	Walk half a mile	.64	.79	.54	.37	.18	.37
	Walk 100 yards	.56	.73	.51	.35	.15	.34
Bathing or dressing	.51	.68	.51	.31	.22	.29	
Psychosocial Functioning	Worry heart condition	.54	.51	.81	.49	.26	.39
	Over-doing it	.51	.53	.78	.49	.24	.32
	Heart attack	.44	.41	.74	.46	.22	.32
	Frightened by pain	.61	.59	.81	.53	.27	.45
	Uncertain	.51	.47	.84	.50	.29	.38
	Depressed	.41	.42	.71	.52	.19	.38
	Frustrated	.53	.57	.77	.56	.29	.37
	Interfered with enjoyment	.59	.62	.83	.61	.32	.47
	Positive outlook	.53	.55	.83	.56	.30	.43
	Difficult to plan	.53	.60	.83	.60	.31	.39
	Family overprotective	.36	.45	.56	.33	.25	.29
	Feeling a burden	.46	.54	.68	.42	.23	.34
Restricted in social activities	.58	.68	.78	.54	.31	.46	
Too far from home	.51	.63	.76	.57	.35	.37	
Cognitive Functioning	Reason	.43	.45	.66	.81	.34	.32
	Forget	.39	.42	.52	.84	.36	.25
	Concentration	.43	.47	.61	.89	.34	.30

CROQ-PTCA scale	CROQ-PTCA item	CROQ-PTCA scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Complications	Pain in groin wound	.24	.19	.28	.30	.76	.18
	Tender groin wound	.31	.21	.32	.31	.78	.24
	Numb groin	.32	.22	.34	.31	.59	.28
	Bruised groin wound	.17	.12	.20	.29	.54	.17
	Problems from catheter	.17	.14	.19	.23	.71	.19
	Concern over bruises	.25	.15	.28	.30	.61	.25
Satisfaction	Satisfied with results	.58	.41	.41	.29	.25	.70
	Satisfied with info about op	.21	.22	.27	.14	.17	.54
	Satisfied with recovery info	.17	.13	.26	.11	.19	.53
	Overall	.57	.37	.40	.25	.25	.58
	Speed of recovery	.40	.29	.34	.25	.21	.62
	Expectation of results	.49	.43	.43	.31	.18	.62

<sup>1</sup> Values in bold indicate probable scaling successes. <sup>2</sup> Values in bold and underlined indicate probable scaling failures.

**TABLE 6.16 Intercorrelations Between Scales: CROQ Pre-Revascularisation (Final Field Test)**

CROQ scale	CROQ scale			
	Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning
<b>CROQ-CABG (N=281)</b>				
Symptoms	(.88) <sup>1</sup>	-	-	-
Physical Functioning	.71	(.90)	-	-
Psychosocial Functioning	.60	.63	(.95)	-
Cognitive Functioning	.41	.44	.59	(.91)
<i>Core Total</i>	.81	.84	.92	.67
<b>CROQ-PTCA (N=159)</b>				
Symptoms	(.89)	-	-	-
Physical Functioning	.74	(.91)	-	-
Psychosocial Functioning	.69	.73	(.95)	-
Cognitive Functioning	.51	.52	.63	(.92)
<i>Core Total</i>	.85	.88	.94	.70

<sup>1</sup> Values in brackets indicate Cronbach's alpha coefficient.

**TABLE 6.17 Intercorrelations Between Scales: CROQ Post-Revascularisation (Final Field Test)**

CROQ scale	CROQ scale						
	Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Core Total	Satisfaction	Complications
<b>CROQ-CABG (N=415)</b>							
Symptoms	(.85)	-	-	-	-	-	-
Physical Functioning	.63	(.90)	-	-	-	-	-
Psychosocial Functioning	.62	.63	(.95)	-	-	-	-
Cognitive Functioning	.44	.46	.69	(.89)	-	-	-
Core Total	.79	.82	.94	.73	(.96)	-	-
Satisfaction	.50	.47	.51	.28	.55	(.81)	-
Complications	.52	.50	.61	.44	.63	.43	(.84)
Total Outcome	.63	.58	.71	.48	.74	.74	.91
<b>CROQ-PTCA (N=345)</b>							
Symptoms	(.91)	-	-	-	-	-	-
Physical Functioning	.71	(.93)	-	-	-	-	-
Psychosocial Functioning	.63	.67	(.96)	-	-	-	-
Cognitive Functioning	.45	.48	.64	(.92)	-	-	-
Core Total	.82	.86	.93	.69	(.97)	-	-
Satisfaction	.55	.42	.48	.31	.53	(.83)	-
Complications	.31	.23	.34	.37	.36	.28	(.87)
Total Outcome	.56	.45	.60	.47	.63	.77	.82

<sup>1</sup> Values in brackets indicate Cronbach's alpha coefficient.

**TABLE 6.18a Principal Axis Factor Analysis: CROQ-CABG Core Items Pre-Revascularisation (Final Field Test)**

CROQ-CABG item	Factor			
	1	2	3	4
Chest pain	.19	.28	<b>.89</b>	.08
Chest discomfort	.20	.33	<b>.81</b>	.11
Shortness of breath <sup>1</sup>	.15	<b>.48</b>	<b>.34</b>	.25
Radiating pain	.23	<b>.37</b> <sup>2</sup>	<b>.50</b>	.13
Palpitations	.27	.21	<b>.29</b>	.16
Nitroglycerin	.15	.28	<b>.63</b>	-.01
Trouble	.26	<b>.49</b>	<b>.60</b>	.16
Moderate activities	.25	<b>.67</b>	.23	.12
Lifting & carrying	.16	<b>.68</b>	.24	.09
Climbing flights of stairs	.13	.72	.24	.13
Climbing one flight of stairs	.13	.73	.22	.11
Bending, keeling, stooping	.24	.57	.10	.10
Walk half a mile	.22	.59	.33	.15
Walk 100 yards	.22	.62	.26	.08
Bathing or dressing	.24	.54	.27	.14
Reason	.40	.20	.11	.73
Forget	.23	.21	.17	.76
Concentration	.26	.21	.04	.89
Worry heart condition	.82	.18	.21	.06
Over-doing it	.72	.31	.23	.05
Heart attack	.77	.08	.22	.06
Frightened by pain	.70	.31	.28	.12
Uncertain	.79	.05	.09	.18
Depressed	.62	.10	.10	.38
Frustrated	.59	.31	.14	.24
Interfered with enjoyment	.67	.35	.17	.22
Positive outlook	.73	.16	.12	.28
Difficult to plan	.56	.28	.07	.23
Family overprotective <sup>1</sup>	<b>.38</b>	<b>.40</b>	.14	.19
Feeling a burden	.52	<b>.51</b>	.09	.22
Restricted in social activities	.56	<b>.52</b>	.15	.16
Too far from home	.63	<b>.44</b>	.17	.11

<sup>1</sup> Item loads higher on the 'wrong factor'. <sup>2</sup> Values in bold indicate items crossloading on more than one factor with a difference < .20.

**TABLE 6.18b Principal Axis Factor Analysis: CROQ-PTCA Core Items Pre-Revascularisation (Final Field Test)**

CROQ-PTCA item	Factor			
	1	2	3	4
Chest pain	.20	.20	.85	.16
Chest discomfort	.26	.34	.72	.17
Shortness of breath <sup>1</sup>	.21	.53	.32	.15
Radiating pain	.23	.34	.60	.21
Palpitations	.34	.27	.32	.18
Nitroglycerin	.21	.22	.63	.05
Trouble	.32	<b>.48</b> <sup>2</sup>	<b>.67</b>	.08
Moderate activities	.28	.69	.27	.14
Lifting & carrying	.33	.69	.26	.14
Climbing flights of stairs	.23	.59	.38	.09
Climbing one flight of stairs	.25	.63	.28	.22
Bending, kneeling, stooping	.17	.65	.08	.22
Walk half a mile	.25	.57	.37	.10
Walk 100 yards	.27	.52	.36	.14
Bathing or dressing	.35	<b>.48</b>	.25	.14
Reason	.40	.17	.20	.72
Forget	.24	.28	.15	.77
Concentration	.30	.19	.17	.85
Worry heart condition	.74	.18	.27	.18
Over-doing it	.73	.24	.32	.12
Heart attack	.69	.08	.29	.15
Frightened by pain	.71	.20	.40	.20
Uncertain	.73	.22	.19	.20
Depressed	.59	.33	.09	.34
Frustrated	.53	.30	.13	.24
Interfered with enjoyment	.62	<b>.43</b>	.16	.21
Positive outlook	.71	.33	.13	.28
Difficult to plan	.62	.42	.12	.28
Family overprotective	.52	.31	.16	.08
Feeling a burden	.53	<b>.46</b>	.20	.12
Restricted in social activities <sup>1</sup>	.49	.62	.19	.14
Too far from home	.64	.44	.21	.10

<sup>1</sup> Item loads higher on the 'wrong factor'. <sup>2</sup> Values in bold indicate items crossloading on more than one factor with a difference <.20.

**TABLE 6.19a Principal Axis Factor Analysis: CROQ-CABG Core Items Post-Revascularisation (Final Field Test)**

CROQ-CABG item	Factor			
	1	2	3	4
Chest pain	.17	.16	.85	.12
Chest discomfort	.22	.19	.83	.12
Shortness of breath <sup>1</sup>	.29	.50	.27	.09
Radiating pain	.19	.30	.67	.07
Palpitations	.33	.19	.20	.02
Nitroglycerin	.14	.24	.59	1.0
Trouble <sup>1</sup>	<b>.50</b> <sup>2</sup>	<b>.42</b>	<b>.43</b>	.02
Moderate activities	.37	.56	.19	.04
Lifting & carrying	.30	.63	.09	.03
Climbing flights of stairs	.20	.71	.15	.09
Climbing one flight of stairs	.14	.79	.11	.18
Bending, keeling, stooping	.16	.64	.19	.16
Walk half a mile	.21	.70	.18	.14
Walk 100 yards	.13	.63	.18	.14
Bathing or dressing	.13	.64	.16	.21
Reason	.43	.21	.15	.64
Forget	.29	.17	.13	.73
Concentration	.40	.22	.12	.77
Worry heart condition	.79	.17	.19	.12
Over-doing it	.69	.22	.15	.19
Heart attack	.70	.08	.18	.20
Frightened by pain	.75	.23	.25	.13
Uncertain	.77	.13	.08	.24
Depressed	.59	.29	.06	.29
Frustrated	.55	.29	.11	.32
Interfered with enjoyment	.69	.31	.18	.24
Positive outlook	.79	.22	.17	.26
Difficult to plan	.71	.32	.13	.25
Family overprotective <sup>3</sup>	.33	.23	.05	.35
Feeling a burden	<b>.48</b>	<b>.41</b>	.15	<b>.35</b>
Restricted in social activities <sup>1</sup>	<b>.48</b>	<b>.53</b>	.20	.32
Too far from home	<b>.52</b>	<b>.49</b>	.20	.24

<sup>1</sup> Item loads higher on the 'wrong factor'. <sup>2</sup> Values in bold indicate items crossloading on more than one factor with a difference <.20. <sup>3</sup> Item doesn't load on a factor >.35.

**TABLE 6.19b Principal Axis Factor Analysis: CROQ-PTCA Core Items Post-Revascularisation (Final Field Test)**

CROQ-PTCA item	Factor			
	1	2	3	4
Chest pain	.26	.27	.85	.14
Chest discomfort	.21	.25	.85	.12
Shortness of breath <sup>1</sup>	.19	<b>.52<sup>2</sup></b>	<b>.42</b>	.13
Radiating pain	.26	.27	.61	.13
Palpitations	.24	.26	.39	.03
Nitroglycerin	.19	.29	.70	.08
Trouble	.35	.43	.67	.11
Moderate activities	.30	.72	.29	.14
Lifting & carrying	.32	.68	.27	.12
Climbing flights of stairs	.24	.74	.19	.20
Climbing one flight of stairs	.22	.75	.22	.14
Bending, keeling, stooping	.22	.63	.18	.21
Walk half a mile	.21	.71	.35	.08
Walk 100 yards	.23	.66	.28	.07
Bathing or dressing	.26	.63	.20	.04
Reason	.48	.18	.15	.69
Forget	.28	.20	.12	.81
Concentration	.36	.21	.16	.83
Worry heart condition	.79	.21	.27	.11
Over-doing it	.71	.27	.22	.13
Heart attack	.76	.12	.20	.11
Frightened by pain	.70	.27	.35	.16
Uncertain	.84	.14	.22	.14
Depressed	.66	.19	.13	.25
Frustrated	.65	.32	.22	.24
Interfered with enjoyment	.69	.33	.25	.29
Positive outlook	.76	.25	.22	.21
Difficult to plan	.71	.33	.17	.30
Family overprotective	.47	.32	.10	.08
Feeling a burden	.55	.37	.15	.15
Restricted in social activities	.59	.48	.22	.23
Too far from home	.59	.44	.16	.28

<sup>1</sup> Item loads higher on the 'wrong factor'. <sup>2</sup> Values in bold indicate items crossloading on more than one factor with a difference <.20.

**TABLE 6.20a Principal Axis Factor Analysis: CROQ-CABG Post-Revascularisation  
Outcome Only Items (Final Field Test)**

CROQ-CABG item	Factor	
	1	2
Satisfied with results	.24	.65
Satisfied with info about op	.13	.59
Satisfied with recovery info	.09	.68
Overall	.16	.51
Speed of recovery	.23	.62
Expectation of results	.17	.63
Symptoms return	.40	.23
Pain in chest wound	.61	.24
Infection in chest wound <sup>1</sup>	.28	.05
Tender chest wound	.56	.22
Numb chest wound	.51	.08
Bruising on chest	.55	.19
Pain leg wound	.76	.17
Other pain in leg	.71	.22
Infection in leg wound	.44	.13
Numb leg	.63	.15
Bruising on leg	.55	.19
Swollen feet	.49	.08

<sup>1</sup> Item doesn't load on a factor >.35.

**TABLE 6.20b Principal Axis Factor Analysis: CROQ-PTCA Post-Revascularisation  
Outcome Only Items (Final Field Test)**

CROQ-PTCA item	Factor	
	1	2
Satisfied with results	.11	.79
Satisfied with info about op	.11	.59
Satisfied with recovery info	.13	.57
Overall	.16	.65
Speed of recovery	.09	.68
Expectation of results	.04	.72
Symptoms return	.19	.39
Pain in groin wound	.86	.07
Tender groin wound	.84	.13
Numb groin	.61	.22
Bruised groin wound	.53	.10
Problems from catheter	.74	.07
Concern over bruises	.61	.20

**TABLE 6.21 Known Group Differences: CROQ Global Improvement Post-Revascularisation (Final Field Test)**

Scale	Mean scores		p
	Improved (n) <sup>1</sup>	Unimproved (n) <sup>2</sup>	
<b>CROQ-CABG (N=415)</b>			
Symptoms	89.05 (378)	68.41 (30)	.000
Physical Functioning	81.23 (375)	68.34 (30)	.039
Psychosocial Functioning	78.99 (378)	67.03 (30)	.020
Cognitive Functioning	78.69 (381)	72.00 (30)	.251
<i>Core Total</i>	50.34 (378)	44.84 (30)	.004
Complications	81.00 (379)	72.08 (30)	.057
Satisfaction	85.42 (382)	53.94 (30)	.000
<i>Total Outcome</i>	50.48 (379)	43.63 (30)	.000
<b>CROQ-PTCA (N=345)</b>			
Symptoms	81.98 (267)	56.65 (67)	.000
Physical Functioning	74.90 (257)	55.51 (64)	.000
Psychosocial Functioning	73.32 (261)	52.47 (66)	.000
Cognitive Functioning	78.62 (266)	64.78 (67)	.003
<i>Core Total</i>	51.29 (262)	44.56 (66)	.000
Complications	95.15 (259)	87.45 (67)	.008
Satisfaction	83.09 (270)	50.86 (66)	.000
<i>Total Outcome</i>	51.45 (266)	44.10 (67)	.000

<sup>1</sup> Patients who reported global improvement in heart condition at 3-months post-revascularisation (scored 4 "a little better", or 5 "much better" on Q12).

<sup>2</sup> Patients who reported no global improvement in heart condition at 3-months post-revascularisation (scored 1 "much worse", 2 "a little worse", or 3 "about the same" on Q12).

**TABLE 6.22 Known Group Differences: CROQ Bothered by Chest Pain Post-Revascularisation (Final Field Test)**

CROQ scale	Mean scores		p
	Bothered (n) <sup>1</sup>	Not bothered (n) <sup>2</sup>	
<b>CROQ-CABG (N=415)</b>			
Symptoms	66.41 (63)	92.05 (340)	.000
Physical Functioning	63.60 (60)	84.12 (335)	.000
Psychosocial Functioning	58.18 (61)	82.16 (338)	.000
Cognitive Functioning	60.85 (63)	81.53 (340)	.000
<i>Core Total</i>	42.30 (61)	51.56 (338)	.000
Complications	67.18 (64)	83.03 (337)	.000
Satisfaction	73.98 (64)	85.23 (340)	.000
<i>Total Outcome</i>	45.37 (64)	50.95 (337)	.000
<b>CROQ-PTCA (N=345)</b>			
Symptoms	60.09 (152)	91.93 (179)	.000
Physical Functioning	58.20 (147)	84.06 (169)	.000
Psychosocial Functioning	58.65 (149)	79.29 (174)	.000
Cognitive Functioning	65.56 (150)	85.51 (176)	.000
<i>Core Total</i>	45.87 (149)	53.80 (175)	.000
Complications	91.41 (144)	95.65 (173)	.011
Satisfaction	69.51 (150)	83.40 (176)	.000
<i>Total Outcome</i>	48.08 (149)	51.77 (174)	.000

<sup>1</sup> Patients who reported they were bothered by chest pain due to angina at 3-months post-revascularisation (scored 1 "a lot", 2 "quite a bit", 3 "moderately", or 4 "a little" on Q1a).

<sup>2</sup> Patients who reported they were not bothered at all by chest pain due to angina at 3-months post-revascularisation (scored 5 "not at all" on Q1a).

**TABLE 6.23 Construct Validity: Comparison with Other HRQoL Measures at Pre-Revascularisation (Final Field Test)**

CROQ scale	SF-36		SAQ				QLMI-2	LIhFE <sup>1</sup>
	PCS	MCS	Exertional capacity	Anginal stability	Anginal frequency	Disease perception	Global	Total
<b>CROQ-CABG</b>								
Symptoms	<b>.71<sup>1</sup></b>	.34	.68	.63	<b>.78</b>	<b>.72</b>	.56	-.84
Physical Functioning	<b>.75</b>	.22	<b>.90</b>	.22	.48	.68	.63	-.82
Psychosocial Functioning	.38	<b>.70</b>	.74	.27	.34	<b>.83</b>	.83	-.86
Cognitive Functioning	.29	<b>.58</b>	.53	.24	.32	.53	.64	-.75
<i>Core Total</i>	.65	.62	.87	.39	.53	.85	<b>.82</b>	<b>-.94</b>
<b>CROQ-PTCA</b>								
Symptoms	<b>.66</b>	.31	.81	.58	<b>.78</b>	<b>.68</b>	.65	-.71
Physical Functioning	<b>.81</b>	.31	<b>.90</b>	.48	.56	.68	.75	-.87
Psychosocial Functioning	.53	<b>.60</b>	.81	.38	.53	<b>.77</b>	.91	-.92
Cognitive Functioning	.35	<b>.57</b>	.58	.19	.39	.42	.76	-.79
<i>Core Total</i>	.71	.56	.89	.49	.65	.76	<b>.90</b>	<b>-.93</b>

<sup>1</sup> Values in bold indicate correlations between scales that purport to measure the same aspect of HRQoL.

<sup>2</sup> The LIhFE is scored in the opposite direction to the other measures; high scores indicate poorer health outcomes.

**TABLE 6.24 Construct Validity: Correlations Between CROQ and SF-36 Dimension Scores at Pre-Revascularisation (Final Field Test)**

CROQ scale	SF-36 scale <sup>1</sup>							
	PF	RP	BP	GH	VT	SF	RE	MH
<b>CROQ-CABG (n=101)</b>								
Symptoms	.65	.54	<b>.75</b>	.48	.47	.48	.45	.31
Physical Functioning	<b>.89</b> <sup>2</sup>	<b>.48</b>	.54	.36	.41	.48	.44	.15
Psychosocial Functioning	.47	.37	.56	.49	.61	<b>.71</b>	<b>.56</b>	<b>.62</b>
Cognitive Functioning	.34	.39	.43	.32	.46	.53	.53	.47
<i>Core Total</i>	.73	.54	.72	.55	.64	.73	.63	.53
<b>CROQ-PTCA (n=48)</b>								
Symptoms	.73	.38	<b>.76</b>	.35	.36	.60	.39	.38
Physical Functioning	<b>.94</b>	<b>.50</b>	.69	.39	.49	.72	.35	.38
Psychosocial Functioning	.71	.44	.53	.37	.54	<b>.77</b>	<b>.58</b>	<b>.46</b>
Cognitive Functioning	.48	.39	.44	.26	.46	.53	.37	.68
<i>Core Total</i>	.87	.51	.72	.43	.57	.82	.55	.53

<sup>1</sup> PF = Physical Functioning scale; RP = Role-Physical scale; BP = Bodily Pain scale; GH = General Health scale ; VT = Vitality scale; SF = Social Functioning scale; RE = Role-Emotional scale; MH = Mental Health scale.

<sup>2</sup> Values in bold indicate correlations between scales that purport to measure similar aspects of HRQoL.

**TABLE 6.25 Discriminant Validity: Correlations Between CROQ and Age, Sex, Social Class at Pre-Revascularisation (Final Field Test)**

<b>CROQ scale</b>	<b>Age</b>	<b>Sex<sup>1</sup></b>	<b>Social class</b>
<b>CROQ-CABG (N=281)</b>			
Symptoms	.03	-.15	-.16
Physical Functioning	-.03	-.22	-.12
Psychosocial Functioning	.15	-.10	-.08
Cognitive Functioning	.02	-.06	-.04
<i>Core Total</i>	.08	-.16	-.12
<b>CROQ-PTCA (N=159)</b>			
Symptoms	.04	-.11	-.14
Physical Functioning	-.05	-.21	-.16
Psychosocial Functioning	.12	-.06	-.16
Cognitive Functioning	.04	-.02	-.13
<i>Core Total</i>	.06	-.11	-.17

<sup>1</sup> Spearman's rho.

**TABLE 6.26 Convergent Validity: Correlations Between CROQ and CCS and NYHA at Pre-Revascularisation (Final Field Test)**

CROQ-CABG item / scale	CCS <sup>1</sup>		NYHA <sup>1</sup>	
	n	r	n	r
<i>CROQ-CABG Items</i>				
Chest pain	107	<b>-.27</b> <sup>2</sup>	90	-.15
Chest discomfort	107	<b>-.22</b>	90	-.13
Radiating pain	107	-.21	90	-.27
Shortness of breath	107	-.21	90	<b>-.27</b>
Nitro frequency	107	-.39	90	-.20
<i>CROQ-CABG Scales</i>				
Symptoms	107	<b>-.30</b>	90	<b>-.27</b>
Physical Functioning	105	<b>-.20</b>	88	<b>-.23</b>
Psychosocial Functioning	107	-.22	90	-.14
Cognitive Functioning	107	-.18	90	-.04
<i>Core Total</i>	107	-.27	90	-.21

<sup>1</sup> CCS and NYHA are graded classifications of angina and dyspnoea; higher grades reflect more severe disease.

<sup>2</sup> Values in bold indicate correlations between scales that purport to measure similar aspects of HRQoL.

TABLE 6.27 Construct Validity: Comparison with Other HRQoL Measures at Post-Revascularisation (Final Field Test)

CROQ scale	SF-36		SAQ				QLMI-2	LihFE <sup>2</sup>	
	PCS	MCS	Exertional capacity	Anginal stability	Anginal frequency	Disease perception	Treatment Satisfaction	Global	Total
<b>CROQ-CABG</b>									
Symptoms	<b>.60</b> <sup>1</sup>	.36	.59	.68	<b>.74</b>	<b>.61</b>	.62	.70	-.62
Physical Functioning	<b>.75</b>	.36	<b>.67</b>	.48	.47	.47	.35	.81	-.70
Psychosocial Functioning	.59	<b>.64</b>	.76	.51	.52	<b>.71</b>	.55	.89	-.83
Cognitive Functioning	.44	<b>.46</b>	.73	.47	.40	.53	.41	.69	-.70
<i>Core Total</i>	.74	.58	.82	.63	.64	.71	.59	<b>.92</b>	<b>-.87</b>
Complications	.51	.46	.44	.33	.51	.48	.52	.65	-.54
Satisfaction	.51	.37	.45	.49	.46	.53	<b>.65</b>	.58	-.54
<i>Total Outcome</i>	.57	.51	.56	.47	.61	.60	.67	.72	-.67
<b>CROQ-PTCA</b>									
Symptoms	<b>.68</b>	.32	.69	.71	<b>.86</b>	<b>.78</b>	.70	.50	-.60
Physical Functioning	<b>.75</b>	.37	<b>.90</b>	.73	.70	.75	.56	.66	-.48
Psychosocial Functioning	.49	<b>.73</b>	.77	.61	.62	<b>.83</b>	.58	.88	-.71
Cognitive Functioning	.36	<b>.49</b>	.65	.40	.50	.52	.38	.76	-.68
<i>Core Total</i>	.69	.62	.86	.70	.74	.85	.64	<b>.89</b>	<b>-.74</b>
Complications	.25	.21	.44	.36	.45	.39	.35	.23	-.19
Satisfaction	.29	.38	.53	.70	.59	.64	<b>.72</b>	.42	-.28
<i>Total Outcome</i>	.37	.46	.61	.62	.61	.62	.61	.51	-.38

<sup>1</sup> Values in bold indicate correlations between scales that purport to measure similar aspects of HRQoL.

<sup>2</sup> The LihFE is scored in the opposite direction to the other measures; high scores indicate poorer health outcomes.

**TABLE 6.28 Construct Validity: Correlations Between CROQ and SF-36 Dimension Scores at Post-Revascularisation (Final Field Test)**

CROQ scale	SF-36 scale <sup>1</sup>							
	PF	RP	BP	GH	VT	SF	RE	MH
<b>CROQ-CABG (n=123)</b>								
Symptoms	.62	.43	<b>.57</b>	.49	.46	.50	.30	.40
Physical Functioning	<b>.83</b> <sup>2</sup>	<b>.52</b>	.60	.53	.63	.68	.29	.38
Psychosocial Functioning	.59	.50	.61	.60	.63	<b>.78</b>	<b>.40</b>	<b>.64</b>
Cognitive Functioning	.46	.49	.40	.42	.46	.48	.38	.44
<i>Core Total</i>	.77	.58	.70	.65	.69	.80	.41	.60
Complications	.47	.36	.65	.39	.45	.52	.32	.48
Satisfaction	.40	.41	.50	.39	.43	.58	.14	.33
<i>Total Outcome</i>	.53	.43	.70	.46	.52	.63	.32	.51
<b>CROQ-PTCA (n=84)</b>								
Symptoms	.65	.44	<b>.66</b>	.40	.52	.58	.20	.45
Physical Functioning	<b>.89</b>	<b>.58</b>	.49	.44	.62	.62	.32	.47
Psychosocial Functioning	.56	.57	.39	.57	.70	<b>.69</b>	<b>.56</b>	<b>.71</b>
Cognitive Functioning	.42	.50	.25	.34	.44	.48	.49	.40
<i>Core Total</i>	.77	.64	.54	.57	.72	.74	.49	.67
Complications	.20	.17	.31	.21	.22	.31	.12	.23
Satisfaction	.26	.22	.40	.40	.31	.33	.33	.34
<i>Total Outcome</i>	.30	.33	.45	.46	.39	.44	.36	.44

<sup>1</sup> PF = Physical Functioning scale; RP = Role-Physical scale; BP = Bodily Pain scale; GH = General Health scale; VT = Vitality scale; SF = Social Functioning scale; RE = Role-Emotional scale; MH = Mental Health scale.

<sup>2</sup> Values in bold indicate correlations between scales that purport to measure similar aspects of HRQoL.

**TABLE 6.29 Discriminant Validity: Correlations Between CROQ and Age, Sex, Social Class at Post-Revascularisation (Final Field Test)**

<b>CROQ scale</b>	<b>Age</b>	<b>Sex<sup>1</sup></b>	<b>Social class</b>
<b>CROQ-CABG (N=415)</b>			
Symptoms	-.08	-.19	-.13
Physical Functioning	-.16	-.28	-.07
Psychosocial Functioning	.06	-.10	-.13
Cognitive Functioning	.02	-.19	-.09
<i>Core Total</i>	-.02	-.23	-.13
Complications	-.10	-.24	-.11
Satisfaction	-.03	-.10	.05
<i>Total Outcome</i>	.07	-.25	-.08
<b>CROQ-PTCA (N=345)</b>			
Symptoms	.09	-.09	-.07
Physical Functioning	-.13	-.26	-.16
Psychosocial Functioning	.15	-.10	-.16
Cognitive Functioning	.06	.01	-.14
<i>Core Total</i>	.07	-.15	-.17
Complications	.04	-.02	-.15
Satisfaction	.06	-.03	.00
<i>Total Outcome</i>	.09	-.06	-.12

<sup>1</sup> Spearman's rho.

**TABLE 6.30 Known Group Differences: Mean CROQ-CABG Symptom Scores by CCS, NYHA and Ejection Fraction at Pre-Revascularisation (Final Field Test)**

	CROQ-CABG Symptom Score			p
	n	Mean	SD	
<b>CCS<sup>1</sup></b>				
Grade 1	3	80.14	19.4	.005
Grade 2	35	47.88	22.2	
Grade 3	53	42.08	22.5	
Grade 4	16	33.97	15.4	
<b>NYHA<sup>1</sup></b>				
Grade 1	17	56.71	21.2	.033
Grade 2	39	40.60	21.4	
Grade 3	52	39.23	22.1	
Grade 4	16	28.86	22.3	
<b>Ejection Fraction<sup>2</sup></b>				
Good	55	45.57	24.2	.193
Fair	13	48.75	22.8	
Poor	3	21.01	23.6	

<sup>1</sup> CCS and NYHA are graded classifications of angina and dyspnoea; higher grades reflect more severe disease.

<sup>2</sup> Defined as good if >50%, fair if 30-50%, poor if <30%.

**TABLE 6.31 Responsiveness: CROQ Pre- to 3-Months Post-Revascularisation (Final Field Test)**

CROQ scale	Mean (SD)			Pre-to 3-months post-revascularisation	
	Pre	3m post	Change <sup>1</sup>	Responsiveness effect size <sup>2</sup>	Standardised response mean <sup>3</sup>
<b>CROQ-CABG (n=198)</b>					
Symptoms	48.98 (24.2)	88.29 (13.9)	39.31 (25.3)	2.83	1.56
Physical Functioning	50.48 (26.9)	82.46 (21.8)	31.98 (29.4)	1.47	1.09
Psychosocial Functioning	49.59 (24.3)	79.65 (19.7)	30.05 (23.1)	1.53	1.30
Cognitive Functioning	62.57 (29.2)	77.94 (22.8)	15.36 (25.7)	0.67	0.59
<b>CROQ-PTCA (n=107)</b>					
Symptoms	51.98 (23.4)	75.07 (21.9)	23.10 (25.2)	0.99	0.92
Physical Functioning	53.39 (27.2)	71.42 (26.0)	18.03 (28.3)	0.66	0.64
Psychosocial Functioning	54.32 (25.1)	71.06 (24.3)	16.74 (21.5)	0.67	0.78
Cognitive Functioning	68.46 (29.5)	75.45 (25.7)	6.99 (23.5)	0.24	0.30

<sup>1</sup> All change scores are statistically significant (p<.05).

<sup>2</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>3</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of the change score.

**TABLE 6.32 Responsiveness: CROQ Pre- to 3-Months Post-Revascularisation for Subsample Who Reported Global Improvement (Final Field Test)**

CROQ scale	Mean (SD)			Pre-to 3-months post-revascularisation	
	Pre	3m post	Change <sup>2</sup>	Responsiveness effect size <sup>3</sup>	Standardised response mean <sup>4</sup>
<b>CROQ-CABG (n=182) <sup>1</sup></b>					
Symptoms	47.32 (23.1)	89.51 (12.3)	42.19 (23.4)	1.82	1.80
Physical Functioning	48.91 (26.0)	83.61 (20.0)	34.70 (28.2)	1.34	1.23
Psychosocial Functioning	80.55 (19.1)	48.18 (23.9)	32.37 (21.7)	1.36	1.50
Cognitive Functioning	61.66 (29.4)	78.45 (22.2)	16.80 (24.9)	0.57	0.67
<b>CROQ-PTCA (n=83) <sup>1</sup></b>					
Symptoms	50.98 (22.6)	81.16 (16.2)	30.18 (22.1)	1.34	1.37
Physical Functioning	53.22 (26.8)	76.93 (22.6)	23.71 (27.8)	0.89	0.85
Psychosocial Functioning	54.53 (24.2)	76.34 (19.6)	21.81 (20.4)	0.90	1.07
Cognitive Functioning	68.29 (29.1)	78.37 (22.0)	10.08 (23.7)	0.35	0.43

<sup>1</sup> Responsiveness subsample: Excludes patients who did not report global improvement in their heart condition compared to before their operation (i.e. those who scored 1 "much worse", 2 "a little worse", or 3 "about the same" on Q12).

<sup>2</sup> All change scores are statistically significant ( $p < .05$ ).

<sup>3</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>4</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of the change score.

**TABLE 6.33 Responsiveness: CROQ Pre- to 9-Months Post-Revascularisation (Final Field Test)**

CROQ scale	Mean (SD)			Pre-to 9-months post-revascularisation	
	Pre	9m post	Change <sup>2</sup>	Responsiveness effect size <sup>3</sup>	Standardised response mean <sup>4</sup>
<b>CROQ-CABG (N=100) <sup>1</sup></b>					
Symptoms	48.80 (24.5)	85.27 (19.5)	36.47 (26.1)	1.87	1.39
Physical Functioning	51.67 (28.0)	84.53 (20.4)	32.86 (28.8)	1.61	1.14
Psychosocial Functioning	51.92 (23.7)	82.89 (21.7)	30.97 (27.3)	1.43	1.13
Cognitive Functioning	60.47 (27.7)	79.50 (23.6)	19.03 (28.9)	0.81	0.66
<b>CROQ-PTCA (N=80) <sup>1</sup></b>					
Symptoms	52.30 (23.6)	74.06 (22.8)	21.76 (22.8)	0.95	0.91
Physical Functioning	52.92 (28.2)	70.89 (28.4)	17.97 (25.2)	0.63	0.71
Psychosocial Functioning	54.83 (27.3)	72.80 (27.9)	17.97 (23.8)	0.64	0.75
Cognitive Functioning	68.86 (30.8)	77.55 (26.7)	8.69 (25.0)	0.33	0.35

<sup>1</sup> Responsiveness subsample who completed pre- and 9-month post-revascularisation questionnaire.

<sup>2</sup> All change scores are statistically significant ( $p < .05$ ).

<sup>3</sup> Calculated as the mean change score between pre- and 9-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>4</sup> Calculated as the mean change score between pre- and 9-months post-revascularisation divided by the standard deviation of the change score.

**TABLE 6.34 Responsiveness: Comparison of CROQ Change Scores for Different Levels of Global Improvement (Final Field Test)**

CROQ scale	Mean Pre-3m change scores			Mean Pre-9m change scores		
	Improved (n) <sup>1</sup>	Unimproved (n) <sup>2</sup>	p	Improved (n) <sup>1</sup>	Unimproved (n) <sup>2</sup>	p
<b>CROQ-CABG</b>						
Symptoms	42.19 (176)	6.78 (15)	.000	41.32 (88)	-3.63 (10)	.000
Physical Functioning	34.70 (174)	0.42 (15)	.000	37.70 (86)	-11.11 (9)	.000
Psychosocial Functioning	32.37 (177)	2.40 (15)	.000	34.30 (89)	2.68 (10)	.000
Cognitive Functioning	16.80 (181)	-3.56 (15)	.003	22.36 (89)	-12.67 (10)	.000
<b>CROQ-PTCA</b>						
Symptoms	30.18 (82)	-4.16 (21)	.000	26.60 (63)	0.10 (13)	.000
Physical Functioning	23.71 (76)	-2.66 (20)	.000	22.93 (63)	-2.34 (13)	.000
Psychosocial Functioning	21.81 (80)	-3.15 (20)	.000	21.59 (63)	-0.53 (13)	.002
Cognitive Functioning	10.08 (82)	-4.76 (21)	.010	12.60 (64)	-11.28 (13)	.001

<sup>1</sup> Patients who reported global improvement in heart condition at 3 / 9-months-post revascularisation (scored 4 “a little better”, or 5 “much better” on Q12).

<sup>2</sup> Patients who reported no global improvement in heart condition at 3 / 9-months-post revascularisation (scored 1 “much worse”, 2 “a little worse”, or 3 “about the same” on Q12).

**TABLE 6.35 CROQ Longitudinal Change: 3 to 9 Months Post-Revascularisation (Final Field Test)**

CROQ scale	Mean (SD)			3-to 9-months post-revascularisation	
	3m post	9m post	Change	Responsiveness effect size <sup>2</sup>	Standardised response mean <sup>3</sup>
<b>CROQ-CABG (N=100) <sup>1</sup></b>					
Symptoms	87.81 (14.7)	85.55 (19.5)	-2.26 (16.9)	-0.12	-0.13
Physical Functioning	81.45 (22.7)	83.38 (21.4)	1.94 (18.2)	0.09	0.11
Psychosocial Functioning	79.35 (18.8)	82.92 (21.9)	3.57 (18.7)	0.16	0.19
Cognitive Functioning	79.12 (19.7)	80.20 (22.6)	1.08 (21.6)	0.05	0.05
Complications	81.59 (15.2)	87.82 (11.7)	6.23 (11.0) <sup>4</sup>	0.53	0.57
Satisfaction	84.82 (19.1)	84.89 (19.6)	0.07 (16.6)	0.00	0.00
<b>CROQ-PTCA (N=80) <sup>1</sup></b>					
Symptoms	76.07 (21.6)	74.06 (22.8)	-2.01 (17.0)	-0.09	-0.12
Physical Functioning	72.25 (25.9)	72.67 (27.8)	0.41 (18.8)	0.01	0.02
Psychosocial Functioning	73.75 (24.2)	74.17 (26.4)	0.42 (13.3)	0.02	0.03
Cognitive Functioning	75.67 (25.6)	78.01 (26.1)	2.34 (16.4)	0.09	0.14
Complications	91.98 (16.9)	93.63 (15.6)	1.65 (10.5)	0.11	0.16
Satisfaction	78.65 (22.0)	79.08 (21.7)	0.43 (19.1)	0.02	0.02

<sup>1</sup> Responsiveness subsample who completed 3- and 9-month post-revascularisation questionnaires.

<sup>2</sup> Calculated as the mean change score between pre- and 9-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>3</sup> Calculated as the mean change score between pre- and 9-months post-revascularisation divided by the standard deviation of the change score.

<sup>4</sup> Change score is statistically significant (p<.05).

**TABLE 6.36 Relative Responsiveness: CROQ and SF-36 (Final Field Test)**

Scale	Mean (SD)			Pre-to 3-months post-revascularisation Responsiveness effect size <sup>2</sup>	Standardised response mean <sup>3</sup>
	Pre	3m post	Change		
<b>CABG Subsample (n=72) <sup>1</sup></b>					
SF-36 PCS	32.79 (9.55)	42.06 (10.93)	9.27 (10.63)	0.85	0.87
SF-36 MCS	43.41 (12.16)	50.29 (10.25)	6.88 (11.84)	0.67	0.58
CROQ Symptoms	52.16 (22.70)	87.83 (14.25)	35.67 (23.76)	2.50	1.50
CROQ Physical Functioning	49.72 (24.50)	79.62 (25.18)	29.90 (30.55)	1.19	0.98
CROQ Psychosocial Functioning	49.41 (23.64)	78.91 (19.42)	29.51 (23.96)	1.52	1.23
CROQ Cognitive Functioning	57.78 (30.19)	73.89 (25.63)	16.11 (25.97)	0.63	0.62
<b>PTCA Subsample (n=38) <sup>1</sup></b>					
SF-36 PCS	32.36 (9.37)	38.26 (10.46)	5.90 (7.87)	0.56	0.75
SF-36 MCS	45.91 (10.35)	46.65 (10.70)	0.74 (9.43) <sup>4</sup>	0.07	0.08
CROQ Symptoms	51.57 (24.86)	73.71 (22.82)	22.14 (3.81)	0.97	0.94
CROQ Physical Functioning	48.41 (26.99)	67.34 (26.08)	18.93 (27.04)	0.73	0.70
CROQ Psychosocial Functioning	55.85 (23.11)	70.21 (22.33)	14.36 (16.41)	0.64	0.88
CROQ Cognitive Functioning	73.69 (21.48)	74.23 (25.00)	0.54 (18.28) <sup>4</sup>	0.02	0.03

<sup>1</sup> Responsiveness subsample who completed the SF-36 and the CROQ at both pre- and 3-months post-revascularisation.

<sup>2</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>3</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of the change score.

<sup>4</sup> Change score is not statistically significant ( $p < .05$ ).

**TABLE 6.37 Responsiveness: SF-36 Dimension Scores (Final Field Test)**

SF-36 dimension <sup>1</sup>	Mean (SD)			Pre-to 3-months post-revascularisation	
	Pre	3m post	Change	Responsiveness effect size <sup>3</sup>	Standardised response mean <sup>4</sup>
<b>CABG Subsample (n=72) <sup>2</sup></b>					
PF	42.77 (24.87)	69.88 (24.87)	27.11 (27.98)	1.14	0.97
RP	17.16 (33.61)	39.34 (43.90)	22.18 (44.39)	0.66	0.50
BP	46.5 (23.46)	64.2 (25.34)	17.69 (27.55)	0.75	0.64
GH	53.4 (23.62)	68.0 (21.99)	14.58 (21.83)	0.62	0.67
VT	35.8 (22.44)	55.9 (23.29)	20.07 (24.55)	0.89	0.82
SF	53.99 (29.36)	78.47 (26.05)	24.48 (35.01)	0.83	0.70
RE	40.20 (43.69)	65.20 (42.88)	25.00 (47.62)	0.57	0.52
MH	64.9 (21.76)	74.90 (17.38)	10.04 (18.54)	0.46	0.54
<b>PTCA Subsample (n=38) <sup>2</sup></b>					
PF	43.53 (25.29)	54.25 (25.79)	10.72 (22.48)	0.42	0.48
RP	16.45 (25.52)	34.21 (39.17)	17.76 (32.31)	0.70	0.55
BP	50.32 (25.08)	60.65 (26.16)	10.32 (20.37)	0.41	0.51
GH	50.12 (21.02)	57.46 (24.35)	7.34 (17.60)	0.35	0.42
VT	34.35 (20.01)	45.46 (24.28)	11.11 (19.54)	0.56	0.57
SF	55.26 (27.67)	62.83 (28.40)	7.57 (27.65) <sup>5</sup>	0.27	0.27
RE	57.41 (46.20)	63.89 (43.19)	6.48 (46.34) <sup>5</sup>	0.14	0.14
MH	65.33 (17.02)	67.56 (19.66)	2.22 (17.41) <sup>5</sup>	0.13	0.13

<sup>1</sup> PF = Physical Functioning scale; RP = Role-Physical scale; BP = Bodily Pain scale; GH = General Health scale ; VT = Vitality scale; SF = Social Functioning scale; RE = Role-Emotional scale; MH = Mental Health scale.

<sup>2</sup> Responsiveness subsample who completed the SF-36 and the CROQ at both pre- and 3-months post-revascularisation.

<sup>3</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>4</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of the change score.

<sup>5</sup> Change score is not statistically significant (p<.05).

**TABLE 6.38 Relative Responsiveness: CROQ and SAQ (Final Field Test)**

Scale	Mean (SD)			Pre-to 3-months post-revascularisation	
	Pre	3m post	Change <sup>2</sup>	Responsiveness effect size <sup>3</sup>	Standardised response mean <sup>4</sup>
<b>CABG Subsample (n=55) <sup>1</sup></b>					
SAQ Exertional	47.09 (23.10)	79.19 (20.58)	32.10 (23.71)	1.56	1.35
Anginal Stability	29.79 (21.89)	90.43 (23.63)	60.64 (28.90)	2.57	2.10
Anginal Frequency	38.43 (29.62)	89.22 (19.58)	50.78 (32.98)	2.59	1.54
SAQ Disease perception	26.84 (18.84)	74.92 (25.03)	48.08 (26.91)	1.92	1.79
<b>CROQ Symptoms</b>					
CROQ Symptoms	44.13 (25.64)	88.44 (16.18)	44.31 (28.28)	2.74	1.57
CROQ Physical Functioning	49.58 (28.30)	83.50 (19.53)	33.92 (30.24)	1.74	1.12
CROQ Psychosocial Functioning	47.98 (26.96)	79.35 (22.26)	31.37 (24.30)	1.41	1.29
CROQ Cognitive Functioning	62.10 (31.56)	81.48 (22.49)	19.38 (27.93)	0.86	0.69
<b>PTCA Subsample (n=34) <sup>1</sup></b>					
SAQ Exertional	44.49 (26.13)	68.06 (28.18)	23.57 (24.23)	0.84	0.97
Anginal Stability	39.17 (33.27)	70.00 (33.73)	30.83 (43.89)	0.91	0.70
Anginal Frequency	52.26 (27.41)	73.87 (27.04)	21.61 (31.21)	0.80	0.69
SAQ Disease perception	30.56 (19.28)	58.59 (28.98)	28.03 (27.31)	0.97	1.03
<b>CROQ Symptoms</b>					
CROQ Symptoms	51.40 (24.10)	75.78 (22.43)	24.38 (25.81)	1.09	0.94
CROQ Physical Functioning	51.25 (29.33)	71.04 (29.70)	19.79 (30.13)	0.67	0.66
CROQ Psychosocial Functioning	50.02 (25.44)	68.19 (26.14)	18.17 (20.56)	0.57	0.67
CROQ Cognitive Functioning	56.36 (34.40)	71.92 (27.32)	15.56 (23.31)	0.70	0.88

<sup>1</sup> Responsiveness subsample who completed the SAQ and the CROQ at both pre- and 3-months post-revascularisation.

<sup>2</sup> All change scores are statistically significant ( $p < .05$ ).

<sup>3</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>4</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of the change score.

**TABLE 7.1 Generalisability of CROQ Sample**

<b>Study</b>	<b>Mean age (yrs)</b>	<b>% male</b>	<b>% white</b>	<b>% manual occupations</b>
Schroter 2001 <sup>1</sup>				
Pre-revascularisation (CABG)	63.6	85	93	48
Pre-revascularisation (PTCA)	60.6	75	91	48
Post-revascularisation (CABG)	65.0	83	89	49
Post-revascularisation (PTCA)	62.3	73	88	46
UK CABG national figures for 1998 <sup>2</sup>	62.7	76	-	-
BARI <sup>3</sup> trial of CABG versus PTCA in patients with multi vessel disease (1996)				
CABG patients	61.1	74	89	-
PTCA patients	61.8	73	91	-
CABRI <sup>4</sup> trial of CABG versus PTCA in patients with multi vessel disease (1995)				
CABG patients	61.5	78	-	-
PTCA patients	61.0	78	-	-
RITA <sup>5</sup> trial of CABG versus PTCA in patients with one, two, or three vessel disease (1993)				
CABG patients	Median age =57 yrs for all 1011 pts	79	-	-
PTCA patients		83	-	-

<sup>1</sup> CROQ validation study (final field test). <sup>2</sup> Society of Cardiothoracic Surgeons adult cardiac surgical database report, 1998.

<sup>3</sup> The Bypass Angioplasty Revascularisation Investigation (BARI) trial. <sup>4</sup> Coronary Angioplasty versus Bypass Revascularisation Investigation (CABRI) trial. <sup>5</sup> The Randomised Intervention Treatment of Angina (RITA) trial.

**TABLE 7.2 Comparison with Other Studies: SF-36 Scores (Pre-Revascularisation)**

Study (mean age ± standard deviation)	N	Assessment point	Mean (SD) SF-36 scale scores <sup>1</sup>									
			PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
Ware <i>et al.</i> 1993 normative data for the general US population (not provided)	2474	-	50.0 (10.0)	50.0 (10.0)	84.2 (23.3)	81.0 (34.0)	75.2 (23.7)	72.0 (20.3)	60.9 (21.0)	83.3 (22.7)	81.3 (33.0)	74.7 (18.1)
Ware <i>et al.</i> 1994 normative data for the general US population with angina (62.6)	107	-	36.4 (12.4)	48.0 (12.4)	-	-	-	-	-	-	-	-
Ware <i>et al.</i> 1994 normative data for comorbid recent angina without MI, with hypertension, MOS <sup>2</sup> participants (59.7)	256	-	38.6 (11.0)	50.4 (9.7)	-	-	-	-	-	-	-	-
<b>CABG</b>												
Schroter 2001 <sup>3</sup> (67 ± 8), UK	101	Pre	32.7 (9.1)	42.8 (12.0)	43.0 (23.5)	16.2 (31.9)	46.3 (23.1)	51.7 (22.5)	34.4 (21.5)	53.2 (27.5)	40.0 (42.6)	63.2 (21.5)
Rumsfeld <i>et al.</i> 1999 (63 ± 9), USA	2480	Pre	32.6 (9.0)	44.0 (12.0)	-	-	-	-	-	-	-	-
McCarthy <i>et al.</i> 1995 (not provided), USA <sup>4</sup>	321	Pre	-	-	40.0 (-)	12.0 (-)	43.0 (-)	53.0 (-)	39.0 (-)	54.0 (-)	38.0 (-)	66.0 (-)
MacDonald <i>et al.</i> 1998 (78.8 ± 3), Canada	100	Pre	-	-	36.6 (22.7)	14.8 (30.0)	58.9 (31.4)	61.5 (19.8)	41.8 (24.0)	60.2 (36.1)	68.0 (41.6)	78.7 (18.8)
<b>PTCA</b>												
Schroter 2001 <sup>3</sup> (63 ± 10), UK	49	Pre	32.5 (9.9)	46.0 (10.5)	44.3 (26.9)	17.7 (29.2)	49.5 (25.0)	50.1 (21.0)	36.2 (22.5)	55.0 (28.5)	55.3 (45.7)	65.8 (17.7)
Krumholz <i>et al.</i> 1996, (60 ± 11), USA	102	Pre	-	-	59.0 (25.7)	28.9 (36.2)	58.9 (23.4)	61.6 (20.3)	45.7 (24.3)	63.3 (27.8)	54.9 (42.2)	67.6 (21.8)
Nash <i>et al.</i> 1999, (63 ± 11), USA	1182	Pre	36.6 (-)	48.5 (-)	-	-	-	-	-	-	-	-
Seto <i>et al.</i> 2000, (57), USA <sup>5</sup>	1445	Pre	40.1 (-)	49.0 (-)	-	-	-	-	-	-	-	-

<sup>1</sup> PF = Physical Functioning scale; RP = Role-Physical scale; BP = Bodily Pain scale; GH = General Health scale; VT = Vitality scale; SF = Social Functioning scale; RE = Role-Emotional scale; MH = Mental Health scale; PCS = Physical Component Summary Score; MCS = Mental Component Summary Score.

<sup>2</sup> MOS Medical Outcomes Study. <sup>3</sup> CROQ validation study subsample. <sup>4</sup> Values estimated as taken from graphical representation of data. <sup>5</sup> Median scores.

**TABLE 7.3 Comparison with Other Studies: SF-36 Scores (Post-Revascularisation)**

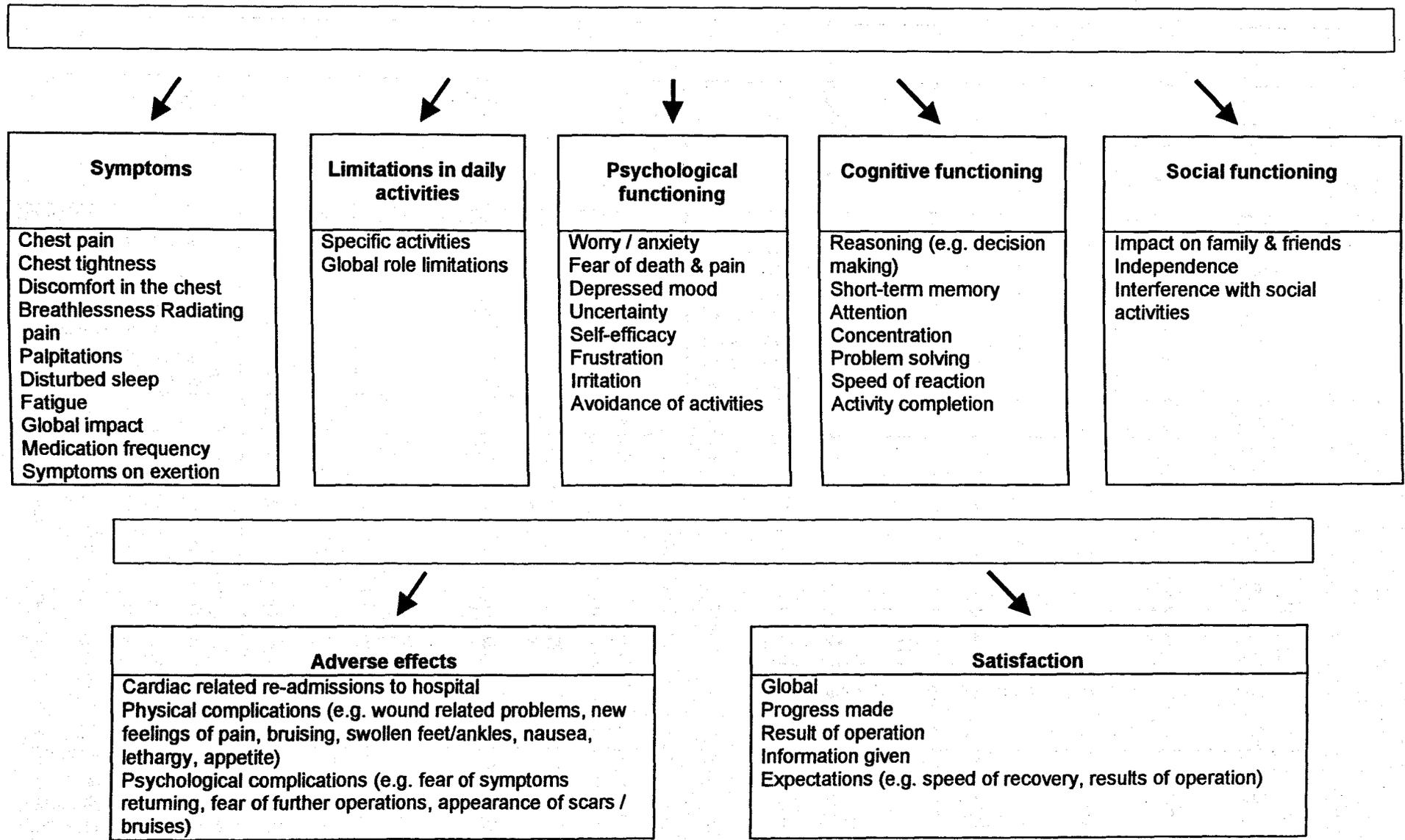
Study (mean age ± standard deviation)	N	Assessment point	Mean (SD) SF-36 scale scores <sup>1</sup>									
			PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
Ware <i>et al.</i> 1993 normative data for the general US population (not provided)	2474	-	<b>50.0</b> (10.0)	<b>50.0</b> (10.0)	84.2 (23.3)	81.0 (34.0)	75.2 (23.7)	72.0 (20.3)	60.9 (21.0)	83.3 (22.7)	81.3 (33.0)	74.7 (18.1)
Ware <i>et al.</i> 1994 normative data for the general US population with angina (62.6)	107	-	<b>36.4</b> (12.4)	<b>48.0</b> (12.4)	-	-	-	-	-	-	-	-
Ware <i>et al.</i> 1994 normative data for comorbid recent angina without MI, with hypertension, MOS <sup>2</sup> participants (59.7)	256	-	<b>38.6</b> (11.0)	<b>50.4</b> (9.7)	-	-	-	-	-	-	-	-
<b>3-months post CABG</b>												
Schroter 2001, <sup>3</sup> (66 ± 8), UK	123	3-months	<b>41.8</b> (10.5)	<b>50.5</b> (10.0)	69.2 (23.7)	38.3 (43.1)	63.8 (25.4)	67.9 (21.6)	54.9 (22.3)	76.6 (27.1)	65.5 (43.3)	75.2 (16.7)
MacDonald <i>et al.</i> 1998 (78.8 ± 3), Canada	96	3-months	-	-	59.5 (27.9)	39.7 (45.7)	74.9 (26.2)	66.5 (20.7)	57.1 (23.8)	74.9 (27.0)	69.5 (42.5)	80.7 (16.5)
<b>3-months post PTCA</b>												
Schroter 2001, <sup>3</sup> (63 ± 9), UK	84	3-months	<b>39.7</b> (11.2)	<b>46.9</b> (11.3)	60.7 (28.0)	37.7 (42.5)	65.7 (25.3)	58.1 (23.8)	47.5 (23.2)	66.7 (29.1)	64.2 (42.2)	68.8 (20.2)
<b>9-months post CABG</b>												
Schroter 2001, <sup>3</sup> (67 ± 9), UK	32	9-months	<b>46.5</b> (9.1)	<b>50.4</b> (9.9)	77.0 (21.4)	64.1 (43.5)	73.1 (22.0)	68.0 (20.8)	58.9 (22.6)	86.3 (17.8)	70.0 (41.4)	76.7 (20.1)
<b>9-months post PTCA</b>												
Schroter 2001, <sup>2</sup> (65 ± 9), UK	31	9-months	<b>38.6</b> (11.1)	<b>48.9</b> (12.6)	57.8 (29.4)	37.5 (42.9)	64.6 (25.3)	56.6 (22.9)	49.5 (25.7)	73.8 (28.9)	64.4 (43.6)	71.2 (21.6)

<sup>1</sup> PF = Physical Functioning scale; RP = Role-Physical scale; BP = Bodily Pain scale; GH = General Health scale; VT = Vitality scale; SF = Social Functioning scale; RE = Role-Emotional scale; MH = Mental Health scale; PCS = Physical Component Summary Score; MCS = Mental Component Summary Score.

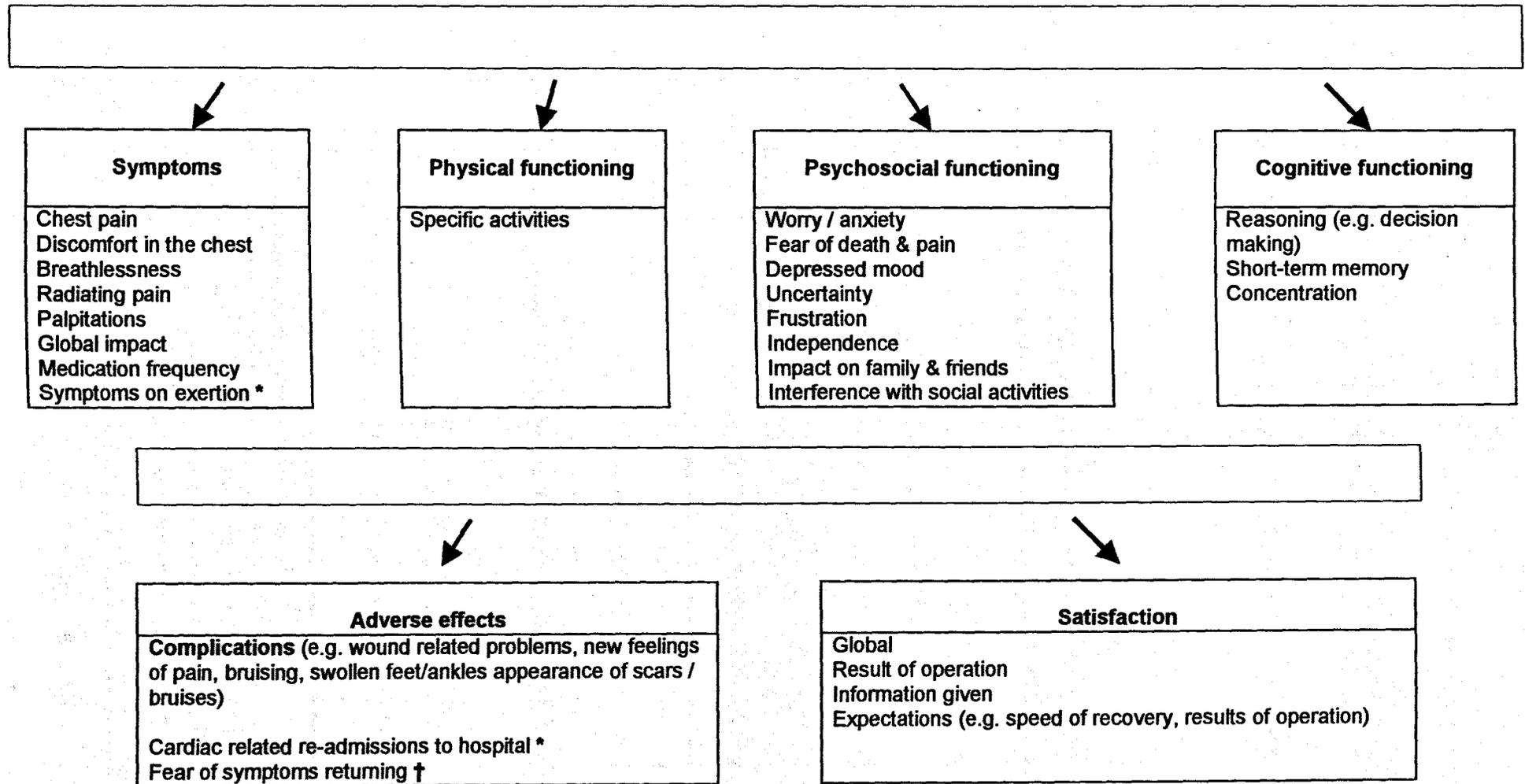
<sup>2</sup> MOS Medical Outcomes Study. <sup>3</sup> CROQ validation study subsample.

## **FIGURES**

**FIGURE 4.1 CROQ Conceptual Model (Pre-test Version)**



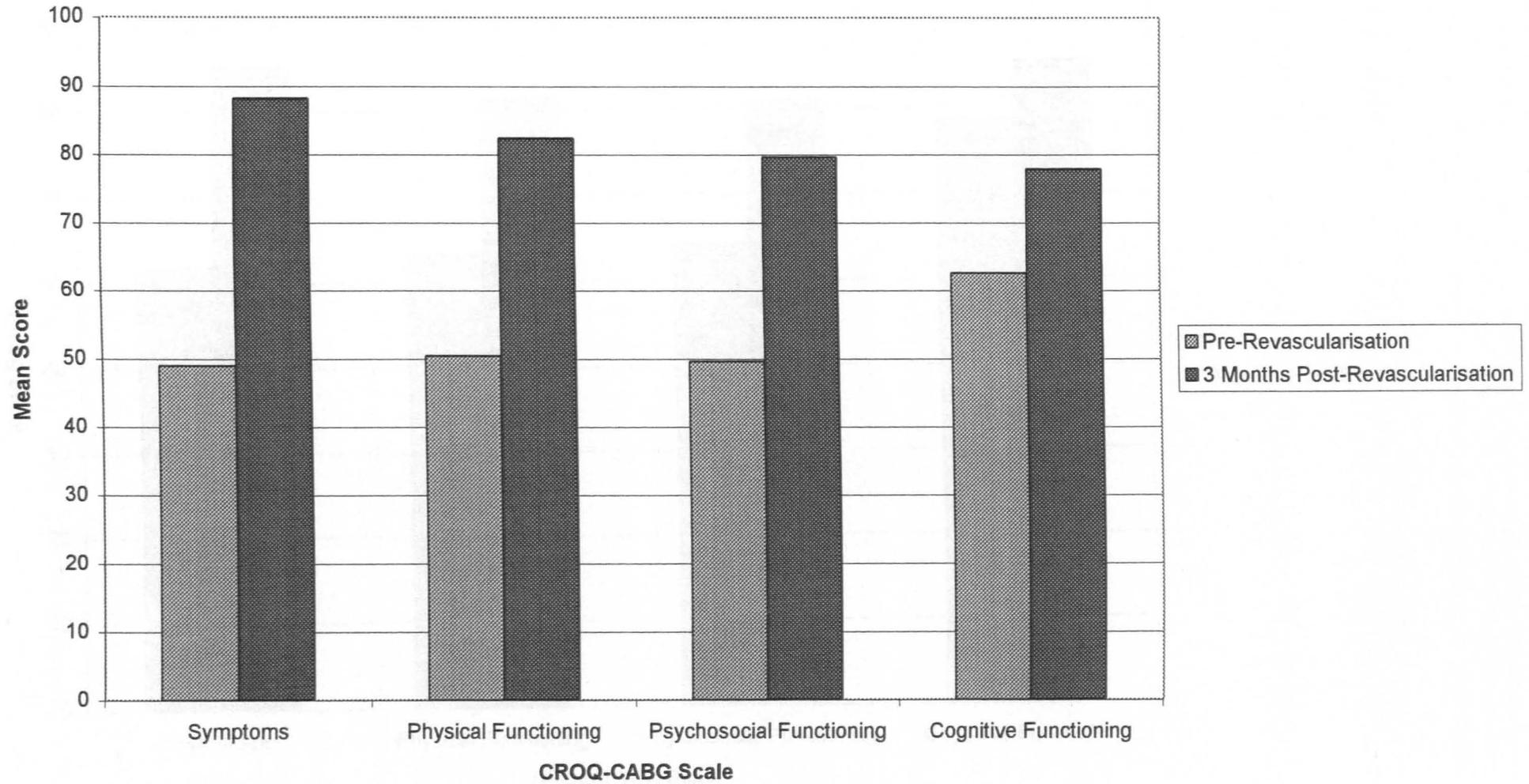
**FIGURE 6.1 CROQ Conceptual Model (Final Version)**



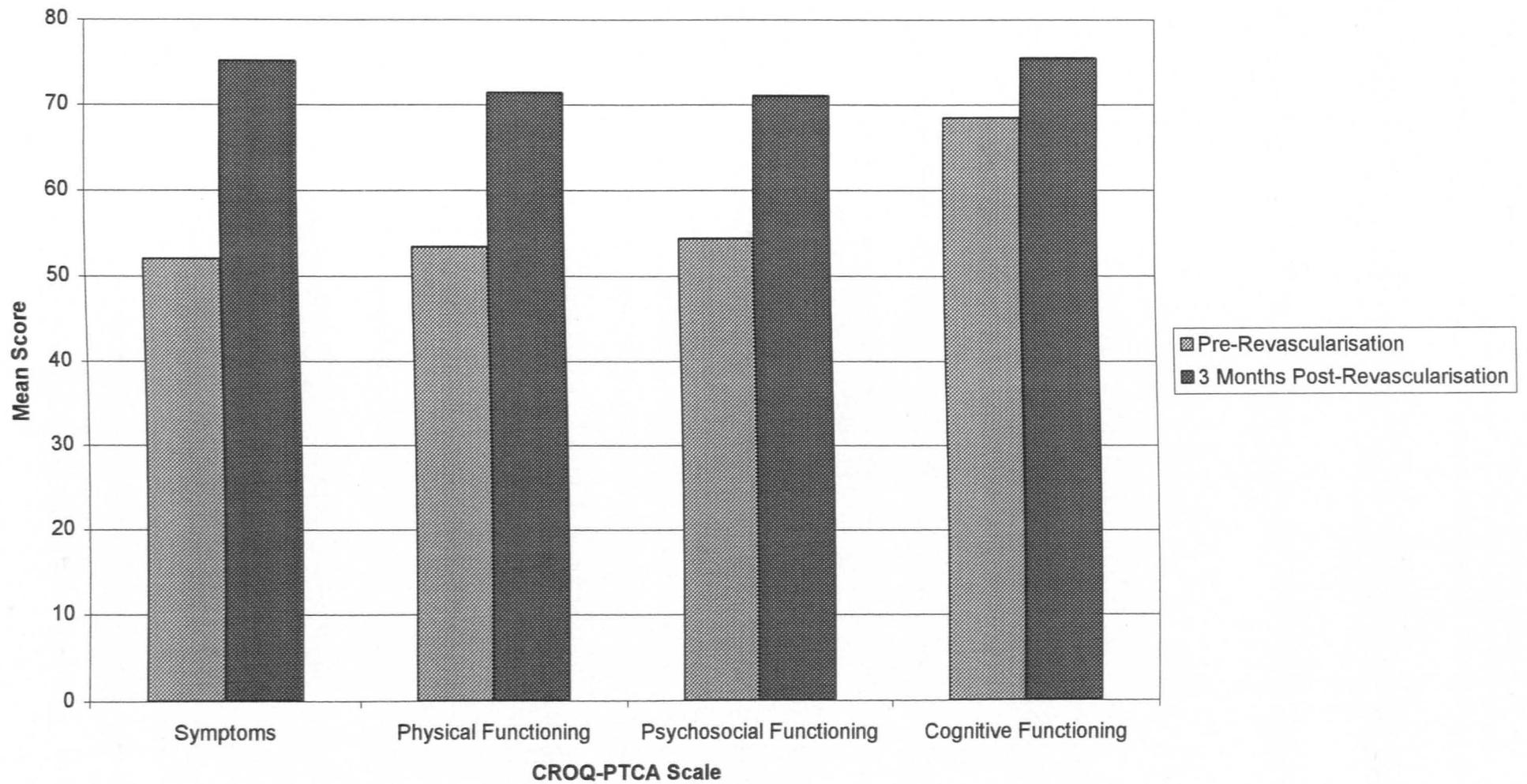
\* Descriptive item.

† Item not scored in the subscales.

**FIGURE 6.2 Mean CROQ-CABG Scores at Pre- and 3-Months Post-Revascularisation in Responsiveness Subsample n=198**



**FIGURE 6.3 Mean CROQ-PTCA Scores at Pre- and 3-Months Post-Revascularisation in Responsiveness Subsample n=107**



## **APPENDICES**

### APPENDIX 3.1 Cardiac-Specific Patient-Based Questionnaires: General Characteristics

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>Coronary revascularisation</b>									
<b>Cleary et al's Battery:</b> Cleary <i>et al.</i> (1991)	-	Various	-	Various	496 PTCA pts (81% men)	Telephone-administered	Baseline & 1m after	Mean age =59 (36-82) yrs	NO USA
<b>Coronary Health Profile:</b> Karlsson (1999)	49	Dichotomous & VAS	-	-	111 CABG pts (80% male)	Self-administered	Week before angiography, day before CABG, 12m post CABG	Mean age =54 (40-60) yrs	NO Sweden
<b>Experience of waiting for CABG:</b> Jonsdottir & Baldursdottir (1998)	-	-	-	-	88 pts awaiting CABG (74% male)	Self-administered	Baseline & 10m later	Mean age =62 yrs	NO Iceland
<b>Global post-operative questionnaire:</b> Pinna Pintor <i>et al.</i> (1992)	-	-	-	-	626 CABG pts (86% male)	Self-administered	Preop & 6-24m post CABG	Mean age =61 ± 8 yrs	NO Italy
<b>Modified Physical Functioning Questionnaire:</b> Faris & Stotts (1990) & Papadantonaki (1994)	-	-	-	-	<i>Faris &amp; Stotts:</i> 20 pts undergoing PTCA. <i>Papadantonaki:</i> 76 CHD pts undergoing PTCA & CABG	Self-administered	On admission & 3 wks after discharge	<i>Papadantonaki:</i> mean age =57.9 ± 8.2 yrs. <i>Faris &amp; Stotts:</i> mean age =60 (39-76) yrs	NO USA
<b>** Perception of the Waiting Period Questionnaire:</b> Pieper <i>et al.</i> (1985)	23	Likert	-	Summated items	28 men waiting for CABG	Interview-administered	Single assessment	Mean age =54.29 ± 6.65 (40-64) yrs	NO USA

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>Problems of cardiac patients in early recovery questionnaire:</b> <i>Jaarsma et al. (1995)</i>	-	-	-	-	82 pts post CABG & MI	Interview-administered	Single assessment	Mean age =61.8 ± 9.1 yrs	NO Netherlands
<b>Prospective study of QOL before &amp; after CABG:</b> <i>Caine et al. (1991)</i>	-	Dichotomous	-	-	100 CABG pts	Self-administered	Preop, 3 & 12m post surgery	Mean age =51 ± 6 (37-59) yrs	YES
<b>Quality of Life during rehabilitation after CABG:</b> <i>Engbolm et al. (1992)</i>	-	-	-	-	201 CABG rehabilitation pts	Self-administered	Preop, 6 & 12m post op	All < 65 yrs	NO Finland
<b>** Quality of Life Index – Novi Sad (QOLI-NS):</b> <i>Potic et al. (1999)</i>	18	Likert	-	Index measure. Weights assigned to each response. Score range 0 to 100. High score indicates good outcome	300 cardiac surgery pts: Valve, CABG, & CABG + Valve	Interview-administered	Preop, 6, 12 & 24m post op	-	NO Yugoslavia
<b>Self-report of recovery questionnaire:</b> <i>Gortner et al. (1994)</i>	41	Various	-	-	199 pts undergoing open heart surgery	Telephone- or self-administered.	Preop, & 1, 2, 3, 6, 12m post	Mean age =75.8 ± 4.6 yrs	NO USA
<b>Symptoms of Illness Factor Score:</b> <i>Jenkins et al. (1994)</i>	-	Various	-	Standardised & summated responses. 9 variables (some of which are scales)	463 surgical pts (374 CABG, 89 Valve)	Self- & interview-administered	Baseline & 6m post op	Age range =25-69 yrs	NO USA
<b>Waiting List Impact Questionnaire (WLIQ):</b> <i>Teo et al. (1998)</i>	47	Likert	-	Used for descriptive purposes only	102 pts waiting for CABG and/or valve surgery (86% male)	Interview-administered	Pts who had been on waiting list for ≥ 6 weeks	Mean age =62 (33-79) yrs	NO Canada

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>Wythenshawe Hospital Cardiothoracic Outcomes Study:</b> Bridgewater <i>et al.</i> (unpublished)	21	Dichotomous & global item	-	Summated scales: Total, Symptoms, Functional activities, Complications, Quality of Life	CABG & Valve (75% male)	Self-administered	Preop, 3, & 12m post op	Mean age =60.5 yrs	YES
<b>Zyzanski's Behavioural Change Scales:</b> Zyzanski <i>et al.</i> (1981)	36	-	-	4 scales. Score zero for items indicating negative outcome and one for neutral or positive responses. Standardised summated scales High scores indicate positive outcome	724 CABG pts & 225 valve pts (75% male)	Self-administered	Post surgery	Mean age =56.7 yrs. 4% over 70 yrs	NO USA
<b>Angina</b>									
<b>Angina Impact Questionnaire (AIQ):</b> Wilson <i>et al.</i> (1991)	22	Likert	-	5 scales: Social, Sleep, Physical, Self-control, Impact	112 angina pts in KarQuol study	Self-administered	Baseline, 6 wks, & 3m	Mean age =61.7 ± 5.5 yrs	NO Finland
<b>Angina Pectoris Quality of Life Questionnaire (APQLQ):</b> Wiklund <i>et al.</i> (1987) - Swedish version	22	VAS & Likert	-	Global, Physical, Symptoms, Emotional, Life Satisfaction. Non-weighted sum of responses. High score indicates less disability	-	Self-administered	Single assessment	-	NO Sweden
<b>** French version Angina Pectoris Quality of Life Questionnaire (APQLQ):</b> Marquis <i>et al.</i> (1995) -	22	VAS & Likert	-	Global, Physical, Symptoms, Emotional, Life Satisfaction. Non-weighted sum of responses. High score indicates less disability	170 CHD pts: post MI, PTCA, CABG (79% male)	Self-administered	Single assessment	Mean age =67 ± 10 yrs	NO France

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>** Angina-related Limitations at Work Questionnaire:</b> Lerner <i>et al.</i> (1998)	17	Likert	-	Total score constructed from the standardised item mean	40 employed individuals with chronic stable angina (excluded post CABG / PTCA)	Self-administered	Single assessment	Aged >18 yrs	NO USA
<b>Angina Type Specification Form:</b> Health Outcomes Institute Database (1997)	-	-	-	-	-	-	-	-	NO USA
<b>** Quality of Life Questionnaire for Angina Pectoris:</b> Marquis <i>et al.</i> (1995)	70	VAS & Likert	-	APQLQ and three specific items on sleep, sexual activity & climatic conditions. 0 - 100 scale. High scores indicate good outcome	170 coronary pts (14% post PTCA, 31% post CABG)	Self-administered	Single assessment	Mean age =67 ± 10yrs	NO France
<b>RAND Chest Pain (Angina) Battery:</b> Berman <i>et al.</i> (1981)	19	Likert & dichotomous	-	Impact scale: 'none' to 'great deal'. Create composite impact	RAND angina subjects	Clinician- or self-administered	-	-	NO USA
<b>Rose Questionnaire (London School of Hygiene Chest Pain / Cardiovascular Questionnaire):</b> Rose <i>et al.</i> (1977)	18	Likert & dichotomous	-	Graded classes	18,403 men with angina	Interview-administered and later adapted for self-administration	A few days before examination	Age range = 40-64 yrs	YES
<b>Rose (London School of Hygiene Dyspnoea) Questionnaire:</b> Rose <i>et al.</i> (1982)	4	Dichotomous	-	Graded classes	-	Interview-administered	-	-	YES

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>** Seattle Angina Questionnaire (SAQ):</b> Spertus <i>et al.</i> (1994, 1995)	19	Likert	-	Five scales. Sum items within scale & transform to 0-100 range (subtract lowest possible scale score, divide by range of scale, multiply by 100). No summary score. High scores indicate good outcome	Used different patient groups to evaluate psychometric properties of each scale	Self-administered	Baseline and 3m later	Used several subsamples	YES & 12 other countries (see Table 3.3)
<b>** Summary Index (SI) for the assessment of quality of life in angina pectoris:</b> Wilson <i>et al.</i> (1991)	51	Likert & VAS	YES – reduced from 69 items	6 subscales and a total score. Zero to 100 range. High score indicates good outcome	112 angina pts in KarQuol study	Self-administered	Baseline, 6 wks & 3m later	Mean age =61.7 ± 5.5 yrs	NO Finland
<b>Myocardial Infarction</b>									
<b>CAST Quality of Life Questionnaire:</b> Wiklund <i>et al.</i> (1992)	-	Various	-	-	1,465 post acute MI pts (82% male)	Self-administered	Baseline, 4m later & annually thereafter	Mean age =61 ± 9.7 yrs. 64% 65 yrs	NO USA, Canada, Sweden
<b>** Heart Patients Psychological Questionnaire:</b> Erdman (1982)	40	-	-	4 scales: Well-being, Feelings of disability, Displeasure, Social inhibition	80 post MI pts	Self-administered	Baseline & post rehabilitation intervention	Mean age = 51 (35-60) yrs	NO Netherlands
<b>** Quality of Life after acute MI (QLMI):</b> Oldridge <i>et al.</i> (1991) Hillers <i>et al.</i> (1994)	26	Likert	YES	5 factors aggregated to 2 dimensions (Limitations & Emotions). Add item scores & divide by number of items (scale score range 1-7)	201 depressed post AMI pts (88% male)	Interview-administered	Baseline, after 8wks rehab prog, & 4, 8, & 12m later	Mean age = 52 yrs	NO Canada
<b>** Modified Quality of Life after acute MI (QLMI-1):</b> Lim <i>et al.</i> (1993)	22 or 25	Likert	YES	3 dimensions: Emotional, Physical, Social. Weighted average of responses. Scale created if answered 50%	375 post AMI pts (71% male)	Self-administered	6m after hospital discharge	Mean age =59 ± 7.4 yrs	NO Australia

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>** Modified Quality of Life after acute MI (QLMI-2):</b> Valenti <i>et al.</i> (1996)	27	Likert	Based on QLMI-1	3 dimensions: Emotional, Physical, Social. High scores indicate good outcome	352 pts with angina or AMI (71% male)	Self-administered	6 wks & 6m after hospital discharge	Age range =25-74 yrs	NO Australia
<b>WHO Rehabilitation Questionnaire:</b> Fridlund (1991)		Likert & dichotomous	-	-	53 rehabilitation pts after MI & 63 controls	Self-administered	Baseline, 6 & 12m post rehabilitation	-	NO Sweden
<b>Heart Failure</b>									
<b>** Chronic Heart Failure Questionnaire (CHQ):</b> Guyatt <i>et al.</i> (1988, 1989)	16	Likert & individualised questions for 5 important & frequent activities	YES – reduced from 123 items	Summed subscales for dyspnoea (5-35), fatigue (4-28), emotional (7-49). High scores indicate poor outcome	88 pts with heart failure (70% male)	Interview-administered	Three administrations over a 4-6 wk period	Mean age =69.1 ± 10.7 yrs	NO Canada
<b>Disease Specific Questionnaire for Severe Heart Failure:</b> Cowley <i>et al.</i> (1994)	30	Likert	-	6 areas of impact. Overall mean scores calculated. High score indicates better well-being	151 pts with severe heart failure	Self-administered	Baseline, & 2 weeks, 3m, 1yr after	-	YES
<b>Heart Failure Functional Status Inventory:</b> Dracup <i>et al.</i> (1992), Walden <i>et al.</i> (1989, 1994)	25	Likert	-	If activity is limited, indicate if it is limited by SOB, fatigue, chest pain, or other	130 pts with advanced heart failure (83% male)	Self-administered	Single assessment	Mean age =50 ± 12 yrs (15-68). 60% were <55yrs	NO USA

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>** Kansas City Heart Failure Questionnaire (KCHFQ):</b> Green <i>et al.</i> (2000)	23	Likert	YES	Summed responses. 7 scales: Physical limitation, Symptoms, QOL, Social limitation, Self-efficacy, KCCQ Functional status, KCCQ Clinical summary. Higher scores reflect better HRQoL	Responsiveness cohort: 39 decompensated CHF pts. Reliability cohort: 39 stable pts. Validation analyses: 129 CHF pts. (67% male)	Self-administered	Baseline and 3m later	Reliability cohort: mean age =64 yrs. Responsiveness cohort: mean age =68 yrs. Validation analyses: mean age =64.3	NO USA
<b>** Left Ventricular Dysfunction Questionnaire:</b> O'Leary & Jones (2000)	36	Dichotomous	YES – reduced from 139 items	Responses are summed & expressed as a percentage (100= worst, 0=best). Questionnaire not scored if any questions left unanswered	60 pts with heart failure (77% male) inc 10 with CHD	Self- & telephone-administered	Baseline, 1 wk & 6m later	Mean age =60 ± 13.3 yrs	YES
<b>** Minnesota Living with Heart Failure Questionnaire (LHFE):</b> Rector <i>et al.</i> (1987)	21	Likert	-	Summed responses for 3 scales: Total, Physical, Emotional. Low scores indicate good outcome. Max total score = 105	83 pts with Left Ventricular Dysfunction (84% men)	Self-administered	Single assessment	Mean age = 61 ± 10 yrs	YES & 19 other countries (see Table 3.3)
<b>Patients' Self Rating Scale:</b> Tandon <i>et al.</i> (1989)	9	Likert	-	Summed responses for total score	111 male pts with CHF	Self-administered	Baseline, 2, 4, 6, 8, 12 wks of treatment phase	Mean age =60 yrs	NO USA
<b>Quality of life in the treatment of heart failure:</b> Blackwood <i>et al.</i> (1990)	-	VAS	-	100mm VAS. A positive change of 1mm or more on the VAS scores was expressed as an improvement	123 pts with mild to moderate heart failure (50% male)	Self-administered	Baseline & 13 wks after start of drug treatment	Median age =60 (37 -79) yrs	YES

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>RAND Congestive Heart Failure Questionnaire (Shortness of Breath Battery):</b> Rosenthal <i>et al.</i> (1981)	19	Likert & dichotomous	-	Impact scale: 'none' to 'great deal'. Create composite impact	RAND heart failure subjects	Clinician-administered. Can be self-administered	-	-	NO USA
<b>** Self Assessment of quality of life in severe heart failure (QLQ-SHF):</b> Wiklund <i>et al.</i> (1987)	26	Likert & VAS	YES	Total scale and 4 subscales (5-7 questions in each scale). Likert scale transformed into an analogue scale by division of actual value by 5 & multiplication by 100. High scores indicate poor outcome	51 pts with severe heart failure (65% male)	Self-administered	Single assessment	Median 64 yrs (44-78). 41% ≥70 yrs	NO Sweden
<b>Self-Management of Heart Failure:</b> Riegel <i>et al.</i> (2000)	65	Likert & dichotomous	YES	6 subscales: Recognising a change, Evaluating the change, Implementing a treatment strategy, Ease of evaluating the treatment strategy, self-efficacy	127 pts with heart failure (53.5%)	Self- & interview-administered	Baseline and follow-up	Mean age =70.9 ± 13.5 yrs	NO USA
<b>Cardiac non-specific</b>									
<b>Cardiac Adjustment Scale:</b> Rumbaugh (1965)	-	-	-	-	74 mixed rehabilitation pts (88% male)	-	Baseline to predict employment status at an average of 33m	Mean age =50.1 (31-64) yrs	NO USA
<b>** Cardiac Denial of Impact Scale:</b> Fowers <i>et al.</i> 1992	8	Likert	YES	-	91 cardiac rehabilitation pts (80% male)	Self-administered	Single assessment	Mean age =63.3 ± 10.9 (35-86) yrs	NO USA

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>** Cardiac Depression Scale: Hare &amp; Davis (1995)</b>	26	Likert	YES	Summed items: 2 dimensions, 7 subscales. Higher scores indicate worse functioning	248 ambulatory cardiac pts: angina, heart failure, post MI, post surgery, valve disease, arrhythmias (64% male)	Self-administered	Single assessment	Mean age =59.3 ± 14.1 (17-88) yrs	NO Australia
<b>** Cardiac Health Profile (CHP): Wahrborg &amp; Emanuelsson (1996)</b>	19	VAS	YES	5 factors. Measure VAS scores in mm & sum. Total sum is divided by number of answered items (mean).	76 angina (68% male) pts awaiting angiography (24 later had CABG & 15 PTCA). 51 controls (73% male)	Self-administered	4 wks before angiography, immed before examination; 18 months after inclusion in study	Angina gp: mean age =62.7 ± 10.5 yrs Control gp: mean age =61.6 ± 9.1 yrs	NO Sweden
<b>** Duke Activity Status Index (DASI): Hlatky, et al. (1989)</b>	12	Hierarchic order of activities	YES	Weights based on known metabolic cost of each activity in METs	50 cardiac pts undergoing exercise test	Self-administered	Single assessment	Mean age =59.3 ± 14.1 (17-88) yrs	NO USA
<b>Expectations and Satisfaction Questionnaire: Staniszewska &amp; Ahmed (2000)</b>	34	Likert	-	-	16 cardiac pts (pilot study only)	Self-administered	Expectations questionnaire administered before treatment & Satisfaction questionnaire after	-	YES

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>** Ferrans &amp; Powers Quality of Life Index: (QLI-Cardiac Version III):</b> Ferrans & Powers (1985), Faris & Stotts (1990)	64	Likert	-	Total score & 4 subscales. Satisfaction scores are weighted for importance. Lowest score: high dissatisfaction & high importance	<i>Faris &amp; Stotts:</i> 20 pts undergoing PTCA (85% male). <i>Papadantonaki:</i> 76 CHD pts undergoing PTCA/CABG	Self-administered	<i>Faris &amp; Stotts:</i> Pre PTCA & 6 wks post  <i>Papadantonaki:</i> Pre PTCA/CABG & 3 wks post.	<i>Faris &amp; Stotts:</i> mean age =60 (39-76) yrs  <i>Papadantonaki:</i> mean age =57.9 ± 8.2 yrs	NO USA, Norway, Spain
<b>** Global Moods Scale (GMS):</b> Denollet (1993)	20	Likert	YES	-	478 pts with CHD: 110 MI, 302 CABG & 66 PTCA (100% male)	Self-administered	Single assessment at 3-6 wks post MI, CABG or PTCA	Mean age =57.8 ± 8.7 yrs	NO Belgium
<b>** Health Complaints Scale (HCS):</b> Denollet (1994)	24	Likert	YES	Summated items: Total, Cognitive & Somatic scales. High scores indicate extremely bothered	535 men with CHD	Self-administered	Single assessment at 3-6 wks post MI, CABG or PTCA	Mean age =57.5 ± 8.6 yrs	NO Belgium
<b>** Multidimensional Index of Quality of Life (MLIQ):</b> Avis <i>et al.</i> (1996)	35	Likert	YES	Sum the 4 items in each of the 9 domains. Total score derived by several methods	348 stable cardiovascular pts (69% male). 43% 6m post CABG & 43% 2m post PTCA	Self-, telephone- or interview-administered	Single assessment	Mean age =63 (25-86) yrs	NO USA
<b>** Cardiac Quality of Life Index (CQLI):</b> Rukholm <i>et al.</i> (1998)	20	VAS	-	Adapted from Padilla & Grant's Quality of Life Instrument for cancer patients	222 people: 95 cardiac pts in rehab, 51 cardiac pts not in rehab & 76 healthy controls	Interview- or self-administered	2-weeks post discharge	-	NO Canada

Questionnaire	Number of items	Response format	Item reduction	Scaling	Patient group	Method of administration	Assessment points	Age of sample (yrs)	Validated in UK?
<b>Reduced Duke Activity Status Index:</b> <i>Alonso et al. (1997)</i>	8	Likert. Questions in hierarchic order, with skip format	Reduced from DASI	Final score calculated by multiplying each item weight by the response category. Scores range = 11.5 - 33. Imputed missing responses	46 stable CHD pts & 44 PTCA pts	Self-administered	On admission & 1m after PTCA	PTCA gp: mean age =55.5 ± 8.1 yrs. Stable gp: mean age =61.2 ± 7.6 yrs	NO Spain
<b>Soderlind et al's Quality of Life Questionnaire:</b> <i>Soderlind et al (1997)</i>	-	Likert	-	-	100 pts after CABG, valve, CABG+ valve	Self-administered	1 & 2 yrs post op	Mean age =66 yrs. 38% > 70 yrs	NO Sweden
<b>Specific Activity Questionnaire:</b> Rankin <i>et al. (1996)</i>	13	-	-	Continuous score of metabolic equivalents. The score is the most demanding activity that pt can complete without symptoms	97 cardiac pts (88% male). 74% had previous MI or revascularisation	Self-administered	-	Mean age =59 ± 10 yrs	NO Australia
<b>Symptom Scale:</b> <i>Keresztes et al. (1993)</i>	-	Likert	-	Summated scales: Total, Angina, SOB, Fatigue. Low scores indicate high level of functional ability	60 cardiac pts undergoing exercise test (70% male)	Self-administered	Single assessment	Mean age =54.1 (31-83) yrs	NO USA
<b>** Utility Based Quality of Life-Heart Questionnaire (UBQ-H):</b> Martin <i>et al. (1999)</i>	32	Likert	-	Summated mean scores	322 cardiovascular outpatients, inc. heart failure & transplant pts (73% male)	Self-administered	Baseline and 10 days after	Mean age =60 ± 10 yrs	NO Australia
<b>Veterans Specific Activity Questionnaire:</b> Myers <i>et al. (1994)</i>	21	Pt to draw a line below the activities they are able to do	-	Continuous score of metabolic equivalents. The score is the most demanding activity that pt can complete without symptoms	212 pts referred for exercise testing	Self-administered	Single assessment	Mean age =62 ± 8 yrs	NO USA

**KEY**

- Details not found

\*\* Questionnaire met minimum reliability and validity criteria.

Pts Patients.

CHF Chronic heart failure.

## APPENDIX 4.1 Letter of Invitation for Interview

### *Official Hospital Letterhead*

(Date)

(Patient's name)

(Patient's address)

Dear (Patient's Name),

A study is currently underway at the Royal Brompton Hospital to develop a new questionnaire for patients who have recently undergone coronary artery bypass surgery or coronary angioplasty. An important part of this study involves interviewing people about their experiences of these procedures. We are inviting you to take part in this study. Patients like you have been selected from those treated at this hospital.

If you agree to participate in this study, you will be interviewed on ONE occasion. The interviewer will ask your views about your quality of life, including questions about your physical, emotional and social well-being, your ability to carry out daily activities, and about your health in general. The interview will be done at your home, unless you prefer the interview to be carried out elsewhere.

Taking part in the study is voluntary. You may choose to take part or you may decide not to take part at all. If you decide not to take part or to withdraw at any point, your future care at the Royal Brompton Hospital will not be affected in any way. All information received will be treated as confidential, and all participants will be identified by a number, not by name.

This study is being undertaken by a research team headed by Dr Donna Lamping and Sara Schroter (London School of Hygiene and Tropical Medicine), and includes Mr Pepper, Mr Moat, and Professor Coats (Royal Brompton Hospital).

I will telephone you in a few days to enquire whether you wish to participate and if so to arrange a possible date for the interview.

Yours sincerely

Sara Schroter

## APPENDIX 4.2 Patient Consent Form for Interviews

### TITLE OF PROJECT:

Development of a patient-based measure of outcome for patients undergoing coronary revascularisation.

### EXPLANATION OF PROJECT:

Invitation: We would like to invite you to participate in a study to develop a questionnaire for finding out the views of patients who are either soon to undergo or have recently undergone coronary artery bypass graft surgery or coronary angioplasty.

If you agree to take part in this study you will be interviewed on one occasion. The interviewer will ask your views about your quality of life, including questions about your physical, emotional and social well-being, your ability to carry out daily activities, and about your health in general.

All the information you give during the study will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on all interview forms. These forms will be kept in locked research files which only the research staff will have access to. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

This study is being undertaken by a research team at the London School of Hygiene and Tropical Medicine in collaboration with Mr Pepper, Mr Moat, and Professor Coats at the Royal Brompton Hospital. Please understand that you need not take part in this study if you do not wish to. If you do take part, you may withdraw at any time, and need give no reason for doing so. If you choose not to take part, or if you withdraw, your normal care and treatment will be unaffected.

Signed by the person in charge of the Project \_\_\_\_\_ Date \_\_\_\_\_

The Ethics Committee of the (Royal Brompton Hospital) has approved the above statement.  
Signed by the Chairman/Representative of the Committee

\_\_\_\_\_ Date \_\_\_\_\_

### FORM OF CONSENT

I, \_\_\_\_\_ of \_\_\_\_\_  
agree to take part in the research project outline above. I understand the nature and purpose of the questionnaire, and that I may withdraw from the research without it affecting my care and treatment at the Royal Brompton Hospital in any way.

Signed \_\_\_\_\_ Date \_\_\_\_\_

**APPENDIX 4.3 Frequency of Comments Made by CABG and PTCA  
Patients For Each Content Domain**

Content domain	Frequency of comments made by CABG patients	Frequency of comments made by PTCA patients
<b>Symptoms</b>		
"Angina"	3	-
"Chest pain"	6	10
"Tightness in the chest"	2	1
"Soreness / discomfort in the chest"	2	-
Pain in the arm(s)	1	6
Breathlessness	5	7
"Heart attack"	-	3
"Racing heart" / "palpitations"	1	-
Difficulty sleeping	2	-
Restless	1	2
"Tired" / "exhausted"	2	6
"Lack of energy"	2	3
"Weak" / "drained"	1	-
Sudden onset of symptoms	1	4
Symptoms returned	-	4
Medication complaints	1	1
<b>Limitations in daily activities</b>		
Work	4	6
"Anything exertional"	6	8
General physical limitations	3	10
Playing with children	2	2
Carrying heavy objects	5	7
General gardening	2	2
Mowing the lawn	3	-
Housekeeping	2	-
Sweeping	3	1
Shopping	1	4
Driving	1	2
Travel	1	1
DIY	2	1
Sawing	1	-
Painting / decorating	1	2
Swimming	1	2
Playing Frisbee	-	1
Walking the dog	1	1
Running	3	4
Walking >1 mile	6	4
Walking short distances	1	4
Walking quickly	5	8
Climbing stairs	5	7
Walking up hill	1	5

Content domain	Frequency of comments made by CABG patients	Frequency of comments made by PTCA patients
Cycling	-	1
Doing light jobs	3	2
Dressing	1	1
Washing	2	1
Standing for long periods	4	2
Hospital visits	1	1
Relaxing brings on pain	1	-
Resting in bed	1	1
Wouldn't go out in the wind	1	-
Gave up work	2	1
Difficulties at work	2	6
<b>Psychological functioning</b>		
"Anxious" pre-revascularisation	2	6
"Anxious" post-revascularisation	5	3
Anger	1	1
Stress	3	3
"Panic"	3	1
Desperation	4	5
Embarrassment	1	-
Denial of condition	-	2
Fear of doing too much / own safety	6	7
Avoidance of some activities	3	6
Frightened by the pain	4	2
Frustrated by heart condition	5	4
Difficult to adjust to being sick	1	2
Learn to cope	-	1
Irritable	2	2
Selfish	-	1
Depression	2	1
Down-hearted / despondent	2	3
"Not a happy person"	1	2
Illness protruded all thoughts	1	2
Needed reassurance of progress	8	4
Importance of having confidence	4	3
Felt safe in hospital	2	1
Uncertain about the future	-	4
Positive about the future	2	6
Fear of future health	5	6
Cause of ill health	3	6
"My destiny" (to be sick)	1	3
Shock of diagnosis of CHD	3	2
Mentioned death	4	4
Thought they were dying	2	1
Afraid of death	3	2
Reference to the life saving operation	4	4
Anxious waiting for operation	3	5
"Relief" to have operation	3	3

Content domain	Frequency of comments made by CABG patients	Frequency of comments made by PTCA patients
<b>Cognitive functioning</b>		
Difficulty concentrating	-	1
Memory problems	1	-
<b>Social functioning</b>		
Impact on spouse / family / friends	6	6
Restricted activities with peers	2	4
Afraid to leave home	3	1
Wanted their independence	5	3
Felt a burden on family & friends	2	2
<b>Re-admission to hospital / adverse events</b>		
Readmission to hospital	1	2
Experienced restenosis	1	3
Atrial fibrillation	1	1
Pleural effusion	1	-
Arrhythmia	1	-
Mini fits	1	-
"Water on the heart"	1	-
<b>Symptoms and problems associated with treatment</b>		
Severe eating / appetite problems	4	-
Nausea	2	1
Sweating	1	-
Faintness	1	-
Sleep difficulties	4	1
Exhaustion	2	2
Weakness	2	3
Cough	1	-
Soreness / discomfort in the chest	1	2
Swollen feet	3	2
Concern over swollen feet	-	1
Oozing / seeping wound(s)	2	-
Wound infection	1	-
Wound pain / soreness / tenderness	4	1
Wound related concern	4	1
Swelling around wound	1	-
Bleeding at wound site	-	1
<b>CABG Only</b>		
Muscle pains from opening chest	2	-
Pain from artery removal	1	-
Chest wall pain	2	-
"Pain in the chest"	1	-
Sore / painful leg	4	-
Numb or cold leg	3	-
Bruising of the leg	1	-
Bruising on chest	1	-

Content domain	Frequency of comments made by CABG patients	Frequency of comments made by PTCA patients
"Clicky sternum"	1	-
<b>PTCA Only</b>		
Bruising of the thigh	-	8
Bruising around groin	-	6
Groin pain	-	2
Numb groin	-	1
Had problem in groin	-	1
Lumps in groin wound	-	1
Concern over groin scar	-	1
<b>New psychological outcomes</b>		
Fear of re-stenosis / symptoms returning	1	5
Fear of needing another operation	1	3
Unattractiveness of scars	3	-
Concern over bruising on thigh (PTCA)	-	2
<b>Satisfaction with care and treatment</b>		
Satisfied with care	6	10
Admiration of the hospital & staff	4	9
Importance of staff-patient relations	-	2
Satisfied with operation	5	7
Dissatisfied with outcome of operation	1	2
Distress at misdiagnosis	1	3
Waiting time for operation	3	5
Helpful booklet guidance on recovery	2	3
Needed more advice	5	-
Good quality of information	2	7
Right quantity of information	2	8
Usefulness of written info / booklets	2	-
Too much information to take in at once	2	-
<b>Expectations</b>		
Expected to improve after operation	9	9
Recovery related satisfaction	2	5
"Paced" themselves	7	9
"Pushed" themselves	-	2
Made comparisons with peers	3	2
Speed of recovery	3	6
Recovery was "a difficult time"	3	2
Felt immediate improvement	5	9

"" Patients' description / phrasing.

# APPENDIX 4.4 Pre-test Version of Post-Revascularisation

## CROQ-CABG Questionnaire

<b>For Office Use Only</b>			
Patient:	<input style="width: 90%;" type="text"/>	Op Date:	<input style="width: 90%;" type="text"/>
Hospital:	<input style="width: 90%;" type="text"/>	Received:	<input style="width: 90%;" type="text"/>

### CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE (CROQ-CABG)

**INSTRUCTIONS:** We are interested in finding out how you have been since your heart operation (**coronary artery bypass graft surgery**) which you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your heart condition?

(Please tick one box on each line)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain	<input type="checkbox"/>				
Chest tightness	<input type="checkbox"/>				
Discomfort in the chest	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Pain that radiates to other parts of your body (eg arms, shoulders, back, neck, throat, jaw, hands)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				
Disturbed sleep	<input type="checkbox"/>				
Feeling worn out or low in energy	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your chest pain, chest tightness or angina? (Please tick only one box).

- |                          |                          |  |                          |                          |                            |
|--------------------------|--------------------------|--|--------------------------|--------------------------|----------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   |
| 4 or more times per day  | 1-3 times per day        | 3 or more times per week but not every day | 1-2 times per week       | Less than once a week    | None over the past 4 weeks |

3. During the past 4 weeks, have you had chest pain, chest tightness or angina:  
(Please tick only one box)

                                                                             
 At rest?                                      Only on exertion?                                      Not at all?

4. During the past 4 weeks, how much trouble has your heart condition caused you?  
(Please tick only one box)

                                                                                         
 A lot                      Quite a bit                      Some                      A little                      None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your heart condition limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below.

(Please tick one box on each line)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking more than a mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking half a mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking one hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **heart condition**?

(Please tick one box on each line)

	YES	NO
Cut down the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>
Were limited in the kind of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
Had difficulty performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt:

(Please tick one box on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or overdoing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Worried that your symptoms might return?	<input type="checkbox"/>				
Worried that you might need another heart operation in the future?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Out of control of your life?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Unsure of yourself or lacking in self-confidence?	<input type="checkbox"/>				
Low in morale?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				

During the <u>past 4 weeks</u> , how often have you felt:					
	(Please tick one box on each line)				
	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Frustrated or impatient?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Irritated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That you had to avoid certain activities because of your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. During the <u>past 4 weeks</u> , how much of the time did you:						
	(Please tick one box on each line)					
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have trouble keeping your attention on any activity for long?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Become confused and start several actions at a time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
React slowly to things that were done or said?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not complete things or activities you started?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. This question is about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:

(Please tick one box on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Difficulties with your personal relationships?	<input type="checkbox"/>				
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)	<input type="checkbox"/>				
Feeling excluded from doing things with other people?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

10. The next section asks about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all".

(Please tick one box on each line)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your <b>chest wound</b>	<input type="checkbox"/>				
Any other pain in your <b>chest or neck</b> due to your operation	<input type="checkbox"/>				
Infection, oozing or tenderness in your <b>chest wound</b>	<input type="checkbox"/>				
Numbness or tingling in your <b>chest</b>	<input type="checkbox"/>				
Pain in your <b>leg or arm wound</b>	<input type="checkbox"/>				
Any other pain in your <b>leg or arm</b> due to your operation	<input type="checkbox"/>				
Infection, oozing or tenderness in your <b>leg or arm wound</b>	<input type="checkbox"/>				

During the past 4 weeks, how much were you bothered by the following problems?  
 If you did not have the problem, tick the last box "Not at all."

(Please tick one box on each line)

	A lot	Quite a bit	Moderately	A little	Not at all
Numbness or tingling in your leg or arm	<input type="checkbox"/>				
Bruising on your chest	<input type="checkbox"/>				
Bruising on your leg or arm where a vein was removed	<input type="checkbox"/>				
Swollen feet or ankles	<input type="checkbox"/>				
Weakness or lethargy	<input type="checkbox"/>				
Nausea	<input type="checkbox"/>				
Loss of appetite	<input type="checkbox"/>				
Concern over the appearance of your surgical scars	<input type="checkbox"/>				

11. Since your heart operation, have you been re-admitted to hospital (for an overnight stay) for any reason to do with your heart condition or your heart operation? Please give as many details as you can below.

No

Yes, I was in hospital for  days

Date

Hospital name

Reason for hospital stay

--	--	--

12. The next question asks about how satisfied you are with your heart operation. How satisfied are you with the:

(Please tick one box on each line)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Progress you have made since your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Results of your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about how you might feel while recovering from your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. Were you given the information about your heart operation at the right time? (Tick one box)

- No  
 Yes

14. Overall, how would you describe your heart condition now compared to before your heart operation?

- Much worse  
 A little worse  
 About the same  
 A little better  
 Much better

15. Has your recovery from your heart operation so far been:

- Slower than you expected?  
 About what you expected?  
 Faster than you expected?  
 Did not know how long it would take?

16. Are the results from your heart operation:

- Worse than you expected?  
 About what you expected?  
 Better than you expected?

**Finally, it would be helpful if you could answer a few general questions about yourself. (Please tick the boxes that best describe your situation).**

17. Are you:  Male  
 Female

18. What is your date of birth?

Day Month Year

19. Please fill in the date you completed this questionnaire:

Day Month Year

20. To which ethnic group do you belong?

- |  |   |
|--|---|
| <input type="checkbox"/> White           | <input type="checkbox"/> Pakistani              |
| <input type="checkbox"/> Black/Caribbean | <input type="checkbox"/> Bangladeshi            |
| <input type="checkbox"/> Black/African   | <input type="checkbox"/> Chinese                |
| <input type="checkbox"/> Black/Other     | <input type="checkbox"/> Any other ethnic group |
| <input type="checkbox"/> Indian          | (please specify) <input type="text"/>           |

21. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No  
 Yes (If yes, what is the matter with you?)

22. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed full-time | <input type="checkbox"/> Retired                                     |
| <input type="checkbox"/> Employed part-time | <input type="checkbox"/> Unable to work/disabled                     |
| <input type="checkbox"/> Voluntary work     | <input type="checkbox"/> Unemployed                                  |
| <input type="checkbox"/> Homemaker          | <input type="checkbox"/> Other (please specify) <input type="text"/> |

23. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What do (did) you actually do in this job? \_\_\_\_\_

What does (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

24. ***For women only.*** What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

The next question asks about your work. If you do not work outside the home, please put a tick in the first box.

25. Did you return to work after your heart operation? Please tick one box only and state how many weeks you were off work after your operation.

I do not work outside the home

OR  Yes, I returned to the **same job** after  weeks

OR  Yes, I returned to a **different job** after  weeks

OR  No, I have not returned to work yet

OR  No, I have stopped working

26. Do you live: (You may tick more than one box.)

Alone?

With your husband or partner?

With children?

With family members?

Other? (please specify )

27. Can you tell us approximately when you were first diagnosed as having heart disease?

          
Month

          
Year

I can not remember when I was first diagnosed

28. Did you need any help in completing this questionnaire? If so, who helped and why?

29. Is there anything else you would like to tell us about your **heart condition or heart operation** that is not covered in this questionnaire? Please write in the box below.

**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

CROQ-PTCA Questionnaire

<b>For Office Use Only</b>			
Patient:	<input style="width: 90%;" type="text"/>	Op Date:	<input style="width: 90%;" type="text"/>
Hospital:	<input style="width: 90%;" type="text"/>	Received:	<input style="width: 90%;" type="text"/>

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

**INSTRUCTIONS:** We are interested in finding out how you have been since your heart operation (**percutaneous transluminal coronary angioplasty**) which you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**?

(Please tick one box on each line)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain	<input type="checkbox"/>				
Chest tightness	<input type="checkbox"/>				
Discomfort in the chest	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Pain that radiates to other parts of your body (eg arms, shoulders, back, neck, throat, jaw, hands)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				
Disturbed sleep	<input type="checkbox"/>				
Feeling worn out or low in energy	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box).

- |                          |                          |  |                          |                          |                            |
|--------------------------|--------------------------|--|--------------------------|--------------------------|----------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   |
| 4 or more times per day  | 1-3 times per day        | 3 or more times per week but not every day | 1-2 times per week       | Less than once a week    | None over the past 4 weeks |



**6. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your heart condition?**

(Please tick one box on each line)

	YES	NO
Cut down the <b>amount of time</b> you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
<b>Accomplished less</b> than you would like	<input type="checkbox"/>	<input type="checkbox"/>
Were limited in the <b>kind of work</b> or other activities	<input type="checkbox"/>	<input type="checkbox"/>
Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

**7. The next questions ask about your feelings about your heart condition. During the past 4 weeks, how often have you felt:**

(Please tick one box on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or over-doing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Worried that your symptoms might return?	<input type="checkbox"/>				
Worried that you might need another heart operation in the future?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Out of control of your life?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Unsure of yourself or lacking in self-confidence?	<input type="checkbox"/>				
Low in morale?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				

During the <u>past 4 weeks</u> , how often have you felt:					
	(Please tick one box on each line)				
	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Frustrated or impatient?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Irritated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That you had to avoid certain activities because of your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. During the <u>past 4 weeks</u> , how much of the time did you:						
	(Please tick one box on each line)					
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have trouble keeping your attention on any activity for long?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Become confused and start several actions at a time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
React slowly to things that were done or said?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not complete things or activities you started?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. This question is about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:

(Please tick one box on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Difficulties with your personal relationships?	<input type="checkbox"/>				
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)	<input type="checkbox"/>				
Feeling excluded from doing things with other people?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

10. The next section asks about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all".

(Please tick one box on each line)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your groin wound	<input type="checkbox"/>				
Infection, oozing or tenderness in your groin wound	<input type="checkbox"/>				
Numbness or tingling in your groin area	<input type="checkbox"/>				
Bruising around your groin wound	<input type="checkbox"/>				
Bruising on your thigh	<input type="checkbox"/>				
Discomfort in your chest due to your operation	<input type="checkbox"/>				
Swollen feet or ankles	<input type="checkbox"/>				
Concern over the appearance of your surgical scar	<input type="checkbox"/>				
Concern over the appearance of your bruises	<input type="checkbox"/>				

11. Since your heart operation, have you been re-admitted to hospital (for an overnight stay) for any reason to do with your **heart condition or your heart operation**? Please give as many details as you can below.

No

Yes, I was in hospital for  days

Date

Hospital name

Reason for hospital stay

--	--	--

12. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the:

(Please tick one box on each line)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Progress you have made since your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Results of your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about how you might feel while recovering from your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. Were you given the information about your **heart operation** at the right time? (Tick one box)

No

Yes

**14. Overall, how would you describe your heart condition now compared to before your heart operation?**

- Much worse
- A little worse
- About the same
- A little better
- Much better

**15. Has your recovery from your heart operation so far been:**

- Slower than you expected?
- About what you expected?
- Faster than you expected?
- Did not know how long it would take?

**16. Are the results from your heart operation:**

- Worse than you expected?
- About what you expected?
- Better than you expected?

**Finally, it would be helpful if you could answer a few general questions about yourself. (Please tick the boxes that best describe your situation).**

**17. Are you:**  Male  
 Female

**18. What is your date of birth?**

             
Day                      Month                      Year

**19. Please fill in the date you completed this questionnaire:**

             
Day                      Month                      Year

20. To which ethnic group do you belong?

- |  |   |
|--|---|
| <input type="checkbox"/> White           | <input type="checkbox"/> Pakistani              |
| <input type="checkbox"/> Black/Caribbean | <input type="checkbox"/> Bangladeshi            |
| <input type="checkbox"/> Black/African   | <input type="checkbox"/> Chinese                |
| <input type="checkbox"/> Black/Other     | <input type="checkbox"/> Any other ethnic group |
| <input type="checkbox"/> Indian          | (please specify) <input type="text"/>           |

21. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No
- Yes (If yes, what is the matter with you?)

22. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed full-time | <input type="checkbox"/> Retired                                     |
| <input type="checkbox"/> Employed part-time | <input type="checkbox"/> Unable to work/disabled                     |
| <input type="checkbox"/> Voluntary work     | <input type="checkbox"/> Unemployed                                  |
| <input type="checkbox"/> Homemaker          | <input type="checkbox"/> Other (please specify) <input type="text"/> |

23. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What do (did) you actually do in this job? \_\_\_\_\_

What does (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

**24. *For women only.*** What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

The next question asks about your work. If you do not work outside the home, please put a tick in the first box.

**25.** Did you return to work after your heart operation? Please tick one box only and state how many weeks you were off work after your operation.

I do not work outside the home

OR  Yes, I returned to the **same job** after  weeks

OR  Yes, I returned to a **different job** after  weeks

OR  No, I have not returned to work yet

OR  No, I have stopped working

**26.** Do you live: (You may tick more than one box.)

Alone?

With your husband or partner?

With children?

With family members?

Other? (please specify)

**27.** Can you tell us approximately when you were first diagnosed as having heart disease?

\_\_\_\_\_  
Month                  Year

I can not remember when I was first diagnosed

**28.** Did you need any help in completing this questionnaire? If so, who helped and why?

**29. Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire? Please write in the box below.**

**Please check that you have answered all the questions on each page.  
THANK YOU FOR YOUR HELP**

### APPENDIX 4.6 CROQ Items (Pre-test Version)

CROQ item (description)	Source of item	Original phrasing of borrowed item	Items in CROQ (pre-test version)
<b>Q1:</b> (Chest pain) (Chest tightness) (Chest discomfort) (Shortness of breath) (Radiating pain) (Palpitations) (Disturbed sleep) (Worn out)	New	NA	During the <u>past 4 weeks</u> , how much were you bothered by each of the following problems related to your <b>heart condition</b> ? <ul style="list-style-type: none"> <li>• Chest pain?</li> <li>• Chest tightness?</li> <li>• Discomfort in the chest?</li> <li>• Shortness of breath?</li> <li>• Pain that radiates to other parts of your body (e.g. arms, shoulders, back, neck, throat, jaw, hands)?</li> <li>• Palpitations (strong or irregular heart beat)?</li> <li>• Disturbed sleep?</li> <li>• Feeling worn out or low in energy?</li> </ul>
<b>Q2:</b> (Nitros)	SAQ	Over the <u>past 4 weeks</u> , on average, how many times have you had to take nitros (nitroglycerin tablets) for your chest pain, chest tightness or angina?	During the <u>past 4 weeks</u> , on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your <b>chest pain, chest tightness or angina</b> ?
<b>Q3:</b> (Symptoms on exertion)	New	NA	During the <u>past 4 weeks</u> , have you had <b>chest pain, chest tightness or angina</b> : <ul style="list-style-type: none"> <li>• At rest?</li> <li>• Only on exertion?</li> <li>• Not at all?</li> </ul>
<b>Q4:</b> (Trouble)	New	NA	During the <u>past 4 weeks</u> , how much trouble has your <b>heart condition</b> caused you?

CROQ item (description)	Source of item	Original phrasing of borrowed item	Items in CROQ (pre-test version)
Q5a-j: (Vigorous activities) (Moderate activities) (Lifting & Carrying) (Climbing flights of stairs) (Climbing one flight of stairs) (Bending, kneeling, stooping) (Walk > 1 mile) (Walk half a mile) (Walk 100 yards) (Bathing or dressing)	SF-36	The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much? <ul style="list-style-type: none"> <li>• <b>Vigorous activities</b>, such as running, lifting heavy objects, participating in strenuous sports</li> <li>• <b>Moderate activities</b>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</li> <li>• Lifting or carrying groceries</li> <li>• Climbing <b>several</b> flights of stairs</li> <li>• Climbing <b>one</b> flight of stairs</li> <li>• Bending, keeling, stooping</li> <li>• Walking <b>more than a mile</b></li> <li>• Walking <b>half a mile</b></li> <li>• Walking <b>one hundred yards</b></li> <li>• Bathing or dressing yourself</li> </ul>	The following questions ask about activities which you might do during a typical day. During the <u>past 4 weeks</u> , has your <b>heart condition</b> limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. <ul style="list-style-type: none"> <li>• <b>Vigorous activities</b>, such as running, lifting heavy objects, participating in strenuous sports?</li> <li>• <b>Moderate activities</b>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?</li> <li>• Lifting or carrying groceries?</li> <li>• Climbing <b>several</b> flights of stairs?</li> <li>• Climbing <b>one</b> flight of stairs?</li> <li>• Bending, keeling, stooping?</li> <li>• Walking <b>more than a mile</b>?</li> <li>• Walking <b>half a mile</b>?</li> <li>• Walking <b>one hundred yards</b>?</li> <li>• Bathing or dressing yourself?</li> </ul>
Q6a-d: (Time spent) (Accomplish) (Kind of work) (Performing)	SF-36	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u> ? <ul style="list-style-type: none"> <li>• Cut down the <b>amount of time</b> spent on work or other activities</li> <li>• <b>Accomplished less</b> than you would like</li> <li>• Were limited in the <b>kind</b> of work or other activities</li> <li>• Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)</li> </ul>	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities as a result of your <b>heart condition</b> ? <ul style="list-style-type: none"> <li>• Cut down the <b>amount of time</b> spent on work or other activities?</li> <li>• <b>Accomplished less</b> than you would like?</li> <li>• Were limited in the <b>kind</b> of work or other activities?</li> <li>• Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)?</li> </ul>
Q7a-b: (Worry heart condition) (Over-doing it)	New	NA	The next questions ask about your feelings about your <b>heart condition</b> . During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>• Worried about your heart condition?</li> <li>• Worried about doing too much or over-doing it?</li> </ul>

CROQ item (description)	Source of item	Original phrasing of borrowed item	Items in CROQ (pre-test version)
Q7c: (Heart attack)	SAQ	How often do you worry that you may have a heart attack or die suddenly?	During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>Worried that you might have a heart attack or die suddenly?</li> </ul>
Q7d-h: (Symptoms return) (Another operation) (Frightened by pain) (Out of control) (Uncertain)	New	NA	The next questions ask about your feelings about your heart condition. During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>Worried that your symptoms might return?</li> <li>Worried that you might need another heart operation in the future?</li> <li>Frightened by the pain or discomfort of your heart condition?</li> <li>Out of control of your life?</li> <li>Uncertain about the future?</li> </ul>
Q7l: (Unsure)	QLMI-2	How often during the last two weeks, have you felt <b>unsure of yourself and lacking in self-confidence?</b>	During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>Unsure of yourself or lacking in self-confidence?</li> </ul>
Q7j-k: (Morale) (Depressed)	New	NA	The next questions ask about your feelings about your heart condition. During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>Low in morale?</li> <li>Depressed?</li> </ul>
Q7l: (Frustrated)	QLMI-2	In general, how much of the time during the last 2 weeks have you felt <b>frustrated, impatient or angry?</b>	During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>Frustrated or impatient?</li> </ul>
Q7m-n: (Irritated) (Avoid activities)	New	NA	The next questions ask about your feelings about your heart condition. During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>Irritated?</li> <li>That you had to avoid certain activities because of your heart condition?</li> </ul>
Q7o: (Interfered with enjoyment)	SAQ	Over the <u>past 4 weeks</u> , how much has your chest pain, chest tightness or angina interfered with your enjoyment of life?	During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>That your heart condition interfered with your enjoyment of life?</li> </ul>

CROQ item (description)	Source of item	Original phrasing of borrowed item	Items in CROQ (pre-test version)
Q7p: Positive outlook	New	NA	The next questions ask about your feelings about your <b>heart condition</b> . During the <u>past 4 weeks</u> , how often have you felt: <ul style="list-style-type: none"> <li>• That it was difficult to keep a positive outlook about your health?</li> </ul>
Q8a-f: (Reason) (Forget) (Attention) (Concentration) (Confusion) (React slowly)	MOS	How much of the time during the past month did you: <ul style="list-style-type: none"> <li>• Have difficulty reasoning and solving problems, for example making plans, making decisions or learning new things?</li> <li>• Forget, for example things that happened recently, where you put things or appointments?</li> <li>• Have trouble keeping your attention on any activity for long?</li> <li>• Have difficulty doing activities involving concentration and thinking?</li> <li>• Become confused and start several actions at a time?</li> <li>• React slowly to things that were said or done?</li> </ul>	During the <u>past 4 weeks</u> , how much of the time did you: <ul style="list-style-type: none"> <li>• Have difficulty reasoning and solving problems, for example making plans, making decisions or learning new things?</li> <li>• Forget, for example things that happened recently, where you put things or appointments?</li> <li>• Have trouble keeping your attention on any activity for long?</li> <li>• Have difficulty doing activities involving concentration and thinking?</li> <li>• Become confused and start several actions at a time?</li> <li>• React slowly to things that were said or done?</li> </ul>
Q8g: (Not complete)	AIQ	How often did you complete things, activities you started?	During the <u>past 4 weeks</u> , how much of the time did you not complete things or activities you started?
Q9a: (Personal relationships)	New	NA	This question is about the impact of your <b>heart condition</b> on your family and friends and the extent to which it has interfered with your social activities. During the <u>past 4 weeks</u> , how often have you experienced the following as a result of your <b>heart condition</b> : <ul style="list-style-type: none"> <li>• Difficulties with your personal relationships?</li> </ul>
Q9b: (Family overprotective)	QLMI-2	How often during the last 2 weeks have you felt as if your family is being overprotective toward you?	During the <u>past 4 weeks</u> , how often have you experienced the following as a result of your <b>heart condition</b> : <ul style="list-style-type: none"> <li>• Family or friends being overprotective toward you?</li> </ul>

CROQ item (description)	Source of item	Original phrasing of borrowed item	Items in CROQ (pre-test version)
Q9c: (Feeling a burden)	QLMI-2	How often, during the past 2 weeks, have you felt as if you are a <b>burden on others</b> ?	During the <u>past 4 weeks</u> , how often have you experienced the following as a result of your <b>heart condition</b> : <ul style="list-style-type: none"> <li>• Feeling like you are a burden on others?</li> </ul>
Q9d: (Restricted in social activities)	SF-36	During the past 4 weeks, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc)?	During the <u>past 4 weeks</u> , how often have you experienced the following as a result of your <b>heart condition</b> : <ul style="list-style-type: none"> <li>• Feeling restricted in your social activities (like visiting with friends, relatives, etc)?</li> </ul>
Q9e: (Feeling excluded)	QLMI-2	How often during the last 2 weeks have you felt <b>excluded</b> from doing things with other people because of your heart problem?	During the <u>past 4 weeks</u> , how often have you experienced the following as a result of your <b>heart condition</b> : <ul style="list-style-type: none"> <li>• Feeling excluded from doing things with other people?</li> </ul>
Q9f: (Too far from home)	New	NA	This question is about the impact of your <b>heart condition</b> on your family and friends and the extent to which it has interfered with your social activities. During the <u>past 4 weeks</u> , how often have you experienced the following as a result of your <b>heart condition</b> : <ul style="list-style-type: none"> <li>• Feeling worried about going too far from home?</li> </ul>
Q10: (Complications)	New	NA	The next section asks about problems you might have had <b>since your heart operation</b> . During the <u>past 4 weeks</u> , how much were you bothered by the following problems? <u>CABG only:</u> <ul style="list-style-type: none"> <li>• Pain in your <b>chest wound</b>?</li> <li>• Any other pain in your <b>chest or neck</b> due to your operation?</li> <li>• Infection, oozing or tenderness in your <b>chest wound</b>?</li> <li>• Numbness or tingling in your <b>chest</b>?</li> <li>• Pain in your <b>leg or arm wound</b>?</li> <li>• Any other pain in your <b>leg or arm</b> due to your operation?</li> <li>• Infection, oozing or tenderness in your <b>leg or arm wound</b>?</li> <li>• Numbness or tingling in your <b>leg or arm</b>?</li> <li>• Bruising on your <b>chest</b>?</li> </ul>

CROQ item (description)	Source of item	Original phrasing of borrowed item	Items in CROQ (pre-test version)
Q10 contd...			<ul style="list-style-type: none"> <li>• Bruising on your leg or arm where a vein was removed?</li> <li>• Swollen feet or ankles?</li> <li>• Weakness or lethargy?</li> <li>• Nausea?</li> <li>• Loss of appetite?</li> <li>• Concern over the appearance of your surgical scars?</li> </ul> <p><u>PTCA only</u></p> <ul style="list-style-type: none"> <li>• Pain in your groin wound?</li> <li>• Infection, oozing or tenderness in your groin wound?</li> <li>• Numbness or tingling in your groin area?</li> <li>• Bruising around your groin wound?</li> <li>• Bruising on your thigh?</li> <li>• Discomfort in your chest due to your operation?</li> <li>• Swollen feet or ankles?</li> <li>• Concern over the appearance of your surgical scar?</li> <li>• Concern over the appearance of your bruises?</li> </ul>
Q11: (Readmission to hospital)	New	NA	<p><u>Since your heart operation</u>, have you been re-admitted to hospital (for an overnight stay) for any reason to do with your <b>heart condition or your heart operation</b>? Please give as many details as you can below.</p>
Q12a-d: (Satisfied with progress) (Satisfied with results) (Satisfied with info about op) (Satisfied with recovery info)	New	NA	<p>The next question asks about how satisfied you are with your <b>heart operation</b>. How satisfied are you with the:</p> <ul style="list-style-type: none"> <li>• Progress you have made since your heart operation?</li> <li>• Results of your heart operation?</li> <li>• Information you were given about your heart operation?</li> <li>• Information you were given about how you might feel while recovering from your heart operation?</li> </ul>
Q13: (Info at the right time)	New	NA	<p>Were you given the information about your <b>heart operation</b> at the right time?</p>

<b>CROQ item (description)</b>	<b>Source of item</b>	<b>Original phrasing of borrowed item</b>	<b>Items in CROQ (pre-test version)</b>
Q14: (Overall compared to before op)	MOQ	Overall, how do you feel now compared to before your operation?	Overall, how would you describe your <b>heart condition <u>now compared to before</u></b> your heart operation?
Q15: (Speed of recovery)	MOQ	Has your recovery from your operation so far been:	Has your recovery from your <b>heart operation</b> so far been: <ul style="list-style-type: none"> <li>• Slower than you expected?</li> <li>• About what you expected?</li> <li>• Faster than you expected?</li> <li>• Did not know how long it would take?</li> </ul>
Q16: (Expectation of results)	POQ	Were the results of your prostate procedure: <ul style="list-style-type: none"> <li>• Worse than you expected?</li> <li>• About what you expected?</li> <li>• Better than you expected?</li> </ul>	Are the results from your <b>heart operation</b> : <ul style="list-style-type: none"> <li>• Worse than you expected?</li> <li>• About what you expected?</li> <li>• Better than you expected?</li> </ul>

**Key to abbreviations:**

- AIQ: Angina Impact questionnaire.  
MOQ: Menorrhagia Outcomes Questionnaire.  
MOS: Medical Outcomes Study.  
New: Newly created item specifically for the CROQ.  
POQ: Prostate Outcomes Questionnaire.  
QLMI-2: Quality of Life after Acute Myocardial Infarction.  
SAQ: Seattle Angina Questionnaire.  
SF-36: Short-Form 36.

**APPENDIX 4.7 3-Months Post-Revascularisation CROQ-CABG**

**Questionnaire (Preliminary Field Test)**

For Office Use Only			
Patient ID: _____		Date of operation: _____	
Hospital: _____		Date received: _____	

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-CABG)**

INSTRUCTIONS: We are interested in finding out how you have been since the heart operation (**coronary artery bypass graft surgery**) you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Chest tightness due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				
Disturbed sleep	<input type="checkbox"/>				
Feeling worn out or low in energy	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks



6. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **heart condition**? (Please tick one box on each line.)

	YES	NO
Cut down the <b>amount of time</b> you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
<b>Accomplished less</b> than you would like	<input type="checkbox"/>	<input type="checkbox"/>
Were limited in the <b>kind</b> of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

7. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>					
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>					
Have trouble keeping your attention on any activity for long?	<input type="checkbox"/>					
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>					
Become confused and start several actions at a time?	<input type="checkbox"/>					
React slowly to things that were done or said?	<input type="checkbox"/>					
Not complete things or activities you started?	<input type="checkbox"/>					

8. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried about doing too much or over- doing it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried that your symptoms might return?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried that you might need another heart operation in the future?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Out of control of your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uncertain about the future?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unsure of yourself or lacking in self- confidence?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low in morale?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frustrated or impatient?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Irritated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That you had to avoid certain activities because of your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Difficulties with your personal relationships?	<input type="checkbox"/>				
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	<input type="checkbox"/>				
Feeling excluded from doing things with other people?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

10. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

- No
- Yes, I was in hospital for \_\_\_\_\_ days

Date of admission

Name of hospital

Reason for hospital stay

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11. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your <b>chest wound</b>	<input type="checkbox"/>				
Any other pain in your <b>chest or neck area</b> due to your operation	<input type="checkbox"/>				
Infection in your <b>chest wound</b>	<input type="checkbox"/>				
Oozing from your <b>chest wound</b>	<input type="checkbox"/>				
Tenderness around your <b>chest wound</b>	<input type="checkbox"/>				
Numbness or tingling around your <b>chest wound</b>	<input type="checkbox"/>				
Bruising on your <b>chest</b>	<input type="checkbox"/>				
Pain in your <b>leg or arm wound</b>	<input type="checkbox"/>				
Any other pain in your <b>leg or arm</b> due to your operation	<input type="checkbox"/>				
Infection in your <b>leg or arm wound</b>	<input type="checkbox"/>				
Oozing from your <b>leg or arm wound</b>	<input type="checkbox"/>				
Tenderness around your <b>leg or arm wound</b>	<input type="checkbox"/>				
Numbness or tingling in your <b>leg or arm</b> due to your operation	<input type="checkbox"/>				
Bruising on your <b>leg or arm</b> where a vein was removed	<input type="checkbox"/>				
Swollen feet or ankles	<input type="checkbox"/>				
Weakness or lethargy	<input type="checkbox"/>				
Nausea	<input type="checkbox"/>				
Loss of appetite	<input type="checkbox"/>				
Concern over the appearance of your surgical scars	<input type="checkbox"/>				

12. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Progress you have made since your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Results of your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about how you might feel while recovering from your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. Were you given the information about your **heart operation** at the time you needed it?

- No
- Yes

14. Overall, how would you describe your **heart condition** now compared to before you had your heart operation? (Please tick one box.)

- Much worse
- A little worse
- About the same
- A little better
- Much better

15. Has your recovery from your **heart operation** so far been: (Please tick one box.)

- Slower than you expected?
- About what you expected?
- Faster than you expected?
- Did not know how long it would take?

16. Are the results from your **heart operation**: (Please tick one box.)

- Worse than you expected?
- About what you expected?
- Better than you expected?



23. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What do (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

24. ***For women only.*** What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

25. This question asks about changes in your work situation after your heart operation. If you do not work outside the home, please put a tick in the first box. (Please tick one box only.)

I do not work outside the home

OR  I returned to the **same job** with the same number of hours after \_\_\_\_\_ weeks

OR  I returned to the **same job** with reduced number of hours after \_\_\_\_\_ weeks

OR  I returned to a **different job** after \_\_\_\_\_ weeks

OR  I have not returned to work yet

OR  I have stopped working

26. Do you live: (You may tick more than one box.)

Alone?

With your husband or partner?

With children?

With family members?

Other? (please specify) \_\_\_\_\_

27. Can you tell us approximately when you were first diagnosed as having heart disease?

                                  
Month            Year

I can not remember when I was first diagnosed

28. Did you need any help in completing this questionnaire? If so, who helped and why?

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29. Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire? If so, please write below.

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**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

**APPENDIX 4.8 3-Months Post-Revascularisation CROQ-PTCA  
Questionnaire (Preliminary Field Test)**

For Office Use Only			
Patient ID: _____		Date of operation: _____	
Hospital: _____		Date received: _____	

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

INSTRUCTIONS: We are interested in finding out how you have been since the heart operation (**percutaneous transluminal coronary angioplasty**) you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is COMPLETELY CONFIDENTIAL. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Chest tightness due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				
Disturbed sleep	<input type="checkbox"/>				
Feeling worn out or low in energy	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

                                             
 At rest?                      Only on exertion?                      Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

                                                                                         
 A lot                      Quite a bit                      Some                      A little                      None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
<b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>several</b> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>one</b> flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>more than a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>half a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>one hundred yards</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **heart condition**? (Please tick one box on each line.)

	YES	NO
Cut down the <b>amount of time</b> you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
<b>Accomplished less</b> than you would like	<input type="checkbox"/>	<input type="checkbox"/>
Were limited in the <b>kind</b> of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

7. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>					
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>					
Have trouble keeping your attention on any activity for long?	<input type="checkbox"/>					
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>					
Become confused and start several actions at a time?	<input type="checkbox"/>					
React slowly to things that were done or said?	<input type="checkbox"/>					
Not complete things or activities you started?	<input type="checkbox"/>					

8. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried about doing too much or over- doing it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried that your symptoms might return?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried that you might need another heart operation in the future?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Out of control of your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uncertain about the future?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unsure of yourself or lacking in self- confidence?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low in morale?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frustrated or impatient?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Irritated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That you had to avoid certain activities because of your heart condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Difficulties with your personal relationships?	<input type="checkbox"/>				
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	<input type="checkbox"/>				
Feeling excluded from doing things with other people?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

10. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

No

Yes, I was in hospital for \_\_\_\_\_ days

Date of admission

Name of hospital

Reason for hospital stay

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11. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your groin wound	<input type="checkbox"/>				
Infection in your groin wound	<input type="checkbox"/>				
Oozing from your groin wound	<input type="checkbox"/>				
Tenderness around your groin wound	<input type="checkbox"/>				
Numbness or tingling in your groin area	<input type="checkbox"/>				
Bruising around your groin wound	<input type="checkbox"/>				
Bruising on your thigh	<input type="checkbox"/>				
Discomfort in your chest due to your operation	<input type="checkbox"/>				
Swollen feet or ankles	<input type="checkbox"/>				
Problems in your groin where the catheter was inserted	<input type="checkbox"/>				
Concern over the appearance of your bruises	<input type="checkbox"/>				

12. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Progress you have made since your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Results of your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about how you might feel while recovering from your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



20. To which ethnic group do you belong?

- |  |   |
|--|---|
| <input type="checkbox"/> White           | <input type="checkbox"/> Pakistani              |
| <input type="checkbox"/> Black/Caribbean | <input type="checkbox"/> Bangladeshi            |
| <input type="checkbox"/> Black/African   | <input type="checkbox"/> Chinese                |
| <input type="checkbox"/> Black/Other     | <input type="checkbox"/> Any other ethnic group |
| <input type="checkbox"/> Indian          | (please specify) _____                          |

21. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No
- Yes (If yes, what is the matter with you?)
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

22. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed / self-employed full-time | <input type="checkbox"/> Retired                 |
| <input type="checkbox"/> Employed / self-employed part-time | <input type="checkbox"/> Unable to work/disabled |
| <input type="checkbox"/> Voluntary work                     | <input type="checkbox"/> Unemployed              |
| <input type="checkbox"/> Homemaker                          | <input type="checkbox"/> Other (please specify)  |
- \_\_\_\_\_

23. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What do (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

24. ***For women only.*** What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

25. This question asks about changes in your work situation after your heart operation. If you do not work outside the home, please put a tick in the first box. (Please tick one box only.)

- I do not work outside the home
- OR  I returned to the **same job** with the same number of hours after \_\_\_\_\_ weeks
- OR  I returned to the **same job** with reduced number of hours after \_\_\_\_\_ weeks
- OR  I returned to a **different job** after \_\_\_\_\_ weeks
- OR  I have not returned to work yet
- OR  I have stopped working

26. Do you live: (You may tick more than one box.)

- Alone?
- With your husband or partner?
- With children?
- With family members?
- Other? (please specify) \_\_\_\_\_

27. Can you tell us approximately when you were first diagnosed as having heart disease?

\_\_\_\_\_  
Month            Year

- I can not remember when I was first diagnosed

28. Did you need any help in completing this questionnaire? If so, who helped and why?

\_\_\_\_\_

29. Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire? If so, please write below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

**APPENDIX 4.9 Pre-Revascularisation CROQ-CABG Questionnaire  
(Preliminary Field Test)**

<b>For Office Use Only</b>		
<b>Patient ID:</b> _____		
<b>Hospital:</b> _____	<b>Date received:</b> _____	

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-CABG)**

**INSTRUCTIONS:** We are interested in finding out how you are now before the heart operation (**coronary artery bypass graft surgery**) you are going to have. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Chest tightness due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				
Disturbed sleep	<input type="checkbox"/>				
Feeling worn out or low in energy	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

At rest?

Only on exertion?

Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

A lot

Quite a bit

Some

A little

None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
<b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>several</b> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>one</b> flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>more than a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>half a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>one hundred yards</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **heart condition**? (Please tick one box on each line.)

	YES	NO
Cut down the <b>amount of time</b> you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
<b>Accomplished less</b> than you would like	<input type="checkbox"/>	<input type="checkbox"/>
Were limited in the <b>kind</b> of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

7. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>					
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>					
Have trouble keeping your attention on any activity for long?	<input type="checkbox"/>					
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>					
Become confused and start several actions at a time?	<input type="checkbox"/>					
React slowly to things that were done or said?	<input type="checkbox"/>					
Not complete things or activities you started?	<input type="checkbox"/>					

8. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or over-doing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Out of control of your life?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Unsure of yourself or lacking in self-confidence?	<input type="checkbox"/>				
Low in morale?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				
Frustrated or impatient?	<input type="checkbox"/>				
Irritated?	<input type="checkbox"/>				
That you had to avoid certain activities because of your heart condition?	<input type="checkbox"/>				
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>				
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>				
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>				

9. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Difficulties with your personal relationships?	<input type="checkbox"/>				
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	<input type="checkbox"/>				
Feeling excluded from doing things with other people?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

Finally, it would be very helpful if you could answer a few general questions about yourself. (Please tick the boxes that best describe your situation.)

10. Are you:  Male  
 Female

11. What is your date of birth?  Day  Month  Year

12. Please fill in the date you completed this questionnaire:  Day  Month  Year

13. To which ethnic group do you belong?

- |  |   |
|--|---|
| <input type="checkbox"/> White           | <input type="checkbox"/> Pakistani              |
| <input type="checkbox"/> Black/Caribbean | <input type="checkbox"/> Bangladeshi            |
| <input type="checkbox"/> Black/African   | <input type="checkbox"/> Chinese                |
| <input type="checkbox"/> Black/Other     | <input type="checkbox"/> Any other ethnic group |
| <input type="checkbox"/> Indian          | (please specify) _____                          |

14. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No  
 Yes (If yes, what is the matter with you?)

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---

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15. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed / self-employed full-time | <input type="checkbox"/> Retired                 |
| <input type="checkbox"/> Employed / self-employed part-time | <input type="checkbox"/> Unable to work/disabled |
| <input type="checkbox"/> Voluntary work                     | <input type="checkbox"/> Unemployed              |
| <input type="checkbox"/> Homemaker                          | <input type="checkbox"/> Other (please specify)  |

---

16. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What do (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

17. ***For women only.*** What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

18. Do you live: (You may tick more than one box.)

- Alone?
- With your husband or partner?
- With children?
- With family members?
- Other? (please specify) \_\_\_\_\_

19. Can you tell us approximately when you were first diagnosed as having heart disease?

\_\_\_\_\_  
Month                  Year

- I can not remember when I was first diagnosed

20. Did you need any help in completing this questionnaire? If so, who helped and why?

\_\_\_\_\_

21. Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire? If so, please write below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

**APPENDIX 4.10 Pre-Revascularisation CROQ-PTCA Questionnaire  
(Preliminary Field Test)**

<b>For Office Use Only</b>		
Patient ID:	_____	
Hospital:	_____	Date received: _____

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

**INSTRUCTIONS:** We are interested in finding out how you are now before the heart operation (**percutaneous transluminal coronary angioplasty**) you are going to have. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Chest tightness due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				
Disturbed sleep	<input type="checkbox"/>				
Feeling worn out or low in energy	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

At rest?

Only on exertion?

Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

A lot

Quite a bit

Some

A little

None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
<b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>several</b> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>one</b> flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>more than a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>half a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>one hundred yards</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **heart condition**? (Please tick one box on each line.)

	YES	NO
Cut down the <b>amount of time</b> you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
<b>Accomplished less</b> than you would like	<input type="checkbox"/>	<input type="checkbox"/>
Were limited in the <b>kind</b> of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

7. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>					
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>					
Have trouble keeping your attention on any activity for long?	<input type="checkbox"/>					
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>					
Become confused and start several actions at a time?	<input type="checkbox"/>					
React slowly to things that were done or said?	<input type="checkbox"/>					
Not complete things or activities you started?	<input type="checkbox"/>					

8. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or over-doing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Out of control of your life?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Unsure of yourself or lacking in self-confidence?	<input type="checkbox"/>				
Low in morale?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				
Frustrated or impatient?	<input type="checkbox"/>				
Irritated?	<input type="checkbox"/>				
That you had to avoid certain activities because of your heart condition?	<input type="checkbox"/>				
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>				
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>				
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>				



14. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No  
 Yes (If yes, what is the matter with you?)

---

---

---

15. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed / self-employed full-time | <input type="checkbox"/> Retired                 |
| <input type="checkbox"/> Employed / self-employed part-time | <input type="checkbox"/> Unable to work/disabled |
| <input type="checkbox"/> Voluntary work                     | <input type="checkbox"/> Unemployed              |
| <input type="checkbox"/> Homemaker                          | <input type="checkbox"/> Other (please specify)  |

---

16. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What do (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

17. ***For women only.*** What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

18. Do you live: (You may tick more than one box.)

- Alone?
- With your husband or partner?
- With children?
- With family members?
- Other? (please specify) \_\_\_\_\_

19. Can you tell us approximately when you were first diagnosed as having heart disease?

\_\_\_\_\_  
Month            Year

- I can not remember when I was first diagnosed

20. Did you need any help in completing this questionnaire? If so, who helped and why?

\_\_\_\_\_

21. Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire? If so, please write below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

**APPENDIX 5.1 Letter of Invitation 1: Pre-Revascularisation  
(Preliminary Field Test)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

This hospital is developing a short questionnaire to help in evaluating the outcome of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). We are asking you to take part in our evaluation by filling in the enclosed questionnaire before you have your heart operation. If you agree to participate in this study we will also send you a similar questionnaire three months after the date of your heart operation.

All the information we collect from you will remain confidential, and no individual will be named in any report. We hope you will be willing to help us in our effort to improve the service we offer to our patients. Agreeing to take part in this study will not alter your treatment in any way. Similarly, if you do not wish to take part, this will not alter your treatment in any way.

The enclosed patient information sheet provides details about the study. If you are willing to take part, please sign the enclosed consent form and return it with your completed questionnaire, **as soon as you possibly can**, to Sara Schroter in the stamped addressed envelope provided.

Thank you for your help. If you have any queries please contact Sara Schroter on 0171 436 5816.

Yours sincerely

Consultant Cardiothoracic Surgeon / Cardiologist

Enclosed: Coronary Revascularisation Questionnaire  
Patient Information Sheet  
Patient Consent Form

**APPENDIX 5.2 Letter of Invitation 1: Pre-Revascularisation  
(Final Field Test)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

This hospital is developing a short questionnaire to help in evaluating the outcome of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). We are asking you to take part in our evaluation by filling in the enclosed questionnaire before you have your heart operation. If you agree to participate in this study we will also send you a similar questionnaire three, and nine months after the date of your heart operation.

All the information we collect from you will remain confidential, and no individual will be named in any report. We hope you will be willing to help us in our effort to improve the service we offer to our patients. Agreeing to take part in this study will not alter your treatment in any way. Similarly, if you do not wish to take part, this will not alter your treatment in any way.

The enclosed patient information sheet provides details about the study. If you are willing to take part, please sign the enclosed consent form and return it with your completed questionnaire, **as soon as you possibly can**, to Sara Schroter in the stamped addressed envelope provided.

Thank you for your help. If you have any queries please contact Sara Schroter on 0171 436 5816.

Yours sincerely

Consultant Cardiothoracic Surgeon / Cardiologist

Enclosed: Coronary Revascularisation Outcome Questionnaire  
Patient Information Sheet  
Patient Consent Form

**APPENDIX 5.3 Patient Information Sheet 1: Pre-Revascularisation  
(Preliminary Field Test)**

*Official Hospital Letterhead*

**Patient Information Sheet 1**

The purpose of this study is to develop a new questionnaire to evaluate patients' views of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). This study is being undertaken by (name of hospital) in collaboration with researchers at the London School of Hygiene and Tropical Medicine.

We are inviting you and other patients who are waiting to undergo coronary revascularisation at the (name of hospital) to help us by completing a series of questionnaires. The enclosed questionnaire asks questions about your current health and includes questions about your symptoms and quality of life before your heart operation. Three months after the date of your heart operation, you will be sent another questionnaire. This questionnaire will be very similar to the one enclosed but there will be additional questions concerning the impact your heart operation has on your quality of life and your satisfaction with the treatment.

It is important that we have your opinions to ensure that the results of our study will represent the views of all patients who have these operations. The questionnaires will be used in making recommendations for improving care provided to cardiac patients.

Taking part in this study is entirely voluntary. Whether you decide to take part or not will not in any way affect the way you are treated. All the information you give will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on all questionnaire forms. These forms will be kept in locked research files which are only accessible to the research staff. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

We hope that you will agree to complete this questionnaire and we would like to thank you in advance for helping us in participating in this study. If you have any queries please contact our Project Co-ordinator, Sara Schroter, on 0171 436 5816.

**Research Team:**

Dr Donna Lamping (Principal Investigator)

Miss Sara Schroter (Project Co-ordinator)

Health Services Research Unit, London School of Hygiene & Tropical Medicine

**Consultant Cardiothoracic Surgeons / Cardiologists:**

Names of participating consultants

**APPENDIX 5.4 Patient Information Sheet 1: Pre-Revascularisation  
(Final Field Test)**

*Official Hospital Letterhead*

**Patient Information Sheet 1**

The purpose of this study is to develop a new questionnaire to evaluate patients' views of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). This study is being undertaken by (name of hospital) in collaboration with researchers at the London School of Hygiene and Tropical Medicine.

We are inviting you and other patients who are waiting to undergo coronary revascularisation at the (name of hospital) to take part in a research study by completing a series of three questionnaires over the next nine months. The enclosed questionnaire asks about how you are feeling, physically and emotionally and about your ability to carry out daily activities. You will notice some repeated questions in Section 2. This is intentional as we are comparing the performance of two different questionnaires – so please answer every question. We will also be sending you this questionnaire three and nine months after the date of your operation.

The questionnaires will be used in making recommendations for improving care provided to cardiac patients. Taking part in this study is entirely voluntary. Whether you decide to take part or not will not in any way affect the way you are treated. All the information you give will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on all questionnaire forms. These forms will be kept in locked research files which are only accessible to the research staff. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

We hope that you will agree to complete this questionnaire and we would like to thank you in advance for helping us in participating in this study. If you have any queries please contact our Project Co-ordinator, Sara Schroter, on 0171 436 5816.

**Research Team:**

Dr Donna Lamping (Principal Investigator)

Miss Sara Schroter (Project Co-ordinator)

Health Services Research Unit, London School of Hygiene & Tropical Medicine

**Consultant Cardiothoracic Surgeons / Cardiologists:**

Names of participating consultants

**APPENDIX 5.5 Patient Consent Form: Pre-Revascularisation  
(Preliminary and Final Field Tests)**

**PATIENT CONSENT FORM**

**TITLE OF PROJECT:**

Validation of a patient-based measure of outcome for patients undergoing coronary revascularisation.

**EXPLANATION OF PROJECT:**

Invitation: This hospital is developing a questionnaire to help us understand better how you are feeling after your heart operation (coronary artery bypass graft surgery and coronary angioplasty). We are asking you to take part in our research by filling in the enclosed questionnaire before you have your heart operation. The questionnaire asks about how you are feeling, physically and emotionally, and about your ability to carry out daily activities, and about your health in general.

All the information you give during the study will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on the questionnaires. These questionnaires will be kept in locked research files which only the research staff will have access to. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

This study is being undertaken by a research team at the London School of Hygiene and Tropical Medicine in collaboration with (name and hospital of leading collaborating consultants). Please understand that you need not take part in this study if you do not wish to. If you do take part, you may withdraw at any time, and need give no reason for doing so. If you choose not to take part, or if you withdraw, your normal care and treatment will be unaffected.

Signed by the person in charge of the Project \_\_\_\_\_ Date \_\_\_\_\_

The Ethics Committee of the (name of hospital) has approved the above statement.

Signed by the Chairman/Representative of the Committee

\_\_\_\_\_ Date \_\_\_\_\_

**FORM OF CONSENT**

I, \_\_\_\_\_ of \_\_\_\_\_  
agree to take part in the research project outline above. I understand the nature and purpose of the questionnaire, and that I may withdraw from the research without it affecting my care and treatment at this hospital in any way.

Signed \_\_\_\_\_ Date \_\_\_\_\_

**APPENDIX 5.6 Pre-Revascularisation CROQ-CABG Questionnaire  
(Final Field Test)**

For Office Use Only			
Patient ID:	_____	Date of operation:	_____
Hospital:	_____	Date received:	_____

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-CABG)**

INSTRUCTIONS: We are interested in finding out how you are now before the heart operation (**coronary artery bypass graft surgery**) you are going to have. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is COMPLETELY CONFIDENTIAL. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

At rest?

On exertion?

At rest and on  
exertion?

Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

A lot

Quite a bit

Some

A little

None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>several</b> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>one</b> flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>half a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>one hundred yards</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or over-doing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				
Frustrated or impatient?	<input type="checkbox"/>				
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>				
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>				
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>				

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>					
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>					
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>					

Finally, it would be very helpful if you could answer a few general questions about yourself. (Please tick the boxes that best describe your situation.)

9. Are you:  Male  
 Female

10. What is your date of birth?                             
Day Month Year

11. Please fill in the date you completed this questionnaire:                             
Day Month Year

12. To which ethnic group do you belong?

- |  |   |
|--|---|
| <input type="checkbox"/> White           | <input type="checkbox"/> Pakistani              |
| <input type="checkbox"/> Black/Caribbean | <input type="checkbox"/> Bangladeshi            |
| <input type="checkbox"/> Black/African   | <input type="checkbox"/> Chinese                |
| <input type="checkbox"/> Black/Other     | <input type="checkbox"/> Any other ethnic group |
| <input type="checkbox"/> Indian          | (please specify) _____                          |

13. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No  
 Yes (If yes, what is the matter with you?)

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14. Do you live: (You may tick more than one box.)

- Alone?  
 With your husband / wife or partner?  
 With children?  
 With family members?  
 Other? (please specify) \_\_\_\_\_

15. Can you tell us approximately when you were first diagnosed as having heart disease?

Month      Year

- I can not remember when I was first diagnosed

16. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed / self-employed full-time | <input type="checkbox"/> Retired                 |
| <input type="checkbox"/> Employed / self-employed part-time | <input type="checkbox"/> Unable to work/disabled |
| <input type="checkbox"/> Voluntary work                     | <input type="checkbox"/> Unemployed              |
| <input type="checkbox"/> Homemaker                          | <input type="checkbox"/> Other (please specify)  |

---

17. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

18. This question (Q18) is for women only:

What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

19. Did you need any help in completing this questionnaire? If so, who helped and why?

\_\_\_\_\_  
\_\_\_\_\_

20. Is there anything else you would like to tell us about your **heart condition or heart operation** that is not covered in this questionnaire? If so, please write below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

**APPENDIX 5.7 Pre-Revascularisation CROQ-PTCA Questionnaire  
(Final Field Test)**

<b>For Office Use Only</b>			
<b>Patient ID:</b>		<b>Date of operation:</b>	
<b>Hospital:</b>		<b>Date received:</b>	

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

**INSTRUCTIONS:** We are interested in finding out how you are now before the heart operation (**percutaneous transluminal coronary angioplasty**) you are going to have. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

**1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)**

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				

**2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

At rest?

On exertion?

At rest and on  
exertion?

Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

A lot

Quite a bit

Some

A little

None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>several</b> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>one</b> flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>half a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>one hundred yards</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or overdoing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				
Frustrated or impatient?	<input type="checkbox"/>				
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>				
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>				
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>				



13. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No
- Yes (If yes, what is the matter with you?)

---

---

---

14. Do you live: (You may tick more than one box.)

- Alone?
- With your husband / wife or partner?
- With children?
- With family members?
- Other? (please specify) \_\_\_\_\_

15. Can you tell us approximately when you were first diagnosed as having heart disease?

\_\_\_\_\_  
Month            Year

- I can not remember when I was first diagnosed

16. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed / self-employed full-time | <input type="checkbox"/> Retired                 |
| <input type="checkbox"/> Employed / self-employed part-time | <input type="checkbox"/> Unable to work/disabled |
| <input type="checkbox"/> Voluntary work                     | <input type="checkbox"/> Unemployed              |
| <input type="checkbox"/> Homemaker                          | <input type="checkbox"/> Other (please specify)  |

---

17. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

18. This question (Q18) is for women only:

What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

19. Did you need any help in completing this questionnaire? If so, who helped and why?

\_\_\_\_\_  
\_\_\_\_\_

20. Is there anything else you would like to tell us about your **heart condition** or **heart operation** that is not covered in this questionnaire? If so, please write below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

**APPENDIX 5.8 Letter of Invitation 2: 3-Month Post-Revascularisation  
(Preliminary Field Test)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

Thank you for sending back the first questionnaire before you had your operation. It has now been approximately 3 months since your heart operation and we would be grateful if you could complete the enclosed questionnaire and return it, **as soon as you possibly can**, to Sara Schroter in the stamped addressed envelope provided.

All the information we collect from you will remain confidential, and no individual will be named in any report. We hope you will be willing to help us in our effort to improve the service we offer to patients. Agreeing to take part in this study will not alter your treatment in any way. Similarly, if you do not wish to continue to take part, this will not alter your treatment in any way.

Thank you for your continued help. If you have any queries please contact me on 0171 436 5816.

Yours sincerely

Sara Schroter

Enclosed: Coronary Revascularisation Outcome Questionnaire  
Patient Information Sheet

**APPENDIX 5.9 Letter of Invitation 2: 3-Month Post-Revascularisation  
(Final Field Test)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

Thank you for sending back the first questionnaire before you had your heart operation. This is the **second** in a series of three questionnaires which we will send you for this study. Approximately three months have passed since your operation and we would be grateful if you would complete the enclosed questionnaire and return it, **as soon as you possibly can**, to Sara Schroter in the stamped addressed envelope provided. We will be sending you the last questionnaire in three months time.

All the information we collect from you will remain confidential, and no individual will be named in any report. We hope you will be willing to help us in our effort to improve the service we offer to patients. Taking part in this study will not alter your treatment in any way. Similarly, if you do not wish to continue to take part, this will not alter your treatment in any way.

Thank you for your continued help. If you have any queries please contact me on 0171 436 5816.

Yours sincerely

Sara Schroter

Enclosed: Coronary Revascularisation Outcome Questionnaire  
Patient Information Sheet

**APPENDIX 5.10 Letter of Invitation 3: 9-month Post-Revascularisation  
(Final Field Test)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

This is the last in a series of three questionnaires which we have sent you for this study. Approximately nine months have passed since your operation and we would be grateful if you would complete the enclosed questionnaire and return it, **as soon as you possibly can**, to Sara Schroter in the stamped addressed envelope provided. Once you have sent back this questionnaire, that will be the end of your participation in this study.

All the information we collect from you will remain confidential, and no individual will be named in any report. We hope you will be willing to help us in our effort to improve the service we offer to patients. Taking part in this study will not alter your treatment in any way. Similarly, if you do not wish to continue to take part, this will not alter your treatment in any way.

Thank you for your continued help. If you have any queries please contact me on 0171 436 5816.

Yours sincerely

Sara Schroter

Enclosed: Coronary Revascularisation Outcome Questionnaire  
Patient Information Sheet

Questionnaire (Final Field Test)

<b>For Office Use Only</b>			
<b>Patient ID:</b>		<b>Date of operation:</b>	
<b>Hospital:</b>		<b>Date received:</b>	

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-CABG)**

INSTRUCTIONS: We are interested in finding out how you have been since the heart operation (**coronary artery bypass graft surgery**) you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is COMPLETELY CONFIDENTIAL. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

At rest?                     
  On exertion?                     
  At rest and on exertion?                     
  Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

A lot                     
  Quite a bit                     
  Some                     
  A little                     
  None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>several</b> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>one</b> flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>half a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>one hundred yards</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or over-doing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Worried that your symptoms might return?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				
Frustrated or impatient?	<input type="checkbox"/>				
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>				
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>				
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>				

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>					
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>					
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>					

9. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

- No  
 Yes

Date of Admission	Name of hospital	Reason for hospital stay	Number of days
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

10. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your <b>chest wound</b>	<input type="checkbox"/>				
Infection in your <b>chest wound</b>	<input type="checkbox"/>				
Tenderness around your <b>chest wound</b>	<input type="checkbox"/>				
Numbness or tingling around your <b>chest wound</b>	<input type="checkbox"/>				
Bruising on your <b>chest</b>	<input type="checkbox"/>				
Pain in your <b>leg or arm wound</b>	<input type="checkbox"/>				
Any other pain in your <b>leg or arm</b> due to your operation	<input type="checkbox"/>				
Infection in your <b>leg or arm wound</b>	<input type="checkbox"/>				
Numbness or tingling in your <b>leg or arm</b> due to your operation	<input type="checkbox"/>				
Bruising on your <b>leg or arm</b> where a vein was removed	<input type="checkbox"/>				
Swollen feet or ankles	<input type="checkbox"/>				

11. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Results of your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about how you might feel while recovering from your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



18. To which ethnic group do you belong?

- |  |   |
|--|---|
| <input type="checkbox"/> White           | <input type="checkbox"/> Pakistani              |
| <input type="checkbox"/> Black/Caribbean | <input type="checkbox"/> Bangladeshi            |
| <input type="checkbox"/> Black/African   | <input type="checkbox"/> Chinese                |
| <input type="checkbox"/> Black/Other     | <input type="checkbox"/> Any other ethnic group |
| <input type="checkbox"/> Indian          | (please specify) _____                          |

19. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No
- Yes (If yes, what is the matter with you?)
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

20. Do you live: (You may tick more than one box.)

- Alone?
- With your husband / wife or partner?
- With children?
- With family members?
- Other? (please specify) \_\_\_\_\_

21. Can you tell us approximately when you were first diagnosed as having heart disease?

\_\_\_\_\_  
Month                  Year

- I can not remember when I was first diagnosed

22. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed / self-employed full-time | <input type="checkbox"/> Retired                 |
| <input type="checkbox"/> Employed / self-employed part-time | <input type="checkbox"/> Unable to work/disabled |
| <input type="checkbox"/> Voluntary work                     | <input type="checkbox"/> Unemployed              |
| <input type="checkbox"/> Homemaker                          | <input type="checkbox"/> Other (please specify)  |
- \_\_\_\_\_

23. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

24. This question (Q24) is for women only:

What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

25. This question asks about changes in your work situation after your heart operation. If you do not work outside the home, please put a tick in the first box. (Please tick one box only.)

I do not work outside the home

OR  I have stopped working

OR  I returned to the **same job** with the same number of hours after \_\_\_\_\_ weeks

OR  I returned to the **same job** with reduced number of hours after \_\_\_\_\_ weeks

OR  I returned to a **different job** after \_\_\_\_\_ weeks

OR  I have not returned to work yet

26. Did you need any help in completing this questionnaire? If so, who helped and why?

\_\_\_\_\_

27. Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire? If so, please write below.

\_\_\_\_\_

\_\_\_\_\_

Please check that you have answered all the questions on each page.

**THANK YOU FOR YOUR HELP**

**APPENDIX 5.12 3-Months Post-Revascularisation CROQ-PTCA  
Questionnaire (Final Field Test)**

For Office Use Only			
Patient ID:	_____	Date of operation:	_____
Hospital:	_____	Date received:	_____

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

INSTRUCTIONS: We are interested in finding out how you have been since the heart operation (**percutaneous transluminal coronary angioplasty**) you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	<input type="checkbox"/>				
Discomfort in your chest due to angina	<input type="checkbox"/>				
Shortness of breath	<input type="checkbox"/>				
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	<input type="checkbox"/>				
Palpitations (strong or irregular heart beat)	<input type="checkbox"/>				

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

At rest?

On exertion?

At rest and on  
exertion?

Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

A lot

Quite a bit

Some

A little

None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<b>ACTIVITIES</b>	<b>Yes, Limited A Lot</b>	<b>Yes, Limited A Little</b>	<b>No, Not Limited At All</b>
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>several</b> flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <b>one</b> flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>half a mile</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking <b>one hundred yards</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	<input type="checkbox"/>				
Feeling like you are a burden on others?	<input type="checkbox"/>				
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	<input type="checkbox"/>				
Feeling worried about going too far from home?	<input type="checkbox"/>				

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	<input type="checkbox"/>				
Worried about doing too much or over-doing it?	<input type="checkbox"/>				
Worried that you might have a heart attack or die suddenly?	<input type="checkbox"/>				
Worried that your symptoms might return?	<input type="checkbox"/>				
Frightened by the pain or discomfort of your heart condition?	<input type="checkbox"/>				
Uncertain about the future?	<input type="checkbox"/>				
Depressed?	<input type="checkbox"/>				
Frustrated or impatient?	<input type="checkbox"/>				
That your heart condition interfered with your enjoyment of life?	<input type="checkbox"/>				
That it was difficult to keep a positive outlook about your health?	<input type="checkbox"/>				
That it was difficult to plan ahead (eg vacations, social events, etc.)?	<input type="checkbox"/>				

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	<input type="checkbox"/>					
Forget, for example things that happened recently, where you put things or appointments?	<input type="checkbox"/>					
Have difficulty doing activities involving concentration and thinking?	<input type="checkbox"/>					

9. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

- No  
 Yes

Date of Admission	Name of hospital	Reason for hospital stay	Number of days
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

10. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your groin wound	<input type="checkbox"/>				
Tenderness around your groin wound	<input type="checkbox"/>				
Numbness or tingling in your groin area	<input type="checkbox"/>				
Bruising around your groin wound or thigh	<input type="checkbox"/>				
Problems in your groin where the catheter was inserted	<input type="checkbox"/>				
Concern over the appearance of your bruises	<input type="checkbox"/>				

11. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Results of your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you were given about how you might feel while recovering from your heart operation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. Overall, how would you describe your **heart condition** now compared to before you had your heart operation? (Please tick one box.)

                                                                                         
 Much worse              A little worse              About the same              A little better              Much better



19. Do you have any other long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time, or that is likely to affect you over a period of time?

- No  
 Yes (If yes, what is the matter with you?)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

20. Do you live: (You may tick more than one box.)

- Alone?  
 With your husband / wife or partner?  
 With children?  
 With family members?  
 Other? (please specify) \_\_\_\_\_

21. Can you tell us approximately when you were first diagnosed as having heart disease?

\_\_\_\_\_  
Month                  Year

- I can not remember when I was first diagnosed

22. What is your current work situation?

- |   |  |
|---|--|
| <input type="checkbox"/> Employed / self-employed full-time | <input type="checkbox"/> Retired                 |
| <input type="checkbox"/> Employed / self-employed part-time | <input type="checkbox"/> Unable to work/disabled |
| <input type="checkbox"/> Voluntary work                     | <input type="checkbox"/> Unemployed              |
| <input type="checkbox"/> Homemaker                          | <input type="checkbox"/> Other (please specify)  |

\_\_\_\_\_

23. What is (or was) your main occupation?

Full job title: \_\_\_\_\_

What (did) you actually do in this job? \_\_\_\_\_

What do (did) your employer make or do? \_\_\_\_\_

OR  I do not work outside the home

24. This question (Q24) is for women only:

What is (or was) your husband's/partner's main occupation?

Full job title: \_\_\_\_\_

What does (did) he actually do in this job? \_\_\_\_\_

What does (did) his employer make or do? \_\_\_\_\_

OR  I do not have a husband/partner

25. This question asks about changes in your work situation after your heart operation. If you do not work outside the home, please put a tick in the first box. (Please tick one box only.)

I do not work outside the home

OR  I have stopped working

OR  I returned to the **same job** with the same number of hours after \_\_\_\_\_ weeks

OR  I returned to the **same job** with reduced number of hours after \_\_\_\_\_ weeks

OR  I returned to a **different job** after \_\_\_\_\_ weeks

OR  I have not returned to work yet

26. Did you need any help in completing this questionnaire? If so, who helped and why?

\_\_\_\_\_

27. Is there anything else you would like to tell us about your heart condition or heart operation that is not covered in this questionnaire? If so, please write below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please check that you have answered all the questions on each page.**

**THANK YOU FOR YOUR HELP**

**APPENDIX 5.13 Patient Information Sheet 2:  
3-Months Post-Revascularisation (Preliminary Field Test)**

*Official Hospital Letterhead*

**Patient Information Sheet 2**

The purpose of this study is to develop a new questionnaire to evaluate patients' views of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). This study is being undertaken by (name of hospital) in collaboration with researchers at the London School of Hygiene and Tropical Medicine.

We sent you a questionnaire before you had your heart operation and we notified you at the time that we would send you another. Approximately three months have passed since your operation and we are interested in how you are feeling now. The enclosed questionnaire asks about the impact your heart operation has had on your day-to-day life and includes questions about symptoms, quality of life, and satisfaction with treatment.

It is important that we have your opinions to ensure that the results of our study will represent the views of all patients who have undergone coronary revascularisation. The questionnaire will be used in making recommendations for improving care provided to cardiac patients.

Taking part in this study is entirely voluntary. Whether you decide to take part or not will not in any way affect the way you are treated. All the information you give will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on all questionnaire forms. These forms will be kept in locked research files which are only accessible to the research staff. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

We hope that you will agree to complete this questionnaire and we would like to thank you in advance for helping us in participating in this study. If you have any queries please contact our Project Co-ordinator, Sara Schroter, on 0171 436 5816.

**Research Team:**

Dr Donna Lamping (Principal Investigator)

Miss Sara Schroter (Project Co-ordinator)

Health Services Research Unit, London School of Hygiene & Tropical Medicine

**Consultant Cardiothoracic Surgeons / Cardiologists:**

Names of participating consultants

**APPENDIX 5.14 Patient Information Sheet 2:  
3-Months Post-Revascularisation (Final Field Test)**

*Official Hospital Letterhead*

**Patient Information Sheet 2**

The purpose of this research project is to develop a new questionnaire to evaluate patients' views of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). This study is being undertaken by (name of hospital) in collaboration with researchers at the London School of Hygiene and Tropical Medicine.

This is the **second** in a series of three questionnaires which we have sent you as part of this study. Approximately three months have passed since your operation and we are interested in how you are feeling now. The enclosed questionnaire asks about the impact your heart operation has had on your day-to-day life and asks about how you are feeling physically and emotionally. You will notice some repeated questions in Section 2. This is intentional as we are comparing the performance of two different questionnaires – so please answer every question. We will also be sending you this questionnaire nine months after the date of your operation.

The questionnaires will be used in making recommendations for improving care provided to cardiac patients. Taking part in this study is entirely voluntary. Whether you decide to take part or not will not in any way affect the way you are treated. All the information you give will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on all questionnaire forms. These forms will be kept in locked research files which are only accessible to the research staff. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

We hope that you will agree to complete this questionnaire and we would like to thank you in advance for helping us in participating in this study. If you have any queries please contact our Project Co-ordinator, Sara Schroter, on 0171 436 5816.

**Research Team:**

Dr Donna Lamping (Principal Investigator)

Miss Sara Schroter (Project Co-ordinator)

Health Services Research Unit, London School of Hygiene & Tropical Medicine

**Consultant Cardiothoracic Surgeons / Cardiologists:**

Names of participating consultants

**APPENDIX 5.15 Patient Information Sheet 3:  
9-Months Post-Revascularisation (Final Field Test)**

*Official Hospital Letterhead*

**Patient Information Sheet 3**

The purpose of this research project is to develop a new questionnaire to evaluate patients' views of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). This study is being undertaken by (name of hospital) in collaboration with researchers at the London School of Hygiene and Tropical Medicine.

This is the **last** in a series of three questionnaires, which we have sent you as part of this study. Approximately nine months have passed since your operation and we are interested in how you are feeling now. The enclosed questionnaire asks about the impact your heart operation has had on your day-to-day life and asks about how you are feeling physically and emotionally. You will notice some repeated questions in Section 2. This is intentional as we are comparing the performance of two different questionnaires – so please answer every question. Once you have sent back this questionnaire, that will be the end of your participation in this study.

The questionnaires will be used in making recommendations for improving care provided to cardiac patients. Taking part in this study is entirely voluntary. Whether you decide to take part or not will not in any way affect the way you are treated. All the information you give will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on all questionnaire forms. These forms will be kept in locked research files, which are only accessible to the research staff. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

We hope that you will agree to complete this questionnaire and we would like to thank you in advance for helping us in participating in this study. If you have any queries please contact our Project Co-ordinator, Sara Schroter, on 0171 436 5816.

**Research Team:**

Dr Donna Lamping (Principal Investigator)

Miss Sara Schroter (Project Co-ordinator)

Health Services Research Unit, London School of Hygiene & Tropical Medicine

**Consultant Cardiothoracic Surgeons / Cardiologists:**

Names of participating consultants

**APPENDIX 5.16 Letter of Invitation: 3-Months Post-Revascularisation  
Only (Preliminary and Final Field Tests)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

We are inviting you to take part in a research project. This hospital is developing a short questionnaire to help in evaluating the outcome of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). It has now been three months since your heart operation and we would be grateful if you would complete the enclosed questionnaire.

All the information we collect from you will remain confidential, and no individual will be named in any report. Agreeing to take part in this study will not alter your treatment in any way. Similarly, if you do not wish to take part, this will not alter your treatment in any way.

The enclosed patient information sheet provides details about the study. If you are willing to take part, please sign the enclosed consent form and return it with your completed questionnaire, **as soon as you possibly can**, to Sara Schroter in the stamped addressed envelope provided.

Thank you for your help. If you have any queries please contact our Project Co-ordinator Sara Schroter on 0171 436 5816.

Yours sincerely

Consultant Cardiothoracic Surgeon / Cardiologist

Enclosed:    Coronary Revascularisation Questionnaire  
                  Patient Information Sheet  
                  Patient Consent Form

## **APPENDIX 5.17 Patient Information Sheet: 3-Month Post-Revascularisation Only (Preliminary and Final Field Tests )**

*Official Hospital Letterhead*

### **Patient Information Sheet**

The purpose of this study is to develop a new questionnaire to evaluate patients' views of coronary revascularisation (coronary artery bypass graft surgery and coronary angioplasty). This study is being undertaken by (name of hospital) in collaboration with researchers at the London School of Hygiene and Tropical Medicine.

It has now been three months since your heart operation and we are inviting you and other patients who have had coronary revascularisation at the (name of hospital) to help us by completing the enclosed questionnaire. The questionnaire asks about how you are feeling, physically and emotionally, and about your ability to carry out daily activities, and your satisfaction with the treatment.

It is important that we have your opinions to ensure that the results of our study will represent the views of all patients who have had these operations. The questionnaire will be used in making recommendations for improving care provided to cardiac patients.

Taking part in this study is entirely voluntary. Whether you decide to take part or not will not in any way affect the way you are treated. All the information you give will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on all questionnaire forms. These forms will be kept in locked research files which are only accessible to the research staff. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

We hope that you will agree to complete this questionnaire and we would like to thank you in advance for helping us in participating in this study. If you have any queries please contact our Project Co-ordinator, Sara Schroter, on 0171 436 5816.

#### **Research Team:**

Dr Donna Lamping (Principal Investigator)

Miss Sara Schroter (Project Co-ordinator)

Health Services Research Unit, London School of Hygiene & Tropical Medicine

#### **Consultant Cardiothoracic Surgeons / Cardiologists:**

Names of participating consultants

**APPENDIX 5.18 Patient Consent Form: 3 Months Post-Revascularisation  
Only (Preliminary and Final Field Tests)**

**PATIENT CONSENT FORM**

**TITLE OF PROJECT:**

Validation of a patient-based measure of outcome for patients undergoing coronary revascularisation.

**EXPLANATION OF PROJECT:**

Invitation: This hospital is developing a questionnaire to help us understand better how you are feeling after your heart operation (coronary artery bypass graft surgery and coronary angioplasty). We are asking you to take part in our research by filling in the enclosed questionnaire. The questionnaire asks about how you are feeling, physically and emotionally, and about your ability to carry out daily activities, and about your health in general.

All the information you give during the study will be completely confidential. In order to protect your privacy, a confidential study number rather than your name will be used on the questionnaires. These questionnaires will be kept in locked research files which only the research staff will have access to. None of the information you give will be available to any of the hospital staff, including doctors, nurses, and technicians, who provide the clinical care associated with your treatment.

This study is being undertaken by a research team at the London School of Hygiene and Tropical Medicine in collaboration with (name and hospital of leading collaborating consultants). Please understand that you need not take part in this study if you do not wish to. If you do take part, you may withdraw at any time, and need give no reason for doing so. If you choose not to take part, or if you withdraw, your normal care and treatment will be unaffected.

Signed by the person in charge of the Project \_\_\_\_\_ Date \_\_\_\_\_

The Ethics Committee of the (name of hospital) has approved the above statement.  
Signed by the Chairman/Representative of the Committee

\_\_\_\_\_ Date \_\_\_\_\_

**FORM OF CONSENT**

I, \_\_\_\_\_ of \_\_\_\_\_  
agree to take part in the research project outline above. I understand the nature and purpose of the questionnaire, and that I may withdraw from the research without it affecting my care and treatment at this hospital in any way.

Signed \_\_\_\_\_ Date \_\_\_\_\_

**APPENDIX 5.19 3-Week Reminder Letter: 3-Months Post-  
Revascularisation  
(Preliminary and Final Field Tests)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

Three weeks ago, we sent you a package consisting of a questionnaire and the letter reproduced below. In case this has gone astray, we are taking the opportunity of sending you another questionnaire, as your information would be of great help to us, and eventually to other patients. If you have already completed and returned the questionnaire to us, please accept our thanks.

Approximately three months have passed since your operation and we would be grateful if you would complete the enclosed questionnaire and return it, **as soon as you possibly can**, to Sara Schroter in the stamped addressed envelope provided.

All the information we collect from you will remain confidential, and no individual will be named in any report. We hope you will be willing to help us in our effort to improve the service we offer to patients. Taking part in this study will not alter your treatment in any way. Similarly, if you do not wish to continue to take part, this will not alter your treatment in any way.

Thank you for your help. If you have any queries please contact me on 0171 436 5816.

Yours sincerely

Sara Schroter  
Project Co-ordinator

Enclosed: Coronary Revascularisation Outcome Questionnaire  
Patient Information Sheet  
Patient Consent Form

**APPENDIX 5.20 5-Week Reminder Letter: 3-Months Post-Revascularisation  
(Preliminary and Final Field Tests)**

*Official Hospital Letterhead*

Dear (Patient's Name)

**Re: Validation of a coronary revascularisation questionnaire**

Five weeks ago, we sent you a questionnaire asking you about the state of your health following your heart operation (coronary artery bypass graft surgery or coronary angioplasty). We then sent you a duplicate questionnaire three weeks ago, in case the first package had gone astray. We do not seem to have received either of them back, so we are taking this opportunity to remind you once more. Your information would be of great help to us, and eventually to other patients.

If you have already completed and returned the questionnaire to us, please accept our thanks. If you have still to do so, could we please ask you to complete it as soon as you can.

If by some chance you did not receive the questionnaire, or it has been misplaced, please telephone me on 0171 436 5816 and I will send you another copy of the questionnaire.

Thank you for your co-operation.

Yours sincerely

Sara Schroter  
Project Co-ordinator

**APPENDIX 5.21 Formulae for Scoring and Transforming the CROQ**

Scale	Number of items in scale	Item	Item recalibration	Lowest and highest possible raw scores for scale	Possible raw score range for scale
Symptoms	7	Q1a + Q1b + Q1c + Q1d + Q1e + Q2 + Q4	Q2: (1=1) (2=1.66) (3=2.50) (4=3.33) (5=4.16) (6=5)	7, 35	28
Physical Functioning	8	Q5a + Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h	-	8, 24	16
Psychosocial Functioning	14	Q6a + Q6b + Q6c + Q6d + Q7a + Q7b + Q7c + Q7e + Q7f + Q7g + Q7h + Q7i + Q7k	-	14, 70	56
Cognitive Functioning	3	Q8a + Q8b + Q8c	-	3, 18	15
Satisfaction	6	Q11a + Q11b + Q11c + Q12 + Q13 + Q14	Q12: (1=1) (2=1.75) (3=2.50) (4=3.25) (5=4). Q13: (4=missing) (1=1) (2=2.5) (3=4). Q14: (1=1) (2=2.5) (3=4).	6, 24	18
Complications (CROQ-CABG)	11	Q10a + Q10b + Q10c + Q10d + Q10e + Q10f + Q10g + Q10h + Q10i + Q10j + Q10k	-	11, 55	44
Complications (CROQ-PTCA)	6	Q10a + Q10b + Q10c + Q10d + Q10e + Q10f	-	6, 30	24
Core Total	32	Q1a + Q1b + Q1c + Q1d + Q1e + Q2 + Q4 + Q5a + Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q6a + Q6b + Q6c + Q6d + Q7a + Q7b + Q7c + Q7e + Q7f + Q7g + Q7h + Q7i + Q7k + Q8a + Q8b + Q8c	-	-	-
Total Outcome (CROQ-CABG)	18	Q11a + Q11b + Q11c + Q12 + Q13 + Q14 + Q10a + Q10b + Q10c + Q10d + Q10e + Q10f + Q10g + Q10h + Q10i + Q10j + Q10k + Q7d	-	-	-

Scale	Number of items in scale	Item	Item recalibration	Lowest and highest possible raw scores for scale	Possible raw score range for scale
Total Outcome (CROQ-PTCA)	13	Q11a + Q11b + Q11c + Q12 + Q13 + Q14 + Q10a + Q10b + Q10c + Q10d + Q10e + Q10f + Q7d	-	-	-

**Formula for transformation of raw scale scores:**

$$\text{Transformed scale} = \frac{(\text{actual raw score} - \text{lowest possible raw score range})}{\text{possible raw score range}} \times 100$$

**Formula for transformation of raw item scores to z-scores:**

$$Z \text{ score} = \frac{X - \bar{X}}{SD}$$

**Formula for transformation of z-scores to t-scores:**

$$(T = 50 + 10z)$$

**APPENDIX 6.1a Item Descriptive Statistics: CROQ-CABG Pre-Revascularisation (Preliminary Field Test)**

Item	% missing data	Endorsement frequencies by response category %						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Chest pain	0.7	18.5	20.5	19.9	28.1	12.3	-	2.95 (1.3)	146	.73
Chest discomfort	0.7	13.7	28.1	23.3	23.3	11.0	-	2.93 (1.3)	146	.75
Shortness of breath	0.7	17.8	26.0	25.3	21.9	8.2	-	2.77 (1.2)	146	.55
Radiating pain	1.4	13.0	15.8	20.5	28.8	20.5	-	3.28 (1.3)	146	.61
Palpitations	2.1	3.4	14.4	17.1	26.0	37.0	-	3.80 (1.2)	146	.60
Nitroglycerin Trouble	0.0	13.0	20.5	23.3	10.3	9.6	23.3	3.53 (1.8)	146	.58
Moderate activities	0.0	16.4	37.7	24.0	17.8	4.1	-	2.55 (1.1)	146	.76
Lifting & carrying	3.4	37.0	43.8	15.8	-	-	-	1.78 (0.7)	143	.71
Climbing flights of stairs	3.4	32.2	42.5	21.9	-	-	-	1.89 (0.7)	143	.82
Climbing one flight of stairs	2.7	61.6	28.8	6.8	-	-	-	1.44 (0.6)	143	.68
Bending, keeling, stooping	2.7	22.6	47.9	26.7	-	-	-	2.04 (0.7)	143	.78
Walk half a mile	2.1	21.2	39.0	37.7	-	-	-	2.17 (0.8)	143	.70
Walk 100 yards	5.0	46.0	28.1	21.9	-	-	-	1.76 (0.8)	143	.72
Bathing or dressing	2.7	20.5	33.6	43.2	-	-	-	2.23 (0.8)	143	.71
Reason	2.1	13.7	26.7	57.5	-	-	-	2.45 (0.7)	143	.68
Forget	0.7	2.7	10.3	10.3	21.9	16.4	37.7	4.53 (1.5)	146	.75
Concentration	0.0	4.1	8.2	10.3	26.0	19.2	32.2	4.45 (1.5)	146	.78
Worry heart condition	0.0	4.1	6.8	11.6	24.7	19.9	32.9	4.48 (1.4)	146	.77
Over-doing it	0.0	21.2	21.2	39.0	12.3	6.2	-	2.61 (1.1)	146	.77
Heart attack	0.0	17.8	24.7	34.2	15.8	7.5	-	2.71 (1.2)	146	.59
Frightened by pain	0.0	15.8	11.0	26.0	28.1	19.2	-	3.24 (1.3)	146	.63
Uncertain	0.0	13.0	14.4	31.5	26.0	15.1	-	3.16 (1.2)	146	.77
Depressed	2.1	10.3	26.7	21.9	27.4	11.6	-	3.04 (1.2)	146	.78
Frustrated	0.7	7.5	11.0	29.5	23.3	28.1	-	3.54 (1.2)	146	.70
Interfered with enjoyment	0.0	14.4	18.5	30.1	25.3	11.6	-	3.01 (1.2)	146	.58
Positive outlook	0.0	32.9	22.6	28.8	9.6	6.2	-	2.34 (1.2)	146	.69
Difficult to plan	0.0	10.3	28.8	27.4	21.2	12.3	-	2.97 (1.2)	146	.70
Family overprotective	0.0	34.2	26.0	24.0	8.9	6.8	-	2.28 (1.2)	146	.61
Feeling a burden	0.7	10.3	18.5	28.8	21.9	19.9	-	3.23 (1.3)	146	.56
Restricted in social activities	1.4	4.8	17.8	21.9	24.7	29.5	-	3.57 (1.2)	146	.63
Too far from home	0.7	14.4	21.2	21.9	16.4	25.3	-	3.17 (1.4)	146	.73
	0.7	17.1	15.8	21.9	13.7	30.8	-	3.26 (1.5)	146	.67

**APPENDIX 6.1b Item Descriptive Statistics: CROQ-PTCA Pre-Revascularisation (Preliminary Field Test)**

Item	% missing data	Endorsement frequencies by response category %						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Chest pain	3.9	8.8	25.8	26.6	20.3	14.8	-	3.07 (1.2)	128	.75
Chest discomfort	3.9	11.7	23.4	26.6	22.7	11.7	-	3.18 (1.3)	128	.75
Shortness of breath	0.0	25.8	27.3	14.1	21.9	10.9	-	2.65 (1.4)	128	.62
Radiating pain	0.8	13.3	25.0	15.6	26.6	18.8	-	3.13 (1.4)	128	.65
Palpitations	3.1	3.9	10.9	21.1	24.2	26.7	-	3.81 (1.2)	128	.53
Nitroglycerin Trouble	0.0	9.4	17.2	25.0	10.9	12.5	25.0	3.75 (1.7)	128	.58
Moderate activities	0.0	14.8	32.0	26.6	15.6	10.9	-	2.76 (1.2)	128	.80
Lifting & carrying	1.6	27.3	52.3	18.8	-	-	-	1.91 (0.7)	128	.71
Climbing flights of stairs	4.7	28.1	44.5	22.7	-	-	-	1.94 (0.7)	128	.70
Climbing one flight of stairs	3.1	56.3	30.5	10.2	-	-	-	1.52 (0.7)	128	.65
Bending, keeling, stooping	1.6	18.8	45.3	34.4	-	-	-	2.16 (0.7)	128	.78
Walk half a mile	1.6	17.2	41.4	39.8	-	-	-	2.23 (0.7)	128	.60
Walk 100 yards	3.9	35.2	35.9	25.0	-	-	-	1.89 (0.8)	128	.73
Bathing or dressing	2.3	11.7	37.5	48.4	-	-	-	2.38 (0.7)	128	.67
Reason	1.6	6.3	31.3	60.9	-	-	-	2.56 (0.6)	128	.61
Forget	1.6	3.9	8.6	13.3	18.8	18.8	35.2	4.48 (1.5)	126	.79
Concentration	0.8	6.3	8.6	10.9	20.3	19.5	33.6	4.40 (1.6)	126	.72
Worry heart condition	1.6	3.9	9.4	10.2	19.5	14.1	41.4	4.57 (1.5)	126	.82
Over-doing it	0.0	18.0	19.5	36.7	18.8	7.0	-	2.77 (1.2)	127	.81
Heart attack	0.0	14.8	23.4	31.3	18.0	12.5	-	2.90 (1.2)	127	.77
Frightened by pain	2.3	13.3	7.8	26.6	26.6	23.4	-	3.40 (1.3)	127	.73
Uncertain	0.0	11.7	14.1	24.2	29.7	20.3	-	3.33 (1.3)	127	.75
Depressed	0.8	11.7	14.8	28.9	32.8	10.9	-	3.17 (1.2)	127	.80
Frustrated	0.8	7.8	10.9	27.3	25.8	27.3	-	3.54 (1.2)	127	.65
Interfered with enjoyment	0.8	12.5	14.1	35.9	21.9	14.8	-	3.13 (1.2)	127	.62
Positive outlook	1.6	22.7	25.0	24.2	16.4	10.2	-	2.66 (1.3)	127	.73
Difficult to plan	3.1	12.5	23.4	22.7	24.2	14.1	-	3.04 (1.3)	127	.85
Family overprotective	1.6	26.6	20.3	22.7	17.2	11.7	-	2.67 (1.4)	127	.74
Feeling a burden	1.6	8.6	14.8	25.0	29.7	20.3	-	3.39 (1.2)	127	.52
Restricted in social activities	0.8	5.5	10.2	25.0	18.0	40.6	-	3.79 (1.2)	127	.72
Too far from home	1.6	10.2	17.2	21.1	25.0	25.0	-	3.38 (1.3)	127	.74
	0.8	13.3	12.5	18.8	19.5	35.2	-	3.51 (1.4)	127	.71

**APPENDIX 6.2a Item Descriptive Statistics: CROQ-CABG Post-Revascularisation (Preliminary Field Test)**

Item	% missing data	Endorsement frequencies by response category %						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Chest pain	1.4	1.7	3.5	3.1	10.7	79.6	-	4.65 (0.8)	286	.73
Chest discomfort	3.1	2.1	3.5	3.1	12.1	76.1	-	4.62 (0.9)	286	.73
Shortness of breath	2.8	6.9	10.0	10.7	36.7	32.9	-	3.81 (1.2)	286	.54
Radiating pain	2.4	1.4	5.2	5.5	12.1	73.4	-	4.55 (0.9)	286	.58
Palpitations	4.5	2.8	4.8	11.1	27.0	49.8	-	4.22 (1.0)	286	.54
Nitroglycerin Trouble	2.1	0.0	1.4	2.4	2.4	4.5	87.2	5.77 (0.7)	286	.55
	1.4	2.1	5.9	9.7	34.3	46.7	-	4.19 (1.0)	286	.60
Moderate activities	2.8	13.8	43.9	39.4	-	-	-	2.26 (0.7)	284	.67
Lifting & carrying	3.5	11.8	41.9	42.9	-	-	-	2.32 (0.7)	284	.66
Climbing flights of stairs	3.8	17.0	40.5	38.8	-	-	-	2.23 (0.7)	284	.64
Climbing one flight of stairs	3.8	4.2	20.4	71.6	-	-	-	2.70 (0.5)	284	.73
Bending, keeling, stooping	2.4	8.0	33.2	56.4	-	-	-	2.50 (0.6)	284	.54
Walk half a mile	4.2	11.1	13.1	71.6	-	-	-	2.63 (0.7)	284	.71
Walk 100 yards	3.8	4.2	9.0	83.0	-	-	-	2.82 (0.5)	284	.69
Bathing or dressing	1.4	3.5	12.5	82.7	-	-	-	2.80 (0.5)	284	.61
Reason	1.4	2.1	4.5	7.6	13.5	20.1	50.9	5.00 (1.3)	287	.84
Forget	0.7	3.5	4.5	7.6	19.0	21.8	42.9	4.81 (1.4)	287	.80
Concentration	0.7	1.4	6.2	7.6	13.5	23.5	47.1	4.94 (1.3)	287	.82
Worry heart condition	0.7	3.8	6.2	21.1	34.3	33.9	-	3.89 (1.1)	287	.69
Over-doing it	1.7	3.8	11.1	28.7	36.7	18.0	-	3.55 (1.0)	287	.69
Heart attack	1.0	2.1	2.4	12.1	21.1	61.2	-	4.38 (0.9)	287	.60
Frightened by pain	1.0	1.0	3.1	13.5	21.8	59.5	-	4.37 (0.9)	287	.65
Uncertain	1.0	3.5	6.2	12.5	33.2	43.6	-	4.08 (1.1)	287	.77
Depressed	1.0	3.1	4.2	15.9	30.1	45.7	-	4.12 (1.0)	287	.72
Frustrated	1.0	5.5	8.0	23.5	31.1	30.8	-	3.74 (1.2)	287	.74
Interfered with enjoyment	1.7	2.8	9.3	19.4	27.0	39.8	-	3.93 (1.1)	287	.78
Positive outlook	1.4	1.4	8.0	15.2	31.5	42.6	-	4.07 (1.0)	287	.85
Difficult to plan	1.7	3.8	9.7	17.0	22.1	45.7	-	3.98 (1.2)	2287	.76
Family overprotective	1.0	3.8	10.7	21.5	34.3	28.7	-	3.74 (1.1)	287	.42
Feeling a burden	0.7	2.1	5.9	17.6	25.6	48.1	-	4.13 (1.0)	287	.67
Restricted in social activities	1.0	2.1	7.6	15.2	18.7	55.4	-	4.19 (1.1)	287	.69
Too far from home	1.0	3.8	6.9	12.1	15.9	60.2	-	4.23 (1.1)	287	.70

Item	% missing data	Endorsement frequencies by response category %						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Pain in chest wound	0.7	5.2	6.9	17.6	32.9	36.7	-	3.90 (1.1)	287	.57
Infection in chest wound	1.4	2.4	1.7	1.4	6.2	86.9	-	4.76 (0.8)	287	.44
Tender chest wound	0.7	6.2	12.1	15.2	44.6	21.1	-	3.63 (1.1)	287	.61
Numb chest wound	1.7	5.5	8.3	15.6	32.2	36.7	-	3.88 (1.2)	287	.49
Bruising on chest	2.1	1.4	3.8	3.1	14.2	75.4	-	4.62 (0.8)	287	.50
Pain leg wound	3.1	6.9	6.2	13.8	25.3	44.6	-	3.98 (1.2)	287	.69
Other pain in leg	3.5	3.8	5.2	5.9	15.2	66.4	-	4.40 (1.1)	287	.56
Infection in leg wound	1.4	3.5	3.5	4.8	4.8	82.0	-	4.61 (1.0)	287	.40
Numb leg	1.0	8.0	12.1	15.9	31.5	31.5	-	3.67 (1.3)	287	.55
Bruising on leg	1.7	2.8	3.8	8.0	16.6	67.1	-	4.44 (1.0)	287	.60
Swollen feet	0.3	9.7	9.0	17.6	26.0	37.4	-	3.73 (1.3)	287	.41
Satisfied with results	1.7	1.4	3.8	14.9	78.2	-	-	3.73 (0.6)	287	.61
Satisfied with info about op	1.0	1.4	6.9	14.5	76.1	-	-	3.67 (0.7)	287	.48
Satisfied with recovery info	1.0	2.8	8.7	20.4	67.1	-	-	3.54 (0.8)	287	.55
Overall compared to before op	0.7	2.1	0.7	3.1	14.2	79.2	-	4.69 (0.8)	287	.47
Speed of recovery	0.3	21.8	31.1	28.7	18.0	-	-	2.08 (0.8)	287	.51
Expectation of results	1.0	9.3	41.5	48.1	-	-	-	2.39 (0.7)	287	.63
Symptoms return	1.7	2.1	7.3	16.3	37.4	35.3	-	3.98 (1.0)	-	-

**APPENDIX 6.2b Item Descriptive Statistics: CROQ-PTCA Post-Revascularisation (Preliminary Field Test)**

Item	% missing data	Endorsement frequencies by response category %						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Chest pain	1.1	4.6	12.1	12.5	21.1	48.6	-	3.98 (1.2)	277	.85
Chest discomfort	5.0	7.5	11.8	10.0	26.4	39.3	-	4.00 (1.3)	277	.84
Shortness of breath	2.1	7.9	17.1	17.1	30.4	25.4	-	3.49 (1.3)	277	.67
Radiating pain	3.9	4.6	10.0	13.9	19.3	48.2	-	4.00 (1.2)	277	.76
Palpitations	5.4	3.2	6.4	9.3	23.2	52.5	-	4.21 (1.1)	277	.48
Nitroglycerin Trouble	1.4	1.8	11.4	10.7	9.6	12.1	52.9	4.80 (1.5)	277	.72
	2.1	6.8	10.0	16.1	30.7	34.3	-	3.77 (1.2)	277	.83
Moderate activities	2.9	16.8	39.6	40.7	-	-	-	2.25 (0.7)	274	.79
Lifting & carrying	2.1	16.4	39.3	42.1	-	-	-	2.26 (0.7)	274	.75
Climbing flights of stairs	3.6	34.6	36.4	25.4	-	-	-	1.90 (0.8)	274	.71
Climbing one flight of stairs	4.3	11.1	29.3	55.4	-	-	-	2.46 (0.7)	274	.81
Bending, keeling, stooping	3.6	11.8	33.6	51.1	-	-	-	2.41 (0.7)	274	.73
Walk half a mile	5.0	18.2	23.2	53.6	-	-	-	2.37 (0.8)	274	.81
Walk 100 yards	32	11.8	14.3	70.7	-	-	-	2.61 (0.7)	274	.74
Bathing or dressing	3.6	5.0	16.4	75.0	-	-	-	2.73 (0.6)	274	.69
Reason	2.5	3.6	7.1	5.4	16.1	17.9	47.5	4.85 (1.5)	275	.84
Forget	1.8	5.7	7.1	9.6	13.6	25.0	37.1	4.59 (1.5)	275	.82
Concentration	1.8	3.2	7.9	5.0	14.3	20.4	47.5	4.87 (1.4)	275	.89
Worry heart condition	1.4	9.6	12.9	23.6	32.5	20.0	-	3.41 (1.2)	277	.80
Over-doing it	1.8	9.6	18.2	21.4	28.6	20.4	-	3.32 (1.3)	277	.77
Heart attack	1.4	10.7	6.4	18.6	26.1	36.8	-	3.73 (1.3)	277	.76
Frightened by pain	1.1	8.6	8.9	20.0	23.6	37.9	-	3.74 (1.7)	277	.75
Uncertain	2.1	12.1	10.7	16.4	28.2	30.4	-	3.55 (1.8)	277	.81
Depressed	1.4	7.1	7.5	22.5	23.6	37.9	-	3.79 (1.5)	277	.78
Frustrated	1.4	9.3	12.1	23.9	25.0	28.2	-	3.51 (1.6)	277	.75
Interfered with enjoyment	1.1	10.7	15.7	19.6	21.4	31.4	-	3.48 (1.9)	277	.83
Positive outlook	1.4	9.3	12.9	20.7	25.0	30.7	-	3.56 (1.3)	277	.90
Difficult to plan	1.1	12.9	16.4	16.4	20.4	32.9	-	3.44 (1.4)	277	.83
Family overprotective	0.7	7.9	15.7	19.3	23.6	32.9	-	3.58 (1.3)	277	.59
Feeling a burden	1.4	10.0	7.9	16.8	12.5	51.4	-	3.89 (1.4)	277	.82
Restricted in social activities	1.1	6.4	11.8	17.5	16.4	46.8	-	3.86 (1.3)	277	.81
Too far from home	1.1	11.1	10.7	13.2	19.3	44.6	-	3.77 (1.4)	277	.78

Item	% missing data	Endorsement frequencies by response category %						Mean (SD)	Item-total correlation	
		1	2	3	4	5	6		n	r
Pain in groin wound	1.4	3.6	1.8	4.6	10.4	78.2	-	4.60 (0.9)	277	.70
Tender groin wound	1.4	1.4	2.5	3.2	15.4	76.1	-	4.64 (0.8)	277	.71
Numb groin	2.1	0.4	0.7	2.1	8.9	85.7	-	4.83 (0.5)	277	.59
Bruised groin wound	2.1	2.5	3.6	3.6	14.6	73.6	-	4.57 (0.9)	277	.58
Problems from catheter	1.4	1.1	2.5	2.1	3.9	88.9	-	4.80 (0.7)	277	.63
Concern over bruises	1.4	0.4	1.1	0.7	2.9	93.6	-	4.91 (0.5)	277	.41
Satisfied with results	2.5	5.7	14.3	16.8	60.7	-	-	3.36 (0.9)	274	.75
Satisfied with info about op	2.1	3.2	7.1	15.4	72.1	-	-	3.60 (0.8)	274	.54
Satisfied with recovery info	2.1	5.7	12.9	25.7	53.6	-	-	3.30 (0.9)	274	.44
Overall compared to before op	1.8	2.9	5.0	12.9	17.1	60.4	-	4.29 (1.1)	274	.67
Speed of recovery	2.5	23.2	30.7	16.1	27.5	-	-	2.49 (1.1)	274	.70
Expectation of results	2.5	20.0	43.2	34.3	-	-	-	2.15 (0.7)	274	.69
Symptoms return	1.4	11.1	15.4	26.8	32.1	13.2	-	3.21 (1.2)	-	-

**APPENDIX 6.3 Scale Descriptive Statistics: CROQ Pre-Revascularisation (Preliminary Field Test)**

Scale	% missing	Range of scores		Mean	SD	Skewness	% floor	% ceiling
		Scale	Sample					
<b>CROQ-CABG (N=146)</b>								
Symptoms	0	0-100	0-100	50.67	23.7	-.106	1	1
Physical Functioning	0	0-100	0-100	48.38	29.1	.039	6	4
Psychosocial Functioning	0	0-100	0-98	50.14	22.6	-.159	1	1
Cognitive Functioning	0	0-100	0-100	69.68	26.1	-.642	2	21
<i>Core Total</i>	0	-	37-62	50.00	6.2	-.079	1	1
<b>CROQ-PTCA (N=128)</b>								
Symptoms	0	0-100	0-100	51.90	24.2	.118	1	3
Physical Functioning	0	0-100	0-100	53.47	26.8	-.005	2	6
Psychosocial Functioning	1	0-100	1-100	54.73	24.2	-.244	0	2
Cognitive Functioning	2	0-100	0-100	69.90	27.6	-.752	1	23
<i>Core Total</i>	0	-	35-64	49.97	6.5	-.048	1	2

APPENDIX 6.4 Scale Descriptive Statistics: CROQ Post-Revascularisation (Preliminary Field Test)

CROQ-Scale	% missing	Range of scores						
		Scale	Sample	Mean	SD	Skewness	% floor	% ceiling
<b>CROQ-CABG (N=289)</b>								
Symptoms	1	0-100	5-100	84.96	16.9	-1.97	0	17
Physical Functioning	2	0-100	0-100	76.43	23.1	-1.26	1	18
Psychosocial Functioning	1	0-100	8-100	75.69	19.7	-1.10	0	3
Cognitive Functioning	1	0-100	0-100	78.39	24.4	-1.23	1	34
<i>Core Total</i>	1	-	23-58	49.97	6.3	-1.40	1	1
Complications	1	0-100	0-100	78.47	17.2	-1.41	1	1
Satisfaction	1	0-100	22-100	81.02	18.7	-1.03	1	27
<i>Total Outcome</i>	1	-	23-57	50.01	5.3	-1.32	1	1
<b>CROQ-PTCA (N=280)</b>								
Symptoms	1	0-100	3-100	72.15	25.0	-.782	0	12
Physical Functioning	2	0-100	0-100	68.52	29.0	-.756	1	18
Psychosocial Functioning	1	0-100	0-100	65.40	26.9	-.659	1	4
Cognitive Functioning	2	0-100	0-100	75.16	27.7	-1.15	2	29
<i>Core Total</i>	1	-	32-59	49.99	7.2	-.689	1	1
Complications	1	0-100	12-100	92.95	13.6	-2.85	0	57
Satisfaction	2	0-100	8-100	72.70	23.6	-.762	0	16
<i>Total Outcome</i>	1	-	21-57	50.04	5.9	-1.76	1	2

APPENDIX 6.5 Reliability: CROQ Pre-Revascularisation (Preliminary Field Test)

CROQ scale	Internal consistency			Cronbach's alpha
	Item-total correlation range (mean)	Inter-item correlation range (mean)	N	
<b>CROQ-CABG (N=146)</b>				
Symptoms (7 items)	.60-.76 (.65)	.30-.72 (.50)	146	.87
Physical Functioning (8 items)	.68-.82 (.73)	.41-.73 (.58)	143	.92
Psychosocial Functioning (14 items)	.56-.78 (.67)	.26-.71 (.49)	146	.93
Cognitive Functioning (3 items)	.75-.78 (.77)	.70-.73 (.71)	146	.88
<i>Core Total (32 items)</i>	.42-.76 (.59)	.05-.73 (.36)	143	.95
<b>CROQ-PTCA (N=128)</b>				
Symptoms (7 items)	.53-.80 (.67)	.33-.72 (.52)	128	.88
Physical Functioning (8 items)	.60-.78 (.68)	.33-.74 (.52)	128	.90
Psychosocial Functioning (14 items)	.52-.85 (.72)	.33-.81 (.56)	127	.95
Cognitive Functioning (3 items)	.72-.82 (.78)	.67-.80 (.72)	126	.89
<i>Core Total (32 items)</i>	.45-.79 (.62)	.08-.81 (.40)	126	.96

APPENDIX 6.6 Reliability: CROQ Post-Revascularisation (Preliminary Field Test)

CROQ scale	Internal consistency			Test-retest sample		
	Item-total correlation range (mean)	Inter-item correlation range (mean)	N	Cronbach's alpha	N	ICC <sup>1</sup>
<b>CROQ-CABG (N=289)</b>						
Symptoms (7 items)	.54-.73 (.61)	.28-.81 (.45)	286	.85	42	.92
Physical Functioning (8 items)	.54-.71 (.66)	.34-.78 (.50)	284	.89	43	.71
Psychosocial Functioning (14 items)	.42-.85 (.70)	.22-.76 (.52)	287	.94	43	.83
Cognitive Functioning (3 items)	.80-.84 (.82)	.74-.80 (.77)	287	.91	42	.79
<i>Core Total (32 items)</i>	.33-.73 (.59)	.04-.83 (.37)	225	.95	43	.89
Complications (11 items)	.40-.69 (.53)	.09-.65 (.33)	287	.85	43	.68
Satisfaction (6 items)	.45-.74 (.63)	.17-.79 (.39)	287	.80	43	.95
<i>Total Outcome (18 items)</i>	.31-.63 (.47)	-.08-.79 (.24)	216	.86	43	.81
<b>CROQ-PTCA (N=280)</b>						
Symptoms (7 items)	.48-.85 (.74)	.35-.89 (.60)	277	.91	46	.95
Physical Functioning (8 items)	.73-.81 (.75)	.46-.79 (.62)	274	.93	48	.93
Psychosocial Functioning (14 items)	.59-.90 (.78)	.42-.84 (.64)	277	.96	48	.94
Cognitive Functioning (3 items)	.82-.89 (.85)	.76-.85 (.81)	275	.93	48	.91
<i>Core Total (32 items)</i>	.48-.85 (.70)	.21-.89 (.51)	228	.97	49	.95
Complications (6 items)	.41-.71 (.60)	.19-.68 (.44)	277	.83	49	.93
Satisfaction (6 items)	.45-.74 (.63)	.24-.76 (.48)	275	.85	49	.94
<i>Total Outcome (13 items)</i>	.40-.66 (.50)	.00-.80 (.30)	187	.85	49	.96

<sup>1</sup> ICC: Intraclass correlation coefficient.

**APPENDIX 6.7a: Item Convergent and Discriminant Correlations: CROQ-CABG Pre-Revascularisation (Preliminary Field Test)**

CROQ-CABG scale	CROQ-CABG item	CROQ-CABG scale			
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning
Symptoms	Chest pain	.73	.45	.39	.25
	Chest discomfort	.75	.52	.50	.35
	Shortness of breath	.55	<b><u>.58</u></b> <sup>2</sup>	.42	.37
	Radiating pain	.61	.44	.38	.30
	Palpitations	.60	<b>.51</b> <sup>1</sup>	.36	.29
	Nitroglycerin	.58	.39	.27	.15
	Trouble	.76	<b>.69</b>	.55	.41
Physical Functioning	Moderate activities	.51	.71	.42	.39
	Lifting & carrying	.65	.82	.50	.37
	Climbing flights of stairs	.51	.68	.29	.30
	Climbing one flight of stairs	.58	.78	.38	.31
	Bending, kneeling, stooping	.43	.70	.32	.30
	Walk half a mile	.52	.72	.34	.25
	Walk 100 yards	.56	.71	.30	.28
	Bathing or dressing	.55	.68	.42	.36
Psychosocial Functioning	Worry heart condition	.40	.24	.77	.25
	Over-doing it	.20	.15	.59	.23
	Heart attack	.38	.19	.63	.17
	Frightened by pain	.56	.41	.77	.32
	Uncertain	.35	.31	.78	.36
	Depressed	.33	.28	.70	.42
	Frustrated	.23	.27	.58	.38
	Interfered with enjoyment	.43	.47	.69	.35
	Positive outlook	.43	.45	.70	.46
	Difficult to plan	.36	.35	.61	.35
	Family overprotective	.33	.21	.56	.29
	Feeling a burden	.39	.37	.63	.32
	Restricted in social activities	.46	.51	.73	.39
Too far from home	.56	.48	.67	.45	
Cognitive Functioning	Reason	.32	.37	.48	.75
	Forget	.38	.35	.37	.78
	Concentration	.36	.33	.41	.77

<sup>1</sup> Values in bold indicate probable scaling successes. <sup>2</sup> Values in bold and underlined indicate probable scaling failures.

**APPENDIX 6.7b: Item Convergent and Discriminant Correlations: CROQ-PTCA Pre-Revascularisation (Preliminary Field Test)**

CROQ-PTCA scale	CROQ-PTCA item	CROQ-PTCA scale			
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning
Symptoms	Chest pain	.75	.56	.50	.32
	Chest discomfort	.75	.56	.52	.40
	Shortness of breath	.62	<b>.61<sup>1</sup></b>	.51	.38
	Radiating pain	.65	.58	.55	.35
	Palpitations	.53	.39	.46	.41
	Nitroglycerin	.58	.41	.32	.24
	Trouble	.80	.55	.61	.48
Physical Functioning	Moderate activities	.59	.71	.47	.31
	Lifting & carrying	.56	.70	.45	.23
	Climbing flights of stairs	.53	.65	.35	.33
	Climbing one flight of stairs	.53	.78	.38	.31
	Bending, kneeling, stooping	.49	.60	.31	.30
	Walk half a mile	.55	.73	.40	.25
	Walk 100 yards	.48	.67	.40	.28
	Bathing or dressing	.43	.61	.40	.25
Psychosocial Functioning	Worry heart condition	.54	.36	.81	.38
	Over-doing it	.56	.42	.77	.40
	Heart attack	.51	.38	.73	.28
	Frightened by pain	.58	.46	.75	.41
	Uncertain	.48	.36	.80	.53
	Depressed	.35	.23	.65	.40
	Frustrated	.43	.20	.62	.48
	Interfered with enjoyment	.58	.47	.73	.41
	Positive outlook	.60	.48	.85	.47
	Difficult to plan	.54	.45	.74	.44
	Family overprotective	.36	.35	.52	.25
	Feeling a burden	.45	.42	.72	.33
	Restricted in social activities	.53	.52	.74	.42
Too far from home	.48	.42	.71	.37	
Cognitive Functioning	Reason	.42	.30	.46	.79
	Forget	.41	.30	.39	.72
	Concentration	.47	.41	.55	.82

<sup>1</sup> Values in bold indicate probable scaling successes.

**APPENDIX 6.8a: Item Convergent and Discriminant Correlations: CROQ-CABG Post-Revascularisation (Preliminary Field Test)**

CROQ-CABG scale	CROQ-CABG item	CROQ-CABG scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Symptoms	Chest pain	.73	.38	.36	.35	.35	.31
	Chest discomfort	.73	.38	.39	.35	.31	.37
	Shortness of breath	.54	.53 <sup>1</sup>	.46	.38	.23	.31
	Radiating pain	.58	.38	.31	.26	.25	.25
	Palpitations	.54	.37	.36	.34	.25	.29
	Nitroglycerin	.55	.34	.38	.28	.23	.30
	Trouble	.60	.55	.53	.40	.32	.43
Physical Functioning	Moderate activities	.40	.67	.42	.30	.27	.45
	Lifting & carrying	.41	.66	.38	.33	.29	.40
	Climbing flights of stairs	.50	.64	.40	.35	.18	.36
	Climbing one flight of stairs	.54	.73	.44	.37	.26	.36
	Bending, kneeling, stooping	.35	.54	.38	.31	.34	.28
	Walk half a mile	.51	.71	.44	.37	.33	.35
	Walk 100 yards	.40	.69	.42	.37	.27	.27
	Bathing or dressing	.43	.61	.34	.31	.26	.28
Psychosocial Functioning	Worry heart condition	.49	.39	.69	.42	.34	.35
	Over-doing it	.36	.40	.69	.47	.30	.34
	Heart attack	.43	.27	.60	.31	.25	.17
	Frightened by pain	.53	.35	.65	.47	.36	.33
	Uncertain	.47	.36	.77	.53	.33	.40
	Depressed	.41	.39	.72	.59	.35	.38
	Frustrated	.46	.45	.74	.55	.35	.38
	Interfered with enjoyment	.43	.43	.78	.54	.30	.41
	Positive outlook	.44	.46	.85	.52	.37	.49
	Difficult to plan	.39	.43	.76	.55	.34	.45
	Family overprotective	.24	.25	.42	.34	.33	.22
	Feeling a burden	.33	.36	.67	.48	.34	.36
Restricted in social activities	.42	.57	.69	.50	.33	.40	
Too far from home	.40	.49	.70	.49	.32	.26	
Cognitive Functioning	Reason	.46	.43	.64	.84	.36	.33
	Forget	.40	.37	.57	.80	.37	.21
	Concentration	.44	.44	.64	.82	.35	.35

CROQ-CABG scale	CROQ-CABG item	CROQ-CABG scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Complications	Pain in chest wound	.38	.30	.42	.41	.57	.31
	Infection in chest wound	.26	.19	.24	.22	.44	.10
	Tender chest wound	.29	.23	.41	.31	.61	.29
	Numb chest wound	.25	.12	.29	.28	.49	.19
	Bruising on chest	.28	.23	.28	.25	.50	.24
	Pain leg wound	.24	.34	.36	.33	.69	.27
	Other pain in leg	.35	.31	.25	.25	.56	.26
	Infection in leg wound	.17	.16	.13	.06	.40	.09
	Numb leg	.16	.15	.29	.24	.55	.20
	Bruising on leg	.22	.23	.28	.25	.60	.27
Swollen feet	.11	.29	.15	.11	.41	.08	
Satisfaction	Satisfied with results	<b>.49</b>	.36	.40	.30	.32	.59
	Satisfied with info about op	.16	.22	.18	.14	.10	.50
	Satisfied with recovery info	.14	.24	.27	.15	.20	.57
	Overall	<b><u>.51</u></b> <sup>1</sup>	<b>.34</b>	<b>.39</b>	.26	.18	.45
	Speed of recovery	.28	.35	.35	.25	.30	.53
	Expectation of results	.41	.44	.43	.26	.26	.64

<sup>1</sup> Values in bold indicate probable scaling successes. <sup>2</sup> Values in bold and underlined indicate probable scaling failures.

**APPENDIX 6.8b: Item Convergent and Discriminant Correlations: CROQ-PTCA Post-Revascularisation (Preliminary Field Test)**

CROQ-PTCA scale	CROQ-PTCA item	CROQ-PTCA scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Symptoms	Chest pain	.85	.55	.55	.39	.28	.60
	Chest discomfort	.84	.56	.56	.43	.27	.59
	Shortness of breath	.67	.64 <sup>1</sup>	.54	.43	.30	.51
	Radiating pain	.76	.55	.58	.48	.37	.48
	Palpitations	.48	.41	.41	.36	.34	.26
	Nitroglycerin Trouble	.72	.48	.51	.32	.16	.50
		.83	.61	.64	.48	.29	.67
Physical Functioning	Moderate activities	.59	.79	.60	.46	.26	.47
	Lifting & carrying	.56	.75	.58	.42	.30	.43
	Climbing flights of stairs	.55	.71	.55	.48	.28	.46
	Climbing one flight of stairs	.60	.81	.56	.49	.30	.38
	Bending, keeling, stooping	.49	.73	.48	.48	.35	.31
	Walk half a mile	.56	.81	.59	.50	.24	.44
	Walk 100 yards	.55	.74	.52	.46	.25	.40
	Bathing or dressing	.50	.69	.49	.46	.21	.30
Psychosocial Functioning	Worry heart condition	.66	.58	.80	.54	.28	.56
	Over-doing it	.54	.53	.77	.55	.29	.48
	Heart attack	.53	.48	.76	.46	.28	.43
	Frightened by pain	.66	.58	.75	.51	.32	.49
	Uncertain	.49	.50	.81	.55	.32	.48
	Depressed	.51	.51	.78	.56	.36	.44
	Frustrated	.52	.51	.75	.55	.29	.47
	Interfered with enjoyment	.62	.62	.83	.57	.30	.59
	Positive outlook	.60	.62	.90	.56	.34	.52
	Difficult to plan	.57	.61	.83	.52	.26	.50
	Family overprotective	.42	.42	.59	.33	.31	.23
	Feeling a burden	.49	.54	.82	.51	.33	.40
	Restricted in social activities	.55	.61	.81	.57	.32	.44
Too far from home	.50	.52	.78	.46	.26	.42	
Cognitive Functioning	Reason	.51	.55	.62	.84	.36	.40
	Forget	.43	.53	.54	.82	.33	.28
	Concentration	.51	.55	.62	.89	.42	.35

CROQ-PTCA scale	CROQ-PTCA item	CROQ-PTCA scale					
		Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Complications	Satisfaction
Complications	Pain in groin wound	.31	.28	.30	.37	.70	.30
	Tender groin wound	.25	.24	.29	.31	.71	.29
	Numb groin	.28	.27	.28	.30	.59	.28
	Bruised groin wound	.25	.25	.26	.19	.58	.26
	Problems from catheter	.25	.23	.28	.32	.63	.28
	Concern over bruises	.19	.22	.25	.26	.41	.25
Satisfaction	Satisfied with results	<b>.64</b>	.50	.50	.34	.21	.74
	Satisfied with info about op	.31	.33	.42	.33	.29	.54
	Satisfied with recovery info	.24	.20	.31	.26	.22	.45
	Overall	<b>.63</b>	.45	.43	.27	.30	.67
	Speed of recovery	.53	.41	.49	.28	.16	.69
	Expectation of results	.52	.33	.41	.23	.13	.70

<sup>1</sup> Values in bold indicate probable scaling successes.

**APPENDIX 6.9 Intercorrelations Between Scales: CROQ Pre-Revascularisation (Preliminary Field Test)**

<b>CROQ scale</b>	<b>Symptoms</b>	<b>Physical Functioning</b>	<b>Psychosocial Functioning</b>	<b>Cognitive Functioning</b>
<b>CROQ-CABG (N=146)</b>				
Symptoms	(.87) <sup>1</sup>	-	-	-
Physical Functioning	.67	(.92)	-	-
Psychosocial Functioning	.54	.47	(.93)	-
Cognitive Functioning	.40	.39	.47	(.88)
<i>Core Total</i>	.81	.79	.87	.61
<b>CROQ-PTCA (N=128)</b>				
Symptoms	(.88)	-	-	-
Physical Functioning	.68	(.90)	-	-
Psychosocial Functioning	.65	.52	(.95)	-
Cognitive Functioning	.48	.37	.52	(.89)
<i>Core Total</i>	.86	.78	.91	.63

<sup>1</sup> Values in brackets indicate Cronbach's alpha coefficient.

APPENDIX 6.10 Intercorrelations Between Scales: CROQ Post-Revascularisation (Preliminary Field Test)

CROQ scale	CROQ scale						
	Symptoms	Physical Functioning	Psychosocial Functioning	Cognitive Functioning	Core Total	Satisfaction	Complications
<b>CROQ-CABG (N=146)</b>							
Symptoms	(.85) <sup>1</sup>	-	-	-	-	-	-
Physical Functioning	.59	(.89)	-	-	-	-	-
Psychosocial Functioning	.56	.54	(.94)	-	-	-	-
Cognitive Functioning	.47	.45	.65	(.91)	-	-	-
Core Total	.78	.78	.91	.73	(.95)	-	-
Satisfaction	.45	.47	.48	.32	.54	(.80)	-
Complications	.38	.37	.45	.39	.49	.33	(.85)
Total Outcome	.54	.49	.61	.45	.66	.70	.89
<b>CROQ-PTCA (N=128)</b>							
Symptoms	(.91)	-	-	-	-	-	-
Physical Functioning	.67	(.93)	-	-	-	-	-
Psychosocial Functioning	.67	.67	(.96)	-	-	-	-
Cognitive Functioning	.51	.58	.63	(.93)	-	-	-
Core Total	.83	.85	.93	.73	(.97)	-	-
Satisfaction	.64	.49	.56	.37	.63	(.85)	-
Complications	.35	.34	.37	.39	.41	.28	(.83)
Total Outcome	.64	.54	.65	.51	.70	.80	.78

<sup>1</sup> Values in brackets indicate Cronbach's alpha coefficient.

APPENDIX 6.11a Principal Axis Factor Analysis: CROQ-CABG Core Items Pre-Revascularisation (Preliminary Field Test)

CROQ-CABG item	Factor			
	1	2	3	4
Chest pain	.21	.21	.77	.05
Chest discomfort	.29	.30	.63	.12
Shortness of breath <sup>1</sup>	.25	.51	.25	.18
Radiating pain	.22	.22	.55	.15
Palpitations	.22	<b>.37</b> <sup>2</sup>	<b>.37</b>	.17
Nitroglycerin	.12	.22	.59	-.01
Trouble <sup>1</sup>	.32	<b>.57</b>	<b>.51</b>	.18
Moderate activities	.20	.68	.13	.25
Lifting & carrying	.27	.81	.21	.14
Climbing flights of stairs	.04	.72	.17	.13
Climbing one flight of stairs	.19	.77	.21	.05
Bending, keeling, stooping	.11	.73	.01	.17
Walk half a mile	.13	.72	.25	.04
Walk 100 yards	.10	.68	.30	.06
Bathing or dressing	.23	.65	.15	.22
Reason	.31	.23	.05	.69
Forget	.13	.23	.16	.77
Concentration	.22	.19	.08	.79
Worry heart condition	.81	.04	.28	.03
Over-doing it	.75	-.01	-.00	-.02
Heart attack	.72	-.00	.28	.02
Frightened by pain	.72	.20	.43	.11
Uncertain	.80	.18	.06	.15
Depressed	.67	.17	.18	.28
Frustrated	.54	.25	.01	.25
Interfered with enjoyment	<b>.59</b>	<b>.42</b>	.14	.12
Positive outlook	.71	.26	.15	.23
Difficult to plan	.57	.30	.05	.22
Family overprotective	.60	.16	.18	.11
Feeling a burden	.52	.27	.25	.14
Restricted in social activities	<b>.60</b>	<b>.45</b>	.24	.12
Too far from home	.60	.25	.35	.18

<sup>1</sup> Item loads higher on the 'wrong factor'. <sup>2</sup> Values in bold indicate items crossloading on more than one factor with a difference < .20.

APPENDIX 6.11b Principal Axis Factor Analysis: CROQ-PTCA Core Items Pre-Revascularisation (Preliminary Field Test)

CROQ-PTCA item	Factor			
	1	2	3	4
Chest pain	.25	.36	.71	.04
Chest discomfort	.31	.32	.66	.16
Shortness of breath	.30	<b>.40</b> <sup>1</sup>	<b>.45</b>	.21
Radiating pain	<b>.39</b>	<b>.39</b>	<b>.47</b>	.13
Palpitations	<b>.35</b>	.29	<b>.37</b>	.21
Nitroglycerin Trouble	.08	.22	.59	.06
Moderate activities	.33	.31	.74	.29
Lifting & carrying	.22	.71	.31	.04
Climbing flights of stairs	.25	.67	.27	-.03
Climbing one flight of stairs	.03	.65	.32	.16
Bending, keeling, stooping	.14	.71	.28	.16
Walk half a mile	.08	.55	.25	.23
Walk 100 yards	.12	.73	.23	.08
Bathing or dressing	.22	.68	.09	.09
Reason	.23	.65	.01	.11
Forget	.27	.10	.15	.84
Concentration	.26	.19	.17	.67
Worry heart condition	.34	.26	.11	.83
Over-doing it	.82	.07	.26	.09
Heart attack	.76	.15	.28	.16
Frightened by pain	.81	.15	.27	-.03
Uncertain	.74	.27	.24	.08
Depressed	.77	.11	.09	.37
Frustrated	.64	.03	.08	.25
Interfered with enjoyment	.57	-.03	.29	.35
Positive outlook	.58	.27	.30	.27
Difficult to plan	.78	.24	.21	.24
Family overprotective	.61	.29	.19	.29
Feeling a burden	<b>.41</b>	<b>.38</b>	.17	.12
Restricted in social activities	.72	.32	.02	.08
Too far from home	.61	.40	.11	.25
	.69	.32	.03	.12

<sup>1</sup> Values in bold indicate items crossloading on more than one factor with a difference < .20.

APPENDIX 6.12a Principal Axis Factor Analysis: CROQ-CABG Core Items Post-Revascularisation (Preliminary Field Test)

CROQ-CABG item	Factor			
	1	2	3	4
Chest pain	.08	.17	.10	.85
Chest discomfort	.10	.16	.15	.82
Shortness of breath <sup>1</sup>	.25	<b>.45</b> <sup>2</sup>	.16	<b>.37</b>
Radiating pain	.02	.24	.11	.68
Palpitations	.19	.20	.20	.48
Nitroglycerin	.17	.21	.07	.40
Trouble <sup>1</sup>	.21	<b>.43</b>	.34	<b>.40</b>
Moderate activities	.14	.69	.21	.12
Lifting & carrying	.13	.70	.10	.14
Climbing flights of stairs	.19	.65	.04	.19
Climbing one flight of stairs	.15	.70	.13	.31
Bending, keeling, stooping	.19	.48	.18	.07
Walk half a mile	.21	.74	.09	.19
Walk 100 yards	.21	.69	.14	.12
Bathing or dressing	.10	.58	.11	.21
Reason	.72	.24	.19	.30
Forget	.74	.18	.02	.29
Concentration	.79	.22	.13	.24
Worry heart condition	.19	.19	.76	.23
Over-doing it	.32	.23	.60	.06
Heart attack	.11	.04	.70	.28
Frightened by pain	.29	.13	.56	.34
Uncertain	<b>.51</b>	.12	<b>.62</b>	.19
Depressed <sup>1</sup>	<b>.67</b>	.18	<b>.37</b>	.13
Frustrated <sup>1</sup>	<b>.62</b>	.29	<b>.38</b>	.12
Interfered with enjoyment <sup>1</sup>	<b>.53</b>	.28	<b>.52</b>	.06
Positive outlook	<b>.52</b>	.23	<b>.66</b>	.07
Difficult to plan <sup>1</sup>	<b>.55</b>	.27	<b>.50</b>	.03
Family overprotective <sup>3</sup>	.34	.08	.23	-.00
Feeling a burden <sup>1</sup>	.56	.19	.34	.02
Restricted in social activities <sup>1</sup>	<b>.49</b>	<b>.43</b>	<b>.37</b>	.02
Too far from home <sup>1</sup>	<b>.46</b>	<b>.36</b>	<b>.45</b>	.06

<sup>1</sup> Item loads higher on the 'wrong factor'. <sup>2</sup> Values in bold indicate items crossloading on more than one factor with a difference <.20. <sup>3</sup> Item doesn't load on a factor >.35.

APPENDIX 6.12b Principal Axis Factor Analysis: CROQ-PTCA Core Items Post-Revascularisation (Preliminary Field Test)

CROQ-PTCA item	Factor			
	1	2	3	4
Chest pain	.26	.26	.84	.12
Chest discomfort	.25	.28	.82	.12
Shortness of breath <sup>1</sup>	.28	<b>.48</b> <sup>2</sup>	<b>.43</b>	.17
Radiating pain	.30	.27	.62	.24
Palpitations <sup>3</sup>	.28	.21	.24	.27
Nitroglycerin	.33	.25	.62	-.01
Trouble	.32	.34	.75	.20
Moderate activities	.28	.71	.28	.11
Lifting & carrying	.33	.66	.25	.10
Climbing flights of stairs	.30	.63	.24	.18
Climbing one flight of stairs	.28	.73	.26	.19
Bending, keeling, stooping	.22	.69	.14	.28
Walk half a mile	.27	.77	.21	.18
Walk 100 yards	.22	.67	.23	.17
Bathing or dressing	.23	.60	.18	.23
Reason	.34	.29	.18	.72
Forget	.29	.34	.12	.68
Concentration	.37	.28	.15	.81
Worry heart condition	.70	.22	.37	.23
Over-doing it	.66	.24	.20	.26
Heart attack	.71	.16	.26	.20
Frightened by pain	.60	.26	.38	.24
Uncertain	.78	.21	.16	.24
Depressed	.69	.20	.19	.38
Frustrated	.62	.23	.23	.34
Interfered with enjoyment	.67	.36	.29	.22
Positive outlook	.77	.34	.27	.23
Difficult to plan	.71	.39	.24	.18
Family overprotective	.55	.21	.19	.04
Feeling a burden	.77	.29	.18	.13
Restricted in social activities	.69	.41	.18	.20
Too far from home	.70	.29	.23	.10

<sup>1</sup> Item loads higher on the 'wrong factor'. <sup>2</sup> Values in bold indicate items crossloading on more than one factor with a difference <.20. <sup>3</sup> Item doesn't load on a factor >.35.

**APPENDIX 6.13a Principal Axis Factor Analysis: CROQ-CABG Post-Revascularisation  
Outcome Only Items (Preliminary Field Test)**

CROQ-CABG item	Factor	
	1	2
Satisfied with results	.23	.65
Satisfied with info about op	-.03	.67
Satisfied with recovery info	.08	.74
Overall	.15	.50
Speed of recovery	.26	.49
Expectation of results	.17	.64
Symptoms return <sup>1</sup>	.29	.31
Pain in chest wound	.62	.25
Infection in chest wound	.40	.04
Tender chest wound	.64	.31
Numb chest wound	.51	.22
Bruising on chest	.48	.26
Pain leg wound	.75	.17
Other pain in leg	.57	.17
Infection in leg wound	.45	.11
Numb leg	.60	.07
Bruising on leg	.60	.24
Swollen feet	.46	-.04

<sup>1</sup> Item doesn't load on a factor >.35.

**APPENDIX 6.13b Principal Axis Factor Analysis: CROQ-PTCA Post-Revascularisation  
Outcome Only Items (Preliminary Field Test)**

CROQ-PTCA item	Factor	
	1	2
Satisfied with results	.85	.08
Satisfied with info about op	.46	.24
Satisfied with recovery info	.44	.16
Overall	.81	.20
Speed of recovery	.78	-.01
Expectation of results	.82	-.04
Symptoms return	.52	.18
Pain in groin wound	.12	.80
Tender groin wound	.04	.83
Numb groin	.13	.66
Bruised groin wound	.16	.63
Problems from catheter	.06	.73
Concern over bruises <sup>1</sup>	.26	.34

<sup>1</sup> Item doesn't load on a factor >.35.

**APPENDIX 6.14 Known Group Differences: CROQ Global Improvement Post-Revascularisation (Preliminary Field Test)**

Scale	Mean scores		p
	Improved (n) <sup>1</sup>	Unimproved (n) <sup>2</sup>	
<b>CROQ-CABG (N=289)</b>			
Symptoms	86.44 (268)	62.30 (16)	.004
Physical Functioning	77.88 (265)	55.03 (17)	.007
Psychosocial Functioning	77.00 (268)	58.69 (17)	.015
Cognitive Functioning	79.54 (268)	63.92 (17)	.009
Complications	78.83 (270)	72.72 (17)	.338
Satisfaction	82.95 (270)	50.33 (17)	.000
<b>CROQ-PTCA (N=280)</b>			
Symptoms	79.22 (213)	45.81 (57)	.000
Physical Functioning	74.19 (213)	46.30 (54)	.000
Psychosocial Functioning	71.40 (213)	43.59 (57)	.000
Cognitive Functioning	79.25 (214)	60.06 (54)	.000
Complications	95.04 (214)	84.67 (56)	.001
Satisfaction	80.73 (215)	42.77 (57)	.000

<sup>1</sup> Patients who reported global improvement in heart condition at 3-months post-revascularisation (scored 4 "a little better", or 5 "much better" on Q12).

<sup>2</sup> Patients who reported no global improvement in heart condition at 3-months post-revascularisation (scored 1 "much worse", 2 "a little worse", or 3 "about the same" on Q12).

**APPENDIX 6.15 Known Group Differences: CROQ Bothered by Chest Pain Post-Revascularisation (Preliminary Field Test)**

CROQ scale	Mean scores		p
	Bothered (n) <sup>1</sup>	Not bothered (n) <sup>2</sup>	
<b>CROQ-CABG (N=289)</b>			
Symptoms	61.96 (55)	90.52 (229)	.000
Physical Functioning	61.78 (54)	80.08 (226)	.000
Psychosocial Functioning	64.13 (55)	78.39 (228)	.000
Cognitive Functioning	65.06 (54)	81.59 (229)	.000
<i>Core Total</i>	44.18 (55)	51.36 (229)	.000
Complications	71.93 (54)	80.20 (229)	.014
Satisfaction	69.91 (54)	83.79 (229)	.000
<i>Total Outcome</i>	46.69 (54)	50.84 (229)	.000
<b>CROQ-PTCA (N=280)</b>			
Symptoms	53.68 (139)	91.28 (134)	.000
Physical Functioning	54.58 (135)	82.81 (134)	.000
Psychosocial Functioning	53.81 (138)	77.57 (134)	.000
Cognitive Functioning	66.59 (135)	83.90 (135)	.000
<i>Core Total</i>	45.87 (138)	54.23 (135)	.000
Complications	90.37 (138)	95.69 (134)	.001
Satisfaction	60.90 (135)	84.36 (135)	.000
<i>Total Outcome</i>	47.57 (137)	52.59 (135)	.000

<sup>1</sup> Patients who reported they were bothered by chest pain due to angina at 3-months post-revascularisation (scored 1 "a lot", 2 "quite a bit", 3 "moderately", or 4 "a little" on Q1a).

<sup>2</sup> Patients who reported they were not bothered at all by chest pain due to angina at 3-months post-revascularisation (scored 5 "not at all" on Q1a).

**APPENDIX 6.16 Responsiveness: CROQ Pre- to 3-Months Post-Revascularisation (Preliminary Field Test)**

CROQ scale	Mean (SD)			Pre-to 3-months post-revascularisation	
	Pre	3m post	Change <sup>1</sup>	Responsiveness effect size <sup>2</sup>	Standardised response mean <sup>3</sup>
<b>CROQ-CABG (n=128)</b>					
Symptoms	52.17 (22.9)	87.46 (13.0)	35.29 (21.8)	1.54	1.62
Physical Functioning	50.31 (28.6)	78.61 (21.4)	28.30 (28.6)	1.01	0.99
Psychosocial Functioning	49.97 (22.0)	77.55 (16.2)	27.58 (21.2)	1.24	1.30
Cognitive Functioning	69.50 (25.9)	79.03 (22.1)	9.53 (20.3)	0.37	0.47
<b>CROQ-PTCA (n=114)</b>					
Symptoms	51.76 (23.8)	73.14 (24.8)	21.38 (21.8)	0.90	0.98
Physical Functioning	53.22 (26.1)	70.70 (28.2)	17.48 (26.0)	0.67	0.67
Psychosocial Functioning	53.94 (24.3)	66.99 (24.3)	13.05 (21.1)	0.54	0.62
Cognitive Functioning	69.82 (27.9)	77.26 (27.9)	7.44 (22.7)	0.27	0.33

<sup>1</sup> All change scores are statistically significant (p<.05).

<sup>2</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>3</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of the change score.

**APPENDIX 6.17 Responsiveness: CROQ Pre- to 3-Months Post-Revascularisation for Subsample Who Reported Global Improvement (Preliminary Field Test)**

CROQ scale	Mean (SD)			Pre-to 3-months post-revascularisation	
	Pre	3m post	Change <sup>2</sup>	Responsiveness effect size <sup>3</sup>	Standardised response mean <sup>4</sup>
<b>CROQ-CABG (n=122) <sup>1</sup></b>					
Symptoms	51.02 (22.4)	88.03 (12.5)	37.01 (20.6)	1.65	1.79
Physical Functioning	48.82 (21.5)	79.01 (21.5)	30.19 (27.8)	1.06	1.09
Psychosocial Functioning	48.71 (21.6)	77.84 (16.0)	29.14 (20.3)	1.35	1.43
Cognitive Functioning	68.54 (26.1)	78.93 (22.4)	10.39 (20.2)	0.40	0.51
<b>CROQ-PTCA (n=88) <sup>1</sup></b>					
Symptoms	53.51 (22.4)	78.89 (21.2)	25.38 (21.5)	1.13	1.18
Physical Functioning	55.39 (25.9)	77.23 (25.0)	21.85 (25.3)	0.84	0.86
Psychosocial Functioning	55.32 (21.9)	72.17 (23.4)	16.85 (20.7)	0.77	0.82
Cognitive Functioning	70.96 (27.6)	82.07 (22.4)	11.11 (23.0)	0.40	0.48

<sup>1</sup> Responsiveness subsample: Excludes patients who did not report global improvement in their heart condition compared to before their operation (i.e. those who scored 1 "much worse", 2 "a little worse", or 3 "about the same" on Q12).

<sup>2</sup> All change scores are statistically significant (p<.05).

<sup>3</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of scores at the pre-revascularisation assessment.

<sup>4</sup> Calculated as the mean change score between pre- and 3-months post-revascularisation divided by the standard deviation of the change score.

**APPENDIX 6.18 Responsiveness: Comparison of CROQ Change Scores for Different Levels of Global Improvement  
(Preliminary Field Test)**

CROQ scale	Mean Pre-3m change scores		p
	Improved (n) <sup>1</sup>	Unimproved (n) <sup>2</sup>	
<b>CROQ-CABG (N=128)</b>			
Symptoms	37.01 (121)	0.57 (6)	.000
Physical Functioning	30.19 (117)	-8.63 (6)	.001
Psychosocial Functioning	29.13 (121)	-3.62 (6)	.000
Cognitive Functioning	10.39 (121)	-7.78 (6)	.032
<b>CROQ-PTCA (N=114)</b>			
Symptoms	25.38 (88)	7.74 (25)	.000
Physical Functioning	21.85 (88)	2.72 (25)	.001
Psychosocial Functioning	16.85 (87)	0.40 (24)	.001
Cognitive Functioning	11.11 (87)	-5.00 (24)	.002

<sup>1</sup> Patients who reported global improvement in heart condition at 3-months post-revascularisation (scored 4 "a little better", or 5 "much better" on Q12).

<sup>2</sup> Patients who reported no global improvement in heart condition at 3-months post-revascularisation (scored 1 "much worse", 2 "a little worse", or 3 "about the same" on Q12).

**APPENDIX 6.19a Percentage Endorsement of the CROQ-CABG at  
Pre-revascularisation (Final Field Test)**

<b>For Office Use Only</b>			
<b>Patient ID:</b>	_____	<b>Date of operation:</b>	_____
<b>Hospital:</b>	_____	<b>Date received:</b>	_____

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-CABG)**

INSTRUCTIONS: We are interested in finding out how you are now before the heart operation (**coronary artery bypass graft surgery**) you are going to have. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

**1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)**

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	15%	24%	24%	23%	12%
Discomfort in your chest due to angina	14%	27%	24%	19%	12%
Shortness of breath	17%	26%	20%	21%	15%
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	15%	21%	18%	20%	25%
Palpitations (strong or irregular heart beat)	4%	11%	14%	27%	41%

**2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)**

	14%	26%	19%	14%	8%	20%
4 or more times per day						
1-3 times per day						
3 or more times per week but not every day						
1-2 times per week						
Less than once a week						
None over the past 4 weeks						

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

9%	39%	40%	11%
At rest?	On exertion?	At rest and on exertion?	Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

16%	28%	30%	17%	8%
A lot	Quite a bit	Some	A little	None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	35%	41%	21%
Lifting or carrying groceries	31%	45%	21%
Climbing <b>several</b> flights of stairs	53%	29%	11%
Climbing <b>one</b> flight of stairs	15%	43%	38%
Bending, kneeling or stooping	15%	43%	38%
Walking <b>half a mile</b>	46%	35%	16%
Walking <b>one hundred yards</b>	16%	43%	38%
Bathing or dressing yourself	6%	35%	57%

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	13%	20%	21%	23%	13%
Feeling like you are a burden on others?	12%	11%	26%	21%	29%
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	14%	19%	27%	14%	25%
Feeling worried about going too far from home?	17%	19%	20%	15%	28%

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	20%	24%	29%	19%	6%
Worried about doing too much or overdoing it?	14%	28%	30%	19%	9%
Worried that you might have a heart attack or die suddenly?	13%	12%	25%	25%	25%
Frightened by the pain or discomfort of your heart condition?	10%	14%	36%	20%	21%
Uncertain about the future?	19%	17%	25%	25%	13%
Depressed?	9%	9%	27%	25%	30%
Frustrated or impatient?	15%	25%	26%	20%	12%
That your heart condition interfered with your enjoyment of life?	24%	28%	24%	17%	7%
That it was difficult to keep a positive outlook about your health?	12%	24%	27%	23%	14%
That it was difficult to plan ahead (eg vacations, social events, etc.)?	34%	30%	15%	14%	7%

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	<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>
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	7%	10%	11%	24%	17%	32%
Forget, for example things that happened recently, where you put things or appointments?	7%	12%	12%	25%	18%	26%
Have difficulty doing activities involving concentration and thinking?	6%	11%	11%	21%	20%	31%

**APPENDIX 6.19b Percentage Endorsement of the CROQ-PTCA at  
Pre-Revascularisation (Final Field Test)**

For Office Use Only			
Patient ID:	_____	Date of operation:	_____
Hospital:	_____	Date received:	_____

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

INSTRUCTIONS: We are interested in finding out how you are now before the heart operation (**percutaneous transluminal coronary angioplasty**) you are going to have. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is COMPLETELY CONFIDENTIAL. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	15%	21%	24%	20%	16%
Discomfort in your chest due to angina	17%	28%	21%	23%	8%
Shortness of breath	18%	28%	20%	21%	11%
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	14%	21%	21%	17%	23%
Palpitations (strong or irregular heart beat)	4%	13%	18%	25%	35%

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

	7%	20%	25%	11%	11%	26%
4 or more times per day						
1-3 times per day						
3 or more times per week but not every day						
1-2 times per week						
Less than once a week						
None over the past 4 weeks						

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

13%	32%	45%	8%
At rest?	On exertion?	At rest and on exertion?	Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

15%	26%	36%	16%	6%
A lot	Quite a bit	Some	A little	None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	37%	36%	25%
Lifting or carrying groceries	31%	41%	23%
Climbing <b>several</b> flights of stairs	55%	30%	11%
Climbing <b>one</b> flight of stairs	21%	41%	35%
Bending, kneeling or stooping	18%	38%	42%
Walking <b>half a mile</b>	47%	35%	15%
Walking <b>one hundred yards</b>	13%	42%	40%
Bathing or dressing yourself	4%	26%	67%

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	10%	21%	24%	23%	21%
Feeling like you are a burden on others?	9%	11%	23%	18%	37%
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	17%	16%	23%	15%	29%
Feeling worried about going too far from home?	20%	13%	19%	16%	33%

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	19%	22%	29%	20%	8%
Worried about doing too much or over-doing it?	19%	24%	31%	16%	9%
Worried that you might have a heart attack or die suddenly?	14%	10%	30%	18%	26%
Frightened by the pain or discomfort of your heart condition?	15%	17%	28%	20%	20%
Uncertain about the future?	27%	18%	21%	17%	16%
Depressed?	8%	12%	27%	22%	30%
Frustrated or impatient?	15%	22%	31%	20%	11%
That your heart condition interfered with your enjoyment of life?	29%	21%	23%	16%	10%
That it was difficult to keep a positive outlook about your health?	19%	13%	29%	17%	21%
That it was difficult to plan ahead (eg vacations, social events, etc.)?	30%	18%	20%	14%	18%

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	<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>
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	8%	12%	11%	11%	18%	38%
Forget, for example things that happened recently, where you put things or appointments?	6%	11%	15%	20%	15%	34%
Have difficulty doing activities involving concentration and thinking?	6%	13%	9%	18%	17%	37%

**APPENDIX 6.20a Percentage Endorsement of the CROQ-CABG at  
3-Months Post-Revascularisation (Final Field Test)**

<b>For Office Use Only</b>			
<b>Patient ID:</b> _____		<b>Date of operation:</b> _____	
<b>Hospital:</b> _____		<b>Date received:</b> _____	

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-CABG)**

INSTRUCTIONS: We are interested in finding out how you have been since the heart operation (**coronary artery bypass graft surgery**) you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is COMPLETELY CONFIDENTIAL. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	1%	1%	3%	11%	82%
Discomfort in your chest due to angina	1%	3%	3%	13%	78%
Shortness of breath	4%	9%	13%	38%	34%
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	2%	3%	4%	14%	75%
Palpitations (strong or irregular heart beat)	1%	4%	9%	25%	58%

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

	1%	1%	1%	1%	5%	89%
4 or more times per day						
1-3 times per day						
3 or more times per week but not every day						
1-2 times per week						
Less than once a week						
None over the past 4 weeks						

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

5%	11%	15%	66%
At rest?	On exertion?	At rest and on exertion?	Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

1%	3%	7%	30%	57%
A lot	Quite a bit	Some	A little	None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	<b>Yes, Limited A Lot</b>	<b>Yes, Limited A Little</b>	<b>No, Not Limited At All</b>
<b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	10%	33%	54%
Lifting or carrying groceries	10%	37%	48%
Climbing <b>several</b> flights of stairs	11%	35%	47%
Climbing <b>one</b> flight of stairs	3%	15%	77%
Bending, kneeling or stooping	7%	28%	62%
Walking <b>half a mile</b>	8%	17%	71%
Walking <b>one hundred yards</b>	4%	10%	83%
Bathing or dressing yourself	3%	11%	84%

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	2%	11%	25%	29%	22%
Feeling like you are a burden on others?	3%	6%	14%	17%	58%
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	4%	5%	12%	15%	62%
Feeling worried about going too far from home?	4%	6%	10%	18%	61%

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	3%	6%	15%	32%	44%
Worried about doing too much or over-doing it?	3%	8%	19%	42%	27%
Worried that you might have a heart attack or die suddenly?	3%	2%	10%	14%	70%
Worried that your symptoms might return?	3%	3%	10%	18%	64%
Frightened by the pain or discomfort of your heart condition?	5%	5%	13%	25%	50%
Uncertain about the future?	3%	3%	14%	21%	57%
Depressed?	3%	9%	21%	30%	34%
Frustrated or impatient?	6%	7%	14%	28%	45%
That your heart condition interfered with your enjoyment of life?	3%	8%	9%	25%	53%
That it was difficult to keep a positive outlook about your health?	7%	7%	15%	20%	49%
That it was difficult to plan ahead (eg vacations, social events, etc.)?	2%	11%	25%	39%	22%

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	2%	4%	6%	14%	24%	49%
Forget, for example things that happened recently, where you put things or appointments?	2%	5%	9%	19%	28%	37%
Have difficulty doing activities involving concentration and thinking?	2%	4%	6%	17%	30%	41%

9. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

82%  No

16%  Yes

Date of Admission	Name of hospital	Reason for hospital stay	Number of days
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

10. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your <b>chest wound</b>	4%	9%	10%	29%	47%
Infection in your <b>chest wound</b>	2%	1%	1%	6%	89%
Tenderness around your <b>chest wound</b>	6%	9%	15%	44%	25%
Numbness or tingling around your <b>chest wound</b>	7%	10%	11%	32%	38%
Bruising on your <b>chest</b>	1%	1%	6%	8%	81%
Pain in your <b>leg or arm wound</b>	5%	7%	11%	26%	48%
Any other pain in your <b>leg or arm</b> due to your operation	4%	6%	6%	13%	67%
Infection in your <b>leg or arm wound</b>	4%	4%	2%	7%	80%
Numbness or tingling in your <b>leg or arm</b> due to your operation	9%	10%	15%	30%	35%
Bruising on your <b>leg or arm</b> where a vein was removed	3%	3%	5%	15%	71%
Swollen feet or ankles	9%	9%	11%	27%	43%

11. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Results of your heart operation?	2%	2%	13%	83%
Information you were given about your heart operation?	2%	4%	15%	78%
Information you were given about how you might feel while recovering from your heart operation?	2%	8%	20%	70%

**12. Overall, how would you describe your heart condition now compared to before you had your heart operation? (Please tick one box.)**

1%	1%	5%	11%	81%
Much worse	A little worse	About the same	A little better	Much better

**13. Has your recovery from your heart operation so far been: (Please tick one box.)**

17%	28%	32%	22%
Slower than you expected?	About what you expected?	Faster than you expected?	Did not know how long it would take?

**14. Are the results from your heart operation: (Please tick one box.)**

7%	42%	50%
Worse than you expected?	About what you expected?	Better than you expected?

**APPENDIX 6.20b Percentage Endorsement of the CROQ-PTCA at  
3-Months Post-Revascularisation (Final Field Test)**

<b>For Office Use Only</b>			
<b>Patient ID:</b> _____		<b>Date of operation:</b> _____	
<b>Hospital:</b> _____		<b>Date received:</b> _____	

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

**INSTRUCTIONS:** We are interested in finding out how you have been since the heart operation (**percutaneous transluminal coronary angioplasty**) you had 3 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

**1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)**

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	3%	7%	9%	24%	52%
Discomfort in your chest due to angina	3%	10%	10%	31%	42%
Shortness of breath	7%	12%	17%	35%	26%
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	3%	7%	10%	21%	54%
Palpitations (strong or irregular heart beat)	2%	5%	6%	28%	57%

**2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)**

1%	7%	10%	6%	19%	55%
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

7%	26%	22%	42%
At rest?	On exertion?	At rest and on exertion?	Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

3%	5%	17%	33%	39%
A lot	Quite a bit	Some	A little	None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	15%	35%	45%
Lifting or carrying groceries	16%	33%	44%
Climbing <b>several</b> flights of stairs	26%	35%	32%
Climbing <b>one</b> flight of stairs	7%	29%	58%
Bending, kneeling or stooping	11%	30%	55%
Walking <b>half a mile</b>	19%	29%	48%
Walking <b>one hundred yards</b>	8%	19%	67%
Bathing or dressing yourself	3%	19%	73%

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	6%	8%	26%	27%	29%
Feeling like you are a burden on others?	4%	5%	14%	18%	57%
Feeling restricted in your social activities (like visiting with friends, relatives, etc.)?	5%	6%	16%	16%	54%
Feeling worried about going too far from home?	7%	9%	12%	23%	46%

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	8%	10%	25%	34%	20%
Worried about doing too much or over-doing it?	6%	13%	25%	26%	27%
Worried that you might have a heart attack or die suddenly?	6%	7%	23%	19%	41%
Worried that your symptoms might return?	8%	8%	15%	24%	42%
Frightened by the pain or discomfort of your heart condition?	12%	13%	17%	27%	28%
Uncertain about the future?	5%	6%	18%	22%	45%
Depressed?	9%	10%	22%	21%	33%
Frustrated or impatient?	10%	12%	21%	22%	31%
That your heart condition interfered with your enjoyment of life?	6%	12%	21%	24%	33%
That it was difficult to keep a positive outlook about your health?	9%	16%	14%	19%	39%
That it was difficult to plan ahead (eg vacations, social events, etc.)?	6%	8%	26%	27%	29%

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	4%	6%	8%	12%	16%	51%
Forget, for example things that happened recently, where you put things or appointments?	5%	6%	10%	14%	24%	39%
Have difficulty doing activities involving concentration and thinking?	5%	6%	8%	14%	18%	48%

9. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

80%  No

17%  Yes

Date of Admission	Name of hospital	Reason for hospital stay	Number of days
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

10. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your groin wound	1%	2%	3%	10%	80%
Tenderness around your groin wound	1%	2%	4%	13%	76%
Numbness or tingling in your groin area	2%	1%	1%	6%	85%
Bruising around your groin wound or thigh	3%	3%	4%	11%	74%
Problems in your groin where the catheter was inserted	1%	1%	2%	5%	85%
Concern over the appearance of your bruises	1%	1%	1%	4%	90%

11. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Results of your heart operation?	5%	8%	20%	65%
Information you were given about your heart operation?	2%	8%	14%	73%
Information you were given about how you might feel while recovering from your heart operation?	5%	13%	23%	57%

12. Overall, how would you describe your **heart condition** now compared to before you had your heart operation? (Please tick one box.)

3%	4%	13%	15%	64%
Much worse	A little worse	About the same	A little better	Much better

**13. Has your recovery from your heart operation so far been: (Please tick one box.)**

14%	25%	21%	37%
Slower than you expected?	About what you expected?	Faster than you expected?	Did not know how long it would take?

**14. Are the results from your heart operation: (Please tick one box.)**

15%	40%	42%
Worse than you expected?	About what you expected?	Better than you expected?

**APPENDIX 6.21a Percentage Endorsement of the CROQ-CABG at  
9-Months Post-Revascularisation (Final Field Test)**

For Office Use Only			
Patient ID:	_____	Date of operation:	_____
Hospital:	_____	Date received:	_____

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-CABG)**

INSTRUCTIONS: We are interested in finding out how you have been since the heart operation (**coronary artery bypass graft surgery**) you had 9 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is COMPLETELY CONFIDENTIAL. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	2%	6%	4%	13%	73%
Discomfort in your chest due to angina	1%	7%	3%	17%	70%
Shortness of breath	3%	6%	18%	32%	40%
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	2%	7%	2%	13%	74%
Palpitations (strong or irregular heart beat)	0%	4%	12%	24%	58%

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box)

	2%	1%	7%	3%	7%	80%
4 or more times per day						
1-3 times per day						
3 or more times per week but not every day						
1-2 times per week						
Less than once a week						
None over the past 4 weeks						

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

2%	21%	11%	64%
At rest?	On exertion?	At rest and on exertion?	Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

1%	9%	4%	26%	59%
A lot	Quite a bit	Some	A little	None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	5%	26%	67%
Lifting or carrying groceries	8%	28%	63%
Climbing <b>several</b> flights of stairs	8%	42%	48%
Climbing <b>one</b> flight of stairs	3%	14%	80%
Bending, kneeling or stooping	4%	29%	63%
Walking <b>half a mile</b>	5%	19%	75%
Walking <b>one hundred yards</b>	1%	13%	83%
Bathing or dressing yourself	3%	8%	87%

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	5%	9%	14%	32%	39%
Feeling like you are a burden on others?	3%	6%	9%	11%	71%
Feeling restricted in your social activities (like visiting with friends, relatives, etc)?	3%	4%	7%	11%	75%
Feeling worried about going too far from home?	4%	3%	5%	11%	77%

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	2%	5%	12%	28%	53%
Worried about doing too much or over-doing it?	1%	4%	14%	36%	45%
Worried that you might have a heart attack or die suddenly?	3%	1%	5%	22%	68%
Worried that your symptoms might return?	2%	5%	16%	30%	47%
Frightened by the pain or discomfort of your heart condition?	2%	4%	5%	17%	70%
Uncertain about the future?	2%	3%	12%	26%	56%
Depressed?	4%	5%	10%	17%	64%
Frustrated or impatient?	7%	7%	10%	28%	48%
That your heart condition interfered with your enjoyment of life?	3%	4%	15%	17%	61%
That it was difficult to keep a positive outlook about your health?	3%	4%	12%	19%	62%
That it was difficult to plan ahead (eg vacations, social events, etc.)?	2%	5%	10%	16%	65%

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	1%	4%	7%	9%	20%	59%
Forget, for example things that happened recently, where you put things or appointments?	4%	3%	12%	11%	38%	31%
Have difficulty doing activities involving concentration and thinking?	2%	4%	4%	15%	26%	48%

9. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

76%  No

21%  Yes

Date of Admission

Name of hospital

Reason for hospital stay

Number of days

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10. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your <b>chest wound</b>	2%	6%	5%	18%	67%
Infection in your <b>chest wound</b>	1%	0%	1%	0%	96%
Tenderness around your <b>chest wound</b>	2%	5%	6%	33%	53%
Numbness or tingling around your <b>chest wound</b>	3%	3%	5%	31%	56%
Bruising on your <b>chest</b>	2%	1%	3%	6%	82%
Pain in your <b>leg or arm wound</b>	3%	3%	5%	18%	65%
Any other pain in your <b>leg or arm</b> due to your operation	3%	2%	3%	15%	72%
Infection in your <b>leg or arm wound</b>	1%	0%	1%	6%	89%
Numbness or tingling in your <b>leg or arm</b> due to your operation	4%	4%	10%	31%	45%
Bruising on your <b>leg or arm</b> where a vein was removed	2%	1%	3%	4%	84%
Swollen feet or ankles	5%	6%	15%	27%	46%

11. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Results of your heart operation?	2%	4%	15%	78%
Information you were given about your heart operation?	2%	5%	13%	79%
Information you were given about how you might feel while recovering from your heart operation?	3%	9%	12%	74%

12. Overall, how would you describe your heart condition now compared to before you had your heart operation? (Please tick one box.)

1%	3%	6%	6%	83%
Much worse	A little worse	About the same	A little better	Much better

13. Has your recovery from your heart operation so far been: (Please tick one box.)

12%	25%	36%	27%
Slower than you expected?	About what you expected?	Faster than you expected?	Did not know how long it would take?

14. Are the results from your heart operation: (Please tick one box.)

6%	32%	62%
Worse than you expected?	About what you expected?	Better than you expected?

**APPENDIX 6.21b Percentage Endorsement of the CROQ-PTCA at  
9-Months Post-Revascularisation (Final Field Test)**

**For Office Use Only**

**Patient ID:** \_\_\_\_\_ **Date of operation:** \_\_\_\_\_  
**Hospital:** \_\_\_\_\_ **Date received:** \_\_\_\_\_

**CORONARY REVASCULARISATION OUTCOME QUESTIONNAIRE  
(CROQ-PTCA)**

**INSTRUCTIONS:** We are interested in finding out how you have been since the heart operation (**percutaneous transluminal coronary angioplasty**) you had 9 months ago. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is **COMPLETELY CONFIDENTIAL**. Please be sure to answer all questions.

1. During the past 4 weeks, how much were you bothered by each of the following problems related to your **heart condition**? (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Chest pain due to angina	4%	11%	8%	30%	43%
Discomfort in your chest due to angina	4%	5%	16%	33%	33%
Shortness of breath	4%	18%	11%	41%	20%
Angina pain that radiates to other parts of your body (eg arms, shoulders, hands, neck, throat, jaw, back)	4%	9%	11%	29%	43%
Palpitations (strong or irregular heart beat)	5%	6%	5%	24%	54%

2. During the past 4 weeks, on average, how many times have you taken nitros (nitroglycerin tablets or spray) for your **chest pain, chest tightness or angina**? (Please tick only one box.)

4%	4%	13%	9%	19%	53%
4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks

3. During the past 4 weeks, have you had **chest pain, chest tightness or angina**:  
(Please tick only one box.)

4%	30%	26%	38%
At rest?	On exertion?	At rest and on exertion?	Not at all?

4. During the past 4 weeks, how much trouble has your **heart condition** caused you?  
(Please tick only one box.)

3%	11%	11%	40%	35%
A lot	Quite a bit	Some	A little	None

5. The following questions ask about activities which you might do during a typical day. During the past 4 weeks, has your **heart condition** limited you in your usual daily activities? Please indicate whether your heart condition limits you a lot, limits you a little, or does not limit you at all in the activities listed below. (Please tick one box on each line.)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	11%	33%	50%
Lifting or carrying groceries	16%	38%	43%
Climbing <b>several</b> flights of stairs	30%	31%	34%
Climbing <b>one</b> flight of stairs	6%	34%	56%
Bending, kneeling or stooping	9%	34%	54%
Walking <b>half a mile</b>	23%	24%	50%
Walking <b>one hundred yards</b>	10%	16%	70%
Bathing or dressing yourself	5%	14%	79%

6. The next questions ask about the impact of your **heart condition** on your family and friends and the extent to which it has interfered with your social activities. During the past 4 weeks, how often have you experienced the following as a result of your **heart condition**:  
(Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Family or friends being overprotective toward you?	5%	5%	15%	26%	45%
Feeling like you are a burden on others?	6%	1%	15%	14%	61%
Feeling restricted in your social activities (like visiting with friends, relatives, etc.)?	6%	6%	15%	14%	56%
Feeling worried about going too far from home?	6%	5%	13%	16%	58%

7. The next questions ask about your feelings about your **heart condition**. During the past 4 weeks, how often have you felt: (Please tick one box on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Worried about your heart condition?	6%	10%	20%	34%	28%
Worried about doing too much or over-doing it?	10%	10%	16%	31%	31%
Worried that you might have a heart attack or die suddenly?	6%	6%	18%	21%	46%
Worried that your symptoms might return?	8%	13%	25%	28%	24%
Frightened by the pain or discomfort of your heart condition?	6%	11%	15%	15%	46%
Uncertain about the future?	10%	16%	15%	16%	40%
Depressed?	4%	6%	18%	14%	53%
Frustrated or impatient?	9%	13%	13%	21%	41%
That your heart condition interfered with your enjoyment of life?	9%	15%	11%	14%	48%
That it was difficult to keep a positive outlook about your health?	6%	9%	13%	25%	45%
That it was difficult to plan ahead (eg vacations, social events, etc.)?	10%	8%	11%	18%	51%

8. The next questions ask about problems related to your **heart condition**. During the past 4 weeks, how much of the time did you: (Please tick one box on each line.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have difficulty reasoning and solving problems, for example making plans, making decisions, learning new things?	4%	5%	5%	10%	16%	60%
Forget, for example things that happened recently, where you put things or appointments?	4%	5%	9%	20%	25%	36%
Have difficulty doing activities involving concentration and thinking?	6%	4%	8%	15%	14%	53%

9. Since your heart operation, have you been re-admitted to hospital for an overnight stay for any reason to do with your **heart condition or heart operation**? Please give as many details as you can below.

73%  No

28%  Yes

Date of Admission	Name of hospital	Reason for hospital stay	Number of days
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

10. The next questions ask about problems you might have had **since your heart operation**. During the past 4 weeks, how much were you bothered by the following problems? If you did not have the problem, tick the last box "Not at all". (Please tick one box on each line.)

	A lot	Quite a bit	Moderately	A little	Not at all
Pain in your groin wound	1%	5%	3%	5%	83%
Tenderness around your groin wound	0%	4%	3%	11%	78%
Numbness or tingling in your groin area	1%	1%	6%	6%	80%
Bruising around your groin wound or thigh	4%	3%	1%	9%	79%
Problems in your groin where the catheter was inserted	3%	1%	3%	5%	83%
Concern over the appearance of your bruises	0%	1%	0%	0%	95%

11. The next question asks about how satisfied you are with your **heart operation**. How satisfied are you with the: (Please tick one box on each line.)

	Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
Results of your heart operation?	5%	19%	18%	68%
Information you were given about your heart operation?	3%	5%	16%	75%
Information you were given about how you might feel while recovering from your heart operation?	3%	9%	19%	69%

12. Overall, how would you describe your **heart condition** now compared to before you had your heart operation? (Please tick one box.)

4%	1%	11%	18%	64%
Much worse	A little worse	About the same	A little better	Much better

**13. Has your recovery from your heart operation so far been: (Please tick one box.)**

5%	33%	25%	35%
Slower than you expected?	About what you expected?	Faster than you expected?	Did not know how long it would take?

**14. Are the results from your heart operation: (Please tick one box.)**

16%	38%	45%
Worse than you expected?	About what you expected?	Better than you expected?